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pHealth 2024

Proceedings of the 20th International Conference on Wearable Micro and Nano Technologies for Personalized Health – Rende, Italy, 27-29 May 2024

Editors: Mauro Giacomini
Bernd Blobel
Pierangelo Veltri

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pHEALTH 2024

Studies in Health Technology and Informatics

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Preface

The pHealth 2024 conference is the 20th in a series of scientific events which bring together expertise from medical, technological, political, administrative, and social domains, and even from philosophy and linguistics. It opens a new chapter in the success story of this series of international conferences on wearable or implantable micro and nano technologies for personalised medicine.

Started in 2003 as a dissemination activity in the framework of a European project on wearable micro and nano technologies for personalised health with personal health management systems, pHealth conferences have evolved to become truly interdisciplinary and global events. All aspects of pHealth are comprehensively represented in the conference series, which also covers technological and biomedical facilities, legal, ethical, social, and organisational requirements and impacts, as well as the basic research necessary to enable future-proof care paradigms. It has advanced from P medicine (personalised medicine) through P2 medicine (also addressing prevention), P3 medicine (including prediction), P4 medicine (the patient is included as an active participant in the process), up to the current P5 medicine: personalised, participative, preventive, predictive, precision medicine. In that context, the conference series attracts experts from all over the world and from many scientific domains, including mathematics, data sciences, system sciences, philosophy, ethics and social sciences, as well as developers and practitioners from various technologies, medical and health disciplines, legal affairs, politics, and administration. The 2024 conference brought together health-service vendor and provider institutions, payer organisations, government departments, academic institutions and professional bodies, as well as patients and citizen representatives.

Smart mobile systems such as microsystems, smart textiles, smart implants, sensor-controlled medical devices, and innovative sensor and actuator principles and techniques, as well as related body, local and wide-area networks up to cloud services, are part of the next-generation of health services, and have become important enablers for telemedicine and ubiquitous pervasive health, , while social media and gamification have added another dimension to pHealth as an eco-system.

The OECD has defined four basic areas which must be managed in the new care model: addressing the big data challenges; fostering meaningful innovation; understanding and addressing potential new risks; and supporting a concerted effort to un-silo communities for a virtual care future. The benefits of pHealth technologies – including artificial intelligence, learning systems and intelligent robots – offer enormous potential for all stakeholder communities, including patients, citizens, health professionals, politicians, healthcare establishments, and companies from biomedical technology, pharmaceutical, and telecommunications domains, not only for the improvement of medical quality and industrial competitiveness, but also for managing healthcare costs and, last but not least, for improving patient experiences.

The pHealth 2024 conference benefits from the experience and lessons learned by the organising committees of previous pHealth events, particularly 2009 in Oslo, 2010 in Berlin, 2011 in Lyon, 2012 in Porto, 2013 in Tallinn, 2014 in Vienna, 2015 in Västerås, 2016 in Heraklion, 2017 in Eindhoven, 2018 in Gjøvik, 2019 in Genoa, 2020

in Prague, 2021, again in Genoa, and 2022, again in Oslo. The 2009 conference introduced the idea of special sessions focused on a particular topic and organised by a mentor or moderator. The Berlin event in 2010 initiated pre-conference workshops on particular topics prior to the main event. Lyon, in 2011, launched so-called dynamic demonstrations, allowing participants to show software and hardware solutions on the fly without the need for a booth. Implementing pre-conference events, pHealth 2012 in Porto gave attendees a platform for presenting and discussing recent developments and provocative ideas, which helped to animate the sessions. The highlights of pHealth 2013 in Tallinn were a special session on the success stories of European projects and the presentations on the newest paradigm changes and challenges associated with Big Data, analytics, translational and nano medicine. Vienna in 2014 focused on lessons learned from national and international R&D activities and practical solutions, particularly those from Horizon 2020, the new EU Framework Programme for Research and Innovation. In addition to reports about technology transfer support and building ecosystems and value chains to ensure better time to market and higher impact of knowledge-based technologies, the acceptability of solutions, especially with regard to security and privacy aspects, were presented and discussed in depth. pHealth 2015, in Västerås, addressed mobile technologies, knowledge-driven applications and computer-assisted decision support, as well as apps designed to support the elderly and chronic patients in their daily, and possibly independent, living. The fundamental scientific and methodological challenges of adaptive, autonomous, and intelligent pHealth approaches, the new role of patients as consumers and an active party with growing autonomy and related responsibilities, as well as requirements and solutions for mHealth in low- and medium-income countries were also considered. The pHealth 2016 conference in Heraklion was aimed at the integration of biological and medical data and the deployment of mobile technologies through the development of micro-nano-bio smart systems. The emphasis was on personalised health, virtual care, precision medicine, big bio-data management and analytics. The 2017 pHealth event in Eindhoven provided an inventory of former conferences, summarising requirements and solutions for pHealth systems, highlighting the importance of trust and the new focus on behavioural aspects in the design and use of pHealth systems. One specific aspect addressed was the need for flexible, adaptive and knowledge-based systems, as well as decision intelligence. pHealth 2018 in Gjøvik established national and European satellite workshops, complementing the more theoretical nature of the majority of papers with organisational and practical experiences. Borrowing from the good experiences of former events, pHealth 2018 responded to national and regional needs to advance healthcare systems and their services to citizens and health professionals. pHealth 2019, in Genoa, put a special emphasis on artificial intelligence (AI) and machine learning (ML) and their deployment for decision support, and ethical challenges and related international manifests were discussed in depth in that context. pHealth 2020, organised in Prague as virtual event, addressed AI and robots, bio-data management and analytics for health and social care, security, privacy and safety challenges, integrated care, and also the intelligent management of specific diseases including the Covid-19 pandemic. pHealth 2021, in Genoa, once again organised as a virtual event, focused on digital health ecosystems in transformation. Topics considered included the deployment of mobile technologies, micro-nano-bio smart systems, bio-data management and analytics, autonomous and intelligent systems, as well as the Health Internet of Things (HIoT) for personalised health, systems medicine, public health and virtual care. pHealth2022, in Oslo combined the former

organisational schemes in a hybrid event. pHealth 2022 focused on personalised, preventive, predictive, participative precision (P5) medicine and the integration and interoperability between health informatics standards, and also on practical experiences with the deployment of HL7 FHIR. The conference also addressed new potential risks for security and privacy, as well as safety opportunities and challenges, trustworthiness of partners and processes, and the motivation and empowerment of patients in the care processes.

The pHealth2024 conference has been organised under the patronage of the Italian Scientific Society of Biomedical Informatics (SIBIM) and of the Department of Informatic, Modelling, Electronic and System Engineering of the University of Calabria. Following a long-standing tradition, the Working Group 'Translational Health Informatics' of the European Federation for Medical Informatics (EFMI) have also been actively involved in the preparation and realisation of the pHealth 2024 event. pHealth2024 was held at Rende (Cosenza – Italy) within the Conference Centre of the University of Calabria. This volume of proceedings covers 1 Keynote Paper, 24 Full Papers, 9 Poster Papers and 1 Panel from 111 authors from 11 countries around the world. All submissions have been carefully and critically reviewed by at least two independent experts from a country other than the author's home country, and additionally by at least one member of the Scientific Programme Committee. This very selective process guarantees the high scientific level of the accepted and ultimately published papers.

The editors are indebted to the internationally acknowledged and highly experienced reviewers for having essentially contributed to the quality of the conference and the book at hand.

The editors are also grateful to the members of the international Scientific Programme Committee, and especially the dedicated efforts of the Local Organising Committee members and their supporters for their careful preparation and the smooth operation of the conference.

Mauro Giacomini, Bernd Blobel, Pierangelo Veltri
pHealh2024 Co-chairs

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The Representational Challenge for Designing and Managing 5P Medicine Ecosystems

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Abstract. Health and social care systems around the globe currently undergo a transformation towards personalized, preventive, predictive, participative precision medicine (5PM), considering the individual health status, conditions, genetic and genomic dispositions, etc., in personal, social, occupational, environmental and behavioral context. This transformation is strongly supported by technologies such as micro- and nanotechnologies, advanced computing, artificial intelligence, edge computing, etc. For enabling communication and cooperation between actors from different domains using different methodologies, languages and ontologies based on different education, experiences, etc., we have to understand the transformed health ecosystems and all its components in structure, function and relationships in the necessary detail ranging from elementary particles up to the universe. That way, we advance design and management of the complex and highly dynamic ecosystem from data to knowledge level. The challenge is the consistent, correct and formalized representation of the transformed health ecosystem from the perspectives of all domains involved, representing and managing them based on related ontologies. The resulting business view of the real-world ecosystem must be interrelated using the ISO/IEC 21838 Top Level Ontologies standard. Thereafter, the outcome can be transformed into implementable solutions using the ISO/IEC 10746 Open Distributed Processing Reference Model. Model and framework for this system-oriented, architecture-centric, ontology-based, policy-driven approach have been developed by the first author and meanwhile standardized as ISO 23903 Interoperability and Integration Reference Architecture.

Keywords. Health and social care transformation, Ecosystems, Systems architecture, Knowledge representation and management, Information modelling, Language types, Ontologies

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Introduction

Over many years, healthcare systems around the globe evolved from empiric medicine, locally providing domain-specific general services through evidence-based medicine, providing domain-specific group-specific services to person-centered medicine, providing coordinated multiple domain services to the subject of care, also called managed care.

Traditionally, own observations and conclusions, in evidence-based medicine also observations and conclusions from other domain experts available in related databases, have been re-used. The paradigm, what work yesterday should work today as well, dominated the practice despite the long-term development of anatomy, toxicology, histology, and pathology up to the cellular level. In the 1990s, it became more and more evident that individuals differentiate in their molecular, physiological and behavioral characteristics, accompanied by different environmental and occupational exposure, etc. but also regarding their individual health history. This lead to the development of personalized medicine by providing multiple domain services to the subject of care including telemedicine. Thereby, the clinically justified individual status and context of the subject of care must be considered and understood.

So far, medicine is just understood as service on diseased subjects, managed by care professionals. The ongoing healthcare systems transformation aims at personalized, preventive, predictive, participative precision medicine (P5M). It considers individual health status, conditions, genetic and genomic dispositions in personal social, occupational, environmental and behavioral context, thus turning health and social care from reactive to proactive. Table 1 summarizes the described health transformation. Further aspects, such as presentational challenges, standards, etc., will be discussed later on.

Table 1. Health and social care transformation towards 5P medicine including related representation styles and standards

Care Paradigm	Services	Way of Practicing	Justification	Representation Style	Electronic Comm./ Coop.	Standard
Phenomeno-logical Medicine	Domain-specific general services – one solution fits all	Observation	Pattern recognition	Data	Local data repository; Inside the unit	Data standards
Evidence-Based Medicine	Domain-specific, group specific services	Observation with objective evaluation	Statistical justification of group-specific treatment outcome	Information	Central data repositories	Information standards
Person-Centered Medicine	Multiple domains' services	Managed care	Process mgmt., Best medical practice guidelines	Agreed terminology, DMP Best Practice Guidelines	Cross-organizational Business Process	Terminology standards; Process standards
Personalized Medicine	Multiple domains' services - Telemedicine	Considering the translational pathology of disease	Clinically justified individual status and context	Disciplinary concepts in situational context	Knowledge management	Domain ontology standards
P5 Medicine	Cross-domain services - Consumerism, Telemedicine	Understanding the pathology of disease from elementary particle up to society	Scientifically justified individual status	Multidisciplinary concepts in comprehensive context	Knowledge Space management	Multiple ontologies guided by Top-Level Ontologies standards

In the P5M approach, we cannot consider the health and social care system in isolation, but must incorporate its political, legal, ethical, economic and ecological framework. Therefore, we must consider all those domains and their actors as well. In other words, we have to manage the 5PM ecosystem. Thereby, an ecosystem is defined as a structural and functional unit of ecology where the living organisms interact with each other and the surrounding environment. It is the community of living organisms in conjunction with non-living components of their environment, interacting as a system [1].

1. Foundations for Designing and Managing Transformed Health and Social Care Ecosystems

It is impossible to represent the highly complex, highly dynamic, multidisciplinary/ multi-domain healthcare system by one domain's terminology or even by using 'simple' ICT ontologies. There are approaches for representing multi-domain concepts in a hierarchical set of ontologies. An ontology is a formal explicit specification of a shared conceptualization of a domain of interest, providing an ordering system of entities of a domain and their relations [2]. A concept is a knowledge component the expert community has agreed on. A concept must be uniquely identifiable, and independently accepted by experts and users. For enabling consistent communication and cooperation, we have to guarantee that all actors refer to the same real world component. For that reason, an abstract and generic reference architecture able to represent any viewpoint or domain of interest for any ecosystem in question is inevitable. Starting point could be an abstract mathematical representation based on universal type theory and universal logics such as the Barendregt Cube [3] to formally and consistently represent any system in the universe. More details can be found in [4].

For managing systems and systems engineering, a system-theoretical approach is more practical. However, for managing systems in their structure and function, a black box approach just considering the relations of the system and its environment is not sufficient. Instead, we must understand all systems elements, their composition and decomposition as well as their internal and external relations by using a white box approach. Moreover, this must be done from the perspectives of all domains and their actors involved in the ecosystem. The granularity level considered depends on the domain experts' objectives in the context of the actual use case of the business system, thereby reaching from elementary particles up to the universe. The resulting generic component model (GCM), introduced by the first author in the early nineties of the last century, consists of the following three perspectives or dimensions [5]:

- System's Architectural Perspective,
- System's Evolutionary or Development Perspective,
- System's Domain Perspective.

Meanwhile, the approach has been standardized as ISO 23903:2021 Interoperability and integration reference architecture – Model and framework [6]. Figure 1 presents the GCM reference architecture.

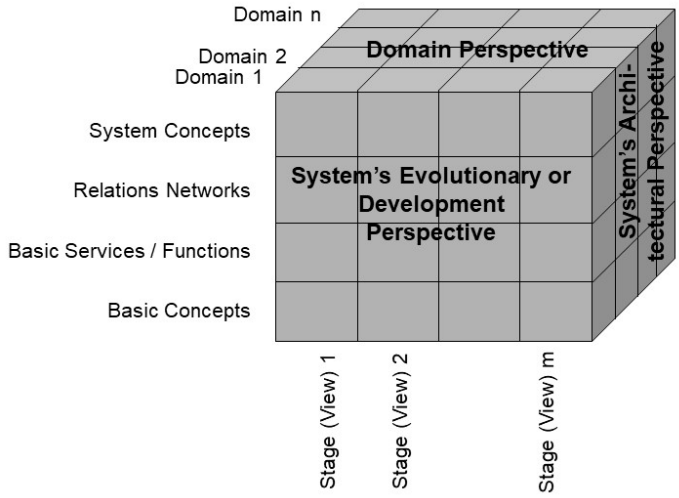

Figure 1. Generic Component Model Reference Architecture

Regarding the dimension of the system's evolution or development process from an architectural perspective, there are different standards to manage this process:

- The Object Management Group (OMG) Model Driven Architecture (MDA) [7]
- ISO/IEC 10746 Reference Model for Open Distributed Processing (RM-ODP) [8]
- ISO 23903 Integration and Interoperability Reference Architecture

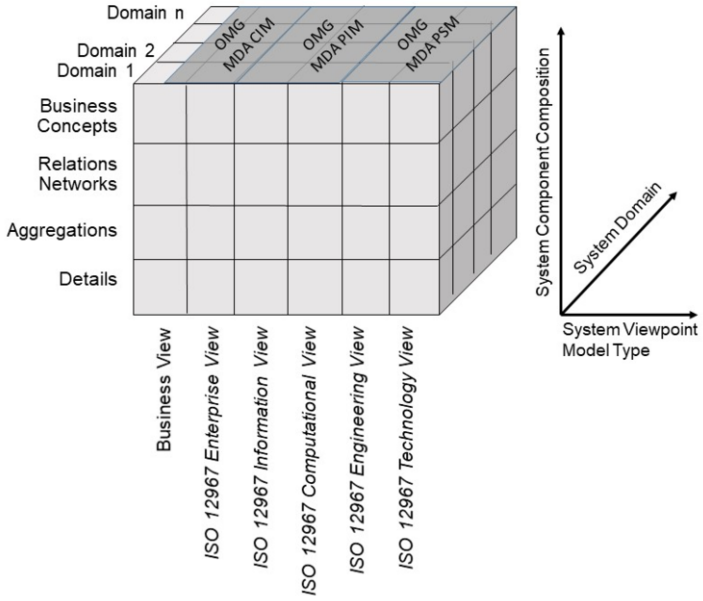

Figure 2. Generic Reference Architecture

The OMG MDA starts with the Computation Independent Model (CIM) as primary model. On that basis, a Platform Independent Model (PIM) is defined, which contains enough information to derive one or more Platform Specific Models (PSMs). The ISO/IEC 10746 Reference Model for Open Distributed Processing provides a methodology for describing and building widely distributed ICT systems and applications. Thereby it defines the following view: Enterprise view, information view, computational view, engineering view and technology view.

ISO 23903 Integration and Interoperability Reference Architecture allows the formal representation, design and management of any ecosystem. Therefore, it must extend the RM-ODP by the real world system viewpoint, called business view. That way, it also provides a methodology for integration and interoperability of any specifications and work products according to the aforementioned standards families. Figure 2 defines it's development process dimension, thereby integrating the two other standards.

2. Modeling Transformed Health Ecosystems

In scientific modeling, we distinguish four dimensions of data modelling: Data, Information, Knowledge, and Knowledge Space [9]. Thereby, the transformation from data to information considers interpretation, meaning and semantics, the transformation from information to knowledge considers action, structure and pragmatics, and the transformation from knowledge to knowledge spaces supports reflection, innovation and collaboration across domains [10]. Another way of classifying models is the data model level [11], ranging from very high data model representing the ISO 23903 Business View, the high level data model according to the ISO/IEC 10746 Enterprise View, the logical data model level corresponding to the ISO/IEC 10746 Information View and Computational View, and finally the physical data model level corresponding to the ISO/IEC 10746 Engineering view [12]. Furthermore, we can classify data models according to the related information model level [13]. Hereby, we distinguish between external (Business View), conceptual (Enterprise View), logical (Information View and Computational View) and physical (Engineering View). Table 2 summarizes those model classifications.

2.1. Knowledge Representation

From the modeling perspective, three levels of knowledge representation are distinguished and must be consecutively processed:

a) epistemological level (domain-specific modeling)
b) notation level (formalization, concept representation)
c) processing level (computational, implementations)

A model is thereby defined as a representation of objects, properties, relations and interactions of a domain, enabling rational and active business in the represented domain.

The generalization of domain-specific epistemological models requires their transformation into a universal KR notation. The outcome must be validated on the real world system and thereafter adopted if needed. [14]

Table 2. Classification of models

Data Model Level	Dimension of Modeling	Data Models at Different Information Levels	Modeling Actors	Model Scope	ISO 23903 Interop. & Integration RA	Examples		
Very-high-level data model	Knowledge space	External	Business domains stakeholders	Scope, requirements and related basic concepts of business case	Business View			ISO 23903 Interoperability and Integration Reference Architecture
High-level data model	Knowledge	Conceptual	Business domains stakeholders	Relevant information and representation & relationships of basic concepts	Enterprise View	DCM, CSO	ISO 10746 ODP-RM	
Logical data model	Information	Logical	Data modelers and analysts	Layout & types of data and object relationships	Information View	HL7 V3 (CMETs), HL7 CIMI, openEHR Archetypes, FHIM		
					Computational View	HL7 FHIR		
Physical data model	Data	Physical	Data modelers and developers	Implementation-related and platform-specific aspects	Engineering View			
					Technology View	HL7 V2/V3 ITS, SQL, OHDSI, OMOP		

Following, we will consider the described aspects in more detail.

2.2. Language Aspect of Knowledge Representation

Symbols, operators, and interpretation theory give sequences of symbols *meaning* within a KR.

A key parameter in choosing or creating a KR is its *expressivity*. The more expressive a KR, the easier and more compact it is to express a fact or element of knowledge within the semantics and grammar of that KR. However, more expressive languages are likely to require more complex logic and algorithms to construct equivalent inferences. A highly expressive KR is also less likely to be complete and decidable. Less expressive KRs may be both complete and decidable. [15]

Any business system can be represented using ICT data ontologies. However, the justification of correctness and completeness of structure and behavior of the represented ecosystem can only be provided at the ecosystem's business view using the involved domains' ontologies. Justification of structure and behavior representation includes the representational components, their underlying concepts, their relations, but also the related constraints.

Therefore, natural languages are not only efficient in representing meaning, shared knowledge, skills, and experiences assumed. They also provide an optimum between *restriction to special structure* and *generative power* according to the Chomsky grammar hierarchy (regular, context-free, context-sensitive, recursively enumerable) enabling the rich and nevertheless decidable representation of real-world concepts, supported of course by common sense knowledge (Figure 3) [16].

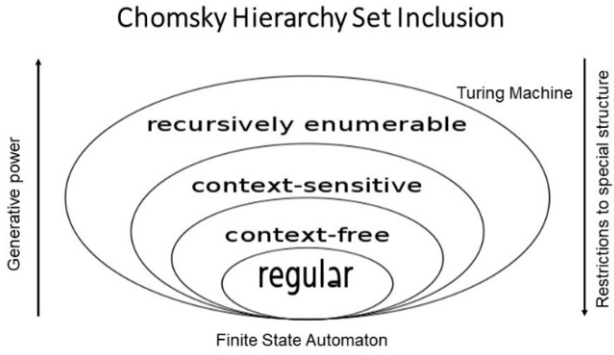

Figure 3. Chomsky Hierarchy [16]

Knowledge can be represented at different levels of abstraction and expressivity, ranging from implicit knowledge (tacit knowledge) up to fully explicit knowledge representation, i.e. from natural language up to universal logic. Figure 4 presents the Different types of ontologies. In case that an ontology is not available, we can deploy as first step the adopted Top-Level Ontology framework according to ISO/IEC 21838 instead (Figure 5) [17].

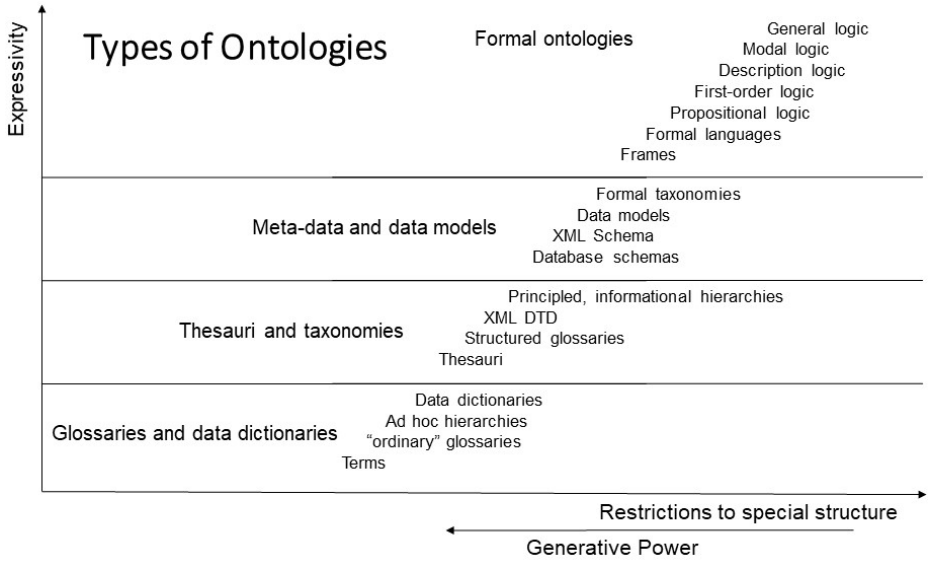

Figure 4. Types of ontologies (after [15])

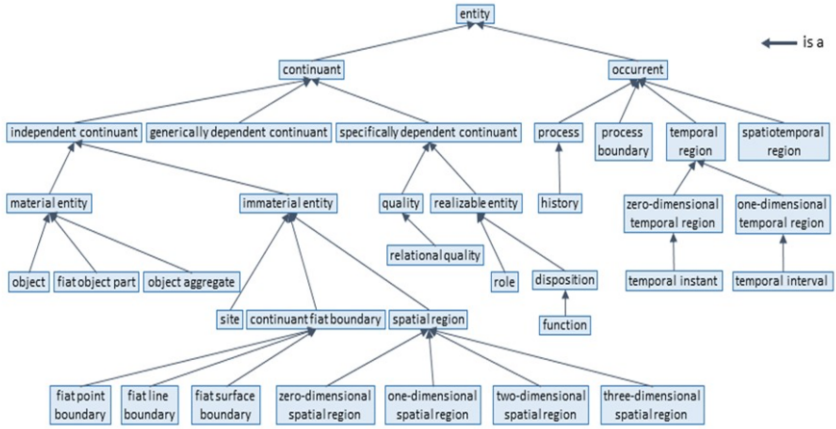

Figure 5. BFO 2020 is_a Hierarchy (after ISO/IEC 21838:2020 [17])

2.3. Good Modeling Practice

A model is an unambiguous, abstract conception of some parts or aspects of the real world corresponding to the modeling goals. Hereby, the domain of discourse, the business objectives, and the stakeholders involved have to be defined. The relevant stakeholders define the provided view of the model as well as the way of structuring and naming the concepts of the problem space. [13]

Data modeling covers the domains' concept space, refined to the business concepts, followed by the logical and finally physical models.

First capturing key concepts and key relations at a high level of abstraction, different abstraction levels should be used iteratively, where the first iteration is performed in a top-down manner to guarantee the conceptual integrity of the model. This requires meeting design principles such as orthogonality, generality, parsimony, and propriety. Figure 6 represents the ISO 23903 Framework in the Light of Good Modeling Best Practices [13].

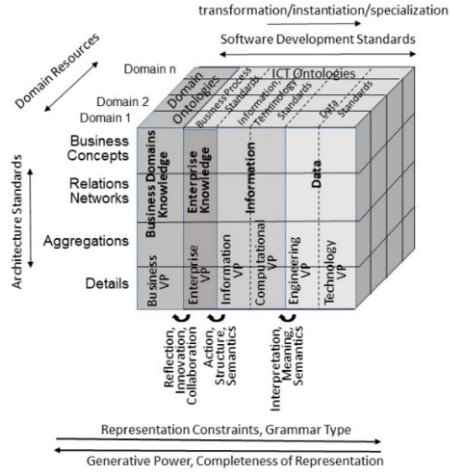

Figure 6. ISO 23903 Framework in the Light of Good Modeling Best Practices

All views are represented through the related ontologies. Facts as outcome of observations are represented by data. The interpretation of facts requires information. Understanding the system requires domain concepts (knowledge), and the integration of systems requires external (non-IT) knowledge represented by knowledge spaces. Fact-based practices are realized through observations resulting in physical data models. Logical data models enable the interpretation of data, while the understanding the system requires the conceptual data model representation. Managing a real-life system requires external model representation. Figure 7 shows the domain ontologies developed by the Open Biological and Biomedical Ontologies Foundry [18]

<table>
<tr><td rowspan="2">RELATION TO TIME
GRANULARITY</td><td colspan="4">CONTINUANT</td><td>OCCURRENT</td></tr>
<tr><td colspan="2">INDEPENDENT</td><td colspan="2">DEPENDENT</td><td></td></tr>
<tr><td>ORGAN AND ORGANISM</td><td>Organism (NCBI Taxonomy)</td><td>Anatomical Entity (FMA, CARO)</td><td>Organ Function (FMP, CPRO)</td><td rowspan="2">Phenotypic Quality (PaTO)</td><td rowspan="2">Biological Process (GO)</td></tr>
<tr><td>CELL AND CELLULAR COMPONENT</td><td>Cell (CL)</td><td>Cellular Component (FMA, GO)</td><td>Cellular Function (GO)</td></tr>
<tr><td>MOLECULE</td><td colspan="2">Molecule (ChEBI, SO, RnaO, PrO)</td><td colspan="2">Molecular Function (GO)</td><td>Molecular Process (GO)</td></tr>
</table>

Figure 7. OBO Foundry Ontologies (after [18])

For correctly designing and managing the transformed health ecosystem, we have to start with the Business view represented by domain experts using their terminologies/ontologies. Thereafter, the resulting model must be use case per use case as well as context/constraints per context/constraints transformed in a strict top-down approach into the different views according to the development process. Thereby, the instantiation of the views must be re-engineered according to the knowledge defining the correct and consistent instances, e.g. information and data from studies or repositories, EHRs, biobanks, etc.

3. Discussion

5PM ecosystems are characterized by the advancement from an empirical data-focused to a knowledge-driven concept-focused approach. This requires starting the design and management process with the real-world system by representing multidisciplinary concepts in comprehensive context, that way reflecting the knowledge spaces of all domains and actors involved in the specific use case. As different actors from different domains may use the same low level models (physical and/or logical) to represent different domain concepts and vice versa, integration and interoperability at this representational level are not decidable. For considering external knowledge spaces and contexts in very high level models domain experts or ecosystem actors deploy, the traditional and still widely practiced interoperability and integration focus on low-level representation style is even more critical.

Starting with data or low level models does not allow a correct decision on the components, their structures, functions and relations. First we have to understand the real-world business system's use case, to correctly represent the different views in the development process to implement and use the correct solution. This makes ISO 23903 to a universal standard enabling the design and management of any system from any domain in any context, covering living and non-living systems, plants, technologies, etc., at any level of granularity from elementary particles up to the universe.

The presented approach provides integration and interoperability between any ecosystem components including the actors by facilitating ontology-based translation within the individual educational background and skills, but also any components of the different viewpoints to re-use existing artifacts such as standards, specifications, information models and data.

4. Conclusions

Being based on a sophisticated, foundational, system-theoretical, architecture-centric, ontology-based, policy-driven approach, ISO 23903

- Enables representation and management of multiple domains' knowledge → Understanding the pathology of diseases and sharing that knowledge
- Enables the integration of different domains
- Enables interoperability and integration of existing specifications and artifacts, so supporting sustainability
- Enables interoperability between any ecosystem components including the involved actors
- Serves as Methodology for Developing Advanced 5P Medicine Solutions

Blindly defining, managing and using data spaces as currently performed in the context of the European Health Data Space (EHDS) are not really helpful, but could even become dangerous, automating killing the patient.

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Invited Paper

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Do Shared Decision-Making and Patient Decision Aids Take Patient's Preferences Seriously?

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Abstract. Most clinical guidelines for the assessment and management of atrial fibrillation emphasize the importance of decision support provided by Patients Decision Aids, but they are to be used and evaluated only in the context of Shared Decision-Making. Detailed examination of 10 clinical decision support tools reveals that many do not engage with patient's preferences at all. Only two take them seriously in terms of their formation, elicitation and processing, aimed at identifying the optimal personalised decision for the patient. This failure is traced to a reluctance to accept the ontological nature of preferences, as instantiations of comparative magnitudes, and to set them in an analytical framework that facilitates their transparent integration with individualised evidence.

Keywords. Patient Decision Aids, Shared Decision-Making, patient's preferences, atrial fibrillation

1. Introduction

In a previous paper [1] it was suggested that if clinical guideline producers wish to walk their talk on patient's preferences they need to (i) make clear when, and how, their recommendations embody preferences that pre-empt those of the patient (which they usually do, through the use of threshold cut-offs); (ii) ensure that the patient can formulate their own informed preferences on the consequences of all their alternative options, having easy access to the necessary probabilistic information on all of them; (iii) provide for the transparent integration of those personalised preferences with the evidence on those option consequences, as individualised as possible. Furthermore, while service level restrictions on provision may be legitimate, especially if based on cost-effectiveness, the guideline should not involve their *covert* introduction into a clinical practice claiming to fully respect the preferences of the informed patient. Most major clinical guidelines, like those of NICE for Atrial Fibrillation scrutinized in that paper, now acknowledge the potential contribution of decision support in improving clinical care and outcomes. While Patient Decision Aids (PDAs) are recognised as the preeminent form of such decision support, most guidelines stress that their contribution should only be made within Shared Decision Making (SDM), a collaborative process

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that involves patient and professional working together to reach a joint decision, based both on the evidence and the person's individual preferences, beliefs, and values [2]. Thus, at the moment, PDAs and other decision support approaches are being evaluated (implicitly if not explicitly) largely by the extent to which they facilitate SDM. As opposed to by the alternative, and our, fundamental criterion: whether they indicate what would be the best decision, defined as the one that identifies the optimal course of action for the patient by transparently integrating the *individualised* evidence regarding the consequences of all their options and the *personalised* weights attached to those consequences.

No evaluation instrument addresses the extent to which the above normative standards in relation to the patient's preferences are met, rather they focus on how the clinician performs by SDM criteria. For example, the OPTION 5 instrument [3] includes two preference-relevant items, but both score the clinician facilitation of patient involvement. "4: The clinician makes an effort to elicit the patient's preferences in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive. 5: The clinician makes an effort to integrate the patient's elicited preferences as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so." The Assessing Communication about Evidence and Patient Preferences (ACEPP) instrument [4] aims to capture the quality and amount of information important to decision-making that is discussed by the clinician with the patient when treatment options are being considered and treatment decisions are made. On its patient preference subscale it scores discussion of patient's expressed preferences regarding the tests or treatment being considered.

Most evaluations of PDAs are also being evaluated as group-level interventions rather than as personalised patient decision support. Their impact on *ex post* downstream outcomes, such as the uptake of anticoagulation medication, or the number of strokes prevented, are being used, when the function of a PDA is to identify the optimal *ex ante* decision of the individual patient. While the widespread use of the Decision Conflict Scale (DCS) avoids the downstream fallacy, the full scale lacks construct validity for the evaluation of a PDA [5]. The inclusion of the Uncertainty subscale means an aid is rewarded for providing false clarity about the extent to which the best option is better, penalising an aid if it correctly portrays the decision as being, or near, 'a tossup'. The DCS also rewards the extent to which the actual decision reflects the output of the aid, thereby allowing the subsequent clinical conversation to improperly affect its evaluation.

Finally, but crucially, what are preferences? Two ontological assumptions condition our verdicts on an aid's treatment of patient's preferences. Firstly, preferences have no ontological connection with their subject, such as option consequences. Each is what they *are*. So, while the consequences may be reasoned about, in the sense of being better understood both individually and in relation to each other, any such reasoning does not and cannot 'explain' the preferences regarding those consequences. It follows that it makes no sense - and in fact constitutes symbolic violence - to ask, explicitly or implicitly, for preferences to be 'justified'. Secondly, preferences are manifestations of a comparative assessment of the *magnitudes* of the (usually probabilistic) consequences of options. Whether one *prefers* that these magnitudes are assessed numerically or verbally and whether they are called 'values' or 'utilities' or 'desirabilities' are second order considerations. But the requirement to accept that preferences involve somehow establishing comparative magnitudes is non-negotiable.

Method

We examined a set of decision support approaches to establish whether they met our fundamental criterion. We restricted them to nine published in the last 10 years which emerged from recent systematic reviews [6-9]. We added the "3-talk model' [10].

2. Results

We were able to quickly eliminate 5 on the basis that, whatever their other (undisputed) merits, they do not involve any serious engagement with patient's preferences, or even patients' preferences [11-15]. The Atrial Fibrillation Shared Decision-Making Tool [16] was also eliminated on the ground that while it introduces patients' preferences these are, as indicated by the positioning of the apostrophe, average population utility values. This left four for detailed discussion: the 3-talk model [10], the Anticoagulation Choice Shared Decision-Making tool [17,18], the Dynamic Computer Interactive Decision Application (DCIDA) Patient Decision Aid [19], and the Atrial Fibrillation Shared Decision-Making Tool (AFSDM) [20].

3. Discussions

*The 3-talk Model***.** In the original 2012 version, 'choice talk', 'option talk' and 'decision talk' made up a deliberative process which led the patient-professional dyad from 'initial preferences' to 'informed preferences'. There was almost no elaboration of what was to go on in the 'decision talk' and, following much supportive critiquing, a revised model was published in 2017 [10]. It was highly promising in relation to patient's preferences.

"Instead of assuming that decisions should be guided by scientific consensus about effectiveness, shared decision making proposes that informed preferences—by which is meant what matters to patients and families—should play a major role in decision making processes. Shared decision making is more than being attentive to patients' needs or concerns: it represents an important shift in the roles of both patients and clinicians. Sharing decisions signals an end to the view that "doctors knows best" and the end to making recommendations without considering how these might align with what matters to patients, informed by the best information available from evidence-based healthcare. Nevertheless, this change is clearly not easy for clinicians, especially for those whose attitudes are shaped by training, mentorship, and role models who have historically paid less attention to the views and preferences of patients... Shared decision making is easier when options are reasonable, and relevant to clinical situations where it is considered ethical to deliberate carefully. Whether such situations are considered to occur rarely or commonly partly depends on the importance given to individual preferences in determining healthcare decisions. Such views are shifting as the scope of personal autonomy and societal expectations change... We do not believe future generations of patients will tolerate important decisions being made without them understanding the key trade-offs between the harms and benefits of interventions. Some patients feel anxious when told about the existence of alternative options and may worry about being abandoned to make decisions alone. However, shared decision making is the solution to this concern, not the cause of it."

The revised model has the 3 talks in a cyclical graphic which retains the overall sequence but emphasises their fluidity within the conversational deliberative SDM process. 1.Team Talk: Work together, describe choices, offer support, and ask about goals ('Let's work as a team to make a decision that suits you best.") 2. Option Talk: Discuss alternatives using risk communication principles. ("Let's compare the possible options") 3. Decision Talk: Get to informed preferences, make preference-based decisions ("Tell me what matters most to you for this decision.")

Verdict by our criterion: Negative. We are still left in a complete 'black box' as to how the dyad 'get to informed preferences and make preference-based decisions'. The reluctance to indicate support for anything approaching an analytic approach in decision talk – or in fact to one that embrace all three talks - is manifest.

*The Anticoagulation Choice Shared Decision-Making tool***.** This is a clinician-directed 'encounter conversation aid' from the Mayo group led by Victor Montori [17,18**]**. It does not elicit preferences and in fact neither aid nor associated papers use the word. Under the heading 'Beyond Trade-offs' we find the following "The classic medical formulation of the problem of anticoagulation is to set the benefits of stroke prevention against the harms of bleeding promotion. This leads to a tendency to compare or trade off strokes and bleeds, or to ask the question of how many bleeds are acceptable in exchange for avoiding a stroke. Although this formulation follows the decision analytic logic of utility maximization, in practice we found direct comparison of strokes and bleeds to be inadequate in determining what to do as the practical and emotional implications of living with a risk of stroke or bleeds exceed the issues of utility." It is, on the contrary, central to the measurement of the relevant 'utilities' that they embrace all 'the practical and emotional implications of living with a risk of stroke or bleeds'. Interestingly, the Mayo tool provides no guidance on how the patient and clinician are to determine that their situation demands anticoagulation and has them move quickly to the second phase of the tool to determine how to anticoagulate. Here it presents "the key issues that distinguish the available options: risk of bleeding, reversibility, need to restrict diet, out-of-pocket costs, and monitoring requirements". But without reference to preferences.

The conclusion from its extensive trialing was that 'the recommendations for SDM in published guidelines... assume that clinicians and health care systems can implement forms of SDM... The finding that the patient's highest priority led the discussion in only a limited number of SDM encounters challenges this assumption... The use of an encounter tool to foster and support SDM resulted in improvements in several aspects of SDM quality and clinician satisfaction, with no significant effect on treatment decisions or encounter duration. These results question the view that implementing SDM tools for anticoagulant treatment can improve care for patients with AF."

Verdict by our criterion. Negative. We are not surprised by the conclusion and suggest that until the central issue of patient's (and clinician's) *preferences* is addressed full-frontally SDM will make no progress in practice.

*The DCIDA Patient Decision Aid***.** This PDA was specified to be a self-guided online tool for chronic AF patients who would self-complete it and show the resulting report to their AF care provider, as the basis for conversation about stroke prevention therapy [19]. "Several other AF stroke prevention therapy decision aids are available, though none help patients map their values and preferences to therapy options using a values clarification technique such as best-worst scaling (BWS). They typically present non-individualized information that patients must appraise for themselves, attempt to make

therapy recommendations without clarifying patients' preferences, use simple methods of eliciting preferences that do not acknowledge tradeoffs, and/or fail to integrate them with attributes of the therapy options...The key step by which the DCIDA aid remedies these defects is the 'Values clarification' one in which a best-worst scaling (BWS) exercise... was used to rank and quantify the strength of patients' values on the 9 most important attributes of AF stroke prevention therapy, as identified by the steering group. These include dietary and alcohol restrictions, number of daily doses, requirement for international normalized ratio blood tests, risk of stroke, risk of major bleeding, risk of intracranial hemorrhage, participation in occupational or recreational activities with a risk of traumatic injury, availability of an antidote, and cost... Uniquely, this PDA incorporated patient's individualized stroke and bleeding risk in the BWS questions relevant to those attributes.... [In this observational pilot study] our PDA was effective for... eliciting patients' values and presenting therapy options that aligned with patients' values and preferences. Using the PDA revealed that many patients have therapy preferences different from their currently prescribed treatment."

Verdict by our criterion: Positive. However, none of the small number (9) citations of the paper in Google Scholar as of March 2024 report or advocate its use. It appears to be no longer accessible.

The Atrial Fibrillation Shared Decision-Making Tool (AFSDM) This differs from the group's Atrial Fibrillation Decision Support Tool (AFDST) [16] in using individual patient preferences, in the form of utilities for key health consequences of AF and antithrombotic therapy [20]. These include stroke with either mild or severe long-term neurological sequelae, major gastrointestinal hemorrhage, and the need to take a pill (warfarin) each day and have blood tests (INR) done on average once or twice a month... Patient utilities were assessed with a computerized preference elicitation tool, the "Gambler," that automates, standardises, and facilitates this process [21]. The standard gamble determines what risk of the worst outcome (in this case death) a patient is willing to take to avoid the otherwise certain outcome of the health state under consideration. The Gambler uses a "poison pill" analogy (the patient chooses a pill from a container with varying probabilities that the pill leads to death or full health) to perform the exercise by iteratively "ping-ponging" between various probabilities until the patient considers the two options (the certainty of the health status under consideration versus the gamble) equal... Zero is equivalent to death, while one-hundred is the best one could hope to be with a diagnosis of AF. Taking warfarin was rated as 95.8 (SD, 8.1); a major gastrointestinal hemorrhage was rated as 89.6 (SD, 14.5); mild stroke was rated 77.1 (SD, 24.1); and major stroke was rated 42.0 (SD, 28.9). The AFSDM does not recommend a change in treatment unless there is a minimum gain of 0.1 QALYs [36.5 days in 'full health'] compared with current treatment. The choice of a 0.1 gain in QALYs as our threshold for a minimum clinically significant difference was empirical. There is no clear definition of how large a gain constitutes a clinically significant gain. When the gain is too small to matter clinically, the decision is considered a toss-up."

Verdict by our criterion: Positive. However, we can find no report of its use and the group reverted to use AFDST with population utilities in a recent study.

4. Conclusion

Only two of the decision support tools we surveyed met our criterion for taking patient's preferences seriously. The DCIDA aid does not appear to have been used since the pilot study and is no longer available. AFSDT has not had any follow-up use. That it was the only post-2017 aid to appear in a scoping review of ones based on decision analysis [22] makes it clear that analysis, particularly an analysis of decisions that treats patient's preferences seriously, is not wanted on the clinical voyage.

Nothing in the above should be taken to imply a failure to recognise that clinical decision making takes place within a wider health ecosystem, where the patient is one of many actors and stakeholders. This system can be seen as evolving to "personalized, preventive, predictive, participative precision medicine (P5M) considering individual health status, conditions, genetic, and genomic dispositions as well as social, occupational, environmental, and behavioral context." [23]. It is uncontroversial that interoperability between the multiple domains and actors in the evolving system requires standards for the representation, harmonization and implementation of concepts, skills and abilities. The International Standards Organisation is undertaking this task; see ISO 23209:2021 [24].

However, 'knowledge' is currently the exclusive focus of these endeavours.

"….good medical practice is based on three pillars: (a) the knowledge gathered by domain experts during the evolution of medicine and related sciences as well as from emerging projects and insights, (b) the practicing clinician's experience in interpreting and applying this knowledge, and (c) the consideration of the patient's individual context and conditions, weighted in that order. Empowered subjects of care gather knowledge through new technologies and social business and actively as well as passively provide data and information, thereby increasingly strengthening the third pillar. The personalized health approach just attaches a greater weight to personal pathogenesis and corresponding individual diagnoses and therapies, i.e., specializes and individualizes medicine toward the patient, His/her context, conditions, and preferences, thereby understanding the individual molecular and cell-specific reasons for, and predicting or better even preventing, the development and course of a disease." [24]

While preferences are mentioned here, this is the only occasion and the fundamental ontological distinction between *preferences* - whether of patients or of any other actors - and *knowledge* is missing. This distinction is key to the proper representation of patient's preferences and to the associated distinction between the individualisation and personalisation of care. However well individualised it is in reflecting knowledge, medical practice is not personalised unless it embodies explicit analytical respect for the preferences of the informed patient - not treating them merely as 'opinions' or 'wishes' expressed within a conversation.

We conclude that the widely acknowledged failure to achieve SDM in practice is mainly the result of a failure to get to grips with the specific issue of preferences - patient's and professional's - at the ontological level concerning their nature, as well with the oft-reported professional and organisational obstacles. However, this failure is paradoxically associated with the outstanding success of the concept of SDM as a 'border object' that sustains an all-pervasive professional movement with an infrastructure encompassing an international society, professional publications, and academic positions. It generates highly-funded research that on our reading is doomed to lack impact in practice because of its 'blanking' of patient's preferences. But it will therefore justify further research - ensuring that 'failure is success'.

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A Comprehensive Framework for Hospital@Home Care Models

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Abstract. Hospital@home is a healthcare approach, where patients receive active treatment from health professionals in their own home for conditions that would normally necessitate a hospital stay. Objective: To develop a framework of relevant features for describing hospital@home care models. Methods: The framework was developed based on a literature review and thematic analysis. We considered 42 papers describing hospital@home care approaches. Extracted features were grouped and aggregated in a framework. Results: The framework consists of nine dimensions: Persons involved, target patient population, service delivery, intended outcome, first point of contact, technology involved, quality, and data collection. The framework provides a comprehensive list of required roles, technologies and service types. Conclusion: The framework can act as a guide for researchers to develop new technologies or interventions to improve hospital@home, particularly in areas such as tele-health, wearable technology, and patient self-management tools. Healthcare providers can use the framework as a guide or blueprint for building or expanding upon their hospital@home services.

Keywords. Hospital at home, Care model, Patient at home, Innovation, Framework

1. Introduction

Hospital@home is a healthcare approach, where patients receive active treatment from health professionals in their own home for conditions that would normally necessitate a hospital stay [1]. This model often involves a comprehensive care team providing a range of services, as follow up after an early hospital discharge or after a patient visit to the emergency room that does not require inpatient hospitalization. The array of services in hospital@home programs include home-based intravenous treatments, remote health monitoring, chemotherapy or laboratory tests [2]. Additionally, hospital@home services include home visits from a variety of healthcare professionals such as doctors, nurse practitioners, nurses, and other health professionals such as social workers, physiotherapists, and pharmacists. There is considerable evidence of hospital@home's effectiveness, but the evidence is of low quality and has to be

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interpreted with caution [3]. This care model is gaining traction as an alternative to traditional inpatient care for certain populations and conditions (e.g. like pneumonia, chronic obstructive pulmonary disease, or heart conditions). However, despite its long history of use in countries such as the United States [3] or Spain, its growing popularity and implementation in countries such as Switzerland, the hospital@home approach lacks a comprehensive framework that encapsulates the multifaceted nature of hospital@home services (including their use of technology supports). This paper aims to introduce a framework of features of hospital@home care models. Such a framework could assist in understanding, evaluating and optimizing hospital@home care models as well as in developing education programs. The main objectives of this paper are to identify a list of features (i.e., dimensions and items) that could be used to describe and compare hospital@home care models (i.e., identify relation between hospital@home features).

2. Framework Development

We reviewed the literature using the preferred items for systematic review and meta-analysis (PRISMA) statements approach [4]. Our focus was on the practical aspects and real-world applications of homecare, rather than only the individual technologies that make it possible. Therefore, we deliberately chose not to collect information from technical databases such as IEEE® Xplore or the ACM® Digital Library. We searched only PubMed®, which specializes in health-related articles, and is not limited to technical details. To identify the relevant literature, we developed a search string that included "hospital@home" and its main equivalents (i.e., "hospital at home" OR "home care" OR "patient at home"). The results of the searches for the period of 2013 to 2022 were considered. A complete search strategy can be found in another paper [see 5] in which the results were used for studying the strengths, weaknesses, opportunities and threats to hospital@home. Out of 1371 retrieved articles, 82 were considered for full-text review. Forty-two papers were included in the qualitative synthesis of that review. These papers were analyzed thematically [6] to aggregate the results into a framework. The objective of the thematic analysis was to answer the research question: “How can we characterize the component elements of current hospital@home approaches?”. The information available about the hospital@home approaches was extracted from the papers and grouped into themes. All the collected information was aggregated in the hospital@home framework. There was one topic added to the framework that was intentionally excluded from the literature review due to its specific nature, which palliative care.

3. A Framework for Hospital@Home Care

Based on our research question (i.e., to identify relevant component elements to characterize hospital@home care models and our literature review), we propose a framework that covers differing attributes or features of hospital@home care models. Figure 1 illustrates these dimensions, described in depth below:

Persons Involved: This dimension captures the human resources involved with hospital@home models. They include (a non-exhaustive list):

- The patient as the primary recipient of care.
- Informal caregivers, relatives and friends (who provide non-professional support).

- Healthcare providers: A wide range of professionals such as doctors, clinicians, paramedics, dieticians, physiotherapists, psychotherapists, pharmacists, telemedicine institutes, physician assistants, nurses, wound specialists, and advanced nurse practitioners. It also includes psychologists.
- Technology-related staff: Professionals who provide technical support for the technologies used such as electronic health records and medical, remote monitoring and telehealth devices (i.e., medical/health informatics professionals, information technology professionals, biomedical engineers).

Target population: This dimension focuses on the candidates' eligibility criteria for receiving hospital@home services and includes patient characteristics such as:

- Medical condition(s): The specific health conditions that can be effectively managed at home including severity of the condition and other characteristics.
- Demographics: Patient characteristics such as age, gender, socio-economic status, etc. that may influence the appropriateness for receiving hospital@home care.
- Literacy level: Health, eHealth and technology literacy of patients
- Social Support: Presence or absence of caregivers and a social network that can provide health supports and interact with health professionals providing care.

Service delivery: Hospital@home care models that deliver differing services. This dimension describes the range of services provided, such as:

- Monitoring and ongoing care.
- Prevention, acute treatment and rehabilitation (covering the different stages of care from prevention through to rehabilitation after treatment).
- Diagnosis and self-management: Helping patients to manage their health.
- Palliative care: Providing comfort in end-of-life situations.
- Accompanying services: Visits from social workers and patient education.
- Emergency handling directives and processes.

Intended outcomes: Hospital@home care models are designed for a specific purpose or intended outcome. These can include:

- Early discharge and avoidance of admission.
- Improving care and economic efficiency of care.
- Improving patient safety and satisfaction.

First point of contact: This dimension refers to the first contact point that the patient is interacting with to decide on inclusion in a hospital@home care model such as:

- The emergency department or hospital ware in a hospital
- Telephone triage

Reimbursement model: Several reimbursement models can be used to finance hospital@home programs, among them:

- Insurance coverage
- Bundled payments

Technology involved: This dimension describes the technological tools used to deliver care or to support care provision including monitoring, such as:

- Communication technologies: These technologies support interaction between patients and care providers for routine and emergent health situations.
- Wearables and sensors: Sensors in the patient's home to support monitoring of health status. Wearables worn by patients to collect data for monitoring purposes.
- Diagnostic instruments: Used to support patient assessments and monitoring; for example, point-of-care laboratory tests, ultrasound, ECG, vital signs monitors.

- Patient apps, and online audiovisual and communication platforms: To help support patient engagement, self-management, education, and decision making.
- Electronic health records (EHRs) and documentation systems for patient data.
- Data analytics platform: Helps in visualizing the collected data.
- Assistive technologies: Helps to analyze data collected from sensors or entered manually and provides assistance either to the patient (i.e., shall I call for help?) or for the care provider (e.g. medical alert systems, medication management system, decision support systems)

Quality: This dimension concerns aspects to ensure the effectiveness and safety of the care model:

- Ethics, accuracy, safety, and effectiveness: Adhering to ethical standards and ensuring the accuracy, safety and efficacy of treatments and technologies.
- User acceptability and cost-effectiveness: Assessing patient and provider acceptability and the economic viability of the model.

Data collection and outcomes: This dimension defines the information collected as part of the hospital@home care delivery and outcomes evaluation. We identified several different types of data collection:

- Surveys and EHR documentation: These include Patient Reported Outcomes and Experience measures (e.g. PROMs/ PREMs) or by healthcare providers (e.g. data entered into the EHR).
- Sensors and third-party monitoring systems: Automated data collection through sensors and integration with other healthcare systems.

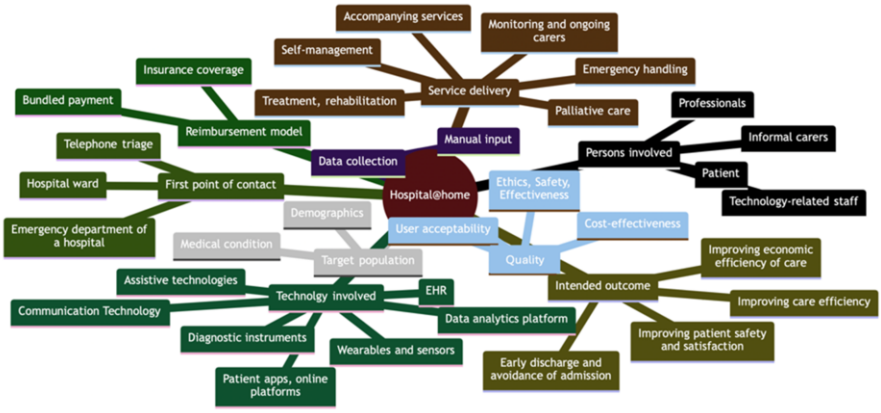

Figure 1. Framework for hospital@home care models

4. Discussion and Conclusion

In this paper, we introduced a framework comprising relevant features of hospital@home care models. Nine relevant dimensions were identified following the review of 42 scientific papers describing hospital@home care models. However, a comprehensive evaluation of the framework or validation by an expert panel is still pending. We plan to use a focus group to validate the literature derived framework. The experts can bring their domain knowledge and practical experience to ensure its applicability to the real world. Additionally, a scenario-based evaluation will be carried

out to demonstrate the utility of the framework. Our framework specifically includes technology and data collection in the context of hospital@home. Involving technology in these care models has been identified as key research issues in previous work [5,7]. In the following, we describe the envisioned use of the framework.

The framework acts as a guide to aid the decision making, planning, development and implementation of hospital@home care models. Researchers can use the framework to design studies that evaluate the effectiveness of hospital@home care for different dimensions retrieved from the framework, such as patient satisfaction, cost-effectiveness, and clinical outcomes. By comparing existing hospital@home models with the framework, researchers can identify gaps in services, use of technology, and/or patient populations served. The framework can help researchers to develop new technologies or interventions to improve hospital@home. This is the case particularly in areas such as telehealth, wearable technology, and patient self-management tools.

Policymakers can use the framework to develop policies and regulations that support the implementation and expansion of hospital@home-based health services. Hospital administrators can help to identify the aspects of hospital@home that require more investment and support, such as technology infrastructure, workforce training or patient education. Furthermore, policy makers and administrators can set standards and guidelines for hospital@home based on the framework's dimensions to ensure the quality, safety and consistency of care. Healthcare providers and administrators can use the framework as a blueprint for building or expanding hospital@home services. Our paper provides a list of required roles, technologies and service types. The paper can guide healthcare professional and support staff training in the delivery of hospital@home care, particularly in aspects such as technology use and ethical competencies related to hospital@home. Healthcare providers can use the dimensions of the framework to develop key performance indicators that help in monitoring and improving the quality of hospital@home care. This includes tracking patient outcomes, technology effectiveness and provider efficiency.

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Aging Population Challenges and the Role of Thai Adolescents in Caring for the Elderly: A Cross-Sectional Study

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Abstract: This cross-sectional study aimed to investigate the perspective and caregiving practices of Thai adolescents towards the elderly in the Northeastern region of Thailand. The study was carried out during July 1st to September 30th, 2023 among 1,551 participants in grades 4-6 from eight randomly selected schools. The analyzing using descriptive statistics. The results found that the average age was 15.30±1.66 years old, 62.4% were female, and most lived with their parents and relatives. About 36.4% of parents have experienced either widowhood or separation, 69.4% of families had a monthly income less than 15,000 THB. While 33.7% had an elderly person in the family, 1.6% lived with bedridden patients, and 40.3% required assistance in daily activities such as cooking, mobility, while 58.7% had diabetes and high blood pressure. 59.3% did not have a primary caregiver in the family, only parents or relatives usually taking on this role. Adolescent grandchildren spent the majority of their time on education. Almost one of three rarely took care of the elderly, even though their parents and teachers taught about moral responsibility. Regarding the belief in the merit that would arise from taking care of the elderly, one of five was indifferent or did not believe, while half of them believed to some extent. From self-assessment of their ability to take care of the elderly, most were in the moderate and low levels, despite receiving information from family, teachers, or various media. The predominant perspective is that caregiving is perceived as the responsibility of parents or health professionals, and the belief that the elderly is captious and irksome. Therefore, it is advisable to present policy-oriented information across education, health, and societal dimensions to support children and young people to learn about elderly individuals and instilling their responsibility within families and societies, fostering a sustainable and well-being-oriented community.

Keywords. The perspective of adolescents towards the elderly, Elderly Care Practices, Thai Young Caregivers

1. Introduction

Thailand became to a completely aging society [1]and had the second highest number in ASEAN countries [2], especially those aged 80 and above increasing from 1.5

million in 2020 to 3.5 million in the next two decades. Approximately 30% of them has income levels below the poverty line [3]. Traditionally, Thai society highly values the elderly for their wisdom and experience [4][5] and caring for elders as a duty for every family member and the culturally rich and virtuous traditions of Thai society [3][6], but the number of family caregivers has reduced to three members per household [3] and family size will continuously fall in the future [7], leading them to seek employment outside the home, especially women who are primary caregivers [8]. Many nearly-elderly parents express concerns about becoming a burden of their children [3] and thus wish to maintain their independence as long as possible [9]. Finding that up to 15% of those elderly have been verbally abused and mistreated by their family members. By the way the population of this group in the Northeastern region of Thailand have been experiencing the highest level of psychological harm [10].

Thailand has strengthened its community health system by training volunteer caregivers (CG) to provide holistic care, encompassing physical, mental, social, and spiritual aspects, under the supervision of primary healthcare personnel [11]. However, there is still an inadequate number of caregivers [12]. Therefore, the adoption of the concept of creating a Young Carer (YC) network to care for the elderly within their family in need of assistance is a viable approach [13][14][15]. However, there remains an insufficient amount, even though relying on the paid caregivers. At the meanwhile the prevailing negative attitudes towards caregiving for the elderly have been exacerbated, leading someone to abandon their training prematurely or shift to other occupations [16].

The study aims to investigate the role and behavior of Thai adolescents in the elderly caregiving in the Northeastern of Thailand. Additionally, the information and recommendations on the relevant issues herein should be helpful in making a policy decision by the educational agencies, especially for the National Commission on Older Persons and the key government agencies to foster warmth and strength within families, communities, and society, aligning with the country's policies on the elderly care system in the future.

2.Methods

The study used a cross-sectional self-report questionnaire survey design to investigate the caring for the elderly practices among Thai adolescents in the Northeastern region of Thailand of eight high schools that located in urban, suburban/ semi-urban areas with one health region each by utilizing a multistage random sampling technique. A sample size of 750 was calculated based on the total student population of 328,856 with the confidence level set at 95% and variance value of 0.40 [17]. In case of a high non-participation rate due to the sensitivity of issue, the 20% was added, so the final sample was 1,551 participants. The responses to the questionnaires are anonymous. The response rate for the questionnaires was 95%. Only the completed questionnaires remain. There were 84 questions in the questionnaires.

This research was reviewed and approved by the Mahasarakham University Human Research Ethics Committee (Reference NO. 151-110/2566), based on the Declaration of Helsinki. Writing informed consent was obtained from all patients and their relatives by providing potential participants with a clear understanding of the study's purpose, their rights, and the assurance of confidential information handling. Following data collection, all participants received a small souvenir as an acknowledgment of their involvement. The entire recruitment and data collection process occurred within a specified timeframe, from July 1st to September 30th, 2023.

The data were analyzed with descriptive statistics. All questionnaire data were checked and double entered into Microsoft Excel version 2007 and validated using Epi-Info (version 3.5.4) and then entered into Stata (version 13.0) to perform statistical calculations.

3.Results

Among the 1,551 participants, the average age was 15.30 ± 1.66 years old, 62.4% were female, and most lived with their parents and relatives. About 36.4% of parents have experienced either widowhood or separation and 69.4% of families had a monthly income of less than THB 15,000. Of 33.7% had an elderly person in the family, 1.6% bedridden patients, and 40.3% required assistance in daily activities such as cooking, mobility, while 58.7% had diabetes and high blood pressure. 59.3% did not have a primary caregiver in the family, only parents or relatives usually taking on this role. Adolescent grandchildren spent the majority of their time on education. Almost one in three rarely supported in taking care of the elderly, even though parents and teachers taught about moral responsibility. Regarding the belief in the merit that would arise from taking care of the elderly, one in five was indifferent or did not believe, while half believed in some extent. From self-assessment of their ability to take care of the elderly, most of them were in the moderate and low levels, despite receiving information from family, teachers, or various media.

Upon studying the caregiving behaviors towards the elderly in the family over the past year, it was found that over half were at the low and moderate levels (40.3%). When arranging the scores of joint activities with the elderly, ranging from low to high scores, it was found that the most common activity was talking, while the moderate level had various activities like preparing the bed, massaging, being a companion, exercising together, managing medication, cooking, doing laundry, running errands, buying snacks, watching TV together, cleaning the bedroom, and washing dishes. However, activities with lower scores included dressing, feeding, accompanying to the bathroom, and wound care (as shown in Table 1).

Table 1. Elderly caring practices (n=1551)

The level of Elderly caring practices	**Number (1,540)**	**% (99.3)**
Low	861	55.9
Medium	614	39.9
High	65	4.2
Caring for the elderly in the family	Level of caregiving	
	$\overline{X}$ (S.D)	Level[a]
• Massage	2.26(1.00)	Low
• Dress up	1.85(0.79)	Low
• Prepare the bed	2.17(1.04)	Low
• Escort to the bathroom	1.89(0.81)	Low
• Feed	1.87(0.83)	Low
• Initiate conversation	3.18(1.50)	Medium
• Prepare and administer medication	2.35(1.15)	Medium
• Set up the dining table	2.66(1.33)	Medium
• Prepare meals	2.46(1.21)	Medium
• Wound care	1.93(0.84)	Low
• Handle errands such as shopping" "Pay utility bills - water, electricity, telephone	2.44(1.15)	Medium
• Do laundry / Iron clothes	2.51(1.21)	Medium

Caring for the elderly in the family	Level of caregiving	
	$\overline{X}$ (S.D)	Level[a]
• Clean and tidy up the room or house	2.70(1.23)	Medium
• Wash dishes	3.00(1.42)	Medium
• Bring groceries/snacks	2.65(1.21)	Medium
• Accompany for a walk/exercise in bed	2.23(1.09)	Low
• Read a book/Watch TV together	2.61(1.27)	Medium
• Sleep as companions	2.23(1.15)	Low

[a]Level was defined for scoring mean, as ''Low''= 1.0-2.33, ''Medium'' =2.34-3.67 and ''High'' = 3.68-5.00).

4.Discussion

The results revealed that the representation of the roles of adolescents in caring for the elderly within the family remains limited. Some pose a risk of accidents if the elderly is not assisted, especially in those who have one or more chronic diseases, cognitive problems, or physical and/or mental disability and limited self-help [11]. These tasks are often perceived as primarily undertaken by parents or older family members [4]. Adolescents may engage in these activities when requested, or when participated in activities that require youthful agility, such as, running errands outside the home, like grocery shopping or paying bills [13] [14][15]. There is a perception that certain tasks cannot be managed, either due to a lack of knowledge or because adolescents believe parents, older individuals or volunteer CGs are better suited for these responsibilities [9]. Despite receiving guidance from parents, teachers, or societal norms promoting filial piety [3], but some people commented that young people today are spoiled and disobey parents citing the internet, computer games and mobile phones and the categorization of age groups is often presented to provide an understanding of the different needs and behaviors of individuals at various life stages [18][19], as bad influences. [8].

Therefore, it is advisable to promote the establishment of Young Carer (YC) programs within families or communities. This initiative aims to cultivate resilience and warmth within the family system and reinforcing the culture and positive beliefs of Thai society, some believe that filial piety remains strong. They emphasize that if parents raise their children properly, the children will, in turn, provide care and support to their parents in old [19][20], to alleviate the financial burden associated with hiring a caretaker [8]. By doing so, it can help prevent or mitigate the risks arising from diseases or health crises, both in normal circumstances and during emergencies. This approach is more beneficial than relying solely on health services. It is unlikely that volunteer programs can realistically meet the need for functional care on a sustained full-time basis [17]. Additionally, it allows children to learn and acquire life skills through the transfer of experiences and wisdom from the elderly. This contributes to the creation of a better society in the future [5] [3]. Furthermore, it fosters a sense of responsibility for families and communities among young people, ensuring their active involvement in caring for the elderly in the future [21].

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Tuberculosis Infection Control: Experiences and Considerations from a Web Based Tool Implementation

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Abstract. Tuberculosis (TB) remains a significant global health challenge. Indeed, according to the World Health Organization (WHO), TB is classified as the second most common cause of death worldwide due to a single infectious agent in 2022, following COVID-19. To effectively manage tuberculosis patients, it is necessary to ensure accurate diagnosis, prompt treatment initiation, and vigilant monitoring of patients' progress. In 2017, the TB Ge network was implemented and launched in two primary hospitals within the Liguria Region in Italy, with the main purpose to manage tuberculosis infections. This system, organized as a web-based tool, simplifies the manual input of patient's data and therapies, while automating the integration of test results from hospitals' Laboratory Information Systems (LIS), without requiring human intervention. The goal of this paper is to highlight the outcomes achieved through the implementation of the TB Ge network in a period seriously affected by the COVID-19 pandemia and outline future directions. More specifically, the aim is to extend its adoption to all hospitals in the Liguria Region, thus improving the management of tuberculosis infections across healthcare facilities.

Keywords. Tuberculosis (TB), Web Based Tool, Interoperability

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1. Introduction

Mycobacterium tuberculosis (MTB) is responsible for a global pandemic, with 7.5 million newly reported cases in 2022 and 410.000 people who developed multidrug-resistant tuberculosis (MDR-TB). In 2022, TB was the second cause of mortality from a single infectious agent, with estimated 1.3 million deaths. The WHO "End TB Strategy 2016-2035" includes global key interventions also addressed to low-incidence settings for accelerating progress towards TB elimination. One of the most recent commitments established was to strengthen research capacity and collaboration through TB research platforms and networks [1]. Indeed, web-based technology can be profitably employed not only for research purposes or epidemiological surveillance but also in the diagnostic, treatment and follow-up processes [2]. The TB Ge network project is a multicentric web-based platform developed in 2017, with the aim of collecting information of patients affected by TB, in order to create a single digital platform easily available for clinical and research purposes [3]. The aim of this paper is to describe our experience with the implementation of a web-based tool for the management of TB infection and its use through a significant number of years.

2. Materials and Methods

When initially implemented, the primary goal of the TB Ge network was to establish a tuberculosis registry enabling the tracking of patients throughout their diagnosis, treatment, and follow-up stages, thereby enhancing compliance, and ensuring appropriate therapeutic interventions. Additionally, the project aimed to achieve two secondary objectives. The first aspect involves minimizing patient loss during follow-up periods to ensure continuity in their care and treatment. The second aspect of the project is identifying the demographic characteristics of patients affected by tuberculosis.

2.1. Study design

The study is designed as a prospective, observational, and multicenter registry. Over the course of 36 months following approval by the Regional Ethical Committee, the aim of the project was to enroll around 200 patients. Data collection was facilitated through an online platform, accessible to participating hospitals involved in compiling the registry. The registry collects data about: demographic characteristics of the study population (nationality, gender, age, zip code of residence, etc.); incidence and prevalence of pulmonary and extra-pulmonary TB disease; clinical presentation of TB disease and associated co-morbidities; mode of diagnosis of pulmonary and extra-pulmonary TB disease; prevalence of anti-TB drug resistance; therapeutic appropriateness; length of hospital stay; therapy-related adverse effects; assessment of follow-up outcomes as defined by WHO. To be included in the project, participants must: have the capacity to provide consent or have consent provided by a legally authorized representative; be diagnosed with active TB, either microbiologically confirmed or clinically/radiologically defined; be receiving hospital care or attending outpatient clinics at participating centers. There are no age restrictions.

2.2. Platform description

The TB Ge network is a multi-centric web-based platform that enables the monitoring of patients throughout the diagnosis and follow-up processes in two primary hospitals located in the Liguria Region in Italy. The system handles de-identified data (listed in paragraph *2.1*) from patients with at least one episode of active TB. Data can be entered into the platform manually or sourced directly from the Electronic Health Record (EHR), if available. Additionally, to mitigate time loss and potential errors associated with manual entry, laboratory data is automatically extracted on a daily basis from the Laboratory Information System (LIS). To provide interoperability, the project adheres to Healthcare Services Specification Project (HSSP) standards proposed by Health Level 7 (HL7) and Object Management Group (OMG). Clinical Document Architecture R2 (CDA R2) standard is used to share clinical data among facilities, and medical terminology standards such as Logical Observation Identifiers Names and Codes (LOINC) and Anatomical Therapeutic Chemical Classification System (ATC) codes syntactic interoperability for clinical parameters and antibiotics.

2.3. Patient management

To manage patients' data, the platform implements the Retrieve Locate and Update Service (RLUS). This service was previously used by some of the authors for a separate regional initiative concerning the Human Immunodeficiency Virus (HIV) [4, 5]. Within the context of the Ligurian HIV Network, the repository contains only hospital-specific patient identification codes, each unique to the respective medical facility. As a result, in cases of transferring patients from one hospital to another, physicians are tasked with manually aligning these codes. In contrast, in the TB Ge network, the database extends its scope to include the patient's encrypted National Insurance Number. This additional layer of information serves to simplify the process of rebuilding a TB patient's medical pathway, thus providing greater clarity and efficiency in healthcare management.

3. Results

The TB Ge network currently connects two major hospitals in the metropolitan city of Genoa (Liguria, Italy), San Martino and Galliera. The project, which was launched in 2017, set an ambitious goal of enrolling about 200 patients over three years. By 2020, the number of patients enrolled exceeded the expectations, reaching a total of 298 patients. However, the onset of the COVID-19 pandemic temporarily shifted the focus away from the project in the years following 2020. Despite these challenges, the platform remained in use, and, to date, the number of patients enrolled increased to 393, showing renewed interest in the adoption of this technology. To effectively manage the platform, a comprehensive database was developed, consisting of 40 tables, to manage patient data during their visits to different centers. Each table has a specific purpose in organizing and storing relevant information related to patient care, treatment, and follow-up, and adding new parameters is simplified by the database structure. A simplified logic sub-diagram, shown in Figure 1, provides a visual representation of the connections between some of the most important tables. These include the tables for patient demographics, center details, events, sessions, and parameter records.

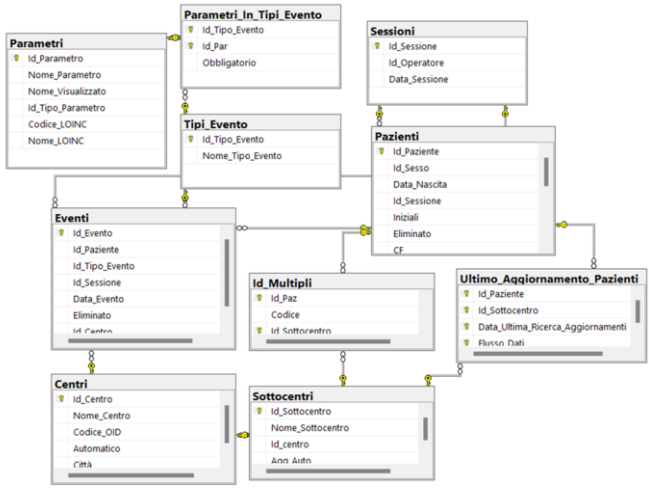

Figure 1. Logic sub-diagram.

The events in the "Events" table are: first visit, visit, instrumental examination, resistance development, laboratory examination, microbiological examination, and therapeutic treatment. Some of these events, in particular first visit, visit, instrumental examination, and therapeutic treatment are entered manually. In contrast, with regard to resistance development, laboratory and microbiological tests, for most cases the results are entered automatically, as shown in Table 1.

Table 1. Prevalence of automatic entry for some event types.

Event Type	Total Events	Automatic Entry
Resistance development	134	132
Laboratory Test	6589	6558
Microbiological Test	1644	1608

A total of 125 parameters are present in the table "Parameters". These parameters include a wide range of crucial information, including clinical symptoms, laboratory and instrumental test results, details of therapy and drugs administrated, hematologic and biochemical evaluations, and survey of patients' personal habits and routines. In Figure 2, a graph is shown containing the set of parameters found to be most associated with the frequency of the events.

4. Discussion and Conclusion

The TB Ge network project was slowed down by the impact of the COVID-19 pandemic, which required priority attention and significant resources to address the health emergency. However, it became even more essential to keep infectious diseases, including TB, under control in order to protect public health and prevent new pandemics from occurring. Therefore, we recognized the importance of revitalizing the project, adapting it to new challenges and emerging needs. We are working to make significant and strategic changes that will improve the effectiveness and utility of the project, enabling better monitoring and management of TB. Indeed, we think that the network should be dynamic and should keep pace with the evolving landscape of TB, which saw important developments in the diagnostics and treatment fields in the past years.

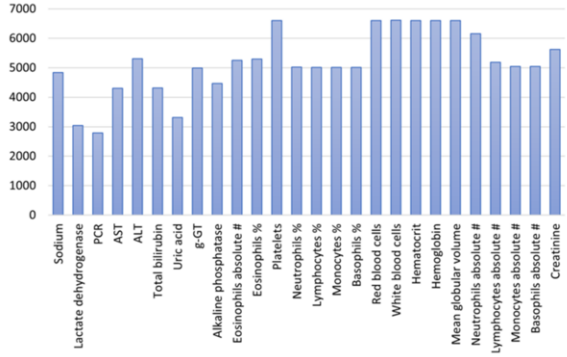

Figure 2. Number of events per parameter. In the Figure, only the most relevant parameters are shown.

Adding parameters regarding new treatment options for recently WHO-endorsed MDR-TB regimens (BPaLM) [6] is among the planned changes we are going to apply to our network. Furthermore, as we are following an increasing number of patients affected by non-tuberculous mycobacteria (NTM), we are planning to modify the structure of the network to comprise these infections. Given our setting of low endemicity and our epidemiology that comprises a high number of infections in migrants, who frequently move within the region and outside of it, one of the future developments involves the expansion of the network to involve a larger number of hospitals in the area of the Liguria Region. An additional relevant aspect to consider is a deep analysis of the security of the platform. A future development will be to verify that all security measures are appropriate and to identify any areas where improvements can be made. In this way, the TB Ge network will keep up with the highest security standards and effectively protect sensitive patient information.

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Time Series Forecasting of Cardiovascular Mortality: Machine Learning Based on State Economic and Local Medical Data

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Abstract. This study focuses on the complex interplay of healthcare, economic factors, and population dynamics, addressing a research gap in regional-level models that integrate diverse features within a temporal framework. Our primary objective is to develop an advanced temporal model for predicting cardiovascular mortality in Russian regions by integrating global and local healthcare features with economic and population dynamics. Utilizing a dataset from the Almazov Center's Department of Mortality Performance Monitoring, covering 94 regions and 752 records from January 1, 2015, to December 31, 2023, our analysis incorporates key parameters such as angioplasty procedures, population morbidity rates, Ischemic Heart Disease (IHD) and Cardiovascular Diseases (CVD) monitoring, and demographic data. Employing XGBoost and a regression model, our methodology ensures the model's robustness and generalizability.

Keywords: cardiovascular mortality, temporal modeling, gradient boosting, regression analysis, public health outcomes

1. Introduction

Cardiovascular diseases (CVDs) persist as a significant global health challenge, necessitating advanced predictive modeling techniques to guide effective public health interventions [1]. The evolving landscape of healthcare, coupled with the intricate interplay of economic and population dynamics, demands a nuanced understanding of the temporal patterns associated with cardiovascular mortality [2]. The existing literature on cardiovascular mortality modeling has traditionally focused on individual risk factors [3]. These studies have often been constrained by a lack of temporal granularity, hindering a comprehensive understanding of the dynamic nature of cardiovascular health outcomes. Recent advancements in predictive modeling techniques, such as machine learning algorithms and ensemble methods [4], have demonstrated the potential to capture complex interactions among healthcare systems, economic conditions, and population characteristics over time [5]. Moreover, studies have recognized the significance of temporal dynamics in mortality prediction [6], emphasizing the need for

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models that can adapt to evolving healthcare landscapes. The integration of diverse features, such as healthcare infrastructure, economic indicators, and demographic shifts, has shown promise in elucidating the multifaceted nature of cardiovascular mortality. However, there remains a notable gap in research that systematically combines these factors within a temporal framework, especially at the regional level [7].

The primary goal of our research is to develop an advanced temporal model for predicting cardiovascular mortality, emphasizing a holistic understanding of the intricate relationships among global and local healthcare features, economic conditions, and population dynamics within the context of Russian regions. By synthesizing these elements, we aim to uncover nuanced temporal patterns that contribute to the prevalence of cardiovascular diseases in specific Russian regions.

This paper conducts a state-of-the-art analysis and presents a novel approach to temporal modeling that integrates global and local healthcare features with economic and population dynamics, specifically tailored for regional analysis using Russian data.

2. Methods

2.1. Data Collection

The study utilized a dataset sourced from the Almazov Center's Department of Mortality Performance Monitoring, encompassing a range of variables related to cardiovascular mortality, healthcare infrastructure, economic indicators, and population demographics. The temporal scope of the data covered from January 1, 2015, to December 31, 2023, enabling a thorough examination of temporal patterns. The dataset consisted of 752 records and 853 features across 94 regions and districts. Key parameters included a series of indicators related to angioplasty procedures, population morbidity rates, monitoring of Ischemic Heart Disease (IHD) and Cardiovascular Diseases (CVD), and data from outpatient observations. The dataset incorporated information from the Electronic Medical Information System, bed capacity statistics, data on heart surgeries, economic indicators, demographic data, and mortality monitoring data related to diseases.

2.2. Feature Selection and Exploratory Data Analysis (EDA)

A rigorous feature selection process was employed to identify the most relevant variables for predicting cardiovascular mortality. This involved a combination of domain expertise, literature review, and statistical analysis, including correlation matrices and feature importance scores derived from initial model runs. An exploratory data analysis was conducted, incorporating a correlation matrix to uncover relationships among variables. This step provided essential insights for feature selection and model interpretation.

2.3. Modeling Approach

The study employed a temporal modeling framework based on gradient boosting algorithms, specifically utilizing XGBoost. This algorithm was chosen for its efficiency in handling large datasets and its adaptability to temporal patterns. Additionally, a

regression model was applied to assess the relationship between selected features and cardiovascular mortality.

2.4. Hyperparameter Tuning

A grid search approach was utilized for hyperparameter tuning to identify the optimal combination of hyperparameters for both the gradient boosting and regression models. The best combination was determined through an evaluation of performance metrics.

2.5. Model Evaluation

The performance of the developed models was assessed using widely accepted regression metrics, including Mean Absolute Error (MAE), Root Mean Squared Error (RMSE), and the coefficient of determination (\(R^2 \)). These metrics were chosen to provide a comprehensive evaluation of the models' accuracy, precision, and goodness of fit. To ensure robustness, a cross-validation strategy was implemented during model training and evaluation. The dataset was split into 80% training and 20% testing sets using a 5-fold cross-validation approach to assess the models' generalizability. All analyses were conducted using Python with scikit-learn and XGBoost libraries. The code and relevant datasets are available upon request for transparency and reproducibility.

3. Results

The Root mean squared error (RMSE) of the model before hyperparameter tuning was 117.2.

Figure 1 demonstrates 10 top predictors for the higher mortality rates in a region.

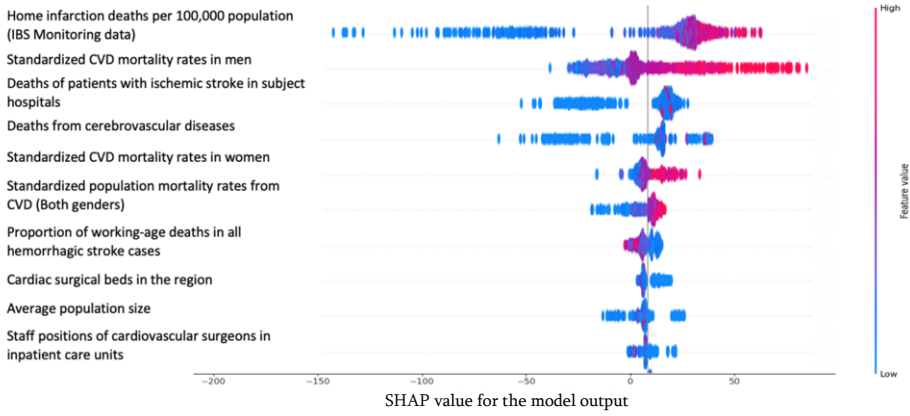

Figure 1. Shapley values for the higher mortality rates in a region

As we see in the Figure 1, the highest mortality rates are registered in regions with a higher proportion of deaths from acute myocardial infarction at home rather than in hospital out of the total number of deaths from myocardial infarction. The high proportion of deaths from acute myocardial infarction at home characterizes the system of emergency care in the region in a complex way - it may reflect the low frequency and

timeliness of call of ambulance crews, and possibly limited availability of ambulance services, limited availability of hospitalization in a specialized hospital. Also, high mortality rates from CVD are associated with high mortality rates from cerebrovascular diseases, mainly in hospitals. The associations with standardized mortality rates confirm the correctness of the data analysis. The association of higher mortality from stroke, especially hemorrhagic subtype of stroke, in the working age group with lower CVD mortality rates in the region is interesting. In other words, the contribution of fatal outcomes from cerebrovascular causes in groups of patients of younger age groups increases in the structure of mortality from CVD in regions with lower rates.

Also, high indices of CVD mortality are associated with high level of mortality from cerebrovascular diseases, mainly in hospital - that reflects the leading contribution of this pathology in the structure of CVD mortality In Figure 2, the decision tree illustrates that a low level of hospitalizations is situated to the right, implying ambiguity in the feature.

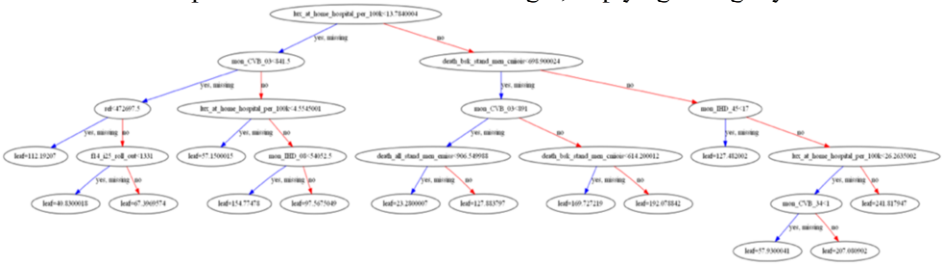

Figure 2. Decision tree for the universal indicator of CVD mortality per 100,000.

The tree showcases a division in the sample based on hospitalizations per 100,000, revealing a distinct pattern starting from 14.

In this context, deviations indicate sharp rises or falls. Where growth occurred, there is a clear association with Ischemic Heart Disease (IHD). Conversely, in cases without growth, the pattern is more stable, but they distinctly split into two groups based on the deviation.

Measures to reduce mortality are directed towards the elderly with ischemic stroke (figure 3), and if successful, hemorrhagic stroke emerges in the mortality structure among the young. In regions where programs are effective, hospitalizations decrease, and the mortality structure undergoes changes.

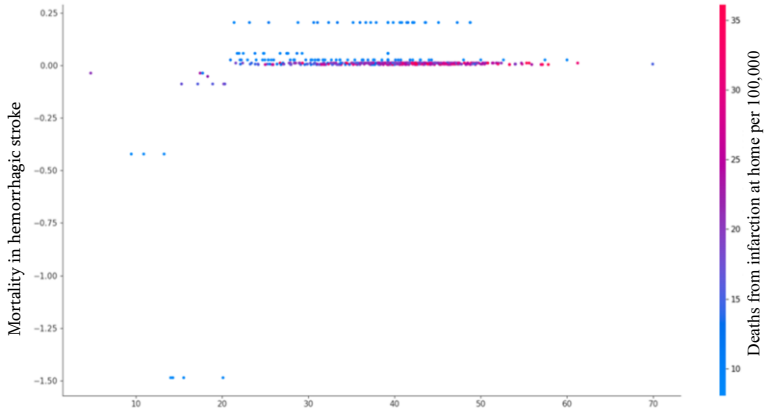

Figure 3. Dependency of the mortality on the hospitalization rate

Additional measures targeting other groups are necessary. When hospitalizations are numerous, the stroke factor is not included in the model. Conversely, when hospitalizations per 100,000 are below 22, it reduces the probability of high mortality from CVD. In cases where hospitalizations exceed 22, if the hospitalization rate is low, stroke contributes to CVD.

4. Discussion and conclusion

The results of our study shed light on critical insights into the dynamics of cardiovascular mortality in Russian regions, providing valuable implications for healthcare planning and intervention strategies. Through our advanced temporal modeling approach, integrating global and local healthcare features with economic and population dynamics, we have uncovered nuanced temporal patterns contributing to the prevalence of cardiovascular diseases. Our research not only advances temporal modeling techniques but also provides actionable insights for policymakers and healthcare practitioners. The model's ability to uncover specific patterns and associations allows for the development of targeted interventions to mitigate the impact of cardiovascular diseases. This model is designed not only to enhance prediction accuracy but also to provide actionable insights for policymakers and healthcare practitioners, facilitating the development of targeted interventions to mitigate the impact of CVDs. Future research endeavors could further refine the model by exploring additional factors and expanding the dataset, enhancing our understanding of regional cardiovascular mortality dynamics.

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Integrating Laboratory Testing Results at Point-of-Care in Hospital@Home Care Settings: A FHIR-Based Approach

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Abstract. The care model Hospital@Home offers hospital-level treatment at home, aiming to alleviate hospital strain and enhance patient comfort. Despite its potential, integrating digital health solutions into this care model still remains limited. This paper proposes a concept for integrating laboratory testing at the Point of Care (POC) into Hospital@Home models to improve efficiency and interoperability. *Methods:* Using the HL7 FHIR standard and cloud infrastructure, we developed a concept for direct transmission of laboratory data collected at POC. Requirements were derived from literature and discussions with a POC testing device producer. An architecture for data exchange was developed based on these requirements. *Results*: Our concept enables access to laboratory data collected at POC, facilitating efficient data transfer and enhancing interoperability. A hypothetical scenario demonstrates the concept's feasibility and benefits, showcasing improved patient care and streamlined processes in Hospital@Home settings. *Conclusions:* Integration of POC data into Hospital@Home models using the HL7 FHIR standard and cloud infrastructure offers potential to enhance patient care and streamline processes. Addressing challenges such as data security and privacy is crucial for its successful implementation into practice.

Keywords. Cloud solutions, FHIR, Hospital@Home, Interoperability, Point-of-Care testing

1. Introduction

Hospital@Home is a care model whereby patients who would normally be treated in hospital are cared for and managed at home [1]. Individual implementations of this care model may vary slightly, but the core of the model is always similar, e.g. there is a hospital involved at least to a certain extent which is in contrast to Care@Home care models where family doctors or other ambulatory care providers are in charge of coordinating the care. The severity of the patient's condition must allow for treating them at home, where they are cared for by nursing staff and medical services including 24-hour access to telemedicine. Home visits by specialist staff can include a range of examinations and diagnostic tests, such as vital signs, blood tests, electrocardiogram or ultrasound [2]. The objective behind this care model is to relieve the pressure on hospital structures and to offer patients who are eligible for Hospital@Home more comfort and privacy in their own environment. Some benefits of this model include a reduction in the risk of infection and falls, as well as an improvement in the quality of care and the

overuse of medication [2]. Recent research found that integration of digital health solutions into Hospital@Home care models is still limited [3] although these technologies promise to support continuous monitoring of vital parameters and other parameters at home or can even deliver treatment. Most available studies on Hospital@Home have been conducted when digital health solutions and point-of-care testing (POCT) were not yet available [4]. Currently, the POCT market is "projected to grow at a compound annual growth rate of 6.1% from 2024 to 2030" [5]. POCT refers to laboratory testing performed directly at the point of care. Laboratory results are generated directly on the ward or in the operating theatre of a hospital, in a doctor's surgery, in emergency situations, in a pharmacy, or in the patient's home. Tests that patients perform themselves, such as pregnancy tests or independent blood glucose monitoring for diabetes mellitus, are also called POC measurements [6].

The aim of this paper is to develop, within the framework of a Hospital@Home model, a possible concept that describes how the data is transferred between the measurements taken at home and the hospital. Specifically, we are addressing the questions of how data can be retrieved by healthcare providers immediately after the measurements have been conducted at home and how the data can be accessed from a hospital for continuous monitoring.

2. Method

To develop the concept, we first collected requirements and defined a scenario. Specifically, we collected information on which data that is often measured as part of Hospital@Home care models. We identified five different groups: vital parameters (pulse, blood pressure etc.), blood glucose, laboratory values, ECG and ultrasound. Given the increase of diabetes in the population, we focused on measuring vital parameters and blood glucose within our concept. As a concrete POCT device, we considered cobas® Pulse from Roche Diagnostics. However, we developed an architecture for accessing data collected by POCT devices in general from a clinical information system or other frontends. Our concept bases upon HL7 FHIR R4 (http://hl7.org/fhir/), a standard developed by Health Level Seven International (HL7). HL7 FHIR is based on web technologies such as the programming interface RESTful APIs and the data formats JSON and XML. The modular structure allows resources to be used and combined individually, providing flexibility and adaptability. HL7 FHIR facilitates the handling of different types of healthcare data, from patient information to laboratory results. Central to HL7 FHIR are the standardized data models that provide clear structures for the representation of health information, which improves interoperability between different healthcare systems and applications.

3. Results

This section first describes the envisioned scenario for Hospital@Home and then outlines our architecture for integrating POCT devices.

3.1. Scenario

Nurse Svenja and a physician visit Mr. Pfister at home for a routine check-up as part of a Hospital@Home care model. The doctor conducts a physical examination, using a mobile ultrasound machine and listening to his lungs, and recommends that the prescribed treatment be continued. Svenja gives Mr. Pfister an antibiotic infusion and checks his vital signs using a POCT device for measuring temperature, blood pressure, pulse and blood glucose. She also uses the device's camera to photograph and monitor a wound. The data is immediately transmitted to a cloud server as soon as an internet connection is available. Svenja can access the data together with previous measurements through her tablet application that retrieves the data from the cloud server. The tablet application allows also to retrieve relevant data from Mr. Pfister's medical records stored in the hospital information system. The technology used ensures efficient and informed care. For healthcare professionals, the system minimizes post-visit documentation. Vital signs and other relevant data resulting from the POCT are automatically retrieved from the cloud server, and the mobile device facilitates on-site care without worrying about internet connectivity. Interdisciplinary coordination is improved due to the data access for all persons involved in the treatment, allowing immediate adjustments to care plans based on real-time data.

3.2. Architecture and HL7 FHIR resources

Our architecture for integrating POCT into Hospital@Home care processes comprises POCT devices, a cloud server and applications such as a tablet application that visualizes the data (see scenario) or a clinical information system that retrieves the data for storing in the medical record of a corresponding patient. Within our concept, we decided for a cloud server to store the data since it offers the possibility to access data quickly and anywhere as long as there is an internet connection.
The general process is as follows: Data from a POCT device is directly converted into HL7 FHIR format after measurements have been conducted, transferred via a cloud gateway and then stored in a cloud service. Once it is stored in the cloud, it can be retrieved upon request through cloud gateways. All data is automatically assigned to a case that belongs to a patient: the 'Encounter' resource of HL7 FHIR is used. Each patient is modeled as a HL7 FHIR 'Patient' resource. By this, all data generated from an examination is directly assigned to a specific (patient) case. The value measured by POCT devices are modelled as 'Observation' resource. Several 'Observation' are aggregated in a HL7 FHIR resource 'DiagnosticReport' (see Figure 1).

4. Discussion

In this paper, we described an approach to integrate POCT devices into the system landscape of Hospital@Home using HL7 FHIR and a cloud server. In Hospital@Home care models multiple stakeholders may be involved (e.g. nurses, physiotherapist, hospital, family doctor etc.) who use their own information systems. Our approach ensures that the data collected at home can be integrated in such systems. The synergy of cloud computing and HL7 FHIR format is pivotal for healthcare's future, providing the infrastructure to support HL7 FHIR while improving flexibility, scalability, and interoperability as well as enhancing information exchange [11]. The architecture itself

was not yet implemented. Only a front-end to visualize the data collected by the POCT device was implemented.


```
{
 "resourceType": "DiagnosticReport",
 "status": "final",
 "code": {
  "coding": [
   {
    "system": "http://loinc.org",
    "code": "2339-0",
    "display": "Glucose [Mass/volume] in Blood"
   }
  ],
  "text": " Glucose [Mass/volume] in Blood "
 },
 "subject": {
  "reference": "Patient/123",
  "type": "Patient"
 },
 "encounter": {
  "reference": "Encounter/encounter-001"
 },
 "effectiveDateTime": "2024-03-04T15:43:00+01:00",
 "result": [
  {
   "reference": "Observation/001",
   "type": "Observation"
  },
  {
   "reference": "Observation/002",
   "type": "Observation"
  }
 ]
}
```


Figure 1: Example in HL7 FHIR for a DiagnosticReport on a glucose in blood with two observations shown in json-Format

In today's digital age, the use of cloud solutions has become a fundamental component for companies of all sizes that want to increase their efficiency and work more flexibly [8]. Cloud storage offers advantages like scalability, flexibility, and improved accessibility, allowing companies to use fewer physical storage devices and enabling easy data access from various locations, enhancing employee collaboration and mobility [9]. They are also cost-efficient, reducing the need for extensive on-site IT infrastructure and personnel for IT system maintenance, as these tasks are handled by cloud providers [10]. However, the concrete benefits in the use case described in this paper still has to be assessed together with the acceptance of a cloud-based solution. A recent paper concluded that security and privacy in cloud environments in healthcare still need to be aligned and considered [11]. This is a relevant factor for acceptance of a cloud -based solution in healthcare. Additionally, compliance of our approach with healthcare regulations such as HIPAA in the U.S. still has to be assessed. Security measures such as encryption and robust authentication mechanisms are critical to be implemented and remained unconsidered in this concept yet.

The suggested cloud service could be replaced by a personal health record, with the data collected at the POC stored in the record in FHIR format. In several countries such personal health records are already in place. The Dutch personal health record for example specifies already a scenario in which a patient uses his Personal Health Record to collect vital data and blood glucose test values from devices and sends these to the care professional, who accepts the incoming values – the data is exchanged in HL7/FHIR (https://informatiestandaarden.nictiz.nl/wiki/MedMij:V2020.01/FHIR_VitalSigns).

Converting data directly into HL7 FHIR format at the POCT device is an efficient approach. It ensures efficient transmission as the data is already in the desired format and can therefore be transmitted more quickly [12]. However, this approach requires that the POCT devices have the necessary computing resources and software capabilities for this conversion. It remains open for future research to assess whether all POCT devices can support this feature. As POCT devices can generate significant amounts of data, performance issues can arise when managing, storing and querying these data on the cloud server. In summary, our concept aims to provide a solution to share data collected in a Hospital@Home care setting with healthcare provider, in particular to store the collected data in information systems at provider side (e.g. clinical or practice information system). This allows for a continuous progress monitoring at the provider's side and can help in supporting patient safety in Hospital@Home care settings. In future work, we want to study whether mHealth apps or data from wearables could be connected in a similar manner. Since these devices generate even more data than POCT devices, data aggregation would have to be conducted.

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Pilot Study for a Model for the Collection of Waiting Lists Data

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Abstract. The analysis of data on waiting lists in Italy is regulated by the PNGLA (National Plan for the Governance of Waiting Lists). However, the Plan does not specify the characteristics of the data to be returned by the Regions for the purposes of monitoring, with the result that it is frequently either in aggregate form, unreadable, or incomplete, and therefore cannot be analysed in any meaningful way.
Fondazione the Bridge and AGENAS, with the University of Genoa and the University of Pavia, conducted a pilot study on a methodological model for the collection of waiting lists data.
The model proved to be effective and replicable, also providing a more valuable opportunity to analyse waiting lists data.

Keywords. Waiting list data; public health; monitoring; analysis; standardization; model; programming

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1. Introduction

Waiting times constitute a fundamental factor in the provision of those services whose delivery is guaranteed by the essential levels of care ("Livelli Essenziali di Assistenza", LEA), crucial to deliver the appropriate care to all citizens. Waiting lists are a factor in the equity of access to health services and in patient satisfaction alike [1,2]. The necessity of monitoring and sharing waiting lists data has been translated into the obligation of transparency adopted by the National Plan for Waiting List Governance ("Piano Nazionale di Governo delle Liste di Attesa", PNGLA) 2019-2021[2], that governs the data relating to waiting lists across the different Regions.

The data collected according to PNGLA guidelines was the object of two studies conducted by the HI Observatory[3], together with the Universities of Genoa and Pavia, that covered the years 2019-2020 [3] and 2021 [4]. However, the analyses highlighted some issues related to the discretion granted by the PNGLA 19-21 in the collection of data and could not lead to significant conclusions.

In fact, the PNGLA 19-21 gave the Regions the possibility to choose between a variety of different methodologies for data collection and dissemination: for example Regions could choose between monitoring the provision of the services ex post or ex ante, between either percentages or raw numbers of the total services provided within the required time, throughout the entire year or during an index period, and so on. These differences hindered the interoperability of data, and made the comparisons difficult not only at the national level, but also at the local, and between the same Region across different years.

For these reasons and building on their previous research, Fondazione the Bridge and AGENAS (National Agency for Regional Health Services), with the support of the Universities of Genoa and Pavia, conducted a pilot study to develop a new model for the collection of waiting lists data, with the aim of finding a valid alternative to the discretionary nature of the current method.

This model aims to collect homogeneous and standardised data and make it available at the regional level, improving the quality of monitoring, also from a prognostic perspective, and thus supporting Regions and healthcare facilities alike in enhancing their organisational-management skills.

The present paper details the methodology of this pilot study.

2. Materials and methods

In the first studies of waiting list times by the HI Observatory, the requested data consisted of the records that the Regions already made available to comply with the PNGLA, which was solicited through the civic access procedure, that therefore was

[2] Recently, a technical table was set up for the development and operational implementation of the National Plan for the Governance of Waiting Lists (PNGLA) 2024-26 (Director's Decree no. 44016 of 22/12/2023).

[3] The HI Observatory (Healthcare Insights) is an independent observatory on healthcare access created by Fondazione the Bridge in 2020. It is focused on monitoring access to the healthcare system and of making information relating to the National Health Service public and accessible. For more information: https://www.hiosservatorio.it/

subject to the limitations already mentioned. For more details on the methodology of these analyses, see Bonetto et al., 2022 [5].

After the decision to launch the pilot study, a working group was set up consisting of AGENAS, Fondazione The Bridge, with the support of the University of Genoa and the University of Pavia. The first decision taken was to ask for precise variables and not merely the data required by the PNGLA, and these variables were then constructed by the working group.

Participation in the trial was on a voluntary basis. The various local health authorities were contacted by means of an invitation letter to the pilot, which was followed by a meeting in which the purpose of the experiment and the commitment required once accepted were explained.

Data was requested in ex ante form, concerning all the specialist visits and diagnostic services already covered by the PNGLA (14 specialist visits and 55 diagnostic services). The participants were sent the form to be filled in excel format. The data collection period was set in the index week of 22-26 May 2023.

The data was then analysed with respect to both the actual waiting list times and the assessment of whether the pilot model was effective and replicable.

3. Results

The study involved 44 Local Health Authorities, 18 Hospital Facilities, 2 Research-based Hospitalization and Treatment Institutions and 1 National Institute for Elderly Care, belonging to 13 out of the 21 Italian Regions. The respondent facilities covered a population base equal to 37 % of the Italian patient population (22,093,599 patients out of 59,030,133).

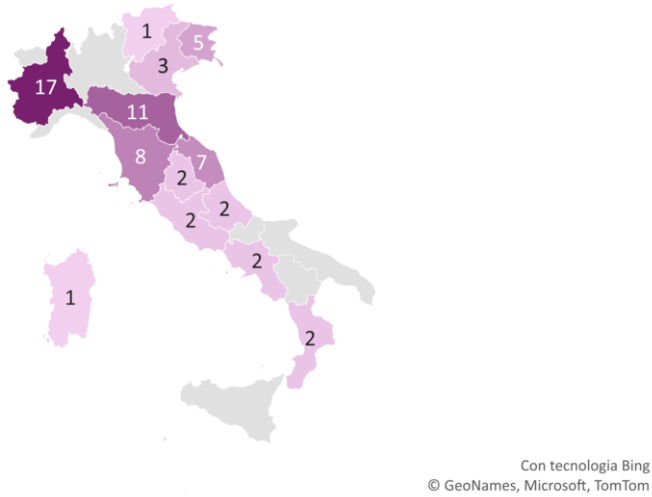

Figure 1. Distribution of participating institution by Region.

The required data were analytical records on individual provisions (anonymised), coded in 27 variables, as shown in Table 1.

Variable name	Description	Value labels
Istat Residence	Istat code of the assisted person's Municipality of Residence	String variable
Municipality Residence	Name of the municipality of residence of the assisted person	String variable
Region code	Code of the booking region where the service will be provided	String variable
Region name	Name of the booking region where the service will be provided	String variable
Company code	Code of the Reservation Health Authority at which the service will be provided	String variable
Company name	Name of the Booking Agency at which the service will be provided	String variable
Structure code	Code of the facility where the service will be provided	String variable (STS11 code)
Structure name	Name of the Structure at which the service will be provided	String variable
Provider code (agenda code)	Code of the Booking Point (agenda) at which the service will be provided	String variable
Provider name (agenda name)	Name of the Booking Point (agenda) at which the service will be provided	String variable
Recipe	Prescription identification code	String variable
Progressive Code	Progressive number identifying the service	String variable
Service Code	Nomenclator code identifying the service	String variable
Discipline Code	Discipline code identifying the specialist visit	String variable, could be null
Service Description	Name of the service	String variable
Class Priority	Priority code reported in the prescription	U= within 72 hours; B= within 10 days; D= within 30 days (specialist visits), within 60 days (diagnostic services); P= within 120 days; N= not given
Access mode	If the service requested refers to a first access (or subsequent access)	1 = first access; 0 = subsequent access
Date of Prescription	Date on which the doctor prescribes the service	DD/MM/YYYY
Date of Contact	Date on which the citizen requesting the service comes into contact with the booking system	DD/MM/YYYY
Date of Prescription	Date assigned at the time of booking for the provision of the outpatient specialist service	DD/MM/YYYY
Date of First Availability	First date proposed by the booking system, taking into account the priority class and the territorial area of assistance and guarantee of the patient	DD/MM/YYYY
Facility Code First Availability	Provider where the first available date suggested by the booking system to the user at the time of contact/request	String variable (STS11 code)
Facility Name First Availability	Booking facility where the first available date is suggested at the time of contact/request	String variable
Provider Code (agenda code) First Availability	Provider point (agenda) where the first available date is suggested at the time of contact/request	String variable
Provider Name (agenda name) First Availability	Provider point (agenda) where the first available date is suggested at the time of contact/request	String variable
Number of services booked	Number of services booked	Number
User choice	User's choice of a date other than first availability	1= the user made no choice, i.e. chose the first availability offered by the system; 2= the user chose a date other than the first availability

Table 1. Variables collected in the pilot study.

Data on service bookings in the index week, from the 22nd to the 26th of May 2023, was provided via the single reservation points ("Centro Unico di Prenotazione", CUP).

The data was collected using the Excel template provided. The use of a univocal format made it possible to perform a homogeneous analysis of the variables. The results of the complete statistical analysis are not yet available.

4. Discussion

The first studies conducted on waiting lists by the HI Observatory had many limitations related to the quality of the data, which was in aggregate form and very often not interoperable, not homogeneous and not comparable.

Despite the fact that the pilot project had far fewer participants, as participation was on a voluntary basis, the quality of the data collected is significantly higher. The data collected is both comparable and intelligible and returns a true picture of the situation of waiting times in the Local Health Authorities from which the data was received. The quality of the data is improved because the format with which the template was provided is .xml, with well-defined and standardised variables, and is therefore interoperable and harmonised. The completeness of the data, in regard to those who were willing to participate, is also considerably higher than that of the PNGLA compliant data provided by the Regions, in whichever form they chose to collect and share it.

5. Conclusions

Despite the fact that after the first two analyses conducted a method of standardising the regional data was hypothesized by the researchers in order to improve the collection of data and the analysis of waiting lists [6], the method of monitoring had inherent limitations resulting from the data required by the PNGLA, and from the fact that the data was often times received in its aggregated form. The present experimental study proved to be effective and replicable, proving that if indicators are proposed, the resulting collected data is readable and comparable. The data must be requested in a specific format that allows it to be analysed, as it is interoperable and standardised. With adjustments concerning the addition of certain variables and the choice of whether or not to ask data to the single hospitals or to regional single reservation points (CUPs), which not all Regions rely on for collection, the proposed model could be extended at the national level, and be a useful tool for a reliable and complete collection of waiting lists data.

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Stroke 5.0: A Technology Ecosystem to Support Acute Stroke Integrated Clinical Management

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Abstract. Stroke remains a significant global health burden, with substantial costs and morbidity associated with its occurrence. To address this challenge, STROKE 5.0 proposes a comprehensive approach to stroke care management, integrating advanced digital technologies and clinical expertise. This paper presents the rationale, design, and potential impact of the STROKE 5.0 platform, which aims to optimize stroke care delivery from pre-hospital assessment through acute hospitalization. The platform facilitates early symptom recognition, efficient emergency response, and streamlined hospital management through intelligent decision support systems. By leveraging predictive analytics and personalized care pathways, STROKE 5.0 seeks to enhance clinical outcomes while providing a platform capable of optimizing the efficiency of service delivery. This innovative model represents a proactive shift towards evidence-based, patient-centered stroke care, with implications for healthcare quality improvement and resource allocation in the digital health domain.

Keywords. stroke, integrated healthcare services, decision support system, predictive analytics

1. Introduction

Based on the latest estimates from the Global Burden of Disease (GBD), approximately 12.2 million new cases of stroke occurred in 2019, resulting in 143 million disability-adjusted life-years (DALYs) lost and 6.6 million deaths worldwide, making stroke the second most common cause of death and the third leading cause of disability globally [1]. In the EU, costs overall associated with stroke were around 50 billion € [2] and are projected to be over 1 trillion US $ globally in 2030 [3]. In Italy, more than 70,000 stroke events per year are registered (53 per 100K population) with an incidence increase to the 2035 estimated close to 30% [4].

To counter these trends, much evidence highlights the importance of the proper application of primary and secondary prevention criteria, such as lifestyle correction, and risk factors treatment (high blood pressure, diabetes mellitus, heart disease, dyslipidemia, etc.) [5]. On the other hand, about intervention in case of an acute stroke event, there is a global consensus about three specific concepts:

1. Management of stroke patients in specialized facilities such as Stroke Units positively impacts mortality rates and outcomes [6];

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2. For ischemic stroke, the most effective treatment in terms of mortality reduction and cerebral functionality preservation is revascularization therapy, regardless of the approach whether pharmacological (intravenous thrombolysis) or endovascular (mechanical thrombectomy), alone or in combination [7];
3. The essential reference concept in stroke management is the therapeutic window ("Time is Brain"), that is, the time between symptoms onset and treatment beginning is crucial to maximize treatment efficacy [8].

For these reasons, the intervention success is directly correlated with the optimization of door-to-needle time: from the pre-hospital phase to the initiation of treatment, to comply with known therapeutic windows. Hence, there is an essential need for the design and implementation of strong integration processes at multiple levels of the health system. This integration should be associated with a systematic organization and management of clinical care pathways (CCP) and related processes, supported by the most advanced digital technologies provided by artificial intelligence and decision sciences.

To adequately address the reduction of avoidable delays, it is crucial to promote:

- The prompt recognition of stroke onset symptoms through informative campaigns targeting the population, accompanied by advanced digital empowerment tools.
- The swift access to the most appropriate hospital facility through efficient network organization and management of the territorial emergency service.
- The reduction of avoidable in-hospital delays by ensuring maximum efficiency in the diagnostic process through the activation of a multidisciplinary team of specifically trained professionals (Stroke Team).

On the other hand, stroke outcomes and costs also depend on the optimal management of the acute hospital phase, usually provided in specific stroke care areas (Stroke Unit/Stroke Area) coordinated by the Stroke Team. Since stroke encompasses patients with varying levels of complexity and differences in stabilization times and prognosis based on etiopathogenetic and clinical characteristics, it is possible to tailor admissions to different types of care settings, promoting system flexibility while ensuring the application of specific diagnostic-therapeutic protocols that characterize and qualify the organizational model of the Stroke Unit/Stroke Area (eventually facilitated by appropriate technological platforms). Early diagnosis, supported by digital decision support services, serves as a catalyst, along with the expertise of the Stroke Team, to promote an early and appropriate individualized continuity of care program, resulting in reduced hospital stay and efficient bed management. Finally, during the in-hospital phase, the early initiation of rehabilitation pathways, aiming for a rapid return home and social reintegration of the patient, is of particular importance.

Based on these principles, STROKE 5.0 aims to make a significant contribution to the reformulation of healthcare service delivery methods, moving from the model of reactive medicine to a proactive healthcare model, strongly characterized by the comprehensive management of the patient.

2. STROKE 5.0 platform

The STROKE 5.0 ecosystem involves the design and management of the CCP for patients affected by ischemic stroke, both in the early diagnosis phase and in the acute situation, thus involving emergency management at the community levels as well as the hospitalization phase.

The CCP will be effectively supported by a digital platform tasked with serving as an intelligent middleware to support the distributed actors of the clinical scenario, namely: (i) Regional Emergency Healthcare System; (ii) Emergency Medical Services Dispatch Center; (iii) Ambulance staff; (iv) Hospital Emergency Department; (v) Hospital Stroke Unit.

In the domestic environment, the risk and occurrence of ischemic attacks are managed predictively, with accurate support for self-diagnosis to enable the early assessment of signs and symptoms. Specifically, a mobile app will be developed, principally focused on the definition of a decision support service for differential stroke diagnosis which will be developed through Machine Learning approaches.

The emergency phase is handled through a pre-alert system to emergency dispatch centers (integrated through interfaces provided by the platform) and with rapid and accurate decision support for clinical triage performed by the ambulance emergency staff. The aim is to clinically evaluate the patient's condition directly at the scene of the event providing preliminary indications that will be crucial for early and appropriate management inside the hospital. These services will be implemented through a Knowledge Representation and Reasoning system based on ontologies and advanced logical programming.

Prompt arrival at the hospital, facilitated through the application of efficient routing techniques and supported by advanced analytics services offered by the platform, allows the patient to be treated as effectively and efficiently as possible while adhering to the treatment windows specified by clinical protocols. In particular, the selection of the best possible treatment will be facilitated with a system integrating machine learning models based on the event data gathered since the emergency call, as well as deep learning approaches for the evaluation of diagnostic images.

The following table provides a structured summary of the key elements characterizing the technological platform.

Table 1. Summary of the intervention for each of the clinical scenarios included in the Stroke 5.0 platform

Home	Analysis of stroke signs and symptoms through a patient empowerment support application. Information access via mobile app, with the ability to receive or retrieve data allowing patient\caregiver alert. Data access to personnel involved in the CCP and registered on the platform.
Public Safety Answering Point (PSAP)	A computerized system deployed at PSAP for the appropriate management of emergency requests. In particular, implementation of a system to allocate the most appropriate resources (intervention units) for the specific case (e.g., with the possible intervention of the recent "Mobile Stroke Unit"), including the evaluation of the most efficient routing for these intervention units. Emergency requests will be also sent automatically through the patient's app when reaching defined clinical values.
Ambulance – ER	The system connects ambulance staff with the hospital, allowing for onboard triage. This will facilitate quicker acceptance in the emergency department, providing more detailed information on the patient's clinical situation.

	This will be further supported through optimal allocation and routing of the intervention unit from the event scene to the most appropriate hospital (e.g., Level I without Stroke Unit, Level II with Stroke Unit).
Stroke Unit	The computerized system in the hospital environment completes the CCP by providing the most advanced support services for clinical evaluation in the emergency department, integrated multifactorial clinical assessment of the patient (clinical assessment and advanced diagnostic imaging evaluation), integrated clinical management of the patient in the Stroke Unit, and planning and management of flows and resources within the in-hospital pathway.

3. STROKE 5.0 impact

The following factors contribute to increasing pressure on healthcare systems:

- Citizens have growing expectations regarding the availability of high-quality healthcare services;
- Healthcare managers focus on lowering the costs of their services, while the need to respond appropriately, promptly, and efficiently to severe acute events in emergency conditions remains constant, further exacerbated by the progressive aging of the population.
- Physicians are increasingly oriented towards evidence-based medicine, with particular attention to accurate clinical risk management.

Improving healthcare quality, with adequate cost control, requires the elimination of all elements that weaken the quality of the entire care process (prevention-diagnosis-prognosis-therapy) and the implementation of innovative and more accurate procedures for clinical risk management. In this regard, eHealth technologies and methods can play an increasingly relevant role. In recent years, there has been a growing development of highly effective technological solutions (especially driven by the growth of AI systems) [9,10] to promote both evidence-based medicine and best clinical practices [11]. These solutions have the potential to reduce errors due to uncertainty while improving the effectiveness and efficiency of clinical processes and services provided [12,13].

In this context, STROKE 5.0 aims to provide an integrated and holistic approach based on continuity and personalization of care, to define and develop procedures and workflows based on scientific evidence and in line with existing best clinical practices, in order to establish highly effective care pathways. To this aim, the key innovation features include the integration of care pathways, together with the implementation of effective and efficient healthcare services, considering the allocation of overall healthcare resources involved, based on advanced decision support systems in optimized clinical patient management.

Significant process innovation involves clinical processes characterized by appropriateness, personalization, and predictive value of care procedures, with advanced support for early and accurate diagnosis and treatment optimization.

STROKE 5.0 is capable of inducing a significant impact in the broad domain of Digital Health, concerning methodological approaches and technological tools characterizing our service platform.

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The Motivation and Empowerment of Patients in Care Processes

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Taking the Patient's Preferences into Account in the Anticoagulation Decision: Largely Lip-Service?

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Abstract. Clinical guidelines for the assessment and management of atrial fibrillation emphasize the importance of taking the patient's preferences into account. A detailed examination of those from the National Institute for Excellence in Health and Social Care (NICE) raise serious questions about whether the recommendations embed preferences about crucial trade-offs that pre-empt those of the patient; do not stress the need to provide them with the information on option consequences necessary for them to become an informed patient; and characterise them as 'concordant' or 'discordant' rather than independently valid. American and European guidelines do not differ significantly in these respects.

Keywords. clinical guidelines, NICE, atrial fibrillation, patient's preferences

1. Introduction

That patient's preferences should be taken into account in their healthcare decision making is increasingly stressed as a feature of good clinical practice, now interpreted to involve 'shared' decision making. To what extent is this talk being walked? Any attempt to answer needs to begin by establishing what exactly clinical guideline producers are saying, and importantly not saying, about which of the patient's preferences should be taken into account, and how this should happen. Three tough questions can be posed about any guideline which talks the talk. First, are the patient's preferences about the fundamental trade-offs involved in the decision covertly or implicitly pre-empted, or handicapped by the non-provision of the information necessary for their development and expression? Secondly, is it implied, in the positioning of the patient and the communicative vocabulary and tone, that the patient need not be bothered by having to do 'preference work' in the consultation? The 'right' preferences for them will have been entered into the recommendation, so that, while the information relevant to them can be provided if requested, it is only for information. Finally, is it implied that if the patient's expressed preferences are 'discordant' with those of the guideline, as interpreted by the clinician, the patient will need to explain and justify them? To avoid misinterpretation, we see asking these questions as consonant with respecting the preference of a patient to

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opt out of information provision and participation in decision making, including preference elicitation and discussion, delegating the decision to the professional.

2. Method

In an initial and limited attempt to address our questions we take the management of Atrial Fibrillation (AF) as a case study and, given the excellent documentation of the basis of the recommendations in its guidelines, examine that of the highly-respected National Institute for Excellence in Health and Social Care (NICE). Guideline NG196 *Atrial fibrillation: diagnosis and management* was published in April 2021 and last updated on 30 June 2021 [1]. We focus on the key decision on whether or not an otherwise uncompromised patient diagnosed with non-valvular AF should go on to oral anti-coagulation (OAC) medication, where the main competing considerations are the benefit from stroke risk reduction and harm from bleeding risk. (We do not pursue the conditional decision on which of four Direct-acting Oral Coagulants - DOACs - to use.)

3. Results

To answer our questions fairly it is necessary to report on the guideline at some length, capturing its tone and vocabulary as well as its substantive details.

The guideline recommends using the CHA_2DS_2-VASc instrument to assess the patient's stroke risk and the ORBIT tool to assess their bleeding risk. The results should be discussed with the patient, taking into account their specific characteristics including their individual needs and preferences - which they should be encouraged to express. The risks, benefits and consequences of each option should be explained, making sure the patient knows they include choosing no treatment. However, it should be pointed out that for most people the benefit of anticoagulation outweighs the bleeding risk.

The primary recommendation is "Offer anticoagulation with a direct-acting oral anticoagulant to people with atrial fibrillation and a CHA_2DS_2-VASc score of 2 or above, taking into account the risk of bleeding... Consider anticoagulation with CHA_2DS_2-VASc score of 1, taking into account the risk of bleeding... Do not offer stroke prevention therapy with anticoagulation to people aged under 65 years with atrial fibrillation and no risk factors other than their sex (that is, very low risk of stroke equating to a CHA_2DS_2-VASc score of 0 for men or 1 for women) ... Do not withhold anticoagulation solely because of a person's age or their risk of falls."

The transparency regarding the reasoning behind the recommendations is welcome, but also telling in relation to our questions (italics added).

"The committee decided to prioritise identifying people above or below a certain risk threshold... The evidence suggested that a score of 2 or more is the *ideal* threshold for the CHA_2DS_2-VASc in terms of indicating the *need* for anticoagulation. (Men with a CHA_2DS_2-VASc score of 1 were regarded as being at intermediate risk, and a group in whom anticoagulation should also be considered.) The evidence showed that this threshold of 2 or more offered a *good* combination of *high* sensitivity (0.92) and *adequate* specificity (0.23). The high sensitivity means that the tool would correctly identify almost everyone who would later have a stroke if they did not receive anticoagulants. Importantly, this will allow them to be prescribed anticoagulants to reduce their risk of stroke. The adequate specificity means that 23% of the people who would not later have

a stroke (even when not taking anticoagulants) would be correctly identified as not *needing* anticoagulation. This would prevent these people from having adverse events from anticoagulants. It also means that 77% of people who would not later have a stroke (without anticoagulation) would be wrongly identified as needing anticoagulation. However, this was thought to be *acceptable* given the perceived lesser harms from unnecessarily giving anticoagulants compared with not giving anticoagulants to people who need them... sensitivity was agreed by the committee to be more important than specificity because *the risks of unnecessary anticoagulation are outweighed by the risks of not treating people who need anticoagulation*." [1]

This makes clear that the recommendation is based not only on the population level probability of the major consequence (stroke), but on the Committee's *preferences* regarding this consequence. The reasoning is invalid in suggesting that 'evidence' can suggest any threshold on a continuous function is better than any other, let alone identify the ideal one. While the evidence can establish the sensitivity and specificity of a scoring tool at a set of cutoffs, whether any particular combination of them is 'good' or 'best' is a pure value judgment. In this case the value judgment is about the 'false anticoagulation to false no anticoagulation' trade-off under uncertainty. This ratio is conditional on the prevalence of the target event in this patient group, a fact not mentioned, and maybe overlooked, by the Committee. If it were 10%, the recommendation based on 92% sensitivity and 23% specificity will generate 24 patients on anticoagulation who are not benefiting, for every one who experiences the avoidable harm from not being on it. (52 at 5% prevalence.). Unfortunately, we have been unable to trace the sensitivity/specificity combination of 92/23 in the appended clinical evidence tables [2]. Most of the studies summarised there show a wider gap and hence a number well above 24. For example, the 98/9 combination from a German study [3] raises the number to 37 (at ≥ 2 and 10% prevalence). More interestingly and perhaps appealing to many patients, raising the cut-off to ≥ 3 reduces it to 21 (combination 93/18) and raising further to ≥ 4 reduces it to 17 (84/32). However, our point is primarily conceptual. By failing to emphasise that this trade-off is preference-based, and instead giving the impression that the recommendations are based on objective data ('the risks of x *are outweighed')*, the guideline undermines its earlier avowal that patient's preferences matter. The use of 'need' and 'high risk' further reinforce this impression that the recommendations are evidence-based rather than evidence-informed.

Even if a clinical dyad is able to resist this powerful recommendation and proceed to the recommended discussion, they are met by a warning that "a bleeding risk tool should not be used to provide a cut off for determining who should have anticoagulation. Instead, the tool should be used to provide accurate knowledge of absolute bleeding risk, which can support discussions between the person and their healthcare professional about bleeding risk modification and appropriate levels of vigilance." This is surprising, and perplexing, since it is not clear how these patient-professional discussions can progress other than by considering the implications of different cutoffs on the scale that provides individualised bleeding risk scores. (Whether it is ORBIT or HAS-BLED is irrelevant.) In a response during the consultation on the draft of the guideline, NICE made it very clear that a bleeding risk tool should not be used as a decision aid to deny anticoagulation. It seems not unreasonable to interpret this as discouraging any consideration of bleeding risk that may lead away from an anti-coagulation prescription.

The preamble to all NICE guidelines' states "When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients... It is not

mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual....” However, this disclaimer does not prevent the recommendations being transformed into effective mandates by commissioning bodies, nor by clinicians seeking to avoid negative professional and legal risks by practising ‘defensive medicine’. This would not be a problem if there were positive recognition for implementing the explicit recommendation to bring patient’s preferences to bear in decision making. But we have not heard of any practice auditing checklist that includes such recognition, independent of whether the preferences are ‘concordant or ‘discordant’. Use of these terms is telling in itself, since it implies ‘discordant preferences’ can be regarded as an explanation for low compliance/adherence.

The guideline stresses that it is to be interpreted within the context of Shared Decision Making (SDM), “a collaborative process that involves a person and their healthcare professional working together to reach a joint decision, based both on evidence and on the person's individual preferences, beliefs and values”, and using quality-assured Patient Decision Aids (PDAs) as one part of the overall 'toolkit' to support SDM. NICE offers an extensive set of normative standards for both the processes of SDM and the development and use of PDAs [4], but both are characterised by a relative lack of attention to the elicitation of the patient’s preferences, avowed to be of such importance. The distinction between providing the *individualised* preference-*insensitive* information necessary for the weighing of risks, and permitting their *personalised* weighing, is frequently blurred or lost.

NICE also wishes to restrict the use of PDAs to within SDM. We do not, but assume that treating patient’s preferences seriously requires decision support for both patient and professional. In a separate paper, we pose our opening questions to available PDAs [5].

4. Discussion

While the major sets of guidelines from Europe and the US conflict on the absolute level of thromboembolic risk required before the protective antithrombotic effect is seen as outweighing the associated serious bleeding [6], they do not diverge significantly from NG196 in the way that concerns us – whether the patient’s preferences are pre-empted by the stroke risk cut-off on CHA_2DS_2-VASc, be it ≥ 1, ≥ 2, or ≥ 3.

The patient preference mantra is repeatedly stressed in the US guidelines [7]. “Selection of stroke risk reduction therapy should be guided by the patient’s risk of stroke, risks of bleeding with therapy, and their individual preferences... Multiple factors need to be considered to select an optimal OAC in patients with AF. Efficacy, safety, insurance coverage, renal/hepatic function, drug interaction screening, medication adherence, and patient preferences are the major factors for consideration... In patients with AF, SDM with the patient is recommended to discuss rhythm- versus rate-control strategies (taking into consideration clinical presentation, comorbidity burden, medication profile, and patient preferences)”. But, as with NICE, there is no suggestion how this should be done or how the relevant information needed for it to happen should be provided. Furthermore, the framing of patient’s preferences as just one factor to be taken into account fails to recognise that they will potentially condition the whole decision in a fundamental way if they involve moving the threshold.

There is less enthusiasm for patient’s preferences in the European equivalent and even a significant indication that it is declining [8]. In 2016 we have “Placing patients in

a central role in decision making should be considered in order to tailor management to patient preferences and improve adherence to long term therapy". In 2020 this becomes "To optimize shared decision making about specific AF treatment option(s) in consideration, it is recommended that physicians: Inform the patient about the advantages/limitations and benefit/risks associated with the treatment option(s) being considered; and discuss the potential burden of the treatment with the patient and include the patient's perception of treatment burden in the treatment decision". So only 'burden perceptions' (not risk preferences) are now to be elicited and included.

5. Conclusion

Clinical guidelines need to be consonant with the movement towards "personalized, preventive, predictive, participative precision medicine (P5M)" which involves consideration of individual health status, conditions, genetic, and genomic dispositions as well as the social, occupational, environmental, and behavioral context." [9]. However, if they wish, within this movement, to ensure the patient's preferences are taken seriously, they will need to accept the ontology-based distinction between the individualisation of care based on context-relevant knowledge and conditions and the personalisation of care based on the patient's preferences.

To avoid accusations of paying lip service, clinical guidelines therefore need to make clear their recommendations embody preferences which potentially pre-empt those of the patient; ensure that the patient can formulate their own informed preferences by having easy access to the necessary information on the consequences of all alternative options; refrain from referring to the patient passive-paternalistically; and stop characterising preferences as concordant or discordant.

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The 'Reasonable Patient' of 2027: A Vision Paper

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Abstract. The verdict of the UK Supreme Court in the case of *Bellman versus Boojum-Snark Integrated Care Trust (2027)* will have profound implications for medical practice, medical education, and medical research, as well as the regulation of medicine and allied healthcare fields. Major changes will result from the definition of person-centred care built into the expanded definition of informed and preference-based consent central to the judgment made in favour of Bellman's negligence claim. (For the avoidance of doubt this is a vision paper.)

Keywords: reasonable patient, consent, scoring systems, thresholds, patient preferences

Introduction

Mr Bellman presented to a GP within the *Boojum-Snark Integrated Care Trust* with recent onset shortness of breath and pleuritic chest pain. The GP referred the 55 year old to the Trust's secondary care for suspected pulmonary embolism (PE). He underwent computed tomography pulmonary angiography (CTPA) and was prescribed anti-coagulation medication on the basis of a diagnosis of PE. He was subsequently found to have minor kidney damage, possibly attributable to post-contrast nephropathy, and, more seriously, suffered an intracranial hemorrhage, accepted to be associated with the anti-coagulation treatment. The Trust's defence accepted that Mr Bellman had experienced these adverse events but argued that they were following established guidelines for referral, based on his Wells' Criteria score (5), Pulmonary Embolism Rule-Out positive result (Age >50, clinician's pre-test probability of PE 15%) and point of care d-Dimer test (.50). His subsequent secondary care also followed well-established local guidelines which recommended CTPA scanning on referral, and if PE was diagnosed following the scan (as in Mr Bellman's case), anti-coagulation treatment given the patient's CHA_2DS_2-VASC stroke risk score was ≥ 2. (Mr Bellman's was 2.)

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Method

Counsel for Bellman argued that Mr Bellman was not asked for his consent to the initial referral and may have refused if informed of the prognostic implications of the alternative options, including the possibility of death or disability from haemorrhage, whatever his Wells', PERC, and d-Dimer results. His preferences were not elicited or discussed at any point, it being taken-for-granted that he consented to the referral for a CTPA scan and its management consequences. Subsequently, he was not adequately informed of the prognostic implications of his scan result, nor those of anti-coagulation medication. The latter was prescribed in a routine manner, without any elicitation of his preferences in relation to the possible consequences - benefits and harms - from this treatment, or none.

While the central basis of the claim related to the failures to provide adequate information regarding benefits and harms, and to elicit consent on its basis, counsel presented evidence on the prognostic characteristics of the Wells and other PE Scores used in primary care, as well as on the prognostic characteristics of a CTPA scan in the context of possible PE, and of anti-coagulation treatments if PE was confirmed [1-7]. The guidelines followed in both primary and secondary settings involved trade-offs that may well have been unacceptable to Mr Bellman if he had been informed of them at the initial point of care. The guidelines had been developed on the basis of population calculations and lacked any empirical basis in population preferences over their health consequences. While such group-based estimates of the balance of benefits and harms could never be applicable to a particular individual such as Mr Bellman, it would have given them some credibility as a population-level default. Considerations of cost-effectiveness from the health service point of view were heavily influential in setting the various diagnostic and treatment related cut-offs.

Counsel made clear that Mr Bellman fully accepted the usefulness, indeed necessity, of practical and 'simple' scoring systems in medical practice. He merely argued that as a reasonable patient in the digital age he was entitled to have the best available estimates of the prognostic implications of a score made available, communicated in straightforward numerical probability form, along with some indication of the uncertainty surrounding the central point estimates. This was a necessary condition of his giving informed and preference-based consent to any action, such as his referral, conditioned on the score.

These prognostic implications would include the possible adverse events and burdens arising from the test and treatments likely within the future conventional pathways. The possibility of 'overdiagnosis' and 'overtreatment' arising further along a PE care journey was no longer disputed in the field, his counsel argued. While in many cases this cannot be established in an individual before death, applying the pragmatic test of an independent expert opinion after 3 months, Mr Bellman's PE did indeed turn out to be a case of overdiagnosis and treatment. A recent study had revealed a 25% rate of overdiagnosis following CTPA. However, counsel stressed that this fact was no part of the basis of his negligence claim, though it was related to the material harm he suffered.

The claim that the parties concerned were simply fulfilling their legal duty of care by following guidelines could not be accepted when his adequately-informed and personal preference-based consent was not obtained. Mr Bellman understood that it would be unreasonable to expect clinicians to be able to meet these reasonable demands unaided, so in his view the profession needed to take urgent steps to increase

the types of decision support tools that could ensure every clinician was able to fulfil them and so avoid potentially negligent practice.
Mr Bellman also wanted to make it clear that, as a citizen, he was not questioning the use of cost-effective criteria in the decisions of a resource-constrained health system. He was however objecting to their covert internalisation in the clinical decision about himself. He was entitled to be fully informed about the clinical harms and benefits to himself before any censoring of options or other restrictions, arising from policies based on system-level criteria, was applied.

Result

The judge ruled in favour of Mr Bellman and awarded him costs and damages.
The judgment in *Bellman versus Boojum-Snark Integrated Care Trust* represents a major extension of the reasonable patient standard as formulated in *Montgomery versus Lanarkshire Health Board 2015* [8]. In order to adequately inform the patient of the material harms and benefits of the alternative treatments, the practitioner must now disclose the prognostic implications of any numerical score, or threshold-based classification introduced into the decision making process, along with (on request) its full provenance. The reasonable patient is entitled to expect these implications, covering mortality as well as morbidity, to be presented in numerical, positively-oriented form - chance of avoiding, not of experiencing, a negative outcome or event - and in percentage format (%) as the most universally accessible mode. (Supplemented by *per mille* (‰) where appropriate.) All other formats, such as a '1 in x' chance, produce more confusion than communication. While the uncertainty surrounding it should be conveyed, a central point estimate for any distribution, specified as either mean or median, must be provided.
Following this judgment, the reasonable patient cannot be asked to consent to a management strategy based on any pre-assigned verbal 'risk' classification (e.g. high, moderate, low) for a single criterion (e.g. chance of stroke), without being informed of the prognostic implications of each level in each class. The absolute percentage probabilities of specified outcomes must not have been transformed by any population-based normalisation or standardisation process - such as those which produce 't-scores' and 'z-scores'. Such transformations mean the resulting numbers are not probabilities and cannot be used in the wider multi-criterial decision framework appropriate in clinical medicine.
The judgement accepts that the logical implication is that the prognostic implications of scores *below* any action threshold must also be provided. The patient must be in a position to give informed consent to any non-referral, such as would have been the situation if Bellman's Wells' score had been 4, his PERC negative (if he had been 48) and d-Dimer .45. It was up to him to set this threshold. In future all test results being made available, in person or online, need to be accompanied by the prognostic implications of the results, along with the location and bases of any attached cut-off, or target value, that could influence or determine the provider's recommendation for action or no action. Existing scoring instrument and systems will need to be updated to meet these legal requirements in order to be defensible in future. A scoring rule or system may only be used if there is full and transparent disclosure of the underlying algorithm, since the reasonable patient is entitled to see the precise variable weightings used in the derivation of his or her individualised score. All guidelines will need to undergo major modification at each decision node in order to ensure that the patient

can make an informed choice from the full set of subsequent possible pathways, rather than merely consenting to moving to the next stage in an effectively automated guideline-based organisational protocol.

Appreciating that practitioners and guideline developers will have difficulty with their expanded task, the judgment requires only that they are (a) able to *cite* the best available prognostic *estimates* from relevant sources, including decision support tools, and (b) *document* any deviation from these made on the basis of their clinical expertise and knowledge of the particular patient, or patients like him or her, in biomedical terms.

Discussion

The judgement has profound implications, not least for the future developers of scoring systems. First, the development will need to work backwards from the obligation to provide the prognostic implications of each individual score level, or threshold-based classification, to the patient in the prescribed format. Considerations of cost-effectiveness have no place in this process, (They are entirely appropriately introduced subsequently and separately.) Second, they will need to publish the underlying data at maximal level of individualisation and granularity to ensure practitioners and patients are able to make optimal use of their instruments.

The judgment stresses the distinction between the population and clinical levels, recognising that while a study may be underpowered for statistically significant conclusions at a specific score level, because of the small number of observations, that data may be the best available prognostic basis for a particular clinical decision. The judgment makes clear that statistical significance in the form of p-values should play no role in clinical decision making. To meet the 'best available absolute percentage probability' requirement, the positive and negative predictive values of each individual score at a relevant range of prevalences (prior odds) must be available, not only their overall discriminatory power or calibration.

While predictive scoring systems must be subjected to validation, it should be made clear that any validation does not extend to the cut-offs and/or risk classifications, which are necessarily based on the preferences of the developers or their implications for cost-effectiveness. Any valid use of a scoring system in person-centred clinical decision making involves incorporating, in the predictive values, the prevalence of the target condition in the population. The system should also permit the preferences of the individual to determine the criterion/item weights in the tool, whether or not any default weights are installed. In other words, the system must be *individualisable* in terms of evidential judgments and *personalisable* in terms of value judgments.

Advancing the argument that the scoring is only to make a descriptive assessment of the patient's status, or to produce a diagnosis or diagnostic judgment, will no longer absolve the practitioner from communicating its prognostic implications. Separating these activities from 'therapeutic decision making' is now incompatible with preference-based consent, since the preferences of the individual patient may be pre-empted by the value judgments embedded in the descriptive or diagnostic score. A further implication is that the convenient cross-sectoral distinction between a 'screening' and 'diagnostic' test no longer has legal force, given that informed consent is necessary both for the test itself and for any action following from it, such as referral or further testing. The frontline practitioner (GP, health visitor) must therefore be able to communicate the prognostic implications of the alternative options prior to

explicitly introducing any restrictions on those options arising from local or national policies.

A major redirection of medical research resources and funding is required to ensure that clinicians and patient (separately and/or in combination) have available preference-sensitive decision support tools populated with the best up-to-date estimates of the prognostic implications of relevant states and conditions. The Bellman judgment is highly critical of the way research findings, including those in respiratory medicine, are currently presented in a way that assumes, fallaciously, that both clinician and patient are capable of translating them into decision-relevant and usable formats. The systemic movement toward 'personalized, preventive, predictive, participative precision medicine' can be a major force for change in this respect [9]. It can also ensure that all actors in the health ecosystem, especially guideline developers, respect the distinction, fundamental to clinical decision support, between knowledge-based individualisation and preference-based personalisation.

Conclusion

Bellman establishes that many practices that have characterised medicine until now, including conceptual distinctions and verbal quantifications, are no longer legally fit for purpose. Large swathes of medical decision making occurs unaided, and, according to *Bellman*, in ways that fail to meet the 'reasonable patient' standard for informed and preference-based consent. By implication, the role of a diagnosis, and the centrality of the diagnostic process, is in peril when the Bellman judgment is fully appreciated and digested. Diagnosis without prognosis is clearly now an unacceptable basis for action (or inaction). Diagnosis as a subcomponent of a prognostic process - itself a subcomponent of the fundamental decision making process - is its future, as envisaged in this vision paper.

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Empathetic and Emotive Design Heuristics: Preliminary Results of Their Application to Evaluating Survey User Interfaces

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Abstract. Empathetic and emotive design is becoming increasingly important in the digital age. In this research we describe the results of a combined cognitive walkthrough and heuristic evaluation using newly developed, empirically derived empathy or emotive design heuristics. We applied the heuristics to the evaluation of four commonly used survey platforms. Our preliminary findings revealed that the heuristics performed effectively in scoring survey platforms on their level of empathy. Survey platforms that are highly empathetic were scored highest.

Keywords. Empathy, emotive, design, heuristics, cognitive walkthrough, surveys, human-computer interaction, evidence-based

1. Introduction

In this paper we describe the results of a combined cognitive walkthrough and heuristic evaluation [1], which was conducted to test out and apply a set of newly developed empathetic design heuristics [2] that the authors developed for the evaluation of the user interface designs of four different survey platforms. Cognitive walkthrough is an approach, where one or more analysts serve as reviewers of a website, system, or user interface to assess its features and functions in a specific domain area such as safety, usability and/or empathy [1-3]. The analysts are instructed to systematically step through the user interface or system while carrying out a specified task. During the combined cognitive walkthrough and heuristic evaluation, the system or user interface design is reviewed in the context of a set of design heuristics (i.e., empathetic and emotive design heuristics) were developed in an earlier phase of the project [2]. The overall method was

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informed by Kushniruk et al.'s [1] and Borycki et al.'s [3] approaches but was extended to empathetic and emotive design [2,4].

2. Method

Cognitive walkthrough is a method that is used to evaluate systems and user interfaces [1]. The method involves several steps or phases, where analysts' conduct a cognitive walkthrough independently of a system or user interface. In this paper we describe the application of a method that integrates both cognitive walkthrough and heuristic evaluation, drawing on the strengths of using both approaches together [1], and its use in the application of newly designed empathetic and emotive design heuristics [2,4]. The main goal of the work in this paper is to use this combined cognitive walkthrough/heuristic evaluation to examine how different survey platform user interface designs comply with newly developed empathetic and emotive design heuristics. To do so, we applied the method to compare several different survey platforms interface designs used to create online questionnaires.

2.1 Participants and Materials

Analysts trained in the practice of combined cognitive walkthrough/heuristic evaluation participated in the evaluation. Analysts were selected, who had no prior experience in using the survey platforms to reduce potential bias. The PHQ-9 mental health assessment tool [5] was implemented on four standard, commonly used commercial survey platforms. This resulted in the creation of running versions of the same questionnaire as it was encoded in the different platforms/user interface designs.

2.2 Setting, Scenario and Task

Each analyst conducted a hybrid cognitive walkthrough/heuristic evaluation in a private office setting like one where individuals would be typically completing a survey. This was done to ensure the ecological validity of the hybrid cognitive walkthrough/heuristic evaluation [6]. To create a realistic experience for the analysts, each analyst was presented with the same scenario and asked to complete each of the surveys. This was done to simulate realistic use of the different commercial survey platforms running the PHQ-9 assessment tool and to maintain the ecological validity of evaluation [6].

2.3 Procedure

The analysts were trained to conduct a hybrid cognitive walkthrough/heuristic evaluation and were introduced to the emotive or empathetic design heuristics in a four-hour training session as it typically done for training professionals in usability evaluation and to ensure consistency in the application of the method amongst different analysts [1]. The goals of the training session included the development of a consistent mental model among the analysts regarding the role, nature, and application of hybrid cognitive walkthrough/heuristic evaluation in the general user interface design literature and the empathetic and emotive design literature [1]. Following this, the analysts received training about: (1) how to apply the emotive design heuristics, (2) how to conduct a hybrid cognitive walkthrough/heuristic evaluation, and (3) how to document this

information. This was followed by a group practice session, where the analysts practiced the application of emotive design heuristics with another software application, to ensure consistency in the application of the hybrid cognitive walkthrough/heuristic evaluation. During the group training and practice session, the analysts were encouraged to ask questions and resolve any differences in approach in discussions with the trainers.

Then, the analysts independently conducted the hybrid cognitive walkthrough/heuristic evaluation by systematically stepping through the user interface of each the survey platforms in response to a scenario while carrying out a representative task (i.e., completing the PHQ-9 questionnaire). The task involved taking the PHQ-9 survey and applying empathetic and emotive design heuristics to determine the user interface's conformance with the heuristics. The analysts were asked to complete the hybrid cognitive walkthrough/heuristic evaluation for each of the survey platforms: platform 1, platform 2, platform 3,and platform 4 (i.e., Tickit Health®). The order of the platforms that underwent the evaluation was determined by two usability experts [6]. The platforms with the most parsimonious user interfaces were examined first, with each additional platform increasing in sophistication and complexity in its user interface design approach presented later in the sequence. This was done to prevent learning and carry over effects [6]. In such instances it is considered important that user interface designs that are most parsimonious and simplest be presented first, followed by designs that are increasingly more complex [6, 7]. Each analyst then worked through each of the surveys on the different platforms (i.e., platform 1 to 4). In doing so, they noted whether the interface conformed to the list of heuristics on a 5-point scoring scale (from 0 as representing no conformance in the user interface through to 4 representing heuristics strongly applied or conformed) see Table 1: Scoring [1].

Table 1. Scoring

Score	Definition (i.e., Meaning) of the Score
0	Does not conform (i.e., not present)
1	Rarely conforms
2	Sometimes conforms
3	Often conforms
4	Always conforms

The heuristics, which were derived from an extensive scoping review [2], focused around several categories of guidelines or heuristics for supporting empathetic and emotive user interaction, including [2]:

- Personalization
- Messaging
- Engagement
- Reward
- Imagery
- Content
- Usability, Access and Quality

The analysts completed the survey on each of the platforms in a stepwise manner while at the same time documenting how well the user interfaces followed the empathy and emotive design heuristics and scoring them, when using the different platforms.

3. Results

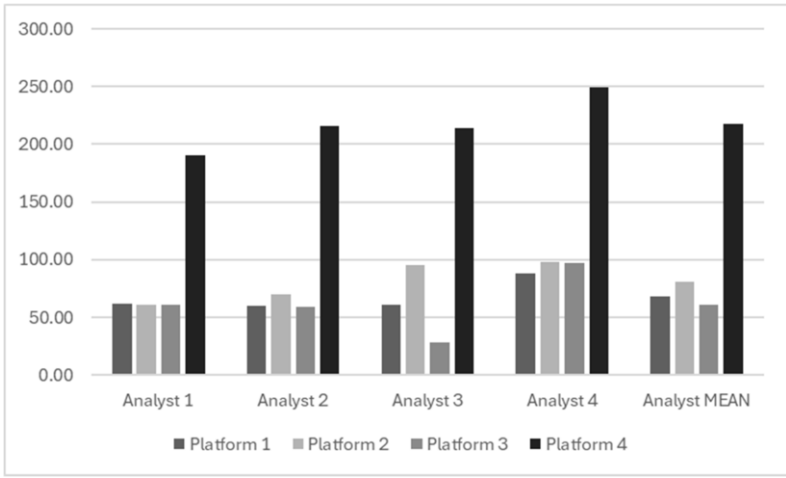
The total scores for conformance with the emotive heuristics for each of the analysts for each of the survey platforms is summarized and presented below (see Table 2). Survey platform 4 (i.e. Tickit Health®) had the highest scores across the analysts, indicating it conformed the most to the empathetic and emotive design heuristics. Tickit Health® came the closest to the maximum possible score of 324. This trend is clearly visible when the total scores are plotted in the graph below (see Figure 1: Conformance Scores for Empathetic and Emotive Heuristics for each of the platforms, by Analyst).

Table 2. Total Scores

Survey Platform	Analyst 1	Analyst 2	Analyst 3	Analyst 4	Analyst MEAN
1	62.00	60.00	61.00	88.00	67.75
2	61.00	70.00	95.00	98.00	81.00
3	61.00	59.00	28.00	97.00	61.25
4	190.00	216.00	214.00	249.00	217.25

Maximum score: 324

Figure 1. Conformance Scores for Empathetic and Emotive Design Heuristics by Analyst and Platform



4. Discussion

The design of user interfaces that elicit positive emotional response (a goal of emotive and empathetic design) can lead to increased completion rates for surveys and may also be associated with a more fulsome and accurate response to survey questionnaires. In this paper we have reported on the application of a set of newly developed heuristics [2] for assessing the degree of alignment of a user interface or system with principles of empathetic and emotive design. To do so, a hybrid cognitive walkthrough/heuristic evaluation was conducted for four different user interface designs for deploying the same

mental health questionnaire on a survey platform. In this preliminary evaluation, it was found that the empathetic and emotive design heuristics used in the evaluation could clearly differentiate among survey tool user interface designs. Future research will involve expanding the number of participants and comparing a larger number of user interfaces and platforms. Qualitative data on which design was associated with emotive response (along with examples) will be presented in a subsequent paper.

5. Conclusions

This research has important implications for the assessment of user interfaces in terms of how well they support positive user emotional responses. We are currently extending the approach to application of heuristics for evaluating the impact of different user interface designs for other domains ranging from artificial intelligence applications to social robots to assess their degree of adherence to empathetic and emotive design.

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Empathetic and Emotive Design Heuristics

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Abstract. The design of user interfaces and systems that promote positive emotional interaction and reaction from end users is becoming a critical area in the design of applications and systems for use by the general population. In this paper we describe our work in the creation of a set of empathetic design heuristics that were developed from examination of the literature in this area within the context of healthcare user interface design. The heuristics and their potential application are explored.

Keywords. Empathy, emotive, design, heuristics, user interface, human-computer interaction, evidence-based

1. Introduction

Empathetic and emotive user interface designs can foster improved user-system interactions [1]. Such interactions are particularly important in specific contexts such as gaming, online sales and healthcare. More specifically, technologies developed for industries such as healthcare need to have empathetic and emotive components to enhance and support user interactions with technologies. In this paper we outline our development of emotive design heuristics and that can be used to assess and evaluate user interfaces taking into consideration population characteristics.

Empathetic and emotive designs promote emotions or feelings that are positive and pleasurable [1]. Although the construct of empathy is multidimensional and difficult to measure, there are ways to focus design, communication, and training on empathy [2]. Designing digital empathy or emotive design in the context of digital tool features and functions remains to be fully explored. We began this work in another publication [see 3] by conducting a scoping review using the method outlined in Borycki et al. [4]. The approach builds on previous research by Borycki and colleagues [4-6] in the development of evidence-based heuristics. This methodology involves first conducting a review of the relevant literature to extract findings that can form the basis for developing heuristics. For example, Borycki et al. [4] describe the approach to identifying specific aspects of health information technology safety from results of published articles on that topic, which can then be reviewed by a panel of experts and phrased as specific heuristics [5-6]. In this paper we extend the approach to the

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development of evidence-based heuristics to be used in evaluating health information technology for assessing the extent to which a digital health tool (or platform design) supports empathy and engagement by users. Such heuristics could also be used to guide the design of empathetic or emotive user interfaces.

2. Procedure

We conducted a scoping review to identify articles that contained findings and results relevant to the development of heuristics on aspects of empathetic or emotive user interface design [see 3]. We now report on the development of heuristics from this process. Extracted data from the articles were analyzed qualitatively in Phase 1 as this formed the basis of a method for deriving a set of heuristics [see 4-6]. A panel of health informatics, and human factors experts reviewed the extraction table results (from the scoping review) to develop a set of emotive and empathetic design heuristics presented in this paper. The panel developed a set of heuristics and a scoring system for the heuristics. This involved considering each data extraction from each of the articles, to develop a heuristic, where applicable. These heuristics were extracted from the review of the papers identified in searches in Phase 1 [3].

Data that were extracted from the relevant studies were presented at a meeting with an expert panel consisting of three human factors experts (i.e. via data extraction tables that resulted from Phase 1). The three experts reviewed the information in the tables and categorized the evidence according to findings. The expert panel interpreted the evidence and developed a list of heuristics (that would be used to inform the cognitive walkthrough in a future phase of our work). As the panel considered each potential heuristic (that emerged from the discussion of the scoping review results for each article), the panel made the determination, if a prior heuristic was developed, or if a new heuristic should be created and added to the growing list. This was done until all the heuristics were developed by the expert panel. Differences of opinion between the panel members were resolved through discussion. The heuristics that emerged from reviewing the data from Phase 1 were then clustered together using a content analysis approach. Content analysis was used to obtain an objective, qualitative description of the heuristic. As each heuristic was composed of text, the text within the heuristic was organized into themes to inform heuristic development [3].

3. Results

3.1 Heuristics: Initial Categories

The application of the method described above lead to the identification of 49 heuristics. The initial clustering of heuristics resulted in 14 categories given below.

Table 1. Heuristic Categories

	Heuristic Category
1.	Personalization
2.	Agreeability
3.	Enjoyment
4.	Engagement
5.	Attention

6.	Communication
7.	Language and Wording
8.	Content
9.	User Satisfaction
10.	Usability
11.	Attrition
12.	Privacy
13.	Information Security
14.	Technical Difficulties, Bugs or Errors

When the above grouping of heuristics was further collapsed (through an iterative process of review by the researchers) the following groupings emerged for review:

- Personalization
- Messaging
- Engagement
- Reward
- Imagery
- Content
- Usability, Access and Quality

3.2 Heuristics: Clustered by Topic

One cluster of heuristics deals with approaches to design that support the individualization or personalization of healthcare user interfaces or applications. For example, **Personalization** has been identified as critical component for designing interfaces that make users feel that presentation of information and responses are tailored specifically to them, supporting emotive design [7] – see Table 2 for examples of emotive design heuristics derived from the literature review process described above related to personalization (and the other groupings listed above).

Table 2: Emotive Design Heuristics

	Personalization:
1.	Personalization improves perceived empathy.
2.	Carrying messages improve perceived empathy.
3.	Real people with personal examples improve perceived empathy.
4.	Personalized messages increase engagement.
5.	Personalization is important to users.
6.	Personalized information increases engagement.
7.	Strategies tailored to health needs and situations increase user engagement.
	Messaging:
8.	Simple messages are more agreeable.
9.	Simple inquiries about how a person is feeling are more agreeable.
10.	Additional helpful resources increase agreeability.
11.	User sense of autonomy and control increases perceived enjoyment.
12.	Enjoyment in using an application increases engagement.
	Engagement:
13.	Imagery and visualization engage users (i.e. increasing likes)
14.	Imagery about the consequences of illness and control mutes responses.
15.	Imagery with a positive affect may increase responses.
16.	Wording targeted to users' needs and background increase engagement.
17.	The user interface has featured that support setting personal goals.
18.	Gamification increases user engagement.
19.	Perceived trustworthiness increases users' engagement.
20.	Meaningful, unexpected and tangible rewards increase user engagement.

21.	Information on behavior health outcomes increases user engagement.
22.	Information about healthy lifestyles increases user engagement.
23.	Feedback increases user engagement.
24.	Instructions and tips increase user engagement.
25.	Adding a storyline increases user engagement.
26.	Identification with and a diversity of characters increases user engagement.
27.	Well defined instructions (which can be skipped) in combination with clear feedback increases user engagement.
28.	Simplifying language improves user engagement.
	Reward:
29.	Rewarding the user enhances user engagement with the system.
30.	Rewarding the user provides positive reinforcement.
	Imagery:
31.	Imagery increases the transmission of messages.
32.	Imagery increases message transmission.
33.	Positive communication increases engagement (i.e. sharing and spreading messages).
34.	The option for social connectivity or ability to connect with others is important to users.
	Content:
35.	Content, wording and language should lead to positive emotions.
36.	Content is personalized.
37.	Features are personalized and specific to health issues.
38.	Content is credible about the subject.
39.	Content with appropriate amount of text increases engagement.
40.	Content is credible about the subject.
41.	Content meets user expectations about presentation.
42.	Graphics and vivid color positively affect users and engagement.
43.	Content matched to reading and literacy level of the audience.
	Usability, Access and Quality:
44.	Engagement is influenced by ease of use.
45.	Provide easy access to support and help.
46.	Provide easy access to information.
47.	Privacy increases engagement.
48.	Trustability increases engagement.
49.	Security increases trust ability and engagement.

The topic of **Messaging** formed another cluster of heuristics whereby the approach to presenting messages to users of systems can be important in creating a sense of agreeability, helpfulness and positive emotion. **Engagement** is another key aspect of interactive systems most closely linked to emotive user interface design (having the highest number of heuristics derived from the literature linking it to emotive user interfaces). As can be seen in Table 2 a number of design techniques and user interface features (e.g. gamification and imagery) are linked in the literature to emotive user interfaces, leading to a number of heuristics under this category. Providing **Rewards** to users is also another approach that has appeared in the literature that can support emotive user interface design and increase positive emotions towards a system or user interface. **Imagery** and the inclusion of features supporting social interaction through a user interface have also been found to support emotive design and positive user interaction. Careful design of **Content** was also noted in the literature as being critical in creating user interfaces that are agreeable, and that promote positive user interaction. This includes presenting users with content that is credible and that is also matched to their

reading and literacy level. Finally, a subset of heuristics emerged around the concepts of **Usability**, **Access** and **Quality**. These included heuristics around creating trustable, secure, and usable user interfaces and applications with trust being closely associated with user confidence and positive reaction to information technology [3].

4. Conclusions and Discussion

In this paper we have described our work in transitioning from the results of a previous literature review to the creation of a new set of evidence-based heuristics extracted from that review. The intent of the heuristics is for their use in evaluating user interfaces and systems in terms of emotive design. They can also be used as guidelines that can be used to drive the design of new user interfaces designed to lead to positive and emotionally satisfying user interactions (which forms the basis for our ongoing work in this area in evaluating and designing user interfaces in healthcare) [4,8].

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Empathetic and Emotive Design: A Scoping Review

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Abstract. With the advent of the digital health era, there has emerged a new emphasis on collecting health information from patients and their families using technology platforms that are both empathetic and emotive in their design to meet the needs and situations of individuals, who are experiencing a health event or crisis. Digital empathy has emerged as an aspect of interactions between individuals and healthcare organizations especially in times of crises as more empathetic and emotive digital health platforms hold greater capacity to engage the user while collecting valuable health information that could be used to respond to the individuals' needs. In this paper we report on the results of a scoping review used to derive an initial set of evidence-based empathetic or emotive design heuristics.

Keywords. Empathy, emotive, design, heuristics, user interface, human-computer interaction, evidence-based

1. Introduction

Empathetic and emotive interaction is an important element in the design of digital health tools. Empathetic and emotive interaction is focused on how users feel and react to technologies. Feeling and reactions affect user engagement with digital tools (e.g., mobile apps, websites, surveys) and can have significant impacts on the use of these tools. Such interactions attend to how emotion affect the user experience from first acquiring or using a software or a product through to its use and abandonment (or user disengagement). Empathetic or emotive interaction is present throughout a user's journey with a software or product. It also deals with how users can become emotionally attached to a software or product [1,2]. Yet, we have few tools available in healthcare to collect information about individuals in a way that addresses their individual sensitivities and health needs while providing health information. This is an area of research that holds great promise for affording us the opportunity to collect information to support effective decision making by healthcare service managers while at the same collecting information from patients. In this paper we describe our work in conducting a

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scoping review of empathetic or emotive design to identify themes and approaches to creation of empathetic user interfaces.

2. Background

Emotive and empathetic design promotes positive emotions [3] or pleasure in users [4] by means of the design properties of products and software. Researchers have laid some of the groundwork for this new area of research, yet more investigation is needed. Through the study of empathetic or emotive user interface designs, knowledge can be gained about what concepts, designs, and frameworks could be used to inform the collection of data and the satisfaction of population health needs in the areas of compliance with health orders, trust in health and government action, and health related stress reduction initiated by health events. Although the construct of empathy is multidimensional in nature and difficult to measure, there are effective strategies for teaching empathy that focus on design, communication and training. The study of digital empathy in the context of features and functions of emotive interface designs remains to be explored and we began our work in this area by conducting a scoping review [5,6].

3. Procedure

A scoping review was undertaken that focused on empathetic and emotive interface design. The scoping review determined the current state of the literature for assessing the empathy of user interfaces. The scoping review focused on user interface design, empathy, emotion, communication and engagement. Arksey and O'Malley's five-step framework [7] as advanced by Levac et al. [8] was used to guide the scoping review. Five electronic databases were searched: (1) Medline®, (2) the Cumulative Index to Nursing and Allied Health Literature (CINAHL)®, (3) Psychinfo®, (4) Web of Science® and (5) IEEExplore®.

Articles selected for further review had to be related or relevant to the topic of empathetic and emotive user interfaces. Keywords used in the search included: "digital empathy", "empathetic design", "content design", "cultural design". "inclusive design", and "persuasive design" (see author for a full list of keywords used). Published peer-reviewed papers that focused on digital empathy, emotive design, and communication and engagement were identified and uploaded to Covidence® for further screening and review. Following the completion of the search, two researchers reviewed each publications' titles and abstracts using the inclusion and exclusion criteria in Table 1.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• a digital tool	• opinion pieces
• empathy	• editorials
• emotion	• paper-based tool
• user interface design	• not in the English language
• communication	
• engagement	
• empathetic or emotive interface designs	
• Peer reviewed	
• English language	

After the two researchers completed their title and abstract reviews, a meeting was held, where the two researchers along with a third researcher discussed conflicts in the selection of articles that emerged after the initial screening. A final decision was made by the three researchers as to whether to include or exclude the article for further full-text review by a majority vote. This screening took place in Covidence®. The review software supports screening and review of peer-reviewed research by the researchers. Irrelevant, unrelated, or duplicate studies were removed prior to screening by the two researchers. A PRISMA flow diagram was created as part of this process. The PRISMA diagram was populated with information regarding paper eligibility arising from the title, abstract and full paper screening. Articles that met the eligibility criteria were read, and data were extracted from these articles that included: the researcher's name, publication date, research questions, subjects/participants, setting, methods, design findings/implications and conclusions [7,8].

4. Results

4.1 PRISMA Diagram

Below are the results from the PRISMA diagram and the review of the data extractions from the articles from Phase 1 (see Figure 1). 559 records were identified. 146 duplicate records were removed before title and abstract screening. 413 records were screened using the inclusion and exclusion criteria. As a result, 357 records were excluded and 62 were sought for full text retrieval. Of the 62 records, three were excluded as they did not deal with digital tools, leaving in the end 59 records available for full text review (see Figure 1: PRISMA Diagram).

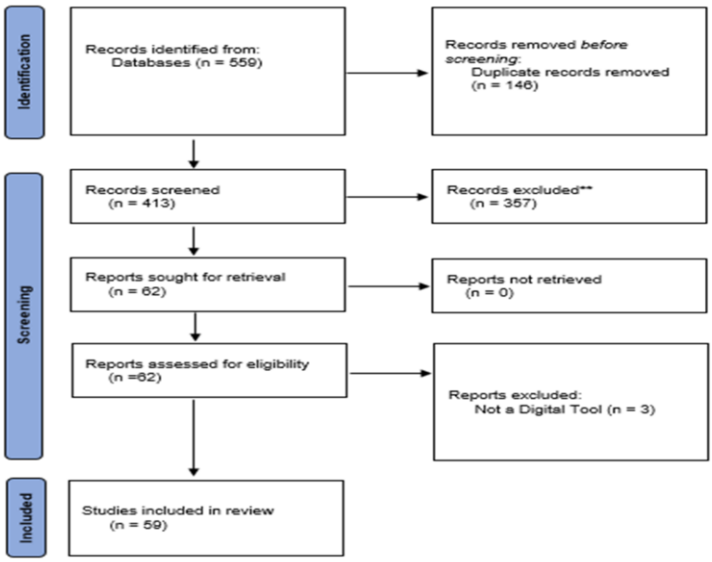

Figure 1. PRISMA Diagram.

4.2 Thematic Analysis of the Data Extractions from the Articles

Several themes emerged from a qualitative analysis of the results found in the data extraction table. Extracted data were analyzed qualitatively for themes [5]. Tools that are designed and developed with digital empathy or emotion perform better than tools that do not. According to the literature, user engagement is an important aspect of digital tool development related to creating empathetic user interfaces [1]. Researchers found that digital tools that have an underlying strategy or plan for enhancing user engagement are more empathetic. Layout and navigation as well as content and support have been found to improve user engagement and empathy [2,3]. Choosing the right design, attending to wording and developing language in a user oriented, participatory design approach improves user engagement and user perceptions of digital tool empathy. Communication improved empathy. Wording and language enhances communication. Timing of messages was identified in the research literature. Some researchers noted the timing of messages provided by digital tools influences use of materials and the information presented by tools [2].

Design influenced empathy [1-4]. Several aspects of design are important such as aesthetics, participant participation, and design conventions for digital empathy to be present. Imagery influences user engagement [2,3]. Graphic designs are a critical aspect of digital tools [2,3]. Comello and colleagues [9] identified graphic design impacts users. Several studies noted that personalization improves empathy and engagement, user satisfaction, and dialog quality. Whiteside and colleagues [10] recommended user endorsed personalization be considered in digital tool development [1,10]. Personalization of digital tools also took the form of customizing the features and information content provided by users. Lastly, digital tool content is important [1,2].

Gamification may improve user engagement and retention. Researchers have found game dynamics may influence user engagement and satisfaction with digital tools and their ability to meet users' needs. Researchers suggested that digital tools should be part of gamified care. Digital tool design is also important from a usability perspective. Usability is an essential aspect of user interface design. Usability is associated with engagement. Here, researchers have suggested that there is a need for designers to create clear consistent and visually appealing designs to ensure tool usability. To enhance usability, interfaces can be designed using strategies that include user input in the design of the interface, which could involve iterative design with cycles of user feedback and re-design. Other digital tool related factors that affect user engagement and empathy include: enjoyment, attention, user satisfaction, privacy, information security and technical difficulties, bugs and errors.

Privacy and information security are essential to engender trust which is fundamental to achieving empathetic interactions and engagement [1,2]. User questions about privacy should be clearly answered and explained. Privacy and data access issues are important to users, and if the user does not feel these issues are adequately addressed this may decrease engagement. Researchers found that user perceptions regarding their being a lack of privacy or information security could be a barrier to engagement with digital tools. Lastly, technical difficulties, bugs or errors could act as a barrier to engagement and may be perceived as un-empathetic and may lead to dis-engagement (e.g., error messages may be perceived as frustrating if designed in an unfriendly sounding text).

5. Discussion and Conclusions

The scoping review reported in this paper explored empathetic and emotive design. From the review a number of themes emerged. These included identification of concepts related to and associated with emotive design as well as specific design approaches and features that were found to support emotive design. This included a focus on careful design of communication and messaging that is simple and geared to the literacy level of the user of systems or user interfaces. Supporting user engagement was found to be highly related to emotive user interfaces. Other aspects related to emotive design include use of personalization and customization, gamification, the use of attractive and visually appealing graphics as well as a focus on both usability and security to engender trust in users. The results of the review reported in this paper are being used as a basis for the development of a new set of evidence-based heuristics that may be used to assess the degree to which different user interface designs support user experience and positive emotional interaction [11,12].

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Note: The full data extraction can be obtained from the corresponding author.

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Machine Learning

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Development of a Method for Automatic Matching of Unstructured Medical Data to ICD-10 Codes

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Abstract. Inconsistent disease coding standards in medicine create hurdles in data exchange and analysis. This paper proposes a machine learning system to address this challenge. The system automatically matches unstructured medical text (doctor notes, complaints) to ICD-10 codes. It leverages a unique architecture featuring a training layer for model development and a knowledge base that captures relationships between symptoms and diseases. Experiments using data from a large medical research center demonstrated the system's effectiveness in disease classification prediction. Logistic regression emerged as the optimal model due to its superior processing speed, achieving an accuracy of 81.07% with acceptable error rates during high-load testing. This approach offers a promising solution to improve healthcare informatics by overcoming coding standard incompatibility and automating code prediction from unstructured medical text.

Keywords. EHR, ICD-10, SNOMED, graph database.

1. Introduction

Within the expansive realm of medicine, the abundance and heterogeneity of data pose formidable challenges. While the adoption of Electronic Health Record (EHR) systems has ameliorated issues related to data storage adherence to specified standards [1], a persistent challenge lies in the incomplete compatibility of these standards [2]. Standards, including HL7 (v2, v3, FHIR), openEHR, and ISO 13606, exhibit distinct characteristics and requirements, contributing to difficulties in selection for specific projects or applications. This diversity impedes comparisons and integration efforts, potentially leading to information loss, data distortion, or heightened system loads when exchanging information across disparate standards.

Machine learning methods have emerged as highly effective tools for such modeling, offering the capacity to utilize implicit datasets and discern underlying relationships. In the realm of medical research, these methods facilitate the simulation of disease progression based on available patient data and conditions [3].

Currently, several studies focus on ensuring compatibility in disease classification. One study explores 4 methods: ICD-10-CM → SNOMED CT → ICD-11, ICD-10-CM → ICD-10 → ICD-11, and additionally explores the intersection and unification of

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methods 1 and 2 [4]. For instance, in method 1, errors occur during translation from ICD-10-CM to SNOMED, while in method 2, issues arise from incomplete coverage and accuracy of the WHO map from ICD-10-CM to ICD-11. Additionally, studies focus on translating Read codes [5]. The examination revealed that achieving a lossless correspondence between Read codes and the ICD10-CM disease coding system is unattainable due to disparities in ontologies and insurmountable ambiguity in the utilization of the Read code system by medical professionals [5].

Thus, it makes sense not to make a direct comparison of one code to another, for example, by compiling a reference book, but to consider the option of predicting the code of the requested classification based on a doctor's opinion, observations, complaints, symptoms.

The goal of this paper is to develop a system to automatically match unstructured medical texts to the ICD-10 codes.

2. Methods

2.1. System's architecture

The proposed methodology features a unique architectural design, emphasizing semantic interoperability in medical data to enable effective information exchange within healthcare systems. It comprises key components such as a disease classification graph for data collection, a training layer for experience accumulation, and model outputs for subsequent classifications.

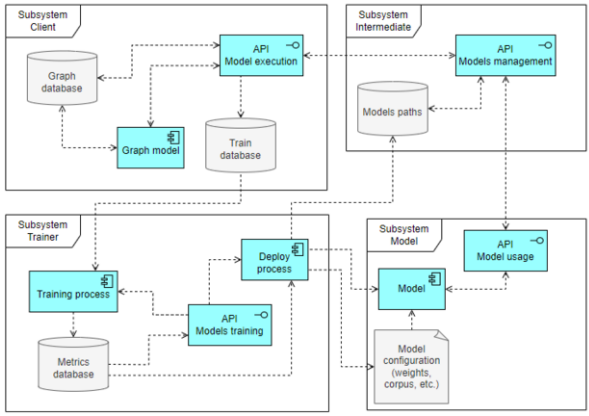

Figure 1. Architecture diagram of the system.

The resulting architecture consists of four main subsystems: client, intermediate, training, and model. Each subsystem is specialized for distinct functions. The "Client" subsystem manages input data reception, processing, and accumulation. The "Intermediate" subsystem facilitates communication between the client layer and the models.

2.2. Training layer

The training layer offers automatic model training and implementation, utilizing training data from the client layer. The "Trainer" subsystem automates model generation and training using accumulated client data. The learning process involves creating, training, and recording metrics and model configurations into the Metrics database, enabling future model selection and configuration loading without retraining. The "Deploy process" component retrieves saved model configurations to create the final model with its API service. To ensure usability, the model path must be added or updated in the directory containing model paths in the intermediate layer, ensuring operational readiness upon launch.

2.3. Knowledge base component

This component accumulates system data, performs two tasks: builds a knowledge base graph from initial component data, and predicts diagnoses and symptoms. For clarity, let's illustrate its function with an example. During the initial launch of the subsystem, each diagnosis is saved from the received set. If the diagnosis already exists in the knowledge base graph, it's not added again; otherwise, the "diagnosis" node is added. Similarly, each symptom from the received set is saved. If it already exists in the graph, it's not added again; otherwise, the "symptom" node is added. Then, each symptom is connected with every "diagnosis" node from the incoming set of diagnoses.

Based on analysis results, an associative graph is created where vertices represent symptoms and diseases, and edges signify associations between them. Graph theory algorithms and visualization methods are employed for presenting the results conveniently.

2.4. Modeling experiments

The training layer, a pivotal subsystem in the machine learning model architecture, is integral to the learning process using data from the Almazov National Medical Research Centre. The dataset comprises 83,000 medical records, including doctors' conclusions and patient complaints. This layer serves as the foundation for model adaptation to the provided data and influences its ability to generalize to new input data. At the moment, only accuracy (1), precision (2), and recall (3) metrics are measured within the process for each trained model.

$$accuracy = \frac{true\ negative + true\ positive}{true\ positive + true\ negative + false\ positive + false\ negative} \quad (1)$$

$$precision = \frac{true\ positive}{true\ positive + true\ negative + false\ positive + false\ negative} \quad (2)$$

$$recall = \frac{true\ positive}{true\ positive + false\ negative} \quad (3)$$

3. Results

3.1. Modeling results

The Random Forest model achieved optimal accuracy, as observed in the test data (Table 1). However, due to limited computational resources and the need for prompt responses in our task, the Logistic Regression model was selected. Logistic Regression demonstrated favorable throughput characteristics, supported by the acquired metrics, making it a suitable alternative. Comparative throughput results for these two options are detailed in the subsequent subsection on load testing outcomes. The resulting metrics are based on data from the Almazov National Medical Research Centre.

Table 1. Summary obtained ICD-10 models metrics on test dataset

Options	Accuracy	Precision	Recal
Decision Tree	0,8569	0,8394	0,8367
Random Forest	0,8728	0,8566	0,8558
Logistic Regression	0,8107	0,7934	0,79
SVM	0,8607	0,8435	0,8436

3.2. Knowledge base component

The resulting associative graph displays the complex relationships between symptoms and diseases identified from the analysis of medical data. In the graph, you can identify clusters of symptoms associated with certain groups of diseases, as well as identify the relationship between individual symptoms and specific pathologies. During the testing procedure, outcomes for three distinct components were garnered (figure 2).

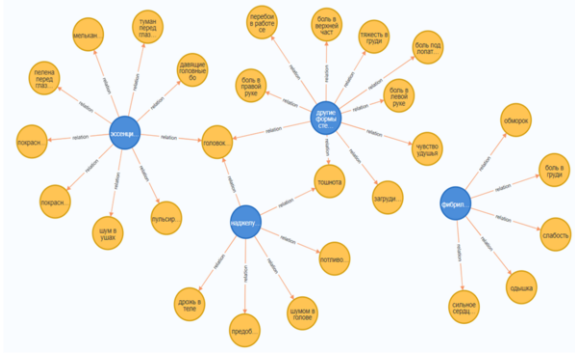

Figure 2. Generated graph derived from test samples of medi8cal data (orange nodes are symptoms, blue nodes are diseases)

3.3. Highload results

The proposed architecture comprises four subsystems, operating within a microservice architecture where communication occurs through APIs. It's crucial to consider the system load. Load testing results indicate that the error rate during execution of the disease prediction component with Logistic Regression is 17.96%.

Table 2. Results of highload testing models API services

Service name	Request count	Failure count	Percent of failures
Disease model ICD-10 (Random Forest)	15 000	10 067	67,11%
Disease model ICD-10 (Logistic Regression)	15 000	2 693	17,96%
Disease model ICD-10 (Decision Forest)	15 000	1 695	11,30%
Disease model ICD-10 (SVM)	15 000	1 480	**9,87**

4. Discussion

The developed system addresses challenges in disease classification compatibility, opting for an automatic matching approach to minimize errors compared to manual mapping methods. The micro-service architecture, with distinct subsystems, ensures scalability and reliability. The training layer and knowledge base component contribute to successful model adaptation and a comprehensive understanding of medical data relationships. The modeling experiments demonstrate the system's efficacy in disease classification prediction, with the Logistic Regression model chosen for its favorable throughput characteristics. Highload testing results indicate the system's robustness, with acceptable error rates in disease prediction and symptom detection.

5. Conclusion

The developed system presents a promising solution for disease classification compatibility, focusing on automatic code prediction in medical texts. While the Logistic Regression model is chosen for optimal throughput, ongoing refinement is necessary to address computational limitations. The system's potential lies in its contribution to improved healthcare informatics by enhancing disease classification compatibility and automating code prediction in unstructured medical texts.

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Exploring Negated Entites for Named Entity Recognition in Italian Lung Cancer Clinical Reports

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Abstract. This paper explores the potential of leveraging electronic health records (EHRs) for personalized health research through the application of artificial intelligence (AI) techniques, specifically Named Entity Recognition (NER). By extracting crucial patient information from clinical texts, including diagnoses, medications, symptoms, and lab tests, AI facilitates the rapid identification of relevant data, paving the way for future care paradigms. The study focuses on Non-small cell lung cancer (NSCLC) in Italian clinical notes, introducing a novel set of 29 clinical entities that include both presence or absence (negation) of relevant information associated with NSCLC. Using a state-of-the-art model pretrained on Italian biomedical texts, we achieve promising results (average F1-score of 80.8%), demonstrating the feasibility of employing AI for extracting biomedical information in the Italian language.

Keywords. EHRs, deep learning, NER, trasformer, NSCLC

1. Introduction

Non-small cell lung cancer (NSCLC) stands as the most prevalent form of lung cancer and remains the leading cause of cancer-related fatalities worldwide [1]. Electronic Health Records (EHRs) have become the standard repository for the vast amount of information related to the comprehensive and complex oncology care process for NSCLC patients [2]. Being able to mine this information represents a precious opportunity to support oncology research for personalised health. Besides the significant challenge due to the unstructured nature of the texts, there have been several efforts using Natural Language Processing (NLP) techniques within the biomedical

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domain [3], and more specifically Named Entity Recognition (NER), which aims at the automatic recognition and classification of biomedical *entities*. Such entities can be individual words or phrases within a text that pertain to predefined biomedical categories, referred to as *entity types*, which provide specific clinical information, e.g. diagnosis, patient health status, therapy, etc.. In this scenario, the state-of-the-art is represented by large-scale pre-trained models based on the Bidirectional Encoder Representations from Transformers (BERT) architecture [4]. To the best of our knowledge there is few work in applying BERT-based models for NER to the specific field of NSCLC: existing work often incorporates clinical reports of lung cancer patients into broader datasets, primarily focusing on extracting general oncological information [5,6]. Only two contributions tackle the NER task with the aim of extracting specific information about lung cancer patients from their clinical reports [7,8]. Although both achieve impressive performance, the literature still lacks adapting transformer-based models for the biomedical domain in less-resourced languages as Italian. In our previous work [9] we propose a first attempt to fill this gap, introducing a set of 25 clinically relevant entity types related to NSCLC patients' stage, therapy, tumour position, comorbidities, etc. We apply a pre-trained trasformer-based architecture [10] to perform NER on the manually annotated clinical reports of a cohort of 257 patients, validating the solution against two other pre-trained models.

Even though our previous work led to promising results, the proposed set of 25 entity types does not take explicitly into account the information related to negations. Indeed, clinical reports often include information about the negation or absence of a particular entity (e.g. absence of a symptom), which is proven to be relevant in automated clinical information extraction [11]. Hence, in this work we improve the previous approach presenting an enlarged set of 29 clinical entity types that encompass *negated entities*, defined as such expressions that refer to the absence of an entity. Further to this we conduct a comparative analysis applying the approach in [9] on the enlarged manually annotated dataset, considering both scenarios with and without the inclusion of negated entities.

The rest of the manuscript is organised as follows. Section 2 presents the materials used in our study and section 3 provides the description of the proposed approach. Section 4 outlines the final validation results. Finally, section 5 provides concluding remarks.

2. Materials

In this study, we employed the CLARO dataset [9], consisting of 257 patients diagnosed with stage III and IV NSCLC. The population was enrolled under two different approvals of the Ethical Committee and written informed consent was obtained from all patients. The authors confirm that all ongoing and related trials for this intervention are registered. For each patient we gathered oncological visits and radiotherapy visits dated before therapy start, resulting in 758 different documents. This corpus is manually annotated using the BIO tagging format with 25 entity types validated by domain experts and encompassing information related to cancer description (i.e. type, stage, metastases, abnormalities, position, progression, morphology, histology, TNM classification), therapy (i.e. type, duration, dosage, drugs, line, medication frequency, exams), patient personal information (i.e. smoking habit,

Table 1. Performance average ± standard deviation over the different datasets.

Dataset	Performance Metrics		
	P	R	F1
Original	0.816 ± 0.109	0.873 ± 0.082	0.843 ± 0.095
29 entities	0.776 ± 0.139	0.846 ± 0.100	0.808 ± 0.121
26 entities	0.808 ± 0.108	0.867 ± 0.082	0.835 ± 0.095

familiarity, comorbidity, weight, height, visit date, pain NRS scale, symptoms, general events).

3. Methods

The proposed pipeline consists of three main steps: (i) corpus generation; (ii) model training; (iii) model validation. First, we enlarge the annotation of the dataset presented in Section 2 in order to encompass negated entities. A negated entity is the mirror of an entity type that represents its absence: hence, the original 25 entity types would generate other 25 entity types that represent their negation, or absence. However, examining the clinical reports we were able to actually retrieve only 4 novel entity types denoting the absence of symptoms, comorbidity, focal anomaly or of an exam. This process results in a novel set of 29 entity type labels and in a new annotated corpus. Second, after preprocessing with sentence detection and tokenization, we use the new dataset for fine-tuning the Italian biomedical checkpoint in [10]. The fine-tuning process was conducted using the hyperparameters validated in [9]: batch size of 8, 12 epochs, dropout rate of 0.1, embedding size of 768, Adam optimizer and learning rate of $5 \cdot 10^{-5}$. We also cope with the class imbalance present in our real-world dataset, employing the focal loss function [12]. By increasing the impact of misclassified examples, focal loss enables the model to pay more attention to the minority classes, thus alleviating the effects of class imbalance. Third, we validate our model with a 10-fold cross-validation technique *per patient*, meaning that reports of the same patient are entirely included in one fold. This approach mitigates potential biases due to the presence of same patient's reports in both training and test folds. Then we aggregate the predicted scores of all test folds into a single set to derive an overall measure of F1-score (F1), Precision (P), and Recall (R). This evaluation employs a stringent criterion at the entity level, considering an entity correctly predicted only if all system-labeled tokens exactly match the ground truth tokens. For the sake of brevity we omit further details that the interested reader can find in [9].

4. Results

Table 1 shows the average and standard deviation results computed among all entity types using the original 25-entities dataset and the novel 29-entities dataset for NER. The introduction of negated entities clearly impacts the overall performance of the model. Including more entity types results in a higher number of classes to recognize, thereby increasing the complexity of the NER problem and contributing to a decline in performance. To further investigate this phenomenon we performed the same

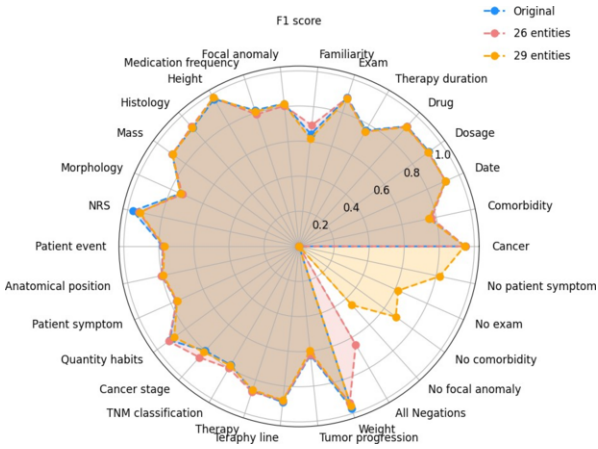

Figure 1. F1-score measured for each entity type across the three different datasets.

experiments collapsing negated entities in only one entity type, resulting in a 26-classes problem. The results are shown in the last row of Table 1. Although they are still lower than those on the original dataset, they outperform the system trained on 29 entity types, confirming the previous consideration.

Despite these results allow for quite evident conclusions on the overall performance of the proposed approach, a deeper analysis is needed. Figure 1 shows a radar plot of the F1-score performance metric for each entity type and each dataset. To maintain brevity, other metrics are excluded, but the following considerations apply to them as well. Looking at the original 25 entity types there is no difference in performance between models, except for a small difference in 'Cancer stage', 'NRS' and 'Familiarity'. This implies that the performance on the original entity types remains unaffected by the introduction of new ones. The observed overall decline might then be attributed to the system's challenge in identifying negated entities. We suspect that this difficulty may arise from the infrequent occurrence of negated entities in clinical reports, exacerbating the issue of imbalance on a broader scale.

5. Conclusions

This study demonstrates the effectiveness of Named Entity Recognition in extracting clinical information from Italian clinical reports of NSCLC patients. The extensive range of identified entities offers a comprehensive overview of both present and absent relevant characteristics of a patient's health status. Given the exponential growth of clinical data, automated and efficient information extraction methods are increasingly essential. While further analysis is needed for downstream use in automated prognostic tasks, this work already provides a tool for clinicians to quickly retrieve pertinent information from unstructured documents. This has the potential to significantly enhance patient care and clinical decision-making, laying the foundation for future research and applications in predictive tasks and personalized health.

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GLSTM: On Using LSTM for Glucose Level Prediction

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Abstract. The Prediabetes impacts one in every three individuals, with a 10% annual probability of transitioning to type 2 diabetes without lifestyle changes or medical interventions. It's crucial to manage glycemic health to deter the progression to type 2 diabetes. In the United States, 13% of individuals (18 years of age and older) have diabetes, while 34.5% meet the criteria for prediabetes. Diabetes mellitus and prediabetes are more common in older persons. Currently, nevertheless, there aren't many noninvasive, commercially accessible methods for tracking glycemic status to help with prediabetes self-management. This study tackles the task of forecasting glucose levels using personalized prediabetes data through the utilization of the Long Short-Term Memory (LSTM) model. Continuous monitoring of interstitial glucose levels, heart rate measurements, and dietary records spanning a week were collected for analysis. The efficacy of the proposed model has been assessed using evaluation metrics including Root Mean Square Error (RMSE), Mean Squared Error (MSE), Mean Absolute Error (MAE), and the coefficient of determination (R2).

Keywords. Glucose prediction, deep learning, LSTM, prediabetes, diabetes, wearable devices

1. Introduction

Prediabetes, with elevated but not diabetic-level blood glucose, often progresses to diabetes. Diabetes is a major global health concern, with rising prevalence, necessitating regular blood glucose monitoring to prevent severe complications like cardiac issues, strokes, and kidney damage [1] [2]. Blood glucose definitions distinguish between Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D). T1D involves autoimmune destruction of insulin-producing cells, while T2D stems from lifestyle and genetic factors causing insulin resistance or insufficient production [3]. T2D constitutes 90-95% of cases and includes hyperglycemia and hypoglycemia. Managing blood glucose levels involves addressing dietary choices, medication, and physical activity for effective diabetes control [4].

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In the US, 37.3 million adults have diabetes, mainly Type 2 (T2D), with 96 million having prediabetes [5]. Diabetes costs $327 billion annually, with healthcare costs 2.3 times higher for diabetics. It's a leading non-communicable disease, and global projections predict a rise to 578 million cases by 2030 and 700 million by 2045 [6]. Digital health tech, including smartphones and wearables, offers personalized interventions for disease management and prevention [7]. Wearable devices with biosensors provide seamless monitoring of health parameters like skin temperature and heart rate, integrating into daily life [8].

The main contribution of this study is to introduce an LSTM deep learning approach for predicting blood glucose levels on a personalized prediabetes participant dataset [9]. Pre-processing of sensor data is conducted, which involves ensuring sampling consistency and interpolating to address missing samples. Furthermore, the effectiveness of the proposed model is assessed using metrics such as RMSE, MSE, MAE, and R2, and its performance is compared with state-of-the-art methods.

2. Data Collection and Methods

Following the introduction to prediabetes and diabetes, this section elaborates on the dataset, data preprocessing, and proposed methodology in detail.

2.1. Data Collection and Preprocessing

Data from 16 participants monitored normal blood glucose levels using Dexcom G6 and Empatica E4 devices for 8-10 days each, excluding those with certain medical histories or lacking access to necessary technology. Data for each participant is stored in folders numbered 001 to 016, with separate CSV files containing timestamped values for seven features including glucose, physiological signals, and food intake details, alongside demographic information [4]. The prediabetes dataset[2] is publicly available [9].

The dataset underwent rigorous preprocessing, excluding entries from participants 003, 007, 013, 015, and 016 due to irregularities such as data recorded in different months, which could impact performance. After this pruning phase, the dataset contains data of 11 prediabetics patients. This data is characterized by the following features: glucose levels, heart rate measurements, sugar intake, and carbohydrate consumption, measured over one week for each patient, as reported in Figure 1. A linear approximation method synchronized these features to ensure dataset coherence, facilitating meaningful analysis.

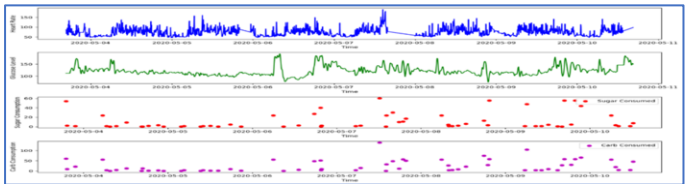

Figure 1: Different features are shown from different sensors and food log for 014 participant such as heart rate, glucose level, sugar, and carb.

[2] BIG IDEAs Lab Glycemic Variability and Wearable Device Data v1.1.2 (physionet.org)

2.2. Glucose Prediction Model

LSTM, a type of recurrent neural network (RNN), excels at processing diverse data types like speech and images. It's widely used in deep learning for tasks such as speech and handwriting recognition. LSTM's unique design includes gates to handle long-term dependencies effectively. This makes it suitable for complex tasks like glucose prediction with extended observation windows [11]. The TensorFlow LSTM Sequential model is designed for sequence prediction tasks, comprising an input layer, LSTM layer, and dense layer. The input layer receives input sequence features, while the LSTM layer learns temporal dependencies with its memory cells and gates. The final prediction is generated by the fully connected Dense layer, as illustrated in the LSTM flow Figure 2.

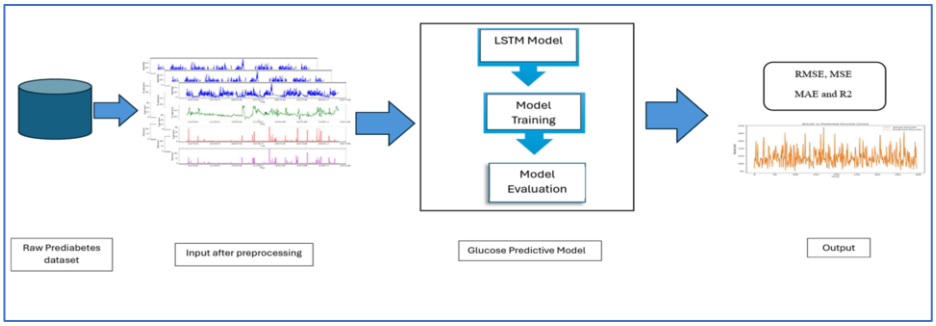

Figure 2: Architecture of the proposed model

3. Experimental Analysis and Discussion

We utilized the Python programming language along with various libraries to preprocess the data and develop predictive models. First necessary libraries including pandas, NumPy, scikit-learn, and TensorFlow were imported for data manipulation, numerical computations, and deep learning tasks, respectively. Followed by outline steps to our approach sequences of glucose values along with related features patient were created. standard scaler is used to scale the data followed by splitting it into training and testing sets. As input sequences to the predictive model 36 lookback values means 3-hour horizon were iteratively used for over 7 days for each participant. LSTM-based deep learning model using TensorFlow's Keras API is deployed by training the prediabetes data. The performance of trained model is evaluated based on various metrics such as MSE, RMSE, MAE, and R2. Hyperparameters used for the proposed model are presented in Table 1.

Table 1: Hyperparameters

Hyperparameter	Value
Lookback	36
Batch size	32
Activation function	relu
Optimization algorithm	Adam
Loss function	MSE
Number of epochs	150

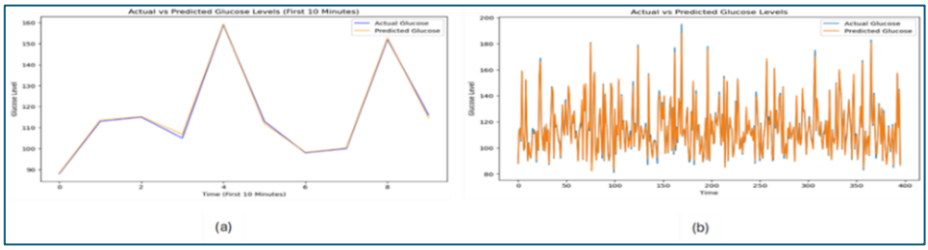

Figure 3: The comparison between actual and predicted glucose levels for participant 014 is illustrated. (a) displays the first 10-minute interval, while (b) presents the data for all intervals.

Extensive analysis has been conducted and the comparison of actual vs predicted glucose levels has been illustrated in Figure 3. Two sets of experiments were undertaken to evaluate the performance of the LSTM model in predicting glucose values. Initially, the LSTM model was assessed using only the historical glucose feature. The proposed model exhibited better performance as evidenced by improved metrics including RMSE, MSE, MAE, and the coefficient of determination (R2), achieving average values of 3.70, 15.08,1.82 and 0.97, respectively.

Table 2: Comparison with state of the art

Reference	Technique	RMSE
[11]	LSTM	4.906
[10]	LSTM	5.04
Proposed Model Experiment I	**LSTM**	**3.70**
Proposed Model Experiment II	**LSTM**	**1.83**

Subsequently, an expanded feature set comprising additional physiological parameters such as heart rate, along with glucose levels and dietary information including sugar and carbohydrate intake, was incorporated into the LSTM model for glucose prediction. The augmented model demonstrated enhanced predictive capabilities, as indicated by improved RMSE, MSE, MAE, and R2 scores, achieving average values of 1.83, 3.44, 1.24 and 0.99, respectively. The performance comparison of the proposed model is described in Table 2. LSTM outperforms ARIMA for blood glucose prediction, with MSE and RMSE of 24.075 and 4.906, respectively, compared to 108.140 and 10.399 for ARIMA [11]. An LSTM approach accurately predicts glucose levels, with MSE of 5.04 and MARD of 2.61, mitigating hypoglycemia risks due to insulin dosage delays [10].

Summarizing, the fact that the model used for experiment II yield a better accuracy compared with the model used for experiment I suggests that the additional features used for yielding predictions in experiments II have a relevant impact on the variations of the glucose levels, opening the way for further analysis of this aspect.

4. Conclusions and Future Work

This study introduces an efficient approach for precise and continuous blood glucose level prediction in individuals with prediabetes. Data preprocessing, including interpolation techniques are evaluated to enhance data quality. A Long Short-Term

Memory (LSTM) model based on recurrent neural networks is trained for glucose prediction, outperforming existing tools. However, the current study is limited by its application at prediabetics patients only. The approach needs to be tested over diabetics patients data in order to prove its utility in practical contexts. Nonetheless, the good performances exhibited by the LSTM model encourage its application in context where additional digital biomarkers are available where higher accuracy levels may be achieved, particularly by integrating features like accelerometry and skin temperature.

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Trustworthy Precision Medicine: An Interpretable Approach to Detecting Anomalous Behavior of IoT Devices

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Abstract. The growing integration of Internet of Things (IoT) technology within the healthcare sector has revolutionized healthcare delivery, enabling advanced personalized care and precise treatments. However, this raises significant challenges, demanding robust, intelligible, and effective monitoring mechanisms. We propose an interpretable machine- learning approach to the trustworthy and effective detection of behavioral anomalies within the realm of medical IoT. The discovered anomalies serve as indicators of potential system failures and security threats. Essentially, the detection of anomalies is accomplished by learning a classifier from the operational data generated by smart devices. The learning problem is dealt with in predictive association modeling, whose expressiveness and intelligibility enforce trustworthiness to offer a comprehensive, fully interpretable, and effective monitoring solution for the medical IoT ecosystem. Preliminary results show the effectiveness of our approach.

Keywords. Interpretable Artificial Intelligence, Precision Medicine, Medical IoT Security, Anomaly Detection

1. Introduction

The proliferation of the Internet of Medical Things (IoMT) has brought about revolutionary changes in healthcare, enabling remote monitoring, efficient data collection, and personalized patient care. However, integrating IoT devices in healthcare also poses significant challenges, necessitating robust monitoring strategies to safeguard sensitive medical information, guarantee the reliable operation of medical devices, and uphold patient confidentiality [8]. IoT-based precision medicine encompasses complex systems often consisting of smart devices with low processing capability, limited radio bandwidth, and battery resources, that provide volumes of data with rapid response times. Two primary challenges that need to be addressed are the smooth operation and security of these systems. Ensuring the smooth operation of such systems is of paramount importance. Any disruption can have significant consequences, making their seamless functioning a top priority. On the other hand, security threats are a persistent concern. Even though a security system may be effective at the time of deployment, it can become vulnerable over time as modern intruders and attackers continually evolve their strategies to avoid detection. Numerous intelligent approaches and platforms have been proposed

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and developed to enhance information security in IoT environments. However, due to the unique characteristics of these systems, there is a need for innovative, advanced, and often custom-designed approaches to address security threats [13].

Anomaly detection [2], a critical field of data analysis, aims to identify un- usual or abnormal data, information, or behaviors. In distributed systems, such as IoMT, anomalies can be considered unusual/abnormal behaviors (or activities) of devices over time. Uncovering corresponding anomalous behavioral patterns is beneficial to revealing malfunctions, failure events, and unusual or anomalous actions of intruders or hacking tools [11].

In this paper, we propose an interpretable and effective approach to detecting anomalies in the operation of smart medical devices. The proposed approach enjoys the intelligibility of predictive association modeling, a seminal method from supervised machine learning, that integrates association-rule mining and classification [9]. Essentially, the anomalies in the behavior of medical IoT devices are dealt with from a classification perspective and carried out through rules uncovered using an Apriori-based search technique. This combines minimum and complement class support so that the number of parameters behind rule learning is limited to one, which is especially advantageous when classes are heavily skewed. The potentially very large set of uncovered rules is eventually distilled into a classifier through pruning. The latter is carried out as a covering procedure for overfitting avoidance, in which the F-measure is used to evaluate the predictive performance of rules over the training data. Thus, the only rules preserved are those enhancing the precision and recall of the resultant classifier across the classes. Preliminary comparison results against similar algorithms showed very interesting results.

2. The Proposed Approach

In this section, a method is presented for classifying device behaviors that relies on Class-Prediction Rule (CPR) to capture the associations between subsets of co-occurring devices and the discriminated classes. The reader is referred to [5] for a detailed formalization of notation, fundamental concepts, and technicalities. Due to space limitations, these details are omitted here. Model learning and prediction are the two stages of classification in our approach. The former constructs an associative classifier C from labeled device behaviors in a dataset. The latter utilizes C to make predictions about the behavior of unlabeled devices. Model learning, as detailed in Algorithm 1, takes four parameters: a dataset B of device behaviors, a set D of smart devices, a set L of various class labels in B, and a single global threshold τ for the identification of the minimum support thresholds relative to the different classes in L. FindCPRs is utilized to uncover a potentially-large collection **R** of CPRs devoted to separate the classes within L. Eventually, using the pruning procedure Distill, the set **R** of CPRs is reduced to a compact (and, hence, intelligible) associative classifier C.

FindCPRs implements an Apriori-based search for significant CPRs in the training data B. FindCPRs improves on the fundamental Apriori algorithm [1] through the incorporation of two effective mechanisms, namely *multiple minimum class support* [10] and *complement class support* [3], for distilling a suitable number of CPRs whose antecedents and consequents are positively correlated within each class in B. The aforesaid mechanisms are especially advantageous when the distribution of classes is

skewed in B. Indeed, without appropriate expedients, class imbalance generally obstacles the extraction of an appropriate number of CPRs from less frequently occurring classes, in addition to negatively acting on the correlation between the antecedents and consequents of CPRs, up to the point of yielding misleading (or, equivalently, negatively-correlated) CPRs.

FindCPRs may generate a huge number of CPRs, that likely overfit the training data and produce conflicting predictions since the associative patterns are inherently combinatorial. To circumvent these issues, an accurate classifier is extracted from **R** using Distill. It first sorts all available CPRs on the basis of the total order $\ll$, which is modeled after the one presented in [9]. Basically, given two CPRs $\mathbf{r}_i, \mathbf{r}_j \in \mathbf{R}$, $\mathbf{r}_i$ precedes $\mathbf{r}_j$, which is formalized as $\mathbf{r}_i \ll \mathbf{r}_j$, if (*i*) *conf* ($\mathbf{r}_i$) is higher than *conf* ($\mathbf{r}_j$), or (*ii*) *conf* ($\mathbf{r}_i$) equals *conf* (r_j), but *supp*($\mathbf{r}_i$) is higher than *supp*($\mathbf{r}_j$), or (*iii*) *conf* ($\mathbf{r}_i$) is identical to *conf* (r_j) and *supp*($\mathbf{r}_i$) equals *supp*($\mathbf{r}_j$), but *length*($\mathbf{r}_i$) is lower than *length*($\mathbf{r}_j$). Here, we refer to the length of a generic CPR $\mathbf{r} : \mathbf{D} \rightarrow c$ as the number of devices within the antecedent **r**, i.e., *length*(**r**) = |**D**|. In the case that $\mathbf{r}_i, \mathbf{r}_j$ share the same confidence, support, and length, $\mathbf{r}_i \ll \mathbf{r}_j$ still holds, provided that $\mathbf{r}_i$ was formed before $\mathbf{r}_j$.

Afterward, a covering procedure yields a compact classifier C composed of the fewest possible CPRs from **R** that achieve high predictive accuracy on unlabeled device behaviors. The covering procedure heuristically aims to maximize the effectiveness F(C) attained by the resulting C over all individual classes. F(C) is defined as [5]:

$$\mathrm{F(C)} = 1/|\mathrm{L}| * \sum_{\mathrm{c}\in\mathrm{L}} \mathrm{F}^{(\mathrm{c})}(\mathrm{C})$$

where $\mathrm{F}^{(\mathrm{c})}$(C) denotes the effectiveness (or, alternatively, predictive performance) of C relative to the generic class c, as defined below. defined below. F(C) gives the same weight to the effectiveness of C over all classes, in spite of their respective occurrence frequencies within the training data. This is particularly advantageous in the case of imbalanced classes, as F(C) is thus not ruled by the predictive performance of C across the most often occurring classes of devices behaviors. The covering procedure increments F(C) by acting separately on each $\mathrm{F}^{(c)}$(C), via the selection of CPRs from **R** that, once appended to C, enhance the predictive capability of the resulting classifier over class *c*. Assume C is the associative classifier shaped by the model learning phase, and U is a dataset of unlabeled device behaviors. C predicts the class C($\mathbf{b_t}$) for the arbitrary devices behavior $\mathbf{b}_t$ in U. C($\mathbf{b_t}$) is provided by the first CPR in C that covers $\mathbf{b_t}$, in order to avoid contradictory predictions from different triggered CPRs.

Algorithm 1 Model-Learning(B, D, L, τ)

Input: a training dataset B of devices behaviors;
a set D of smart devices;
a set L of class labels in B;
a support threshold τ;
Output: A classifier C= {$r_1 \vee \ldots \vee r_k$};
1: **R** ← ∅;
2: **B**′ ← ∅;
3: **for each** $b_t \in$ B **do**
4: b ← {d|d ∈ D, d is on over b_t};
5: **B**′ ← **B**′ ∪ {b};
6: **end for**
7: **R** ← FindCPRs(**B**′, D, L, τ);
8: C ← Distill(**R**, **B**′, L);
9: RETURN C

3. Preliminary Evaluation

We conducted a very preliminary evaluation comparing the performance of our approach in terms of precision, recall, and F-measure against two well-known rule-based baseline classifiers, One-R and LAC, using a publicly available IoT dataset, the smart-home Kyoto apartment collection [12]. OneR [7] is a rule-based classifier that builds a rule for each attribute in the training set before selecting the rule with the lowest error rate as its single rule, while LAC - lazy associative classifier - [14] produces classification association rules specific to each test tuple, unlike traditional associative classifiers, which focus on a collection of ranked classification association rules from the training data. As shown in Figure 1, our strategy outperforms all other approaches on the considered dataset.

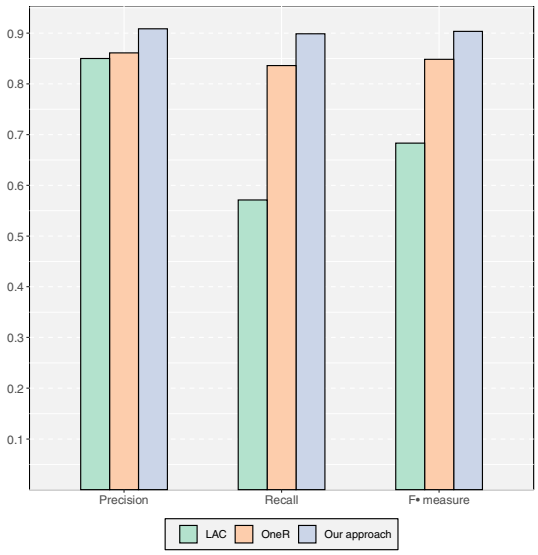

Figure 1. Comparison on Kyoto dataset

4. Conclusion

We proposed a machine-learning approach to the trustworthy detection of IoT behavioral anomalies that involves the classification of traces of smart device operation through predictive association modeling. Its peculiar design allows IoT threat detection to be governed by only one parameter. The results of preliminary comparative tests on real-world benchmark data showed the effectiveness of the proposed approach. Our proposal aims to emphasize the importance of user trust and comprehension in the deployment of monitoring solutions, thereby marking a significant step forward in the development of robust, interpretable, and user-friendly medical IoT systems. Exploring the utilization of co-clustering techniques [6] for smart devices could yield an understanding of relationships among devices exhibiting similar behavior. Such insights would be valuable for further behavioral analysis, more accurately recommending [4] and enforcing specific security policies,

and optimizing resource allocation, which are of significant practical importance in precision medicine.

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Continuous Markov Models for Analyzing the Effect of Environmental Personal Exposure on Multiple Sclerosis Progression

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Abstract. Multiple sclerosis (MS) is an inflammatory autoimmune demyelinating disorder of the central nervous system, leading to progressive functional impairments. Predicting disease progression with a probabilistic and time-dependent approach might help suggest interventions for a better management of the disease. Recently, there has been increasing focus on the impact of air pollutants as environmental factors influencing disease progression. This study employs a Continuous-Time Markov Model (CMM) to explore the impact of air pollution measurements on MS progression using longitudinal data from MS patients in Italy between 2013 and 2022. Preliminary findings indicate a relationship between air pollution and MS progression, with pollutants like Particulate Matter with a diameter of 10 micrometers (PM_{10}) or 2.5 micrometers ($PM_{2.5}$), Nitrogen Dioxide (NO_2), and Carbon Monoxide (CO) showing potential effects on disease activity.

Keywords. Continuous Markov Model, Multiple Sclerosis progression, personal exposure, air pollution

1. Introduction

Multiple sclerosis (MS) is an autoimmune neurodegenerative disease that affects nearly three million people worldwide, including approximately 137,000 in Italy, an area of high MS prevalence [1]. It presents varied clinical symptoms and is a major cause of neurological disability in young adults. MS prognosis is measured by the Expanded Disability Status Scale (EDSS), a clinical score that describes the severity of disability on a scale from 0 to 10 in 0.5-unit increments, with higher scores indicating higher level of disability [2]. Although the precise etiology of MS remains unknown, recent studies [3–6] suggest air pollution as a potential environmental factor influencing MS risk and activity. In [3] authors have found meaningful relationships between exposure to certain pollutants like Particulate Matter with a diameter of 10 micrometers or smaller (PM_{10}),

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Ozone (O_3), and Nitrogen Dioxide (NO_2), and the MS progression. Specifically, PM_{10} has been linked to an increased risk of relapses in MS patients, with oxidative stress likely being a key mechanism [4]. Consequently, there is a growing need to thoroughly investigate the role of air pollution on MS progression.

As commonly employed, survival analysis assumes unidirectional changes and does not account for potential improvements in patients' conditions; additionally, it treats all deteriorations in the same way, disregarding potential differences in factors influencing early versus later transitions. Markov models, in contrast, offer a solution by accommodating both deterioration and recovery transitions, providing a flexible framework for modeling covariates [7].

This study aims to explore the impact of air pollutants on MS progression using the Continuous-Time Markov Model (CTMM), which allows to analyze irregular follow-up visits, making it suitable for capturing the dynamic nature of the disease over time.

2. Methods

2.1. Dataset

The study utilized longitudinal data from MS patients treated at the MS center of the IRCCS Mondino Foundation. The original dataset comprised 14,226 observations from 919 patients with 14 features, including demographic and clinical data (i.e., impairments in functional systems), with the EDSS score expressing disease progression. To define MS progression stages, EDSS scores were categorized into three states: ***1-very-mild disability*** (EDSS score in [0-1] interval), ***2-mild*** (EDSS score in the [1.5-2.5] interval), and ***3-moderate-to-severe*** (EDSS score greater than 2.5). Missing values in clinical features were imputed using the Exponentially Weighted Moving Average (EWMA) algorithm, considering four neighboring cases.

Environmental data were collected from the European Environment Agency [8] and the Copernicus [9] portals from 2013 to 2022. Daily values of air pollutants and weather conditions were integrated based on the closest monitoring station to each patient's postcode. Data were aggregated with a weekly temporal granularity (as averages), and we included in the analysis the mean value of environmental features from the preceding five-week period prior to the subsequent visit.

Ultimately, 3,291 observations from 383 patients with 28 features, considering demographic, clinical, and environmental data, were used for the CTMM model to assess the impact of air pollutant factors on disease progression. Table 1 provides an overview of the final dataset used in the study.

2.2. Continuous- Time Markov Model

We exploited a CTMM for its suitability in modeling the complex dynamics of our longitudinal dataset with varying follow-ups frequencies. Moreover, its multistate framework suits our study of MS progression across three states. Additionally, CTMM's capacity to integrate covariates helps in exploring factors influencing disease progression. We implemented CTMM using the R library ‘msm’ [10], which allows the determination of the state distribution at any given time t.

Consider a longitudinal dataset where M denote the number of individuals and N_m is the number of observation times for the mth subject. Each subject can move among s =

1, 2, ... N_s states. The time of the subject *m*'s *k*th observation is denoted by t_{mk} when we observe the subject's state as a feature denoted by $s_{mk} \in S$. States has to be in the first-order continuous time. Discrete state Markov model is defined as in Equation (1), and we denote the probability of the subject *m*th transition from state *i* to state *j* as in Equation (2):

$$Pr(s_{mk}|s_{m(k-1)}, s_{m(k-2)}, s_{m1}) = Pr(s_{mk}|s_{m(k-1)}) \quad (1)$$

$$p_{ij}(t_{m(k-1)}, t_{mk}) = Pr(s_{mk} = j|s_{m(k-1)} = i) \quad (2)$$

The probability of moving to the subsequent state *j* depends only on the current state *i*, disregarding prior states. For each subject, the likelihood is derived from the product of all transitions across observation times.

Several preprocessing steps were employed, including normalizing the dataset using the z-score method and excluding subjects with only one observation. Then, we applied CTMM to compute the frequency of transitions between different disease states. Personal exposure factors are integrated as covariates into the CTMM to explore the individual impact of each specific feature on MS progression.

Table 1 Demographic and clinical features values computed at the first visit. Summary statistics are presented as frequency (percentage), and median (range) or mean ± standard deviation

Feature	Total	Very-Mild State (1)	Mild State (2)	Moderate-To-Severe State (3)
Patients	383	138 (36%)	171 (44%)	74 (19%)
EDSS	1.5 (0-8.5)	1 (0-1.5)	2 (2-3)	6 (3.5-8.5)
Age (years)	41.5 ± 11.5	37.2 ± 9.5	42.7 ± 11	51.8 ± 10.2
Sex: Female	255 (66%)	96 (69%)	117 (68%)	42 (56%)
MS in pediatric age	361 (94%)	131 (94%)	159 (92%)	71 (95%)
Pyramidal score	1 (0-6)	1 (0-5)	1 (0-5)	2 (0-6)
Cerebellar score	0 (0-9)	0 (0-4)	0 (0-4)	1 (0-9)
Brain Stem score	0 (0-5)	0 (0-3)	0 (0-4)	1 (0-5)
Sensory score	1 (0-5)	0 (0-3)	1 (0-3)	1 (0-5)
Bladder Bowel score	0 (0-5)	0 (0-3)	0 (0-4)	0 (0-5)
Visual score	0 (0-9)	0 (0-5)	0 (0-5)	0 (0-9)
Mental score	0 (0-4)	0 (0-2)	0 (0-1)	0 (0-4)
Other score	0 (0-13)	0 (0-6)	0 (0-11)	2 (0-11)

3. Results and Discussion

Figure 1 and Figure 2 illustrate the state transitions hazard ratios (HRs) when the covariate is set to its mean value, with corresponding 95% confidence intervals. Although we provided HRs for all potential transitions, our focus was primarily on transitions indicative of disease progression, specifically transitions from very-mild to mild (1-2), from very-mild to moderate-to-severe (1-3), and from mild to moderate-to-severe (2-3).

In Figure 1, it is possible to note that the HRs for nearly all investigated air pollutants exceed HR=1. $PM_{2.5}$ demonstrates a significant impact on disease progression from very-mild to mild state, with a discernible influence on progression from very-mild or mild to moderate-to-severe states. This is consistent with prior studies indicating $PM_{2.5}$'s substantial detrimental effects on individual with MS. Furthermore, HRs for NO_2 and CO are also relatively high, suggesting that these pollutants may also play a role in MS progression especially in transition from very-mild to moderate-to-severe. Conversely, HRs for Sulfur Dioxide (SO_2) and O_3 are low, which suggest that these pollutants may have some negative effects on MS patients.

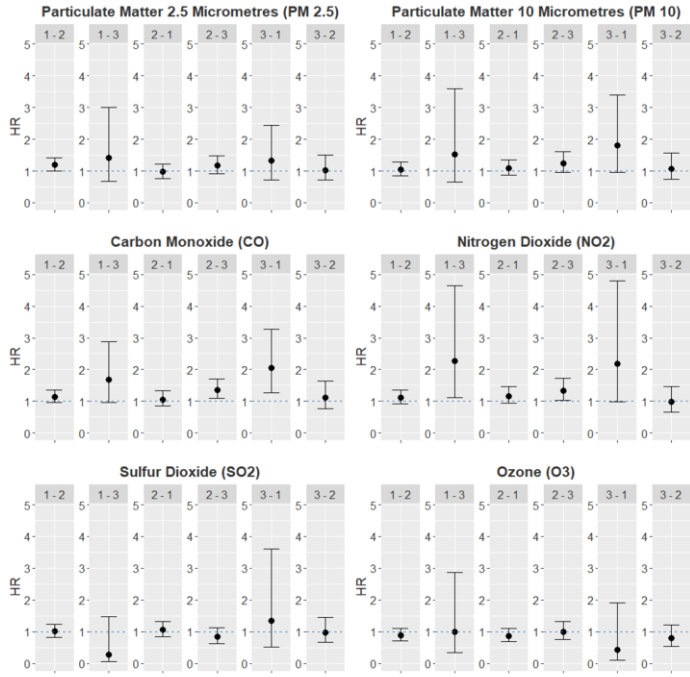

Figure 1 – Estimated hazard ratios of air pollutants covariates on EDSS state progression transition (error bars show 95% confidence intervals).

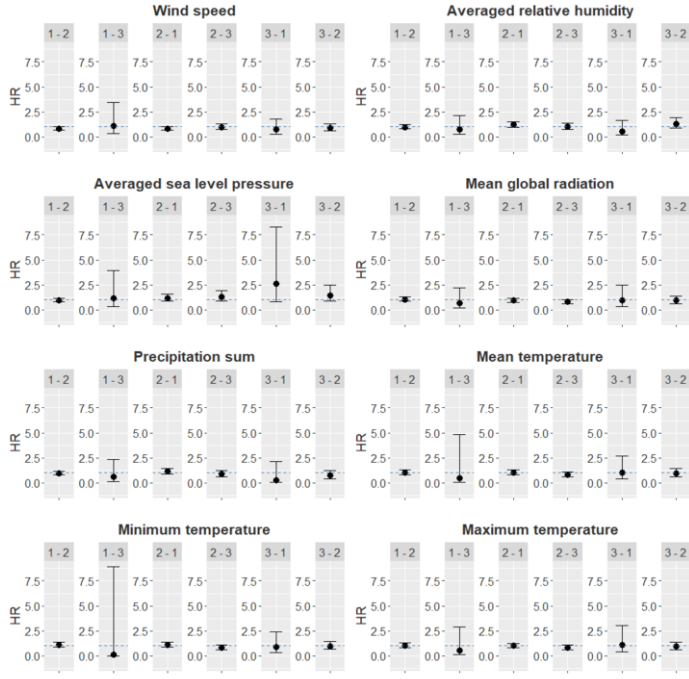

Figure 2 – Estimated hazard ratios of weather conditions covariates on EDSS state progression transition (error bars show 95% confidence intervals).

Figure 2 presents the HRs associated with weather conditions. It suggests that an increase in relative humidity may affect the disease progression when moving from very-mild or mild to moderate-to-severe state. In general, several HRs values result not significant, suggesting a small impact on disease progression. This is also due to the current lack of preprocessing of these measurements, which we have treated as continuous values (e.g., HR accounts for increases or decreases of one unit of measure). Further efforts will be dedicated to finding more appropriate and meaningful environmental and weather measures representations, for example, using state or trend abstractions.

4. Conclusions

This study aimed to investigate the association between environmental exposure and disease progression in patients with MS using a real-world dataset and a CTMM. It identified potential relationships between changes in disability levels and personal exposure over time, suggesting that these environmental factors might impact on disease progression. Future research will explore the specific effects of changes in personal exposures on relapses in MS patients.

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Clustering Pseudo Time Series: Exploring Trajectories in the Ageing Process

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Abstract. Investigating the natural ageing process typically involves the use of extensive longitudinal datasets that can capture changes associated with the progression of ageing. However, they are often resource-intensive and time-consuming to conduct. Cross-sectional data, on the other hand, provides a snapshot of a population at many different ages and can capture many disease processes but do not incorporate the time dimension. Pseudo time series can be reconstructed from cross sectional data, with the aim to explore dynamic processes (such as the ageing process). In this paper we focus on employing pseudo time series analysis on cross-sectional population data that we constrain using age information to create realistic trajectories of people with different degrees of cardiovascular disease. We then use clustering methods to construct and label trajectory-based phenotypes, aiming to enhance our understanding of ageing and disease progression.

Keywords. pseudo time series, clustering analysis, disease progression, ageing

1. Introduction

Investigations into the natural ageing process and its impact on disease development have predominantly depended on gathering and analyzing longitudinal data. These datasets are crucial for monitoring temporal variations in individuals, shedding light on the intricate relationship between ageing and health. Nonetheless, obtaining longitudinal information is beset with obstacles, particularly due to the substantial time and resources required to regularly measure clinical tests on the same individuals. In contrast to longitudinal studies, cross-sectional research provides a snapshot of a population at a single point in time. While this approach is less resource-intensive and offers a broad population level overview of disease prevalence and characteristics, it lacks the temporal dimension necessary to understand how diseases progress or how ageing impacts health over time [1].
Pseudo time series analysis is able to build realistic trajectories through non-time series data based upon appropriate distance metrics and features knowledge. Age information of patients can be used to create more realistic trajectories, thereby enhancing our ability to describe and comprehend the ageing process. By constraining the generation of pseudo time-series based on age information we are able to identify distinct age-related points in trajectories that are associated with specific disease states. The use of clustering allows us to group and label pseudo time-series into different types of

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trajectory, discerning unique patterns or variations of progression within the dataset, thereby gaining a deeper comprehension of different processes through which ageing and disease manifest.

2. Methods

The idea behind pseudo time series (PTS) is to exploit resampling, distance metrics, and assigned class labels to build realistic trajectories from one label state to another [2]. Let a cross sectional dataset D be defined as a matrix of *m* by *n*, where *m* (rows) is the number of samples and *n* (columns) is the number of clinical features. A full distance matrix is computed through the application of Euclidean distances [3]. Thus, a graph is built and its minimum spanning tree is computed. This step allows to understand the minimal connections that span all data points without creating loops, providing insights into the underlying structure of the data. Subsequently, the shortest path between two points is identified, highlighting the most direct progression between from 'early' states to 'advanced' states.
A PTS is created to show how the trajectories progress from a starting vertex (young state) to an ending vertex (old state). This approach could discover trajectories not only from young to old states, highlighting natural ageing processes but also between different disease states. The PTS points are extracted from the model to perform a clustering analysis to group and label PTS into different types of trajectory and detect unique patterns or variations of progression within the dataset.

3. Results

We applied the method described above to analyze a cross-sectional multivariate dataset of patients diagnosed with heart disease. The dataset is assigned two class labels, that contain age information, where one is deemed to be the starting class or the "young" class and the other as "old" class. The distribution of heart disease status over pseudo time is mapped into 4 values, from 0-healthy to 4-advanced status. Results shows that there is a general trend for younger categories to be correctly identified earlier in pseudo time and later older categories to be identified with later points.

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Artificial Intelligence and Robotics for Personalized Health

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AI Approach for Enhanced Thalassemia Diagnosis Using Blood Smear Images

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Abstract. This paper aims to propose an approach leveraging Artificial Intelligence (AI) to diagnose thalassemia through medical imaging. The idea is to employ a U-net neural network architecture for precise erythrocyte morphology detection and classification in thalassemia diagnosis. This accomplishment was realized by developing and assessing a supervised semantic segmentation model of blood smear images, coupled with the deployment of various data engineering techniques. This methodology enables new applications in tailored medical interventions and contributes to the evolution of AI within precision healthcare, establishing new benchmarks in personalized treatment planning and disease management.

Keywords. Artificial Intelligence, Thalassemia, U-Net architecture, Personalized Medicine

1. Introduction

Thalassemia is a genetic disorder characterized by lower than normal hemoglobin levels due to the absence or malfunction of genes vital for hemoglobin production. Hemoglobin, a protein in red blood cells, is crucial for oxygen transport. Thalassemia is categorized into alpha and beta types based on the specific genes affected. Its symptoms vary from none to severe anemia, and in the most severe cases, it can lead to fetal mortality. Symptoms may manifest early in life, potentially impacting lifespan. Although incurable, treatments are available to alleviate symptoms. The application of artificial intelligence in diagnosing and managing thalassemia has seen significant advancements, as evidenced by various studies. [1] explores the effectiveness of AI in diagnosing and classifying thalassemia. It discusses the challenges of distinguishing thalassemia from other causes of microcytic anemia and how AI can aid in accurate diagnosis and treatment planning through analysis of complete blood count (CBC) parameters. [3] introduces a novel AI

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framework for diagnosing thalassemia using deep learning and medical imaging. It focuses on developing a supervised semantic image segmentation model, leveraging data engineering methods for improved diagnosis accuracy, and demonstrating significant advancements in medical imaging for thalassemia diagnosis. The utilization of AI to analyze erythrocyte morphology and machine learning to identify thalassemia gene carriers in non-anemic populations were proposed in [4]. By quantitatively analyzing abnormal erythrocytes, the study developed a prediction model, demonstrating AI's potential to enhance thalassemia carrier identification.

2. Proposed Approach

We propose a novel application of AI methodologies for the detection and classification of erythrocyte morphology, facilitating the diagnostic process for thalassemia. This approach relies on the application of the U-net architecture [2] for semantic image segmentation of blood smear images. The U-net architecture, renowned for its effectiveness in semantic image segmentation, especially in medical imaging, includes a contraction path (encoder) that captures context and an expansion path (decoder) for accurate localization. The architecture's innovative use of skip connections bridges the encoder and decoder, ensuring detailed feature preservation and accurate segmentation. Initially designed for biomedical image segmentation with limited data, U-net's structure and functionality have significantly impacted medical imaging and beyond, inspiring a range of modifications and applications in various segmentation tasks. This precision is crucial for identifying subtle morphological variations indicative of thalassemia. By automating the segmentation and classification process, the proposed approach allows for reducing the time required to diagnose thalassemia, with notable benefits for patient care. The implementation of U-net for erythrocyte morphology classification also provides an avenue for exploring explainable AI (XAI) principles in medical diagnosis. By analyzing the network's attention and feature maps, researchers can gain insights into the model's decision-making process, contributing to the development of more transparent and interpretable AI tools in personalized healthcare.

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Enhancing Thrombophilia Risk Prediction Through AI-Based Methodologies

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Abstract. Thrombophilia, a predisposition to thrombosis, poses significant diagnostic challenges due to its multi-factorial nature, encompassing genetic and acquired factors. Current diagnostic paradigms, primarily relying on a combination of clinical assessment and targeted laboratory tests, often fail to capture the complex interplay of factors contributing to thrombophilia risk. This paper proposes an innovative artificial intelligence (AI)-based methodology aimed to enhance the prediction of thrombophilia risk. The designed multidimensional risk assessment model integrates and elaborates through AI a comprehensive collection of patient data types, including genetic markers, clinical parameters, patient history, and lifestyle factors, in order to obtain advanced and personalized *explainable* diagnoses.

Keywords. Artificial Intelligence, Thrombophilia, Risk Prediction, Personalized Medicine, eXplainable AI

1. Introduction

The study aims to weave an interdisciplinary approach able to combine insights from molecular biology, nanotechnology, and AI to analyze patient data from different sources to predict thrombophilia risk, also providing *explanations* about results. Central to this innovation is the application of AI methodologies, particularly Machine/Deep Learning algorithms (D/ML), for the analysis and interpretation of data collected by clinicians. By training these algorithms on vast datasets of patient information and test results, the system learns to identify patterns and correlations that may not be immediately apparent to human analysts. This AI-driven approach enables the predictive modeling of thrombophilia risk, offering not only immediate diagnostic results but also prognostic insights that can guide clinical decision-making and patient management.

Several AI approaches in the thrombophilia context have been proposed recently. A retrospective study evaluating an AI-powered algorithm (XGBoost) for its utility in diagnosing thrombophilia and stratifying thrombosis risk was presented in [3]. The study demonstrated the model's effectiveness in accurately predicting thrombophilia, highlighting the potential of tree-based AI models to support the complex diagnosis of

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thrombophilia and risk stratification, offering insights into AI-powered decision-making processes. [1] proposed a novel approach for predicting thrombophilia in pregnancy using machine learning algorithms, focusing on neural networks. The research utilized demographic, lifestyle, and clinical information to train and evaluate different models, demonstrating the effectiveness of decision trees and neural networks in predicting thrombophilia risk during pregnancy.

2. Methodology

The pillar of our methodology is the development of a hybrid AI model that combines DL algorithms with traditional ML techniques for the processing of both structured and unstructured data, facilitating the extraction of interesting patterns and correlations that may elude conventional analysis. The DL component employs Convolutional Neural Networks (CNNs) to analyze genetic data in visual/numerical format [2] and Natural Language Processing (NLP) algorithms to interpret clinical notes and patient histories [4]. Moreover, the model's explainability aspect, facilitated by the incorporation of SHAP (SHapley Additive exPlanations) values, provides insights into the relative importance of various predictors, thereby enhancing the interpretability of the results for clinical decision-making. The integration of these techniques enables advanced analytics by facilitating the comprehensive and simultaneous interacting investigation of diverse patient data sources, enhancing the model's ability to unearth intricate patterns and correlations among them. This study represents a significant advancement in thrombophilia diagnostics, offering a more accurate, comprehensive, and interpretable tool for assessing thrombophilia risk. By harnessing the power of AI to integrate and analyze a wide spectrum of patient data, our methodology promises to facilitate personalized patient care, enabling timely and targeted interventions.

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Unraveling Endometrial Cancer Survival Predictors Through Advanced Machine Learning Techniques

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Abstract. This study explores endometrial cancer (EC) within the broader context of oncogynecology, focusing on 3,845 EC patients at the Almazov National Research Center. The research analyzes clinical data, employing machine learning techniques like random forest regression and decision tree analysis. Key findings include age-dependent impacts on EC outcomes, unexpected correlations between dietary habits and recurrence risk (e.g., higher risk for vegans), and intriguing associations like soft drink consumption influencing relapse. Despite limitations like a retrospective design and self-reported data, the study's extended eight-year follow-up and robust database enhance its credibility. The nuanced insights into EC risk factors, influenced by factors like physical activity and diet, open avenues for targeted diagnostics and prevention strategies, showcasing the potential of machine learning in predicting outcomes.

1. Introduction

Oncogynecology addresses a cluster of diseases originating in female reproductive organs, with five primary sites: ovaries, uterus (corpus and cervix separately), vulva, and vagina. Globally, over 1.3 million new cancer cases emerged from these sites in 2019 [1]. Despite their grouping, each disease signifies a distinct clinical entity with unique incidence rates, risk factors, clinical presentations, and prognoses [2]. Endometrial cancer (EC), prevalent in high-income countries, has seen an escalating incidence [3-4]. In 2023, 401,069 EC cases were reported worldwide [1], predominantly affecting women over 40, with occasional instances in younger demographics [5]. The median age for EC diagnosis typically peaks around 60. EC, categorized as a hormone-responsive cancer, associates with estrogen exposure, stemming from factors like hormone replacement therapy, early menarche, late menopause, and obesity [3]. Endocrine disruptors and cadmium, mimicking estrogens, also elevate EC risk [6]. Prolonged, unopposed estrogen exposure, whether exogenous or endogenous, stands as a critical risk factor [7], influenced by dietary choices. Early EC diagnosis and risk of relapse hinge on patient age, tumor characteristics, and progesterone receptor expression [8]. Despite recognized risk factors, challenges persist, impacting diagnostic and treatment outcomes, as highlighted in recent systematic reviews [9]. A profound analysis of risk factors and their combinations offers insights into EC diagnostics and prevention. Studying factor

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combinations poses additional challenges, further compounded by the time-intensive nature of clinical trials. Machine learning, adept at processing vast information swiftly, proves valuable in exploring factors influencing cancer progression. While cancer predisposition is linked to unmodifiable factors, its manifestation timing remains variable. Machine learning emerges as a promising tool to address persistent challenges, aiding the identification of risk factors and correlations ahead of clinical trials, enhancing focus. This paper unveils research results from the correlation analysis of Endometrial cancer risk factors.

2. Methods

2.1. Eligibility Criteria

The study included women diagnosed with EC and admitted to the Almazov National Research Center hospital between 2021 and 2024.

2.2. Collection of Clinical Data

All participants underwent radical surgical intervention for EC, followed by outpatient follow-up visits. Patients suspected of relapse were readmitted to the hospital.

We extracted lifestyle, dietary, socioeconomic, and reproductive parameters from the Almazov databases. Data from 4,271 women were analyzed anonymously. Only women with sufficient diet information in their medical history were considered, and 9.8% of them experienced relapse or EC-related death. The median age (IQR) at diagnosis was 70.0 (65.3 - 77.0), and BMI was 26.3 (23.7 - 30.1).

2.3. Endpoint Events

Progression-free survival (PFS) and overall survival (OS) were calculated, representing the time living with cancer without progression and the duration from a defined start point to death from any cause, respectively.

2.4. Data Analysis

Experiments were conducted using stratified 5-fold cross-validation, maintaining target class ratios. The area under the curve (AUC) was calculated based on averages from 5 curves. After determining optimal dataset and model parameters, a detailed ROC analysis (100 x 5-fold cross-validation) was performed to establish the optimal probability threshold for label assignment. Classification models within scikit-learn, including the random forest method, were employed for predictive analysis with specific parameters.

3. Results

The ROC-AUC values were determined as 0.93 for PFS and 0.94 for OS, while Figure 1 illustrates the decision tree. The model exhibits age-dependent outcome variations.

Patients aged over 78 with low physical activity face a higher risk of recurrence. Among individuals aged 78 to 83 with low activity, the presence of prunes in their diet increases the likelihood of death (OS event).

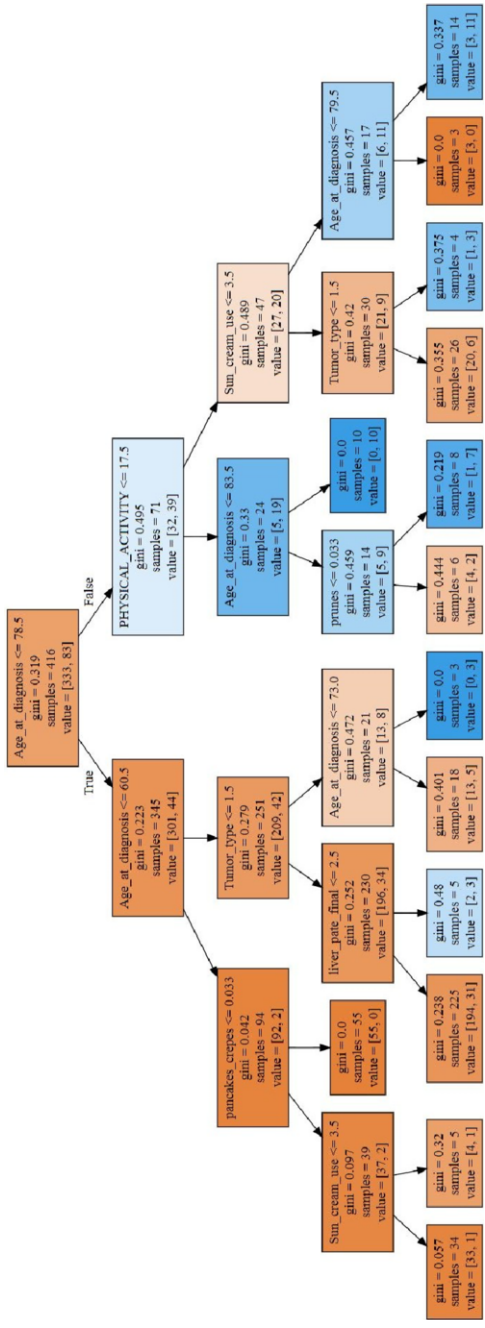

Figure 1. PFS Decision tree

Sunscreen serves as a protective cream for those with normal exercise. For patients aged 60 to 78, diet types influence cancer progression (prune consumption raises risk, while liver pate consumption enhances survival probability). Patients under 60 experience age and activity-dependent influences on cancer progression, with carbohydrate intake and sun exposure elevating the risk. The random forest regression yielded an ROC-AUC of 89%. The R^2 Training Score was 0.88, the OOB Score was 0.06, and the R^2 Validation Score was 0.10.

The correlation analysis highlighted a noteworthy association between relapse and diet type (diet_type). Of particular interest is the observation regarding Diet Type, given its encoding as follows: 0=mixed, 1=vegetarian, 2=vegan. Surprisingly, the findings suggest that vegans exhibit a higher risk of recurrence. This intriguing result may be linked to the elevated consumption of soybeans and plant-based products within the vegan diet, containing phytoestrogens recognized as potential agents influencing endometrial cancer.

Additionally, the role of nut consumption in vegetarian diets may not be overlooked, considering the potential impact of cadmium levels. Cadmium, found in nuts, exerts an estrogen-like effect in the body, representing a well-known risk factor for endometrial cancer. This nuanced understanding of dietary factors and their correlation with cancer relapse sheds light on the multifaceted nature of risk determinants in oncology.

4. Discussion

Drawing insights from our outcomes, the susceptibility to endometrial cancer (EC) relapse and mortality aligns with well-established factors such as disease stage, tumor type, differentiation, and patient age. As anticipated, prognosis deteriorates with advanced stages and older age, with Type 2 EC exhibiting a lower survival rate.

A compelling revelation emerges from the inverse correlation between physical activity and relapse and mortality rates, reinforcing existing literature emphasizing the preventive benefits of regular physical activity against endometrial cancer [8-10]. Intriguingly, soft drinks consumption exhibits a direct correlation with relapse risk and an even stronger association with the risk of death due to EC. This linkage may be attributed to the insulin-stimulating effects of high-sugar foods, influencing factors like increased BMI, type II diabetes, and potentially contributing directly to endometrial cancer progression [11,12]. Nonetheless, the contradictory results in existing literature warrant further investigations.

A less elucidated aspect pertains to the unexpected correlation between sun cream use and an elevated risk of both relapse and EC-related death. Skin phototypes, influenced by genetic inheritance, play a role in sun cream application. Unraveling the underlying mechanisms of this observation may require scrutiny of various genetic features.

Exploration of additional dietary habits and their impact necessitates dedicated case-control studies for a comprehensive understanding. The extended eight-year follow-up duration and utilization of a robust national database enhance the study's strength. However, the retrospective design introduces inherent limitations, and self-completed patient questionnaires pose a potential source of bias, demanding cautious interpretation of the results.

5. Conclusion

This study highlights the impact of dietary factors on EC development and relapse, underscoring the potential of machine learning in predicting outcomes. The findings contribute to a nuanced understanding of EC risk factors, paving the way for more targeted diagnostics and prevention strategies.

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Evaluating MediBetter: A Mobile Application for Health Monitoring and Medication Management

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Abstract. This study introduces MediBetter, a mobile application designed to empower patients undergoing routine medication in health monitoring and medication adherence. It is a mobile application designed to serve as a supportive health technology for patients to monitor their health status and manage their routine medication. It offers three main features: text-based daily self health report, AI-based summarization of the health report, and medication taking reminder. To evaluate the quality of generated summaries generated by both the user and AI (ChatGPT), we conducted human expert evaluation process. Furthermore, we also evaluated the usefulness of existing features in the app. The experiment results show that ChatGPT-generated summaries outperformed user-generated ones, demonstrating superior informativeness, coherence, fluency, consistency, and contradiction handling. Participants found the app's features highly useful for health monitoring and medication adherence, with strong agreement on their utility.

Keywords. mobile application, summary, AI, usefulness

1. Introduction

The rise of mobile technology in recent years has drastically changed many facets of healthcare, giving people the tools they need to take control of their health in a tailored and easily accessible way [1,2]. This shift towards mobile health solutions is particularly crucial for patients undergoing routine medication, as it addresses the need for consistent monitoring and management of their health status. Recording daily health status or diary entries allows patients to track their symptoms, activities, and vital signs, providing valuable data for both self-assessment and communication with healthcare providers [3]. Additionally, the ability to summarize these diary entries offers a convenient way for patients to review their health trends and patterns over time, facilitating informed decision-making and proactive health management. Furthermore, medication-taking reminders integrated into mobile apps ensure adherence, minimizing

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the risk of missed doses and improving medication adherence rates among patients [4]. The objective of this research is to evaluate the feature of a mobile application called MediBetter that is tailored for patients undergoing routine medication. This application aims to help patients undergoing routine medication with features for recording text-based health status, summarizing diary entries, and providing medication reminders. In this paper, we assess the usefulness of the application features. In addition, since we employ AI to do the health diary summarization, we also evaluate the efficacy of the generated summary.

2. Methods

MediBetter is a mobile application designed to serve as a supportive health technology for patients to monitor their health status and manage their routine medication. The app consists of three main functions related to medication and health monitoring: daily self health report, summarization of the health report, and medication taking reminder. Screenshots of the app are displayed in Figure 1.

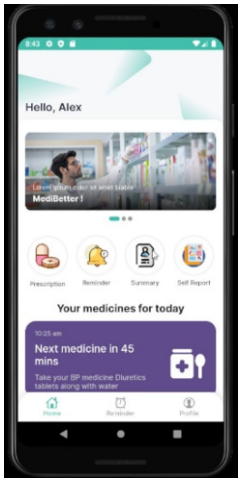

Figure 1. The home screen of the app

In this research, we aim to evaluate the efficacy and user experience of MediBetter application among patients undergoing routine medication. Participants will be instructed to utilize the mobile app for recording daily health-related activities, symptoms, and vital signs. They will be prompted to summarize their health diary entries periodically. Additionally, ChatGPT, an AI-based tool, will be tasked with automatically summarizing participants' health diary entries, offering an alternative approach to data summarization. The summarization results produced by the user and ChatGPT will undergo expert evaluation by healthcare professionals.

To evaluate the quality of generated summaries generated by both the user and ChatGPT, we employed extensive human assessments. We adopted standardized metrics commonly used in previous studies [5,6,7,8] . These metrics encompass the following dimensions: (1) Informativeness or Relevance: Quantifying the ability of the summary to retain important and relevant facts and information. (2) Coherence:

Assessing the presence of smooth logical transitions between summary sentences or paragraphs. (3) Redundancy: Evaluating whether the summary contains repeated information or facts. This metric measures the summary should contain few repetition, with a higher score indicating a lower level of redundancy. (4) Fluency: Measuring the grammatical correctness and linguistic fluency of the summary text. (5) Consistency or Factuality: Verifying the factual accuracy of the summary in comparison to the source article. (6) Contradiction: Identifying instances where information within the summaries contradicts other information or disagrees with another piece of information. This metric measures the summary should contain few contradiction, with a higher score indicating a lower level of contradiction.

In our human evaluation process, both the generated summaries and their corresponding reference health diaries are needed. We utilized all generated summaries and their corresponding reference texts from the dataset were utilized. We enlisted the participation of four expert volunteers for evaluation, comprising one physicians and three nurses. They were tasked with rating these summaries across six aspects using a scale ranging from 1 (very bad) to 5 (very good). Furthermore, we also asked the human evaluator about their preference, whether they prefer summary by user or ChatGPT.

Furthermore, participants will be surveyed to gather feedback on the usefulness of the app's features in health and medication management. We adopted usefulness items from previous studies [9]. After using the app for four weeks, participants were tasked with rating the usefulness of the app's features using a Likert scale with responses ranged from 1 to 5, spanning from strongly disagree to strongly agree. The following are the items:

- The diary / daily health status report feature helps in health monitoring.
- The diary / daily health status report summary feature helps in health monitoring.
- The medication taking reminder feature helps in health monitoring.

By incorporating both user-generated and AI-generated summarizations, along with expert evaluations and user feedback, this research aims to provide a comprehensive assessment of the mobile app's utility in facilitating health diary management and improving user engagement in personal health monitoring and medication management.

3. Result

3.1. Participant Characteristics

In this study, 23 patients were participated in using the application and providing the user summary. However, only 19 participants were filling the demographic and app usefulness survey. Table 1 summarizes demographic characteristics of 19 participants included in this study. We had more female participants (12) than the male one (7). More than half of the participants are 21-30 years old (52.63%) while there are 3 participants for each age category of 31-40, 41-50, and over 50. In term of education, most of them got their last education at bachelor level (63.16%).

Table 1. Participant Characteristics

Variable	Category	n	%
Gender	Female	12	63.16 %
	Male	7	36.84 %
Age	21-30	10	52.63 %
	31-40	3	15.79 %
	41-50	3	15.79 %
	Over 50	3	15.79 %
Education	Elementary school	1	5.26 %
	High school	3	15.79 %
	Bachelor	12	63.16 %
	Master	3	15.79 %

Table 2. Summary evaluation results using human expert evaluation

Aspect	Summary generated by user			Summary generated by ChatGPT			t-test result
	mean	std	kappa	mean	std	kappa	
Informativeness	3.20	1.30	0.066	4.60	0.70	-0.067	t(91)=-8.494, p<.001
Coherence	3.39	1.31	0.134	4.45	0.80	-0.038	t(91)=-5.907, p<.001
Redundancy	3.83	1.20	-0.074	3.52	1.52	-0.127	t(91)=2.233, p=.028
Fluency	3.47	1.34	0.022	4.49	0.78	-0.009	t(91)=-5.690, p<.001
Consistency	3.52	1.30	0.038	4.52	0.72	-0.080	t(91)=-6.086, p<.001
Contradiction	3.83	1.41	0.045	4.30	1.10	-0.076	t(91)=-3.118, p=.002

3.2. Summarization

We obtained 23 pair of summaries by user and ChatGPT. We asked four expert to rate the summary result on six aspects based on the corresponding health diaries. The results of the human expert evaluation are depicted in Table 2. We computed the mean and standard deviation for each aspect. In addition, we also measured the agreement between experts using Fleiss's kappas. Furthermore, we evaluated the mean score difference between summary generated by user and summary generated by ChatGPT. A two-tailed paired t-test with $p<.001$ was employed to test whether the difference is significant.

The results show that ChatGPT gave a better summary that user in five aspects, including informativeness, coherence, fluency, consistency, and contradiction. The t-test results indicates that summary generated by ChatGPT is significantly better that summary generated by user in four aspects, including informativeness, coherence, fluency, and consistency. For the contradiction aspect, even though it is not significant, the p value is 0.002, which is can be considered significant if we use $p<.005$. Summary by user is only better in one aspect, namely redundancy. However, the t-test result shows that the difference is not significant. Meanwhile, the kappas score indicates that the agreement between human evaluators are very poor for both the evaluation for summay generated by user and summary generated by ChatGPT.

Furthermore, we also asked the human evaluator about their preference, whether they prefer summary by user or ChatGPT in term of patient care support. The results that are shown in Table 3 indicates that all of the expert prefer summary by ChatGPT more than summary by user.

Table 3. The number of summary based on expert preference.

Preference	Expert I	Expert II	Expert III	Expert IV
Prefer summary by user	3	7	2	4
Prefer summary by ChatGPT	20	16	21	19

3.3. Usefulness

Majority of the participants perceived that of the three app features are useful. The mean score for health diary feature, summary feature, and medication taking reminder feature are 4.32 (SD 0.75), 4.21 (SD 0.71), and 4.42 (SD 0.69), respectively.

4. Conclusion

In conclusion, our findings indicate that the automated summarization by ChatGPT demonstrating superior performance in terms of informativeness, coherence, fluency, consistency, and contradiction compared to manual summarization by user. Expert evaluations also favored ChatGPT-generated summaries, highlighting the potential of AI-driven approaches in healthcare data summarization. Furthermore, participants perceived the app features, including the health diary, summary, and medication reminder, as highly useful. The high ratings obtained for these features underscore their importance in empowering patients to actively engage in their healthcare journey and adhere to prescribed treatment regimens. Further research and development efforts can focus on refining the app's features and enhancing its integration into routine clinical practice, ultimately improving patient outcomes and enhancing healthcare delivery.

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Health Systems Challenges in Developing Countries

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Development and Implementation of an Integrated Standard e-Prescription Model in Alignment with Iranian National EHR

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Abstract. The implementation of an Electronic Prescribing (EP) system offers numerous advantages in enhancing the efficiency of prescribing practices. To ensure successful implementation, a comprehensive understanding of the workflow in paper-based prescribing is crucial. In Iran, the Ministry of Health, and Medical Education (MOHME) has been actively involved in developing an EP system since 2011. The pilot results within MOHME have garnered significant support from all basic insurance organizations, primarily due to the importance of addressing financial considerations. As a result, these insurance organizations have taken the lead in the national development of the EP system, as responsibilities have shifted. The development of an Integrated Care Electronic Health Record (ICEHR or EHR) and the approach adopted by MOHME have paved the way for the creation of a standardized set of Application Programming Interfaces (APIs) based on openEHR and ISO13606 standards. These APIs facilitate the secure transfer of consolidated data from the EP systems, stored in the data warehouses of basic insurance organizations, to the Iranian EHR. This model follows an ICEHR architecture that emphasizes the transmission of this information to the Iranian EHR. This paper provides a detailed discussion of the various aspects and accomplishments related to these developments.

Keywords. Electronic Prescription (EP), Electronic Health Record (EHR), Medical errors, Data Integration, Basic Insurance Organizations

1. Introduction

E-prescription is a digital system that enables healthcare professionals to send prescriptions directly to pharmacies electronically. It eliminates the need for handwritten or printed prescriptions, making the process more efficient, accurate, and convenient [1]. With e-prescription, healthcare providers can securely transmit prescription details, including medication name, dosage, and instructions, to pharmacies[2]. This technology streamlines the prescription process, reduces errors, improves patient safety, and enhances the overall quality of healthcare services [3, 4].

E-prescription systems play a crucial role in digital health and are instrumental in improving patient safety. E-prescription systems play a crucial role in digital health and are

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instrumental in improving patient safety. E-prescription systems are gaining popularity in healthcare systems worldwide. However, there is a need for better understanding and analysis of the architecture and digital security of these systems on an international scale [1]. E-prescribing offers several benefits that contribute to improved patient safety, reduced fraud, and optimized drug information systems [5]. Firstly, it reduces the need for paper prescriptions, eliminating the risk of errors due to illegible handwriting. Secondly, it enhances patient safety by screening for drug interactions, dosing accuracy, and allergies. This helps prevent medication errors and adverse reactions [3, 6]. Additionally, e-prescribing optimizes drug information system investments by efficiently storing and accessing prescription records, saving time and resources. It also decreases administrative workload, freeing up more time for healthcare professionals to focus on patient care and consultations. Ultimately, e-prescribing facilitates better health outcomes for citizens by ensuring accurate and convenient medication management [7].

From initiating of Iranian EHR infrastructure, MOHME attempts to design the national e-prescription data model based on the international experiences and standards such as openEHR reference model, ISO13606 standard and other ISO TC215(Health Informatics) standard series [8, 9]. Therefore, in 2011, the development and pilot of e-prescription APIs were carried out in Babolsar town. The results of the pilot showed that the collaboration of stakeholders, particularly healthcare providers, and basic insurance organizations, was crucial for the success of the project. The regulation of financial issues in e-health services played a key role as well. Additionally, it was important to have policies in place to encourage all prescribers to use electronic tools. As a first step, MOHME needed to collaborate with payment organizations such as basic insurance organizations. These organizations had already developed their own e-prescription systems in their healthcare centers and were leading the way. However, due to the presence of multiple insurances in Iran with different systems and technologies, the e-prescription data was stored in decentralized warehouses without any connection to each other or national EHR. To address this, MOHME designed a set of APIs standards that were compatible with the EHR and instructed insurance organizations to transfer patient-centric data to the national EHR, known as SEPAS locally. This paper describes this process as the national model for e-prescription in Iran.

2. Methods

We conducted a literature review using MEDLINE to understand how e-prescribing frameworks are implemented globally. We identified relevant studies using MeSH terms related to electronic prescription and computerized physician order entry. We also searched for keywords related to adverse events and medical errors. The findings from these studies served as the basis for our interviews with experts to determine the necessary attributes and functions of the framework. The findings from investigations and studies were used as scientific input for an expert committee. This served as the foundation for conducting interviews with experts to determine the essential attributes and output functions of the e-prescribing framework. The preferences of the system were initially identified based on input from experts and universal work models. The initial features and functionality were defined and approved through discussions with key stakeholders, including primary and secondary insurance providers, medical schools, physicians, health centers, and private patient electronic health record (EHR) requirements. The preparation phase of our project involved emphasizing the concept of development

cooperation. We provided a set of instructions for EP systems developers, specifically those from basic insurance organizations, to adhere to. These developers were required to obtain a certificate from MOHME to demonstrate their compliance with the defined points and requirements. The points and requirements were determined using the MoSCoW strategy. The following section will provide an overview of the essential findings.

3. Results

3.1 Analyzing "As Is" vs "To Be" Model

Several web-based systems have been developed to facilitate the prescription of various types of orders, including medication, imaging, laboratory tests, physiotherapy, and other para-clinical services. In our research, we identified four distinct data models. One of these models follows the openEHR infrastructure and utilizes archetype/template modeling, which has been developed within the framework of MOHME. The remaining three models have been established by basic insurance organizations, each with its own unique approach that primarily focuses on financial management considerations. These models share common data elements but differ in their structure, as they have been developed to create data registries within each insurance organization and to support EP exclusively for their respective clients or customers. However, a national model is necessary to fulfill various requirements, ranging from financial objectives to governmental and clinical approaches, as well as improving patient safety and identifying medication errors and adverse drug events. Therefore, we recommend adopting a combined model that incorporates elements from the previous data model developed by MOHME and the models utilized by individual insurance organizations, which have been tailored to serve their specific customer base. Furthermore, by gathering EP data, it becomes feasible to electronically transmit this information to supplementary insurance companies for processing EP documents or e-reimbursement. This procedure operates through a pipeline system, where the prescription information is swiftly relayed from the MOHME to the supplementary insurance organizations.

3.2 Standard hybrid model and requirements

The complexity of developing a combined model that meets all requirements is a challenging issue. This is especially true when considering the need for basic insurance providers to transfer all their registered data to MOHME as mandated by regulations.
Table1 outlines the key requirements of every decentralized electronic EP system, which were determined based on expert opinions and consider governmental and clinical concerns using the MoSCoW approach. To effectively monitor prescription orders for patients and make informed policy decisions regarding patient safety and overall care quality, the integrated information should be able to provide the necessary facts. Additionally, careful consideration must be given to the design of data elements and the model for transitioning data to the SEPAS. As a result, a structured model, data elements, archetypes, and templates have been developed, along with non-relational databases and an API. Consequently, insurance organizations' EP systems will need to work with the standard API and transfer all patient records to SEPAS, the Iranian EHR.

Table 1. Decentralized EP requirement to joining in national data integration process.

MoSCoW	Requirements
Must-haves	‣ All EP systems must adhere MOHME instructions for e-prescribing by physicians or other prescribers, encompassing content, and data transmission to SEPAS. ‣ The systems must incorporate anti-counterfeiting mechanisms to ensure accuracy. ‣ Confidentiality must be maintained throughout all processes. ‣ All EP systems must to utilize national standard coding systems to significantly reduce medication errors and improve data integration accuracy. ‣ Safety alerts must be triggered by all EP systems.
Should-haves	‣ Within the next three years, all EP systems should aim to implement at least two-thirds of the provided guidelines. ‣ The process should be capable of verifying the validity of the EP. ‣ All EP systems should perform reliably according to predefined quality indicators. ‣ Every EP system should have access to patient medical history information retrieved from their national EHR. ‣ Safety alerts in all EP systems should be prioritized based on clinical importance, considering factors such as frequency, severity, and certainty of potential adverse effects. ‣ The systems should function with the activation of triggers, such as the absence of allergies, other medications, or other medical conditions. ‣ All EP systems should be capable of reviewing prescribers' prescribing patterns to determine if there is overprescribing or under prescribing of specific drugs for certain patient groups.
Could-haves	‣ EP systems could develop mechanisms to prevent dose miscalculations/entry errors. ‣ The systems could detect misreading of Rx codes or doses by office staff, as compatibility issues may lead to delayed prescription delivery. ‣ Compliance with EHR requirements, including coverage information and forms, is encouraged for the systems. ‣ The systems could function with activation of the trigger (i.e., absence of allergies, other medications, or other medical conditions).

4. Discussion

This paper describes the results of a proposed statewide data integration model for electronic prescribing. A set of key features that provide a standard API to integrate all stored data from the underlying insurance provider. These features consider based on international experience and expert opinion and the model design is ultimately based on Iranian EHR reference model. When calling the API, all EP data must be mapped to the openEHR structure and, if submitted successfully, the ID pair for each EP will be output as a patient ID and composition ID. These IDs indicate that this portion of patient record is being stored in SEPAS. The figure 1 shown the big schema of this model.

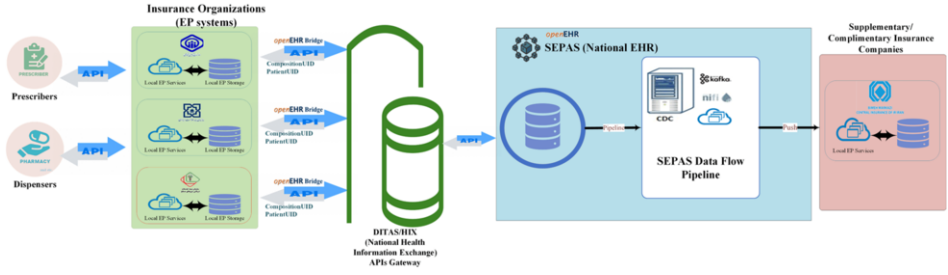

Figure1: The Comprehensive Framework of the Integration Process

With a population of over 85 million in Iran, integrating their EHRs is crucial from a national perspective. The system will facilitate decision-making for disease management, cost-benefit analysis in medicine production, import/export medicine or medical equipment and other areas. MOHME and the governance will be able to track patients, manage patient treatment who referred to healthcare centers, and make policies for the supply of additional medicines.

In addition, this system enables government executive boards to oversee the ordering practices of physicians and prescribers, while also granting supplementary insurance providers access to electronic prescriptions for e-reimbursement purposes. Although our system design is unique, its reliability has yet to be tested. In the future, there may be a need to add elements or items to the national data model structure. Further studies are necessary to assess the reliability of this system.

5. Conflicts of Interest

This project was supported by the Ministry of Health and Medical Education of Iran (MOHME). The executive results have been endorsed and confirmed by "Dr. Amin Biglarkhani", who was head of Statistics and Information Technology Office, Ministry of Health and Medical Education of Iran when the project has implemented. As teamwork, all the authors participated in project launching and they approved the final version of the manuscript.

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New Potential Risks for Security and Privacy as Well as Safety Chances and Challenges

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E-Health: Security, Privacy, and Ethics Requirements from a National Perspective in I. R. Iran

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Abstract: This paper explores the security, privacy, and ethical implications of e-health data in Iran's healthcare network. A framework is proposed to ensure security and privacy in electronic health information processing across various institutions. The framework addresses aspects such as software/hardware, communication networks, patient safety, privacy, confidentiality, online health service regulations, commercial and judicial exploitation, and education/research. The study categorizes these requirements into seven main categories to safeguard health-oriented service recipients' security and privacy.

Keywords: E-health, Data Security, Privacy and ethics, E-health data

Introduction

Trust in digital health information's privacy and security is vital for better health outcomes. Lack of confidence may lead patients to withhold information, fearing compromised confidentiality and accuracy of electronic health records[1]. Patients' trust in healthcare providers and the HIT system enables a comprehensive understanding of their health. HIPAA and the Health Information Technology Act protect patient privacy and require data breach reporting, facilitating informed decision-making by administrators, policymakers, and patients [2-3]. Data breaches compromising patient records were common between 2010 and 2013 and may increase with electronic health records. Healthcare providers and health plans are often affected, highlighting the need for strong safeguards. Defining and protecting ethical principles in e-health is crucial to maintaining standards and avoiding compromising service quality and social interaction in healthcare[5]. Accordingly, this paper aims to identify relevant laws and legal documents related to e-health data privacy in Iran issued by authorized organizations or the government. Based on these findings, a comprehensive framework comprising seven main layers is proposed to ensure compliance with regulations and considerations.

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1. Methods

To identify and classify all safety requirements for people in the e-health domain, it was necessary to clarify the concepts of some subjects such as healthcare centers, healthcare services, individual data or sensitive individual data, data processing, healthcare information systems, privacy, data sharing, electronic health services and even Electronic Health Record (EHR) and e-Prescription. In this regard, the definition of the said issues based on national and international references such as WHO was refined, and actually, we described the concepts in the first step. More than 70 official documents were reviewed and analyzed. According to 10 experts and more than 300 hours of analysis, and evolved from the operational domain, the considerations mentioned in the documents are divided into different parts. The categories fall into seven concept groups as main layers including more than 200 items to implement in the process of e-Health privacy infrastructure. After evaluating the experts' point of view and analyzing previous studies, and based on domestic experiences, a 7-layer framework with details of the indicators was proposed, which is described below.

2. Results

To ensure reliability, responsibility, and implementation in the field of e-health, clear concepts and a common understanding of privacy and ethics are necessary. This study examined documents and laws related to privacy, security, and ethics in e-health, issued by authorized organizations in Iran. Over 250 official and legal papers were compiled, and 70 relevant documents were analyzed. Based on expert opinions and national regulations, 200 considerations were identified that should be implemented in e-health systems. These considerations, categorized into seven groups, aim to ensure privacy, patient safety, and ethical healthcare provision alongside information technology, providing relative security for patients, service providers, and the health system in the country.

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Systems Medicine

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A Novel Algorithm Application in Vocal Signals Processing

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Abstract. This study proposes an innovative application of the Goertzel Algorithm (GA) for the processing of vocal signals in dysphonia evaluation. Compared to the Fast Fourier Transform (FFT) representing the gold standard analysis technique in this context, GA demonstrates higher efficiency in terms of processing time and memory usage, also showing an improved discrimination between healthy and pathological conditions. This suggests that GA-based approaches could enhance the reliability and efficiency of vocal signal analysis, thus supporting physicians in dysphonia research and clinical monitoring.

Keywords. Vocal signal, Goertzel algorithm, Signal Analysis

1. Introduction

Dysphonia is an impairment of vocal production affecting the phonatory apparatus, resulting in more serious laryngeal diseases. In the context of pathologies related to the vocal tract, one of the most relevant tests is videostroboscopy. Laryngeal videostroboscopy is a diagnostic procedure used to evaluate the condition of the larynx and vocal cords for the diagnosis of pathologies associated with vocal disorders and vocal conditions. Furthermore, it can be used in combination with audio signal analysis techniques, such as the Fast Fourier Transform (FFT) [1].
Signal processing represents a non-invasive approach to analyzing vocal signals aiming to detect and evaluate the diagnosis of laryngeal dysfunctions in patients with vocal fold disorders [2]. Fast Fourier Transform (FFT) represents the gold standard in signal processing of vocal signals.
This paper proposes the novel application of the Goertzel Algorithm (GA) as a processing technique in vocal signal analysis. The aim is to evaluate the application of GA in dysphonia detection and evaluation, also compared to the FFT-based algorithm. Preliminary results indicate the clinical potential of using GA in dysphonia analysis, highlighting the better GA performance in terms of speed and memory usage w.r.t. FFT algorithm. This contribution considers GA as a valuable tool for dysphonia diagnosis and monitoring in medical contexts.

2. Proposal and Preliminary results

We propose the use of the Goertzel algorithm (GA) tailored specifically for vocal signal processing. The proposed methodology consists of two main modules: (i) a vocal

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acquisition module and (ii) a signal processing and feature extraction module. The signal processing and feature extraction module has been developed in two different versions: one using the GA algorithm and the other one utilizing the Fast Fourier Transform (FFT) algorithm. For both implementations, we utilized source code in Java and Octave languages, each with different performances in terms of CPU and memory usage. We employed the GA and FFT-based source code to conduct the tests reported in our study. Additionally, we performed statistical tests to compare the performance of the two implemented algorithms and significant and relevant information was extracted during the analysis of vocal signals.

The proposed methodology has been tested on the vocal signals of subjects extracted from a publicly available dataset of healthy and pathological patients composed by 56 healthy subjects, 70 Hyperkinetic dysphonia, 36 Hypokinetic dysphonia, and 38 Reflux laryngitis [3]. Different implementations of vocal signal processing with GA and FFT-based algorithms have been tested and preliminary results show that GA performs better in both CPU and memory usage footprints than the FFT algorithm. Results reported in Table 1. It highlights the efficiency of GA-based processing in analyzing vocal signals and its potential to discriminate between healthy subjects and pathological subjects affected by specific vocal disorders.

Table 1. Comparison of Processing Time and Memory Usage for GA and FFT implementations.

Method	Processing time (ms)	Memory (Kbytes)
FFT	16.78	2128
GA	12.26	565

3. Conclusions

The use of the Goertzel algorithm for dysphonia-related vocal signal processing indicates better GA performance in diagnosing dysphonia and footprint w.r.t. FFT and its potential to enhance clinical monitoring and dysphonia studies. Future investigations will be able to further demonstrate the great impact of the Goertzel algorithm application in vocal signal analysis for dysphonia characterization.

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Virtual Care

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Personalized Detection of Motion Artifacts for Telemonitoring Applications

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Abstract. Among its main benefits, telemonitoring enables personalized management of chronic diseases by means of biomarkers extracted from signals. In these applications, a thorough quality assessment is required to ensure the reliability of the monitored parameters. Motion artifacts are a common problem in recordings with wearable devices. In this work, we propose a fully automated and personalized method to detect motion artifacts in multimodal recordings devoted to the monitoring of the Cardiac Time Intervals (CTIs). The detection of motion artifacts was carried out by using template matching with a personalized template. The method yielded a balanced accuracy of 86%. Moreover, it proved effective to decrease the variability of the estimated CTIs by at least 17%. Our preliminary results show that personalized detection of motion artifacts improves the robustness of the assessment CTIs and opens to the use in wearable systems.

Keywords. Telemonitoring, motion artifacts, Cardiac Time Intervals, template matching, personalized medicine, heart sounds

1. Introduction

The spread of wearable sensors has opened to novel possibilities in terms of monitoring the health status of chronic patients in a telemedicine framework. Telemonitoring has several well-known advantages: reduced burden, time and costs for the hospital, increased quality of life and empowerment for patients [1]. Telemonitoring is particularly effective in the management of chronic diseases because it enables a timely follow-up and the detection of the earliest physiological changes leading to an acute episode [1,2]. Moreover, telemonitoring allows for a personalized management of the disease, based on biomarkers extracted from signals [2]. The assessment of the signal quality is a critical point in telemonitoring. In fact, signals are typically recorded by inexperienced users who cannot be trusted to define whether the signal is good enough for processing or not. Nevertheless, good signals are key to ensure the reliability of extracted biomarkers.

In this work, we focus on the telemonitoring of patients affected by chronic heart

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failure to prevent acute episodes and related hospitalizations. It was found that variations in the Cardiac Time Intervals (CTI), extracted from simultaneous recordings of electrocardiogram (ECG) and heart sounds (phonocardiogram, PCG), are correlated with variations in the status of compensation of the patient [3,4]. In a previous study, we studied how the quality of the heart sounds recordings affects the CTIs' estimate [5]. In this study, we tackle the problem of motion artifacts, i.e., artifacts due to a reciprocal movement between the sensor and the skin. This is a common problem of wearable acquisitions, particularly in acoustics [6]. Identifying a motion artifact in the PCG signal is not naïve, because its frequency content may overlap with the one of heart sounds, leading to the artifact being misrecognized as a sound generated by the heart [6]. The goal of this study is to propose a personalized method to automatically detect motion artifacts in multimodal recordings of heart sounds and thoracic accelerations and analyze its effect on the estimated CTIs.

2. Materials and Methods

2.1. Recording system and experimental protocol

Multimodality was obtained by integrating two different devices, both designed and developed by our research group. Simultaneous ECG and PCG signals were recorded by a wearable array designed for the purpose. The flexible pad is designed to adapt to the left hemithorax of the patient and embeds 48 electret condenser microphones along with 3 electrodes. The distribution of the microphones was proved to enable inexperienced users to perform good-quality recordings without the help of clinical nor technical staff. More details about the device can be found in [7]. Accelerations were recorded by means of a miniaturized system based on a 3D magneto-inertial sensor. Data processing is handled on-board by a highly capable floating-point microcontroller. The inertial system was located on top of the array, on the sternal area, as shown in Figure 1. The two systems are asynchronous. The alignment between the two recordings was performed by considering that, when filtered in the bandwidth of heart sound (20Hz to 100Hz), PCG and accelerometer signals convey similar information. Therefore, a cross-correlation based alignment could be performed [8]. All signals were resampled to 1 kHz.

Two-minute recordings were carried out on ten volunteers who denied any history of cardiopathy. Volunteers were asked to lay on an examination table in a supine position with a bare chest. The two devices were positioned by an investigator as described. The

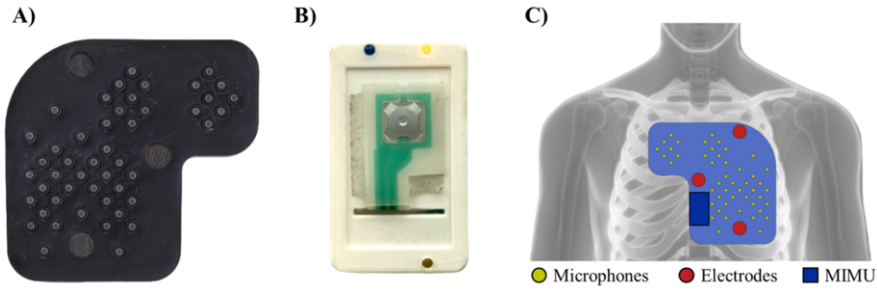

Figure 1. Recording system. A) Array to record ECG and PCG signals. B) Inertial sensor to record accelerometric signals (MIMU). C) Positioning of the devices on the thorax. Adapted from [7].

volunteers were instructed to perform five different tasks at given time instants, with the timing set by a video. Tasks included: coughing, head flex-extension, head right-left rotation, right arm protraction, pronouncing the sentence: "Can you bring me a glass of water, please?". The tasks were defined to simulate possible types of behavior that may occur during a short recording performed in a domicile setting without the supervision of clinical staff. The timing of the tasks is graphically represented in Figure 2.

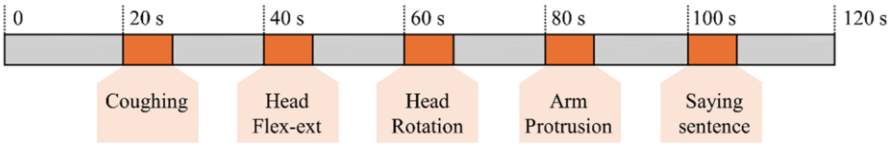

Figure 2. Experimental protocol. Heartbeats in the grey intervals are labelled as "clean". Heartbeats in the orange intervals are labelled as "artifact".

2.2. Motion artifacts detection and Cardiac Time Intervals estimation

Motion artifacts detection was performed on the accelerometer signals. The designed methodology grounds the detection on an envelope-based template matching approach. Contrarily to typical template matching algorithms, our method does not require any a priori assumption on the signal: a personalized template was estimated for each recording to make the detection sensitive to the characteristic of the cardiac cycle of the patient.

First, each axis was highpass filtered at 2 Hz to remove baseline wandering. The information from each axis was aggregated through the Euclidean norm. The envelope of the norm was extracted using the Hilbert transform. The envelope was segmented into heartbeats using the R-peaks, extracted from the ECG, as reference. The average heartbeat was used as a template. Two template matching approaches were tested:

1. *RMSE*. The RMSE between each heartbeat and the template was assessed. Heartbeats with an above-threshold RMSE were classified as "artifact".
2. *Correlation*. A sliding window of the length of the template was used and the Pearson correlation coefficient was computed point by point. For each heartbeat, the maximum correlation coefficient was used. Heartbeats with a below-threshold correlation were classified as "artifact".

In both cases, thresholds were defined specifically for each recording as a percentile of the distribution of respectively the RMSE and the correlation over the heartbeats belonging to the recording itself. In this sense, the detection is fully personalized. The percentile was tuned by constructing the ROC curves for all percentiles from 0 to 100 and selecting the point with the highest balanced accuracy.

The estimation of the CTIs relies on the ECG-PCG signals recorded using the multi-sensor array. The definition of the CTIs grounds on the estimate of the time of closure of the four cardiac valves from the first and second heart sounds (S1 and S2), with respect to the ventricular depolarization. Therefore, the intervals between the R-wave peak and respectively the mitral ($RS_{1,M}$) and triscupid ($RS_{1,T}$) component of S1, and the aortic ($RS_{2,A}$) and pulmonary ($RS_{2,P}$) component of S2 was considered. The R-wave peaks were identified in the ECG signal using Pan-Tompkin's algorithm. The mitral and tricuspid components in S1 and the aortic and pulmonary components in S2 were identified using our previously published envelope-based method [9].

2.3. Evaluation of the performances

The goal of the motion artifact detection phase is classifying the heartbeats of each recording as "clean" vs "artifact". The ROC curves were constructed for the entire sample population to optimize the percentile to be used for thresholding respectively the RMSE and the correlation values. The sensitivity, specificity and balanced accuracy at the selected operating point were used to evaluate the performances of the motion artifact detection phase. Balanced accuracy was preferred because of the imbalance of the dataset. The time of closure of the four cardiac valves was computed before and after the removal of heartbeats classified as "artifact". The effectiveness of our proposed approach to improve the robustness of the estimate was quantified by assessing the percentage reduction of the standard deviation of the estimate.

3. Results and Discussion

The obtained ROC curves are proposed in Figure 3A. Each point of the ROC curve corresponds to a different percentile used to threshold the RMSE and correlation values respectively. The two selected operating points are highlighted on the curves. Figure 3B presents the sensitivity, specificity and balanced accuracy subject by subject.

Results show that reasonable performances can be achieved by both approaches, but correlation outperforms RMSE by yielding a better sensitivity at the same specificity. When observing the subject-wise performance metrics, it can be appreciated that RMSE favors specificity, whereas correlation favors sensitivity: the best method can be defined according to the application of interest. Table 1 reports the percentage variation of the standard deviation of the estimate of the time of closure of the four cardiac valves using either reference labeling or template matching, with either correlation or RMSE. All methods produce a significant reduction of the estimated standard deviation, given that the original standard deviation is over 20 milliseconds. It can be observed that the proposed automatic, personalized approach decreases the variability of the estimate better than the labelling used as reference. It can be explained by the fact that heartbeats

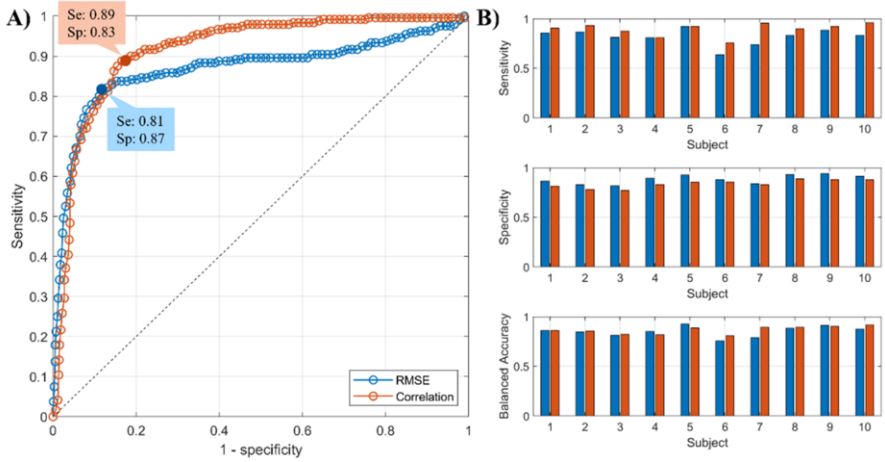

Figure 1. Performances of the motion artifacts detection algorithm. A) ROC curves using either RMSE or correlation for template matching. B) Sensitivity, specificity, and balanced accuracy for each subject.

without a simulated motion artifact are not necessarily free from artifacts: template matching removes heartbeats with a low correlation (or high distance) from the template independently on the type of artifact. From this perspective, the real performances may be even higher at a visual inspection. In the overall, the proposed approach proves effective in removing the motion artifacts and obtain a more robust estimate of the CTIs.

Table 1. Percentage variation in the standard deviation of the estimate of the time of closure of each cardiac valve using reference labeling, template matching (correlation) or template matching (RMSE).

	Reference labeling	Template matching (correlation)	Template matching (RMSE)
$\mathbf{RS_{1,M}}$	-8%	-22%	-20%
$\mathbf{RS_{1,T}}$	-14%	-19%	-20%
$\mathbf{RS_{2,A}}$	-7%	-17%	-18%
$\mathbf{RS_{2,P}}$	-7%	-17%	-17%

4. Conclusions

In this work, we propose an automatic method to detect motion artifacts in multimodal recordings devoted to estimate CTIs in chronic heart failure patients. The approach proved effective to improve the robustness of the estimate in a small sample population. The use of a fully personalized method improves the efficacy by being sensitive to the characteristics of the cardiac cycle of the subject and is suitable for telemonitoring, where a thorough assessment of the signal quality is required to obtain reliable biomarkers.

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Development of Health-Promoting Edible Cricket Products by Using Sensory Evaluation Techniques

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Abstract. Background: In the fields of food science and technology, sensory evaluation is extensively studied to assess personal perception and acceptability. However, studies on Thai consumers' personal perceptions of and acceptability of food products containing crickets have not been conducted. Objectives: The overall goal of this study was to find out how well-liked two food products containing house crickets were by Thai customers in good health regarding their sensory qualities. Methods: The 3-point Just-About-Right (JAR) scale measured the foods' sensory characteristics, including thickness, color, odor, sweetness, and saltiness. Food product approval among consumers was assessed using the 9-point Hedonic scale. Nutrient density was measured using the nutrient-rich foods (NRF) index, highlighting the potential health benefits of these products. Results: For every attribute, the goodness-of-fit score of the cricket puffed rice (CPR) was higher than 70%. The cricket-galangal chili paste (CGCP) received a score of greater than 70% for color and odor, but the sweetness was required more since it had a JAR score of 53.3 percent. The customer acceptance scores of CPR and CGCP were 6.63-7.60 and 6.60-7.50 on the 9-point Hedonic scale. The NRF indices of the CPR and CGCP were 19.19 and 20.44 (intermediate levels). Conclusion: There was no need for improvements in the cricket puffed rice product, but cricket-galangal chili paste should be improved. Further study on nutrition facts is required.

Keywords. Sensory evaluation, Just About Right scale, 9-point Hedonic scale, Edible insects, Personal health

1. Introduction

The diverse area of sensory science includes a broad range of recently created and well-established tests to record how people react to stimuli. Sensory evaluation is widespread in food science and technology [4]. The sensory attributes of the foods can be assessed using the 3-point Just About Right scale (3-JAR). The 3-JAR scale has been designed as a category scale measuring sensory attributes for food products, such as color, odor, sweetness, thickness, and saltiness [8]. The consumer acceptance of food products can be evaluated using the 9-point Hedonic scale [9]. Edible insects may be found worldwide, and most species prefer warm, tropical climes over other climatic conditions to thrive [10]. Nutrients from insects like crickets can assist with digestive health and reduce chronic disease symptoms due to their bioactivity [5]. Nevertheless, it has not yet been widely embraced as a mainstream protein substitute worldwide due to

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low consumer acceptance [7]. Under the European Union (EU) 2015/2283, the regulation on Novel Foods (NF), which includes edible insects, requires that food companies that seek to distribute NFs on the EU market submit a company-specific authorization application [14]. Therefore, food optimization with personal sensory and acceptance tests might be necessary to obtain authorized certificates. Various types of meat, such as shrimps [3], fish [11], and edible insects [13], have made chili pastes. However, there were no studies on sensory characteristics and acceptance of cricket-containing food products among Thai people. The objective of the present study was to investigate the sensory attributes and acceptance of house cricket-containing food products among healthy Thai consumers. Also, nutrient density based on the overall nutrient profile was calculated using the nutrient-rich foods (NRF) index.

2. Methods

2.1 Cricket-containing food product development

We have developed the product formulas for CPR and CGCP from three publicly available formulas for each product. We set 20 preliminary testers to establish an experimental formula, as shown in Tables 1 and 2.

Table 1. Formulas of cricket puffed rice

Ingredients	Percentage (%)
Puffed rice	49.79
Cricket powder	33.20
Fried garlic	6.64
Coconut palm sugar	5.81
Salt	0.83
Coriander roots	1.24
Black pepper	0.83

The CGCP was started by mixing roasted red chilies and peppers, ground and aliquoted according to the recipe. All were pounded and finely roasted with galangal over low heat until dry and fragrant, flavored with sugar, seasoning powder, salt, chili, crushed fried garlic, and fried onion. All were fried until dry (moisture ≤ 20 percent) and put in a container. The NRF of CPR and CGCP, calculated according to Hess's method, were 19.19 and 20.44 (intermediate levels) [6].

Table 2. Formulas of cricket-galangal chili paste

Ingredients	Percentage (%)
Cricket powder	25
Ground galangal	25
Ground-dried bird's eye chili	3
Ground garlic	20
Ground shallot	20
Seasoning powder	1.5
Coconut palm sugar	4
Salt	1
Plant oil	0.5

2.2 Sensory tests and participants

The 3-JAR scale was designed as a category scale that a participant can respond to, and the numbers of categories are odd with three descriptive anchors [8]. Testing attributes for CPR products included color, odor, sweetness, and saltiness. The test attributes of the CGCP product were the same as those of the CPR and spiciness. All testing attributes were re-evaluated with the 9-point Hedonic scale for consumer acceptance [1 (dislike extremely) to 9 (like extremely)] [9]. The inclusion criteria for 30 participants were general consumers aged 18-35 who were not allergic to the products. The 3 grams/servings of the products were served in 3 ounces at room temperature with

3-digit random codes to reduce tester bias. Drinking water was provided for mouth rinsing.

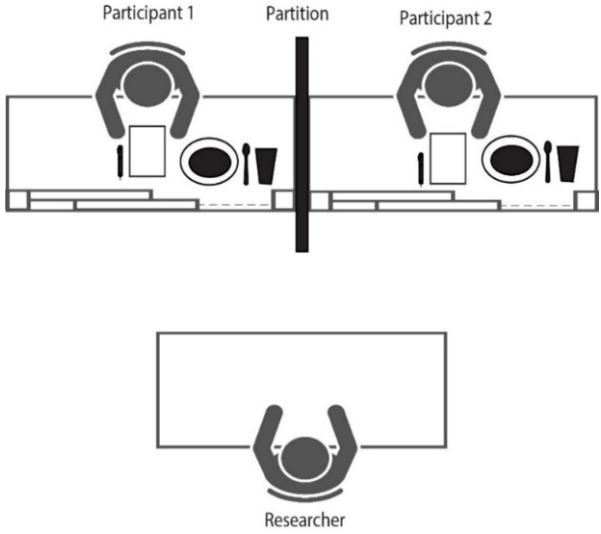


Figure 1. Sensory test station

2.3 Calculation of the nutrient density of products

The products were calculated for nutritional value using the Thai Nutri Survey (TNS) and the amount of nutrient density based on the overall nutrient profile using the Nutrient-Rich Foods (NRF) index.

3. Results

3.1 Sensory test results for the cricket puffed rice product

The CPR had a goodness-of-fit score of more than 70 percent for all attributes. Therefore, no improvements were required, as detailed in Table 3.

Table 3. Sensory test results for the cricket puffed rice product using the 3-JAR

Sensory attributes	3-JAR scale			
	Low intensity	Just about right	High intensity	Net effect
Color	1 (3.3)	28 (93.3)	1 (3.3)	0.00
Odor	6 (20.0)	22 (73.3)	2 (6.7)	13.33
Sweetness	8 (26.7)	22 (73.3)	0 (0.0)	26.67
Saltiness	8 (26.7)	22 (73.3)	0 (0.0)	26.67

3.2 Sensory test results for the cricket-galangal chili paste product

The CGCP had a goodness-of-fit score of more than 70 percent for color and odor. On the other hand, sweetness had a JAR score of 53.3 percent and a net effect of more than 20 percent, so more sweetness was needed. Saltiness and spiciness had scores less than 70 percent, but the net effects were lower than 20 percent and needed no improvement. Therefore, no improvements were required, as detailed in Table 4.

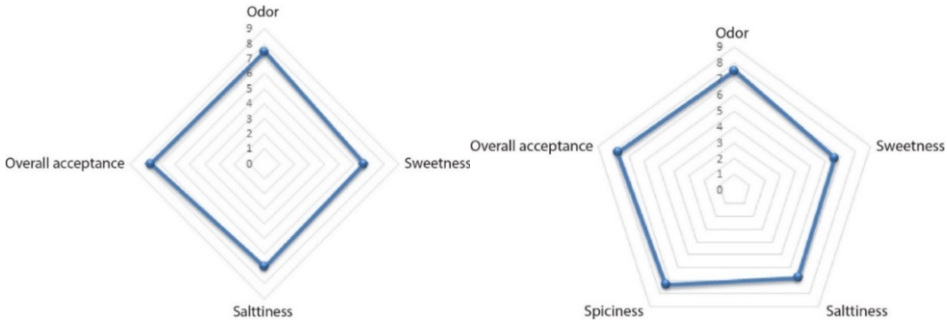
Table 4. Sensory test results for the cricket-galangal chili paste product using the 3-JAR

Sensory attributes	3-JAR scale			
	Low intensity	Just about right	High intensity	Net effect
Color	0 (0.0)	26 (86.7)	4 (13.3)	13.33
Odor	3 (10.0)	24 (80.0)	3 (10.0)	0.00

Sweetness	13 (43.3)	16 (53.3)	1 (3.3)	40.00
Saltiness	4 (13.3)	19 (63.3)	7 (23.3)	10.00
Spiciness	5 (16.7)	20 (66.7)	5 (16.7)	10.00

3.3 Consumer acceptance test results for the cricket products

Results of CPR and CGCP acceptance by the consumers from the 9-point Hedonic scale are shown in Fig. 2. Overall, the acceptance score of the CPR was rather moderate to rather like very much (6.63-7.60). Likewise, the acceptance score of the CGCP product was rather moderate to rather very much (6.60-7.50).



(a) (b)

Figure 2. Radar chart of consumer acceptance test results for the CPR (a) and CGCP (b)

3.4 Nutrient density of products

One hundred grams of CPR and CGCP provided 336.77 and 126.02 Kcal of energy, respectively. The nutrient density of the products was calculated to determine whether a food was healthy. The NRF scores of CPR and CGCP are shown in Table 5. This reveals that the products had an intermediate level of nutrient density.

Table 5 Nutrient-Rich Foods Index Score Calculation for CPR and CGCP

Nutrients	**Amount in 100 Kcal of a product**		**Daily Reference Value**	**Percent Daily Value**	
	CPR	**CGCP**		**CPR**	**CGCP**
Protein (g.)	2.24	1.67	50	4.49	3.35
Calcium (mg.)	14.31	11.97	1000	1.43	1.20
Vitamin D (IU)	0.00	0.00	400	0.00	0.00
Potassium (mg.)	45.82	113.51	3500	1.31	3.24
Magnesium (mg.)	0.00	0.00	40	0.00	0.00
Iron (mg.)	1.50	1.13	18	8.31	6.29
Vitamin A (RE.)	0.44	6.65	5000	0.01	0.13
Vitamin C (mg.)	0.39	2.54	60	0.65	4.23
Vitamin E (IU)	0.00	0.00	30	0.00	0.00
Fiber (g.)	0.35	0.74	25	1.41	2.96
Saturated fat (g.)	0.00	0.00	20	0.00	0.00
Sodium (g.)	0.0	0.0	2400	0.00	0.00
Total Sugar (g.)	1.78	1.19	125	1.43	0.95
Nutrient-Rich Food Index score				16.19	
(*sum of nutrients to encourage - **sum of nutrients to limit)					20.44

Note: No daily value for total sugars. The daily reference value used here (125 g) was adopted from an overview of the nutrient-rich foods index, *sum of nutrients, to encourage refer to the sum of protein, calcium, fiber, iron, vitamin A, potassium, vitamin C, magnesium, and vitamin D, ** sum of nutrients to limit sum among of total sugar, saturated fat, and sodium.

4 Discussion

This experimental sensory evaluation study shows that CPR and CGCP are acceptable. This conclusion is based on the following findings. First, the CPR scored more than 70 percent for all sensory attributes. Secondly, the CGCP scored more than

70 percent for color and odor, but more sweetness was required. Third, the overall acceptance score of both products was moderate to high.

Sensory evaluation techniques have been widely used in food science and technology [12]. Although they are abundant and have long been consumed by humans, edible insects have recently been rediscovered for food use [15]. A previous study showed that complementary food formulas from sweet potatoes in combination with palm weevil larvae, soybeans, or crickets were used as protein and micronutrient sources for stunting prevention in Ghanaian children [1]. The study elaborated that the mixed sweet potatoes and crickets were moderately acceptable, and odor, taste, and texture should be improved.

In contrast, the acceptability of crickets among Ugandan people was low compared to other insects (soldier and winged termites) [2]. This finding indicates that cricket consumption preferences are exclusive to different geographies and food recipes. In conclusion, the CPR was acceptable, but the CGCP should be improved. Both products had NRF scores with moderate levels. This indicates that the products had an intermediate level of nutrient density. Further study on food safety and nutrition facts might be performed.

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How Patients Feel with Telemedicine Devices as an Enabling Factor for Personalised Medicine: A Preliminary Study

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Abstract. Telemonitoring tools have become essential in today's healthcare, representing fundamental resources for chronic disease home management supporting early detection of clinical worsening with great reduction of hospitalization costs. Therefore the investigation of the patient compliance is a key enabling point. We aim to assess how patients with chronic coronary syndromes evaluate a telemonitoring device meant for ongoing health monitoring. Twenty-six patients used the device for a week and subsequently filled out a well-designed questionnaire. The survey questions were about the device's ease of use, satisfaction levels, perceived effectiveness, and its influence on the patients' healthcare experiences. This study emphasizes the significance of focusing on patient needs in telemedicine and the importance of addressing these concerns to improve telehealth interventions.

Keywords. Telemedicine, Wearable Device, Compliance

1. Background

Monitoring patients through telemonitoring is an essential part of the advancement towards personalised medicine [1]. It provides a constant and immediate flow of health data that the patients generate. This method enables the remote monitoring of vital signs and physiological parameters and makes it easier to gather information about their behaviour and lifestyle [2].

Integrating telemonitoring technologies creates a rich dataset that can be analysed to gain insights into individual health patterns, contributing to a more personalised approach to medical care. Studies such as that by Mistry et al. [3] emphasise the role of telemonitoring in tailoring interventions based on patient-specific data, ultimately improving outcomes and patient satisfaction. In essence, telemonitoring is a fundamental enabling step in realising personalised medicine, fostering a patient-centric and data-driven healthcare paradigm.

The widespread adoption of telemedicine tools in cardiology would necessitate a comprehensive evaluation and adjustment of various ecosystem factors to ensure

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effective implementation. It is of fundamental importance to encourage the development of some procedural aspects establishing protocols for virtual consultations, including patient screening, scheduling, and follow-up procedures, developing guidelines for remote monitoring of cardiac conditions, including data collection, transmission, and interpretation and implementing telemedicine-specific documentation. From an organizational point of view, training healthcare providers in telemedicine technology and communication skills will facilitate effective virtual consultations, redefining roles and responsibilities within cardiology departments to accommodate telemedicine practices and optimize workflow efficiency. It will also be essential to ensure the security and privacy of patient data transmitted during telemedicine encounters through robust encryption and data storage measures, address connectivity issues and device compatibility to minimize disruptions during virtual consultations and logistical barriers to telemedicine adoption, such as geographic disparities in internet access and socioeconomic inequalities in digital literacy.

In such a field, the cardiology unit of the University of Catanzaro, jointly with the Telemedicine unit and the Computer Science group, is conducting an initial investigation into telemonitoring patients by using wristband devices, monitoring patients' heart rate, level of saturation and movement habits [4]

Our goal was to analyse the data obtained from telemonitoring and assess the user preferences and experiences through comprehensive questionnaires delivered through a simple web interface. These questionnaires provide critical insights into the reception and efficacy of wristband devices within a medical context. Utilising wristband devices for telemonitoring represents a notable progress and potential customisation of healthcare management. Considering the lack of public transportation and the presence of many patients living in remote rural areas, these devices present an effective solution for overcoming geographical and resource constraints in accessing healthcare.

The study employed Sidly wristbands [5], which are equipped with various sensors to measure essential health indicators and can offer continuous health data through a web interface [6]. The system allows the doctor to set alarms and be aware in real time of anomalies in heart rate, saturation or loss of balance (as in the case of syncope).

Since the patients' satisfaction with wristbands is crucial, we defined a questionnaire to collect extensive feedback from patients using these wristband devices. These questionnaires are crafted to encompass a broad range of user experiences, including the ease of use, comfort, the perceived accuracy of health data, and general satisfaction with the device. This method facilitates a thorough understanding of patient interaction with the technology and their comfort and confidence in utilising it for health monitoring.

In addition, the questionnaires are created to obtain a deeper understanding of how the wristband devices are incorporated into patients' everyday lives. These questionnaires consist of inquiries that seek to comprehend the effects of these devices on daily schedules, their ability to shape patient actions and choices related to lifestyle, and their contribution to fostering a feeling of personal control in managing one's health.

The information gathered through these questionnaires also provides a distinct view of the patient-healthcare provider relationship in telemonitoring. It is instrumental in evaluating how wristband-generated data is employed in clinical decision-making and how these devices improve communication between patients and healthcare providers.

Privacy and data security are paramount in the utilisation of wearable health tech-

nology. The questionnaires address patients' perceptions and concerns regarding data privacy, security measures, and confidence in the technology's capacity to safeguard sensitive health information.
In summary, using questionnaires in this study is essential for understanding patient perspectives regarding wristband telemonitoring devices. This approach not only collects quantitative data on user preferences but also provides qualitative insights into the patient experience, concerns, and the broader impact of these devices on healthcare delivery in the region. The results from these questionnaires are expected to shape future advancements in telemedicine, ensuring that patient-centred care remains a central focus in the ongoing evolution of healthcare technology.

2. Methods

We made our selection from a database of approximately 800 patients with myocardial infarction at a young age (less than 50 years). We examined 66 patients as follow up and 26 of them completed the questionnaire (that will be submitted to all the patients). After gathering informed consensus we conducted a thorough assessment of their medical history, physical examination, electrocardiogram, and evaluation of their hemodynamic compensation. At the end of the visit, we applied and instructed patients to wear the Sidly telemonitoring device for seven days, which allows remote monitoring of their health status via a web-based platform https://sidly.eu/.
After a week, each patient completed a detailed questionnaire that consisted of different sections. The introductory section examined the patient's age, gender, and education level. Age was classified into five specific ranges: 18 to 30 years, 31 to 40 years, 41 to 50 years, 51 to 60 years, and over 60 years. Education level was categorized as primary school diploma, middle school diploma, high school diploma, degree, and post-degree qualifications such as doctorate, master's degree, and specialization.
The second section evaluated the patient's knowledge of informatics using a self-assessment scale from poor to excellent skills. The questionnaire assessed the patient's ability to send and receive emails, make purchases, read newspapers, use banking apps, games and/or gaming, using social media and apps on the web.
The third section investigated on a scale from one to ten how important the patient considered the use of the telemonitoring system. The questionnaire asked the patient whether they preferred a smartwatch-based monitoring system or a system not associated with each phone device. It also inquired whether the patient preferred a system with manual or fully automatic updating, a system connected exclusively to their phone or to a remote team of healthcare professionals. The questionnaire assessed how many patients desired a telemonitoring device reimbursed by healthcare systems and how important patients considered on a scale of one to ten the access to their parameters (for example, trends in frequency, saturation, and steps). Finally, it was assessed whether the device feedback had improved the patient's health state and whether they would prefer automatic feedback (e.g. based on artificial intelligence) or feedback generated by medical personnel.

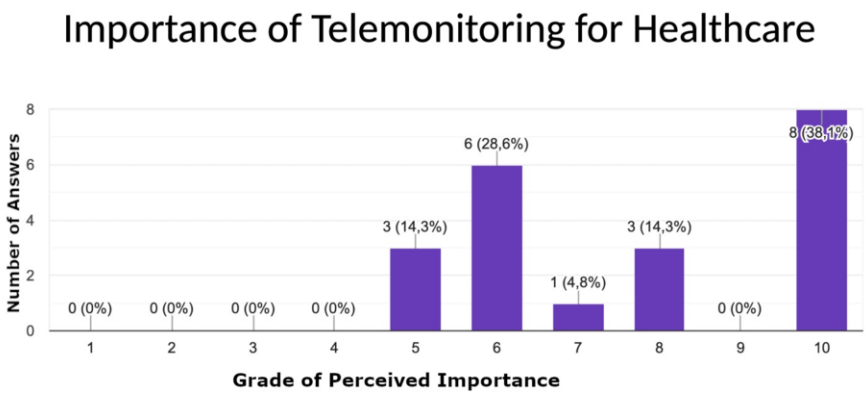

Figure 1. Figure reports the perceived importance of telemonitoring for improving healtcare. The x-axis report the perceived importance on a 0-10 scale, while for each level we report the number of answers. Only a single answer was admitted.

3. Results

The questionnaire provided valuable information to better understand the patient's perspective on the telemedicine devices use. Most patients are aged between 41 and 50 years (61,5 percent), are male (80.8 percent) and with a middle school diploma (57,7 percent) Only 30 percent of patients reported excellent ability to send and receive emails. A good ability to read newspapers on the Internet has emerged (38,5 per cent), and a poor ability to use Internet/APP Banking Systems (38,5 per cent)-We highlighted a good ability to use games and/or recreational apps (34,6 per cent), television apps (e.g. streaming channels) (42,3 per cent), video calling and video conferencing systems (26,9 per cent), social networks (e.g. Facebook, Instagram, e.g. Whatsapp, Telegram) (26,9 per cent) and of Messaging Systems (e.g. Whatsapp, Telegram) (30,8 per cent).
46,2 percent of patient thought telemonitoring is fundamental for improving both healthcare system and health status of patients as reported in Figure 1, preferring a smartwatch-based monitoring system (69,2 percent) with automatic updat (92,3 percent). Patient preferred a device system connected to remote team of healthcare professionals (69,2 percent) and desired a telemonitoring device reimbursed by healthcare systems (92,3 percent). Most patients believed it is important to a continuous vital parameters monitoring (65,4 percent) and to have a device feedback on health state (53,8 percent) preferably with a feedback generated by medical personnel rather then from artificial intelligence system (88,5 percent).

4. Discussion

Our study revealed that there is a wide range of digital literacy among participants, with only 30% reporting excellent ability to use email and make online purchases. This indicates the need for telemonitoring systems to be easy to use and accessible to people with varying levels of technological proficiency.
Patients' desire for devices that are reimbursed by healthcare systems reflects the im-

portance of affordability and accessibility in adopting telemonitoring technologies. This points to a broader issue within the healthcare system, where innovative technologies require supportive policies and funding mechanisms to reduce barriers to access.
A significant finding from our study is the high value placed on continuous monitoring and feedback from medical personnel. This suggests that patients are interested in being actively engaged in their health management, supported by a professional healthcare framework. The preference for feedback generated by medical personnel over artificial intelligence solutions indicates a trust in human-based clinical judgment and a desire for a more personalized healthcare experience.
The results suggest that telemonitoring can play a critical role in improving patient outcomes and satisfaction. However, the success of these technologies depends on addressing concerns related to data privacy and security. Thus, there is a need for robust safeguards and transparent communication about how personal health information is protected. The main limitation of this study is the small sample of patients who completed the questionnaire. At the moment the obtained data are not solid enough to have statistically relevant information. Our goal is to extend the questionnaire to all patients who have already used our monitoring system and to those who will use it in the future.

5. Conclusion

This study highlights the potential of telemonitoring technologies to advance personalized medicine, particularly through the use of Sidly wristband devices for patient monitoring. Our investigation found that the majority of participants, who were mostly men aged between 41 and 50 years with a middle school education level, displayed varying degrees of proficiency in using digital technologies. This emphasizes the importance of user-friendly telemonitoring solutions.

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Stakeholder Perception's of Cybersecurity for Welfare Technology and Remote Care Devices

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Abstract. In healthcare, there are various stakeholders who hold different understandings of technology. Cybersecurity risks may also be something these stakeholder have varying perceptions of. This papers explores how cybersecurity risks are understood by two key stakeholder groups in the Norwegian healthcare sector related to welfare technology and personal healthcare devices. Two stakeholder groups (healthcare workers and technology vendors) have been interviewed to gather data on this topic. Key findings highlight that there are differences in how risks are perceived, both in terms of likelihood and in consequence. We apply risk perception theory to analyze these findings and provide suggestions for further research within this topic.

Keywords. Cybersecurity risk perception, Cybersecurity, welfare technology, healthcare technology, stakeholder perspective

1. Introduction

The healthcare sector is making use of more and more technology in their care provision, both in the in-hospital care and in remote care (e.g in nursing homes, patient's home)(Read et al. 2022; Ma et al. 2023). The need for these technologies is increasing alongside the demanding need for healthcare personnel across Europe and Asia. Making use of and implementing technology is a complex task where different people and organizations have varying acceptance criteria (Nilsen et al. 2016; Davis, 1989). Hence, people have different understandings of the world and how they make sense of it, which also affects how they understand and perceive risks in nearly all aspects of our society.
Risk perception, a field with multiple scientific viewpoints such as from psychology, sociology and engineering (Fischhoff et al., 1978;Kostyuk & Wayne, 2021; Huang et al., 2012; Sjöberg, 2000; Slovic, 1987; Slovic et al., 1982; Starr, 1969). Risk perception can be seen in light of decision making and the cognitive limitations, the structure of the environment and the uncertainty affiliated with expressing risk numerically (Gigerenzer & Todd, 1999). The individual's ability to have accessible information, and which information is available also influence risk perception (Kahneman, 2011), associated with fear or benefit (Finucane et al., 2000; Starr, 1969) and variability of different hazards (Fischhoff et al., 1978; Goh et al., 2022). The psychometric perspective views human activity and behavior and potential effects on this behavior such as context (Slovic, 1987). Another theory commonly applied to explain behavior related to risk is protection

motivation theory (PMT), where risk understanding (e.g risk perception) is explained as how individuals perceive potential danger and how dangers are coped with. Specifically, we speak of threat appraisal (perceived severity and perceived vulnerability) and the coping appraisal (response efficacy and self-efficacy) and how the individual adapts their behavior according to these (Rogers, 1983). Hence, risk perception is divided into three themes by Spencer (2016) where risk perception is influenced by mainly 1) cognitive bias, 2) social and cultural factors and 3) emotion and effect. When applying the risk perception understanding in the cybersecurity field, Huang et al. (2010) conceptualized risk perception through hazards occurring in the digital domain, and the predictors were affiliated with the severity of consequences, impact and possibility of exposure to mention a few. Another study viewed the cause-effect of the construal fit perspective to demonstrate the impact on information security risk perception (Goh et al., 2022). Cybersecurity risk perception (referred to as risk perception in the following) can be understood as the risk associated with cyber threats and the potential impact on information and communication technology (ICT) and data. This entails cyber incidents such as data breaches, hacking, malware attacks which implicate the confidentiality, integrity, availability and functionality of ICT systems and data.

In this paper, we explore how different stakeholders in the Norwegian healthcare sector perceive cybersecurity risks related to welfare technology and remote care devices. In this quest, we have limited the context to Norway and to the devices that are currently deployed in the healthcare sector, but we have not narrowed the investigation to one specific technology.

2. Method

Data can be collected in various ways, often differentiated by the qualitative and quantitative approach. We seek to explore the perception of stakeholders which requires a need to go in depth in the individual understanding and sensemaking – which is best collected through a qualitative approach. By conducting in-depth interviews, we have collected a large data material on topics relevant for cybersecurity risk perception, risk understanding and healthcare technology (welfare technology and remote care solutions) from four stakeholder groups. The inclusion criteria were:

- Needed to belong to one of the identified stakeholder groups
- Have experience with welfare technology *or* cybersecurity in the Norwegian healthcare sector

In this paper, we have included 10 interviews, with the following distribution

- Healthcare workers (N=5)
- Vendors (N=5)

The vendors included in this study deliver welfare technological services and devices widely distributed in the Norwegian healthcare system (both primary healthcare system and specialist healthcare). To preserve the anonymity of the vendors in a relatively small market, we have chosen not to disclose what type of technology they deliver. These two groups were chosen based on their opposing roles in the healthcare sector, where the healthcare workers are the ones using technology as a part of their care provision, while the vendor of technology is responsible for developing the technology that is used in this task. Albeit these two groups may be biased due to their benefit of using technology or relation to technology (e.g. as producer of technology), their

opposite roles enable us to discover if there are differences in how cybersecurity risk is perceived. The interviews lasted between 45-60 minutes and were conducted through teams. All interviews have been transcribed and analyzed following the step-by-step deduction induction analysis process (Tjora, 2021). First, the data material was coded, then we reiterated the codes to catalogue codes which was finally categorized in overarching themes. The themes form the structure of the next section – results and discussion.

3. Results and discussion

In this section, we will present the key findings and discuss these in light of relevant theory. Further, we illustrate the two stakeholder groups cybersecurity risk perception to better view similarities and differences in their understanding. Cybersecurity can be expressed in various ways. One of the most common approaches is to view risk in light of likelihood (probability) and consequence (impact), and within cybersecurity this is related to the confidentiality, integrity and availability. However, in healthcare, the dimension of quality/patient safety is also highly important in thee consequence dimension (Carayon et al., 2021).

Before going into the depth of our findings, it must be noted that the two groups explored hold varying responsibility in the healthcare context. The vendors are providers of technology, used for care, whilst the healthcare workers are providing direct care for patients. Given the responses from the two stakeholder groups, it is evident that this has implication on their perception, as the vendors focus more on the business aspects and consequences if their devices were subjected to cybersecurity incidents, while the healthcare workers primary concern is the life and health of their patients. This is an interesting, and not surprising finding. However, as the vendors of technology provide equipment that is used directly in patient care, patient safety and responsibility should be a key priority. The vendors included in this study state that "Our equipment does not provide any critical tasks in the patient care, therefore we are not very concerned about the patient harm" (Vendor 1). Still, simple and basic technologies such as digital safety alarm and medicine dispenser (which are the most common in the Norwegian healthcare sector) can have potential negative consequences on patient safety. There is a mutual agreement amongst both groups that cybersecurity is important however, there were great differences on how they actually understood cybersecurity risks.

The vendors of healthcare technology have a large focus on data confidentiality i.e to ensure the privacy of data, while healthcare workers also focused on confidentiality they also cared a lot about the availability-aspect of the devices and affiliated data. When discussing risk, it is natural to explore how the two groups perceive their ability to effect and manage risk. Our respondents hold varying viewpoints in this regard, where vendors perceive the severity mainly in terms of breaches affecting confidentiality, but acknowledge the availability-aspect, such as service disruption. Healthcare workers were more concerned for the impacts for patients and their abilities to ensure patient safety, resulting in a larger focus on availability and a larger concern for related consequences. There is a shared concern for the vulnerability presented by third parties. Within coping appraisal, the vendors are aligned in their understanding, where they all believe that their strong risk management processes, in-house competence (and certifications) indicated that they have a strong coping appraisal. Risk assessments focused on CIA and patient safety (life/health) was used as an example of their self-efficacy. The healthcare workers

demonstrated a low self-efficacy as they viewed cybersecurity to be the responsibility of someone else. Although, healthcare workers viewed cybersecurity as important, they also displayed limited knowledge and competence, which may implicate both perception and their self-efficacy.

Drawing on the theory of Spencer (2016) the risk perceptions of the respondents is highly influenced by especially dimension 2) Social and cultural beliefs, as there is a strong difference in their focus on business risk and consequences versus patient safety/ health risk. The primary concern of the healthcare workers is patient-focused, meaning cybersecurity incidents (intended and unintended) that can affect the care provision and safety of inhabitants, whilst the vendors focus less on this type of risk, as they also view it as highly unlikely that patients may be affected. Further, a finding that is prevalent amongst both groups is the reliance and trust placed in other parties, where healthcare workers trust and rely on the vendors for sufficient security, whilst the vendors rely on third-party providers through cloud solutions and security features such as incident detection and response. From the 10 interviews it is hard to accurately evaluate their approach to likelihood and consequence, although our findings demonstrate the healthcare workers are more concerned in terms of consequences and has less knowledge about the likelihood of cybersecurity incidents. Conversely, vendors seem less concerned about the consequences as they view the technologies deployed to be of low impact, but the dimension of data breach is viewed as likely with potential business impacts.

4. Conclusion

This study has demonstrated that there are some distinct differences in how cybersecurity risks are perceived for welfare technologies deployed in Norway amongst the two groups. Even though the two groups both view the likelihood of cybersecurity incidents to be low, there are differences in how they understand the terms and consequences of such risk. Mainly, vendors are more concerned about their business and license to operate in the healthcare sector, while healthcare workers are more concerned for the potential patient safety consequences – and they also view the consequences as more serious than the vendors. In the extension of this study, a larger number of informants should be included and one should consider conducting a tailored survey to capture the risk perception of different stakeholder groups. Another aspect that would be interesting is to examine is if there are differences between healthcare organizations, or between public/private organizations. Further, as welfare technology is a term mainly applied in the Nordics, it could be interesting to view assisted living technologies in the context of other countries than Norway to see if there are differences in how cybersecurity risks are perceived.

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Sustainable Agrochemical Exploitation of Ligurian Aromatic Plant Ecotypes

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Abstract. The characterization of local improved varieties as well as the reduction of synthetic chemical fertilizers are sustainable approaches in the vision of a new precision Farming. Aim of our study was to improve the geographical characterization of local ecotypes and to identify peculiar features of new crops in terms of bioactive compounds. NMR and LC-MS metabolite profiling approaches followed by multivariate data analysis were applied to characterize local rosemary and garlic ecotypes. With the aim of applying for a protected designation of origin, orthogonal partial least squares discriminant analysis (OPLS-DA) was used to identify representative sensory quality indicators for Vessalico garlic and rosemary "Eretto Liguria" local ecotypes, Variable Influence on Projections (VIP) values of OPLS-DA indicated six metabolites as quality indicators for Vessalico garlic and sixteen metabolites as quality indicators for rosemary "Eretto Liguria". Finally, to discover and utilize new ecotypes in a sustainable way, Vessalico garlic extracts antiviral activity, previously evaluated against *Tomato brown rugose fruit virus* (ToBRFV), a Tobamovirus affecting tomato crops, was extended to *Pepino mosaic virus* (PepMV) with positive results.

Keywords. Precision Farming, garlic ecotype, rosemary ecotype, metabolite profiling, multivariate data analysis, antiviral activity, antibacterial activity

1. Introduction

Agriculture plays a crucial role in ensuring food security, a primary focus of Sustainable Development Goal 2 (SDG 2 - Zero Hunger), as well as other SDGs outlined in the UN Agenda 2030 for sustainable development. Eco-efficiency is essential in agriculture to assess this economic activity concerning both the exploitation of natural resources and revenue generation [8]. Dubbed "Agriculture 4.0," this transformation

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involves integrating cutting-edge technologies and sustainable practices into agricultural operations. "Agriculture 4.0" represents a paradigm shift in agricultural practices, marked by the convergence of digital technologies, precision agriculture, and sustainable farming methods. This note explores the innovations justifying this designation, alongside the evolving requirements of the European Green Deal, particularly within the Farm to Fork Strategy. The Farm to Fork objectives for 2030 include a 50% reduction in overall plant protection product use, a 50% reduction in the use of the most hazardous products, and an increase in organic farming. Notable measures include the study of the efficacy and mechanism of action of plant extracts introduced both as plant protection products and as bio stimulants (Reg. EU 1009/2019). The revision of EU Directive 128/2009 proposes a shift towards a more sustainable approach to plant protection, emphasizing integrated pest management (IPM) practices and the use of non-chemical methods where possible. The accurate detection of biomarkers and the discovery of new bioactive compounds could lead to the opportunities to "personalize" agriculture [13]

Our laboratory focuses on pure extracts and compounds isolated from aromatic plants as potential allelopathic and biopesticide agents [2-4]. Recently, we have been working on pure extracts and compounds from local ecotypes of rosemary and garlic. Rosemary extracts are used by some chemical companies as a pathogen and pest control or as biostimulants (EU Regulation 1009/2019). Garlic extract is also currently recognized as an active mixture authorized in organic farming and included in Annex II of EC Regulation 889/2008, whose approval as nematocide has been renewed pursuant to EU Implementing Regulation 2021/129. *Salvia rosmarinus* "Eretto Liguria" ecotype is widespread in Liguria (Northwest Italy) and farmers commonly use it by for cuttings and for marketing. Vessalico garlic, a local ecoytpe of *Allium sativum*, is cultivated in Ligurian region, and it is considered as agri-food excellence of the region.

To improve the geographical characterization of local ecotypes and landraces and to identify peculiar features in terms of bioactive compounds, NMR and LC-MS metabolic profiling approaches followed by multivariate data analysis are commonly used [14; 16; 17]. These techniques were then applied to characterize local rosemary and garlic ecotypes [5; 7]. Moreover, considering the massive production of plant waste biomass in Liguria, we focused on the possibility to find a new sustainable exploitation of the selected ecotypes[5; 7]. In the present study we analyzed the data obtained in our previous work by orthogonal partial least squares discriminant analysis (OPLS-DA), to identify representative sensory quality indicators for Vessalico garlic and rosemary "Eretto Liguria" local ecotypes, with the aim of applying for a protected designation of origin. Finally, the investigation into the antiviral activity of garlic extracts was extended and *Pepino mosaic* virus (PepMV) was considered.

2. Methods

2.1. Plant Material

Thirty-two accessions of *S. rosmarinus* ecotypes and cultivars grown in field conditions in Liguria (Northern Italy), as well as twenty-two accessions of Vessalico garlic, grown in field conditions, along with 12 and 6 of the French cultivars Messidrôme and Messidor, respectively, and 12 of "Aglio di Caraglio" were used for the study, as previously described [5; 7].

2.2. Statistical Analysis

The data obtained from previous studies on garlic and rosemary, namely from UHPLC-Q-trap and NMR analysis, respectively, were entered into a Matlab extension called PLS_toolbox by Eigenvector to perform Orthogonal Partial Least Square Discriminant Analysis (OPLS-DA). The OPLS-DA model was validated, and its quality was evaluated in terms of R^2 and Q^2 and by means of misclassification matrices. The Variable Influence on Projections (VIP) value was chosen as variable selection method to select a small set of very relevant metabolites correlated to the category index [17]. The variables with VIP > 1 were then considered as discriminant metabolites between the classes.

2.3. Antiviral activity of garlic extract

The effectiveness of the garlic extracts in degrading the RNA of the viral agent *Pepino mosaic* virus (PepMV) on a contaminated surface was evaluated by *in vitro* test (repeated three times) as previously reported [7]. Based on previous results of ToBRFV deactivation, as a possible consequence of disassembly of virus coat protein (CP), molecular docking studies were then carried out to investigate the possible interaction between the organosulfur compounds identified in garlic extract and PepMV CP [7].

3. Results

3.1. Screening of discriminant metabolites

OPLS-DA was used for discriminating the representative samples of Vessalico ecotype from the French cultivars, as well as rosemary "Eretto Liguria" from other cultivars and ecotypes. The two data sets obtained from the previous studies, after Pareto scaling (garlic dataset) or autoscaling (rosemary dataset), were entered into a Matlab extension called PLS_toolbox by Eigenvector to perform Orthogonal Partial Least Square Discriminant Analysis (OPLS-DA). An OPLS-DA model with 3 components was established and the model quality was evaluated, with $R^2(X) = 0.652$, $R^2(Y) = 0.928$ and $Q^2 = 0.738$ and an OPLS-DA model with 3 components was established and the model quality was evaluated, with $R^2(X) = 0.618$ $R^2(Y) = 0.894$ and $Q^2 = 0.795$ for garlic and rosemary data, respectively.

The most characterizing metabolites were selected on the basis of the Variable Influence on Projections (VIP) values of OPLS-DA. Six variables [*S*-allyl-cysteine sulfoxide (ACSO or alliin), *S*-allyl-cysteine (SAC), *S*-methyl-cysteine (SMC), γ-L-glutamyl-*S*-allyl-L-cysteine (GSAC), γ-glutamyl-*S*-(trans-1-propenyl)-cysteine (GS1PC), γ-glutamyl-phenylalanine (GPA)] were shown to be quality indicators for Vessalico garlic. Sixteen variables [acetate, malonate, sucrose, fumarate, methylrosmarinate, epicatechin, carnosic acid, acacetin, carnosol, catechin hydrate, rosmarinic acid, ferulic acid, coumaric acid, chlorogenic acid, rutin, and isorhamnetin-3-O-rutinoside (narcissin)] were shown to be quality indicators for rosemary "Eretto Liguria".

3.2. Antiviral activity

Vessalico garlic extracts showed ability to deactivate PepMV, a plant virus, as a possible consequence of disassembly of the virus coat protein (CP). Plants inoculated with swabs used for the sampling of inoculated and treated wells, as well as negative control plants, did not develop symptoms. Homology modeling was then applied to prepare the protein model of PepMV CP, and its structure was optimized [1]. Molecular docking simulation showed the interactions of the two compounds with the amino acid residues responsible for CP-CP interactions. All the compounds showed very good results in term of binding energy value in comparison with ribavirin, a common antiviral agent. PepMV CP was found to self-associate and interact with each other, possibly to support virus movement, since CP is indispensable for PepMV cell-to-cell and long-distance movement [15].

4. Discussion

The application of multivariate analysis techniques for the characterisation of local crops, with a view to their protection and commercialization, together with the definition of possible biological activities that can form the basis of use in organic or integrated farming is the part of a vision of customized agriculture. In our study six garlic sulfur compounds, among the 19 considered, were found to be quality indicators of Vessalico garlic extracts. Specifically, they were *S*-allyl-cysteine sulfoxide (ACSO or alliin), γ-glutamyl peptides (γ-L-glutamyl-*S*-allyl-L-cysteine (GSAC), γ-glutamyl-*S*-(trans-1-propenyl)-cysteine (GS1PC), γ-glutamyl-phenylalanine (GPA), that are the polar sulfur compounds found in fresh-picked garlic [11], and *S*-alk(en)ylcysteines [*S*-allyl-cysteine (SAC), *S*-methyl-cysteine (SMC)], that are characteristic compounds of aged garlic [9]. Rosemary "Eretto Ligura" was characterized by sixteen variables, among the 38 considered, belonging both to primary and secondary metabolites, *i.e.* abietane diterpenoids, together with other terpenoids, flavonoids, and polyphenolic acids [5; 6]. Moreover, Vessalico garlic extracts showed ability to deactivate PepMV, a common plant virus commonly associated to *Tomato brown rugose fruit virus* (ToBRFV), a *Tobamovirus* that affects tomato crops and poses a serious threat to their profitable production.

5. Conclusions

The long-term resilience of ecosystems to climate change can be ensured by agricultural biodiversity [12]. In this scenario, ecotype and landrace enhancement can be a winning choice for agricultural development, especially in areas where there is a niche agricultural system [10]. Based on previous results, in the present study we identified quality indicators for a fast identification of two local ecotypes, that can be considered agricultural excellence of the territory. Moreover, the possibility of using plant bio-residues as a source of high-added value products potentially useful as agrochemicals is a crucial point for the development of a personalized agriculture.

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An Ensemble Architecture for Melanoma Classification

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Abstract. Melanoma represents an extremely aggressive type of skin lesion. Despite its high mortality rate, when detected in its initial stage, the projected five-year survival rate is notably high. The advancement of Artificial Intelligence in recent years has facilitated the creation of diverse solutions aimed at assisting medical diagnosis. This proposal presents an architecture for melanoma classification.

Keywords. Melanoma Classification, Ensemble Architecture

1. An Ensemble Architecture for Melanoma Classification

The World Health Organization (WHO) [1] has reported that cutaneous melanoma accounts for the highest number of fatalities among skin cancers, with 58,000 deaths and over 320,000 new cases detected annually [2]. This number is expected to rise. Although incurable, cutaneous melanoma can be effectively treated if diagnosed early. Classifying skin lesions remains a significant challenge due to the ambiguous nature of some lesions [3,4] Recent works in the literature compare different proposals from the scientific community. These studies emphasize the existence of numerous approaches employing deep neural networks [5,6], whereas some other proposals combine outputs of different models to generate a unified response to classification challenges, as reported in [7]. As known neural networks offer significant predictive capabilities, especially in the field of image analysis, whereas machine learning models provide explainability, albeit at the cost of predictive capability. Figure 1 reports the architecture of an ensemble transfer learning approach for melanoma classification that captures the benefits of both machine and deep models. It consists of different functional blocks, whose role will be sketched in the sequel. Firstly, input images undergo preprocessing and are then classified using a pre-trained deep neural network customized to the context, employing Transfer Learning techniques. This process also involves feature extraction for subsequent use in the sequential block. Secondly, various machine learning models are trained using the extracted features from the network in combination with statistical hand-crafted features. Thirdly, classifications from both the network and ML models are merged using an ensemble technique.

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The proposed architecture exhibits an AUC of 0.97 and a F1-Score of 92% and guarantees explainability [8,9].

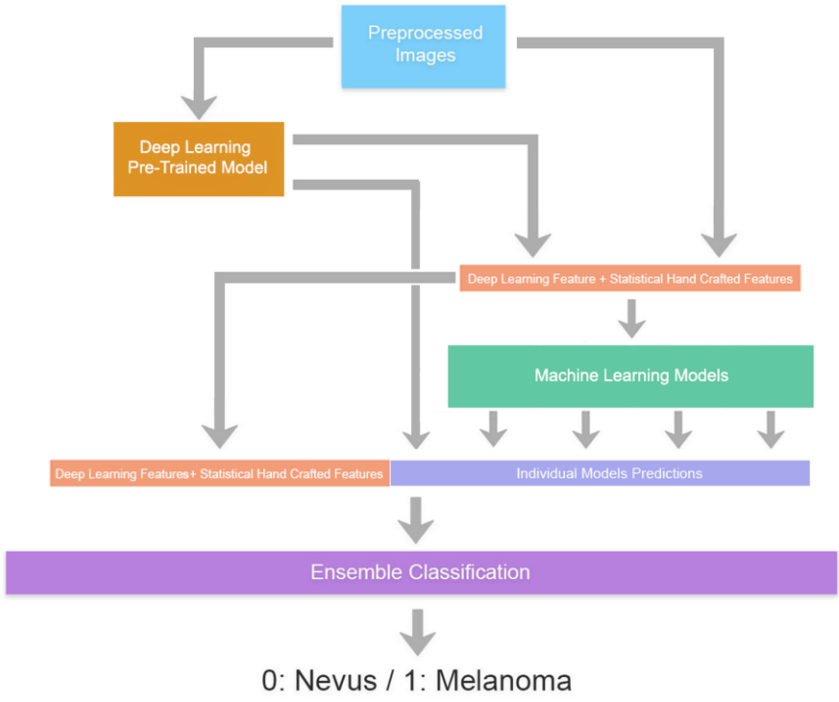

Figure 1. Architecture of the Approach

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Education in Health Informatics: Perspectives from the Italian Society for Biomedical Informatics (SIBIM)

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Abstract. The evolution of socio-technological habits together with the widespread demand of post-acute and chronic treatments outside hospital boundaries drove the increased demand of medical informatics experts to develop tools for and support healthcare professionals. The recent COVID-19 pandemic further highlighted the need of physicians able to manage diseases virtually and remotely. Moreover, healthcare professionals need to access to innovative techniques and procedures to manage biomedical data, cloud-based communication, and data sharing procedures, often connected to innovative devices to support an effective precision in the health treatments. In this paper we report the experiences of the Italian Biomedical Informatics Society (SIBIM), in the definition and promotion of eHealth educational topics in medical and health professions teaching programs, as well as in bioengineering schools, showing how SIBIM members' efforts have been applied towards increasing the level of eHealth contents in medical schools.

Keywords. Biomedical and health Informatics, Education, Scientific Society, Personalized Health, Digital Health

1. Introduction

The Italian Society of Biomedical Informatics (Società Italiana di Informatica Biomedica, SIBIM) [1] is a scientific and cultural association founded in 2016, and member of the European Federation of Medical Informatics (EFMI) [2]. SIBIM mission is to link the heterogeneous and complementary expertise existing in the Italian academic and clinical institutions regarding eHealth and digital health. SIBIM members have expertise in a wide range of research topics, including healthcare data integration and standards, clinical informatics, data management, artificial intelligence, patient-centered care and telemedicine, decision support systems, process mining in healthcare, bioinformatics, and regulatory issues regarding software as medical devices, security and privacy. Most of these multiple experiences are the basis of a correct process of personalizing medical care. The SIBIM scientific mission to link academic and clinical institutions with

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industrial partners to develop advanced research projects is complemented by the efforts provided to support eHealth and digital health high-level education (academic courses, PhD, masters, etc.).

While some years ago the efforts of medical informatics education were mostly devoted to creating and preparing a workforce of developers, mainly computer scientists and biomedical engineers, able to implement effective eHealth solutions, the fast evolution of the technology democracy and the emerging definition of 5P eHealth ecosystems [4] highlighted the increased need of improving eHealth literacy of healthcare professionals as end users. This is even more challenging considering the complexity of the eHealth field, in which complexity uncertainty and personalization have a long-standing trade-off with safety, privacy, and confidentiality [10-14].

The geographic coverage of SIBIM members spans all over Italy with representatives from the major Universities of the Country. SIBIM members largely contribute to education in both Medical and Technical Schools, with experience in building degree in medicine including bioengineering programs, such as the ones reported in [3].

This paper illustrates the results of a survey conducted among SIBIM members in June 2023, and focused on the eHealth education for the digital healthcare workforce, including both medical and technical curricula.

2. The Survey

The questions in the survey were related to the availability of health informatics courses within the Institutions of SIBIM members, and to the programs where such courses are offered. As mentioned, we were interested not only into technical degrees (such as biomedical engineering or computer science), but also into health-related education programs (e.g., medical school, nursing school, etc.). We then asked specific questions aimed at having additional details on the courses, such as the number of lecture hours, the number of students, and the general objective of the course (data analysis, use of software or biomedical devices, application of ICT solutions to clinical settings, fundamentals of computer science applied to biomedical disciplines, data bases and health data management). We also had a free text section where it was possible to specify the topics covered in the course and, finally, we asked the members to give a rate between 1 and 5 to the relevance of the course within the program it belongs to.

3. Results

Members belonging to 12 different institutions (out of the 17 participating to the Society) in 10 sites answered to the survey, covering a wide range of the Italian eHealth education offer (Figure 1). Interdisciplinary experiences have been reported, showing contribution both in undergraduate as well as graduate students.

Figure 1. Geographical distribution of the survey respondents (created using Google Maps).

Figure 2 shows the overall distribution of the education programs that offer courses related to health informatics as a result of the survey. The chart shows that the courses are almost equally distributed among technical programs (Engineering, Computer Science, and technical postgraduate courses) and healthcare-related programs (Medical School, Health Professions including nursing school, postgraduate medical school).

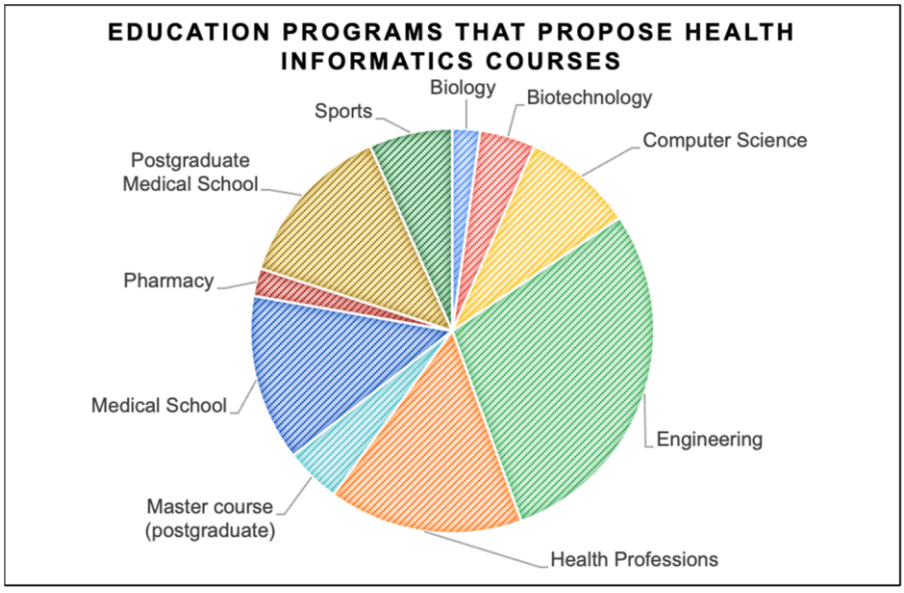

Figure 2. Education programs that offer health informatics courses.

The SIBIM members participating in the survey are involved in Medical School courses, including both Medicine and Health professions such as Nursing. In Medical Schools, most courses are dealing with fundamentals of informatics and general aspects

in eHealth such as EHR principles and hospital information systems. In addition, some advanced content is provided, such as an introduction to standards (with focus on HL7[5] and DICOM [6]), data analysis and basics of AI, and applications of data mining to clinical studies.

Ten out of the twelve responding sites have an active Biomedical/Clinical Engineering or Biomedical Computer Sciences degree with a track on eHealth. Several courses included in these tracks specifically address technologies supporting the process of personalizing medical treatment. Figure 3 shows a detailed view of the data we collected regarding the courses delivered in the bioengineering programs. Such courses are delivered both for undergraduate and for graduate students. Undergraduate courses usually deal with the fundamentals of medical informatics (standards, semantic interoperability, EHR, hospital information systems, telemedicine, software as medical device, UML modeling), as well as an introduction to the organization and processes included in the Italian national healthcare system. All the undergraduate programs also include courses related to databases and information systems, a basic course on image and signals analysis, and programming courses (Java, Python, C, Matlab). Graduate courses include advanced topics such as machine learning and artificial intelligence, ontologies, clinical guidelines, bioinformatics, telemedicine, advanced biomedical signal processing, and process modeling.

Figure 3. Most frequent topics in biomedical engineering programs (Created with WordClouds.com https://www.wordclouds.com/).

Multidisciplinary Ph.D. programs are available at several institution members of SIBIM and offer students the opportunity to study subjects such as biomedical data management and analysis, and to apply techniques in digital medicine. As the national level, in 2021, the National PhD in Artificial Intelligence was started, and "Health and life sciences" has been identified as one of the five strategic areas of specialization. The National Ph.D. course AI Health and Life Sciences [7] is led by Campus Bio-Medico University in Rome and it involves twenty organizations, including universities and research institutions across the country. It is focused on the application of AI in the field of health and life sciences with particular attention to the integration of AI, IoT and biorobotics. This is aimed at enriching the possibilities of forming new profiles able to work not only in medical schools or in research institutions, but also in industries, where the capacity of managing multidisciplinary topics in a large competitive market is crucial.

4. Conclusion

The eHealth curricula offered by technical schools are becoming attractive for companies, where positions related to the medical informatics field are becoming more frequent. On the other hand, the eHealth education in medical curricula is often limited only to basic informatics skills, thus suggesting that national eHealth organizations should focus their efforts towards increasing the level of eHealth contents in medical schools (both Medicine and Medical professions). This consideration is coherent with the result of [8], where 451 responses from medical students of 39 European countries show a lack of eHealth contents in medical education. This result was also confirmed at a national level by the survey performed by the board of SIBIM and presented in this paper. The need for advancing eHealth literacy in medical and clinical staff has become fundamental in the light of the National Recovery and Resilience Plan (PNRR), which allocates huge resources (i.e. C 15.6 billion) for the digitalization of medical management in Italy [9]: large numbers of adequately trained technicians will be needed to develop innovative systems, but without a group of adequately trained health professionals these systems are at risk for remaining underused.

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