

pHealth 2022

*Proceedings of the 19th International Conference
on Wearable Micro and Nano Technologies for
Personalized Health*



Editors: Bernd Blobel
Bian Yang
Mauro Giacomini



IOS Press

Personalized health technologies offer many benefits. Smart mobile systems, textiles and implants and sensor-controlled medical devices have become important enablers for telemedicine and ubiquitous pervasive health as the next-generation health services, while social media and gamification have added another dimension to pHealth as an eco-system.

This book presents the proceedings of pHealth 2022, the 19th in the conference series, held as a hybrid event in Oslo, Norway, from 8 – 10 November 2022. The pHealth 2022 conference attracted experts from many scientific domains and brought together health-service vendor and provider institutions, payer organizations, government departments, academic institutions, professional bodies, and patients and citizen representatives. Topics covered include mobile technologies, micro-nano-bio smart systems, bio-data management and analytics, machine learning, artificial intelligence and robotics for personalized health, the Health Internet of Things (HIoT), systems medicine, public health and virtual care. The book includes 2 keynote papers, 10 invited papers, 20 full papers, and 4 poster papers by 113 authors from 23 countries. All submissions were 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 Program Committee, guaranteeing a high scientific level of the accepted and ultimately published papers.

Exploring the enormous potential of pHealth for improvements in medical quality and also for the management of healthcare costs and the provision of a better patient experience, the book will be of interest to all those involved in the development and provision of healthcare.



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8–10 November 2022 Oslo, Norway

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Preface

pHealth 2022 is the 19th conference in a series of scientific events which brings 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 as personalised medicine through P2 medicine, which also addresses prevention, P3 medicine with the inclusion of prediction, P4 medicine, where 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 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 from all over the world. The 2022 conference brought together health-service vendor and provider institutions, payer organisations, government departments, academic institutions, 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, have become important enablers for telemedicine and ubiquitous pervasive health as the next-generation health services, 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: address the big data challenges; foster meaningful innovation; understand and address the potential new risks; and support concerted effort to un-silo communities for a virtual care future. The benefits of pHealth technologies for all stakeholder communities, including patients, citizens, health professionals, politicians, healthcare establishments, and companies from biomedical technology, pharmaceutical, and telecommunications domains, offers enormous potential, not only for the improvement of medical quality and industrial competitiveness, but also for managing healthcare costs.

The pHealth 2022 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, and 2021, again in Genoa. The 2009 conference introduced the idea of

having special sessions focusing 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 the special session on the success stories of European projects, and also the presentations on the newest paradigm changes and challenges associated with Big Data, analytics, translational and nano medicine, etc. Vienna in 2014 focused on lessons learned from international and national R&D activities, and practical solutions, particularly those from Horizon 2020, the new EU Framework Programme for Research and Innovation. Besides 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, and also 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 have been also considered. The pHealth 2016 conference in Heraklion 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 pHealth 2017 event in Eindhoven provided an inventory of the 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 consideration of the majority of the papers with organisational and practical experiences. Borrowing from the good experiences of former events, pHealth 2018 responded to the 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. In that context, ethical challenges and related international manifests were discussed in depth. 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. Thereby, 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 especially have been considered. The 2022 edition of the pHealth conference series combines the former organisational schemes towards a hybrid event

in Oslo. The conference marks the conclusion of the ten year period during which Bernd Blobel has served as Chair of the pHealth SPC and the pHealth Steering Committee, and summarises the evolution that has occurred during this time. Consequently, pHealth 2022 focuses on personalised, preventive, predictive, participative precision (P5) medicine and the integration and interoperability between health informatics standards, but also on practical experiences with the deployment of HL7 FHIR. The conference also addresses 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 multilateral benefits of pHealth technologies – including artificial intelligence, learning systems, intelligent robots, etc. – for all stakeholder communities offer enormous potential, not only for the improvement of medical quality and industrial competitiveness, but also for the management of healthcare costs and, last but not least, for improving patient experiences.

The conference is organised under the patronage of the Norwegian University of Science and Technology (NTNU), Gjøvik, and in particular the eHealth and Welfare Security group at the Center for Cyber and Information Security (CCIS) and the Department of Information Security and Communication Technology (IIK), which, together with the Research Council of Norway, also partially funds this event. In addition, the Norwegian Research Center in Oslo provides the venue for the meeting. Following a long-standing tradition, the Working Groups “Electronic Health Records (EHR)”, “Personal Portable Devices (PPD)”, “Security, Safety and Ethics (SSE)”, and “Translational Health Informatics” of the European Federation for Medical Informatics (EFMI) have also been actively involved in the preparation and realisation of the pHealth 2022 event.

This proceedings volume covers 2 Keynote Papers, 10 Invited Papers, 20 Full Papers, and 4 Poster Papers from 113 authors from 23 countries all 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 guaranteed 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.

Neither the pHealth 2022 Conference nor the publication of the pHealth 2022 Proceedings by IOS Press would have been possible without the pecuniary and spiritual supporters and sponsors. These also include the Research Council of Norway and the Center for Cyber and Information Security (CCIS) of the Norwegian University of Science and Technology (NTNU) and the European Federation for Medical Informatics (EFMI) and standards-developing organisations such as HL7 International, ISO/TC215 or CEN/TC251.

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 smooth operation of the conference.

Bernd Blobel, Bian Yang, Mauro Giacomini
(Editors)

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Standards and Principles to Enable Interoperability and Integration of 5P Medicine Ecosystems

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Abstract. Health and social care ecosystems are currently a matter of foundational organizational, methodological and technological paradigm changes towards personalized, preventive, predictive, participative precision (5P) medicine. For designing and implementing such advanced ecosystems, an understanding and correct representation of structure, function and relations of their components is inevitable. To guarantee consistent and conformant processes and outcomes, the specifications and principles must be internationally standardized. Summarizing the first author's Keynotes over the last 15 years of pHealth conferences, the paper discusses concepts, standards and principles of 5P medicine ecosystems including their design and implementation. Furthermore, a guidance to find and to deploy corresponding international standards in practical projects is provided.

Keywords. 5P medicine, ecosystem. System architecture, knowledge representation, knowledge management, modeling, integration, interoperability

Introduction

Health and social care around the globe undergo a transformation into advanced health ecosystems. An ecosystem is a system or network of living and nonliving interconnecting and interacting elements to meet specific objectives. The transformation is bound to fundamental organizational, methodological and technological paradigm changes. Organizationally, the systems move from organization-centered local services through cross-organizational local services, distributed local and remote services to ubiquitous care. Methodologically, they transform health from empirical, phenomenological medicine with one solution fitting all, through evidence-based medicine with domain-specific services for disease-specifically defined groups, person-centered medicine, and personalized medicine, up to 5P medicine. 5P medicine, i.e., personalized, preventive, predictive, participative precision medicine or systems medicine considers the individual

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in its personal, environmental, social, occupational, and behavioral context, thereby deploying life sciences, social sciences, and engineering sciences, but also specialties such as the bunch of omics disciplines and others. The actors' community expands from regulated professionals through regulated and non-regulated professionals up to the inclusion of laymen and technical systems. Interoperability advances thereby from signal sharing through data sharing, information sharing, knowledge sharing at IT-concept level, knowledge sharing at business concept level, knowledge sharing at domain level (cross-domain cooperation), up to skills-based knowledge sharing (moderated end-user collaboration). Such transformation must be supported by appropriate technologies from mobile devices through wearable and implantable sensors and actuators, pervasive sensors, actuators and network connectivity, up to micro, molecular, and quantum level. By combining the advancements in societies, sciences including data sciences, and technologies, health and social care systems are transformed into 5P medicine ecosystems. The outcome of the process enables early identification, proactive intervention and full understanding of the course of disease, i.e., its pathology and its effective treatment. It allows for health service provision everywhere anytime, thereby individualizing the system according to status, context, needs, expectations, wishes, etc., of the subject of health and social care. More details can be found at [1].

Table 1 summarizes the organizational paradigm changes in transformed health and social care ecosystems.

Table 1. Organizational paradigm changes in transformed health and social care

Care Type	Organization, Service Provision	Actors	Services	Target
Phenomenological medicine	Organization-centered - Local services	Regulated professionals	Domain-specific general services – one solution fits all	Humanity
Evidence-based medicine	Organization-centered - Local services	Regulated professionals	Domain-specific, group specific services	Disease-specifically defined group
Person-centered medicine	Cross-organizational - Local services	Regulated professionals	Multiple domains' services	Individual
Personalized medicine	Distributed - Local and remote services	Reg. and non-reg. professionals, laymen, technical systems	Multiple domains' services - Telemedicine	Individual in personal disposition
Systems medicine - 5P Medicine	Distributed cross-domain services, Smart healthcare	Reg. and non-reg. professionals, laymen, technical systems	Cross-domain services - Consumerism, Telemedicine	Individual in personal, environmental, social, occupational. and behavioral context
Ubiquitous personal health	Ubiquitous autonomous and intelligent services	Reg. and non-reg. professionals, laymen, technical systems	Integrated services - Consumerism, Ubiquitous medicine	Individual under comprehensive focus

Table 2 highlights the methodological and technological paradigm changes as well as related requirements for standards in transformed health and social care ecosystems. The column addressing the standardization just focuses on the representation and specification of the real-world business systems. The specification for designing and implementing information and communication technology (ICT) solutions requires of course other standards and specifications, also discussed in this paper.

Table 2. Methodological, technological and standardization paradigm change in transformed health and social care

Care Paradigm	Justification	Way of Practicing	Representation Style	Electronic Comm./ Cooperation	Standards
Phenomenological Medicine	Pattern recognition	Observation	Data	Local data repository; Inside the unit	Data standards
Evidence-Based Medicine	Statistical justification of group-specific treatment outcome	Observation with objective evaluation	Information	Central data repositories	Information standards
Person-Centered Medicine	Process mgmt.; Best medical practice guidelines	Managed care	Agreed terminology, DMP Best Practice Guidelines	Cross-organizational Business Process	Terminology standards; Process standards
Personalized Medicine	Clinically justified individual status and context	Considering the pathology of disease	Disciplinary concepts in situational context	Knowledge management	Domain ontology standards
5P Medicine	Scientifically justified individual status	Understanding the pathology of disease	Multidisciplinary concepts in comprehensive context	Knowledge Space management	Multiple ontologies guided by Top Level Ontologies standards

Table 2 clearly demonstrates that the advancement in health and social care paradigms must be accompanied by related advancements in the standards world. Healthcare transformation must be supported through appropriate technologies. Table 3 presents the objectives of 5P medicine, the requirements for enabling those objectives as well as the methodologies and technologies to realize them [2, 3].

In Section 1, we will provide a comprehensive and scientifically sound representation of 5P medicine ecosystems as well as the standards for defining, modeling and implementing the related system elements.

Table 3. 5P medicine objectives, characteristics and methodologies/technologies to meet objectives (after [2], changed)

Objective	Characteristics	Methodologies/Technologies
Provision of health services everywhere anytime	• Openness • Distribution • Mobility • Pervasiveness • Ubiquity	• Wearable and implantable sensors and actuators • Pervasive sensor, actuator and network connectivity • Embedded intelligence • Context awareness
Individualization of the system according to status, context, needs, expectations, wishes, environments, etc., of the subject of care	• Flexibility • Scalability • Cognition • Affect and Behavior • Autonomy • Adaptability • Self-organization • Subject of care involvement • Subject of care centration	• Personal and environmental data integration and analytics • Service integration • Context awareness • Knowledge integration • Process and decision intelligence • Presentation layer for all actors
Integration of different actors from different disciplines/domains (incl. the participation/empowerment of the subject of care), using their own languages, methodologies, terminologies, ontologies, thereby meeting any behavioral aspects, rules and regulations	• Architectural framework • End-user interoperability • Management and harmonization of multiple domains including policy domains	• Advanced systems architecture • Terminology and ontology management and harmonization • Knowledge harmonization • Language transformation/translation
Usability and acceptability of 5P Medicine solutions	• Preparedness of the individual subject of care - Security, privacy, trust and ethics framework • Consumerization • Subject of care empowerment • Subject of care as manager • Information based assessment and selection of services, service quality and safety as well as trustworthiness • Lifestyle improvement and Ambient Assisted Living (AAL) services	• Tool-based ontology management • Individual terminologies • Individual ontologies • Tool-based enhancement of individual knowledge and skills • Human Centered Design of solutions • User Experience Evaluation • Individual, context-sensitive Privacy Agreements • Trust calculation services

1. Representation of 5P Medicine Ecosystems

To represent 5P medicine ecosystems, all domains involved, specific objectives and contexts, but also all steps in the development process represented as system views must be considered, thereby strictly following the good modeling best practices [4].

P5 medicine requires communication and cooperation of actors from multiple disciplines with specific perspectives, contexts, and objectives, using their special methodologies, languages, knowledge and skills to name and define the business use case concepts and relations for correctly deriving the system requirements. The challenge

of P5 medicine ecosystems is the proper representation, mapping and matching of their domain-specific knowledge at any representation level. The different representation levels or viewpoints range from the real-world business system defined by domain ontologies through the Enterprise View of the ICT system to manage the business process, the Information View and the Computational View representing the semantic interpretation of data to information, and finally the Engineering and Technology Views representing the implementable solution and its maintenance. The last five views are defined using corresponding ICT ontologies. Their according to the Chomski grammar hierarchy more and more constrained representation languages start with domain-specific or natural languages to represent the business system by domain experts. At next level, business process modeling languages like BPML and BPML+, followed by information representation languages such as vocabularies, thesauri, taxonomies, glossaries, data dictionaries, or information models, and finally data representation languages such as data/meta-data definitions, database management system (DBMS) schemes, or programming languages are used. In their data modeling hierarchy, Hoberman et al. [5] call the aforementioned representation levels as very high level, high level, logical level, and physical level, respectively. The corresponding representation of a multi-domain, ontology-based, policy-driven P5 ecosystems using the model and framework of the ISO 23903 Interoperability and Integration Reference Architecture [6], discussed in the next section, is shown in Figure 1.

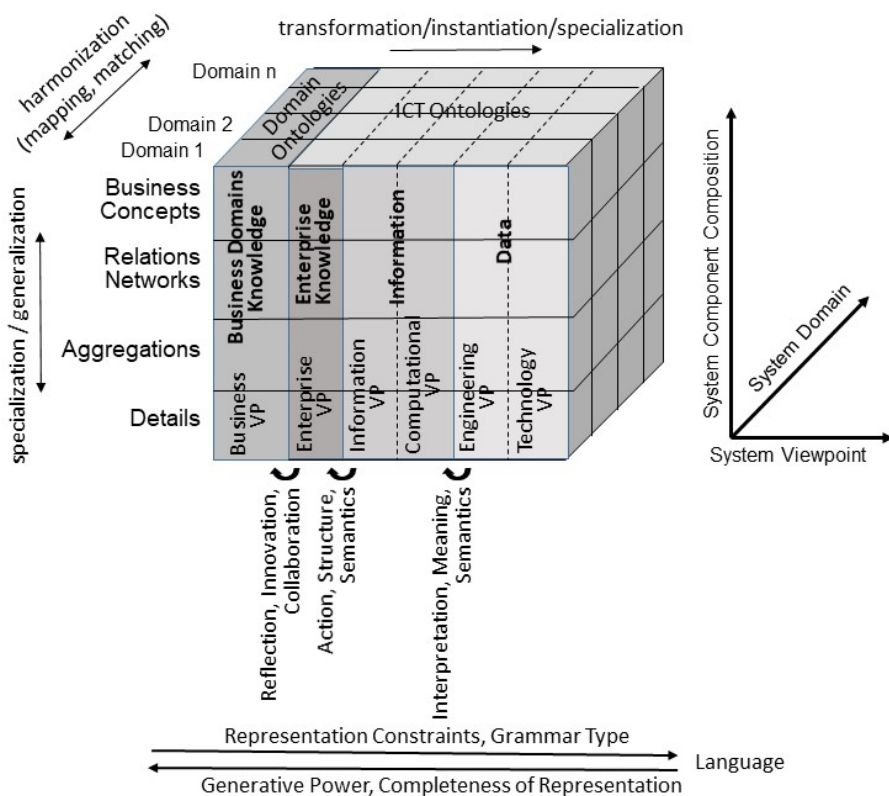


Figure 1. Model and framework for representing multi-domain, knowledge-based, ontology-based, policy-driven ecosystems.

The mapping between elements from different domains or different viewpoints can only be performed at horizontal level, i.e., at the same level of granularity. To get there, components must be specialized or generalized, respectively.

For designing, developing and implementing P5 medicine ecosystems, we must generically model the system architecture and the unified process around. Thereafter, we have to represent formally the domains involved in the use case of the business system considered. Then, we have to represent the different views in the contexts and under the perspectives of the domain experts participating in the business use case. A domain controlling the business system behavior and therefore being relevant across all specific use cases is, e.g., the policy domain, covering legal, administrative, security, privacy and trustworthiness as well as ethical aspects.

For managing organizations to meet their objectives, interests and needs, strategic, operational and tactical aspects must be considered. In that context, related standards and procedures have to be established beside policies to create a strong governance structure. Security and privacy policies addresses the operational needs [7].

Consequently, we need architecture standards, knowledge representation and management standards including ontology standards and terminology standards, policy standards, business process modeling standards, information standards and data standards to model and implement the 5P medicine ecosystem in a compliant and conformant way. Each standards family will be discussed and exemplified in some detail in the next sections.

2. Standards for Modeling 5P Medicine Ecosystems

The solution for designing, managing and implementing the intended ecosystem is a system-theoretical white box, architecture-centric, ontology-based and policy-controlled approach, meanwhile standardized as ISO 23903 Interoperability and Integration Reference Architecture – Model and Framework and re-used by many international Standards Developing Organizations (SDOs) such as ISO, CEN, IEC, IEEE, OMG, but also HL7. Beside the definition of the modeling and system development process, ISO 23903 also covers challenges such as domain-specific knowledge representation and management at epistemological level as well as its harmonization. In that context, it supports ontology development and harmonization, but also the implementation of good modeling best practices.

2.1. Architecture Standards

Regarding the architectural approach, ISO 23903 builds on ISO/IEC/IEEE 42010:2011 Systems and Software Engineering – Architecture Description² [8] and ISO/IEC/IEEE 42020:2019 Software, Systems and Enterprise – Architecture Processes [9]. On that basis, ISO/IEC 10746 Open Distributed Processing [10] has been widely introduced, which is a family of international standards for describing and developing distributed systems and applications. Regarding the system development process, ISO 23903 refers to ISO/IEC 10746 and the Rational Unified Process (RUP) [11]. Another architectural approach, reusing the Reference Model of Open Distributing Processing (RM-ODP) is the HL7

² ISO/IEC/IEEE 42010 is originally based on ANSI/IEEE 1471-2000 Recommended Practice for Architectural Description of Software-Intensive Systems.

Version 3 Development Framework (HDF), advancing the messaging approach HL7 started with.

Almost all architecture standards focus on the ICT perspective and ignore the importance of real-world communication and cooperation between the domain experts, which is however crucial for all ecosystems and especially for the 5P medicine ecosystems. ISO 23903 extended the aforementioned standards by the business view represented by domain experts. Contrary to those standards, ISO 23903 introduced a three-dimensional model with the additional domain perspective dimension to represent multiple domains involved in the ecosystem's specific use cases and with the component composition dimension, thereby re-using the OMG Model Driven Architecture hierarchy [12]. The latter starts with the computation independent model (CIM) or requirement model defining the system in its environment. CIM is transformed into the platform independent model (PIM) or analysis and design model defining the system's architecture. PIM is then transformed into the platform specific model (PSM) or realization model defining how the system is built. At the end, the code of the system and configuration artifacts is generated [13]. An overview on architecture standards and approaches including their relations to ISO 23903 is provided in [14]. Table 4 compares those data model levels as well as the dimensions of modeling with the model and framework of ISO 23903 and ISO/IEC 10746.

Table 4. Comparing Data Model Levels and Dimensions of Modeling with ISO 23903 and ISO 10746

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

2.2. Knowledge Representation and Knowledge Management Standards

Regarding the business system representation from the perspective and context of the domain experts involved by formally representing their knowledge, we deploy the related domain ontologies. An ontology provides an explicit specification of a conceptualization [15]. It is a collection of terms, relational expressions and associated natural-language definitions in combination with formal theories [16] to represent that knowledge.

Medical/clinical domain terminologies and ontologies for 5P medicine ecosystems are, e.g., the Unified Medical Language System (UMLS) [17], the SNOMED International products Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and Systematized Nomenclature of Medicine Clinical Term Ontology (SCTO) [18], ISO 25720 Genomic Sequence Variation Markup Language [19], Human Phenotype Ontology (HPO) [20], Infectious Diseases Ontology (IDO) [21], Epilepsy and Seizures Ontology (EPSO) [22], Alzheimer’s Disease Ontology (ADO) [23], or the Gene Ontology (GO) [24].

2.3. The Policy Domain

A policy defines a set of legal, regulatory, ethical, and contextual requirements and obligations for communication and cooperation including privacy and trustworthiness. That way controlling the intended behavior of business systems, a policy domain representing policy knowledge, concepts and relations is crucial for defining, designing and running any type of ecosystems. Using the ISO 23903 model and framework, Figure 2 demonstrates the specialization of the policy domain into the sub-policy domains relevant for P5 medicine ecosystems. The user policy domain – sometimes also called personal policy domain or individual’s policy domains – represents the intentions, expectations, wishes, etc., of the individual engaged in the business case such as a patient.

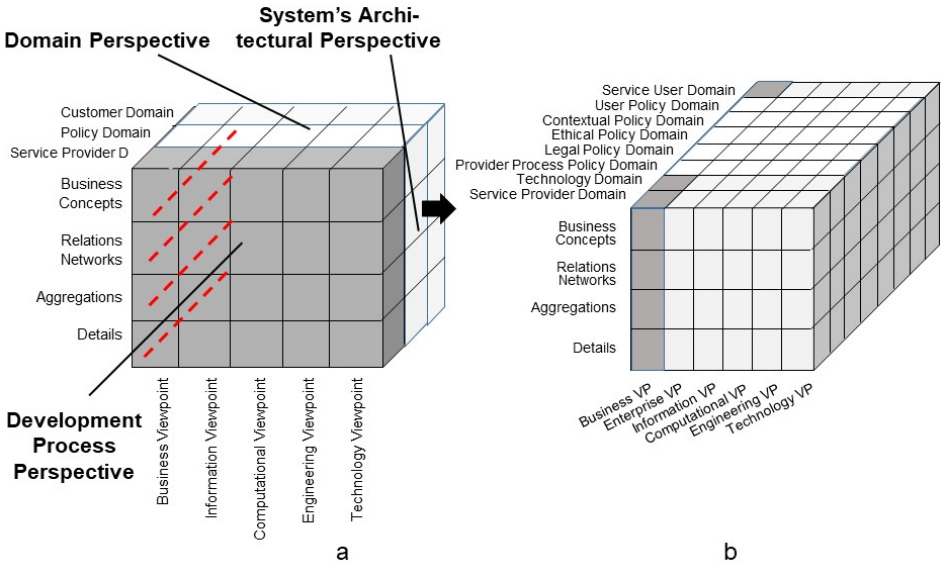


Figure 2. Specialization of the policy domain into sub-policy domains relevant for P5 medicine ecosystems (after [25], changed)

An example for a provider process policy domain instance are best practice clinical guidelines. All sub-policy domains must be represented using related ontologies.

Based on the Ponder Language specification [26], a policy ontology to formalize the rules and constraints controlling the behavior of a business system has been provided by ISO 22600 [27], instantiated for the security and privacy domain (Figure 3).

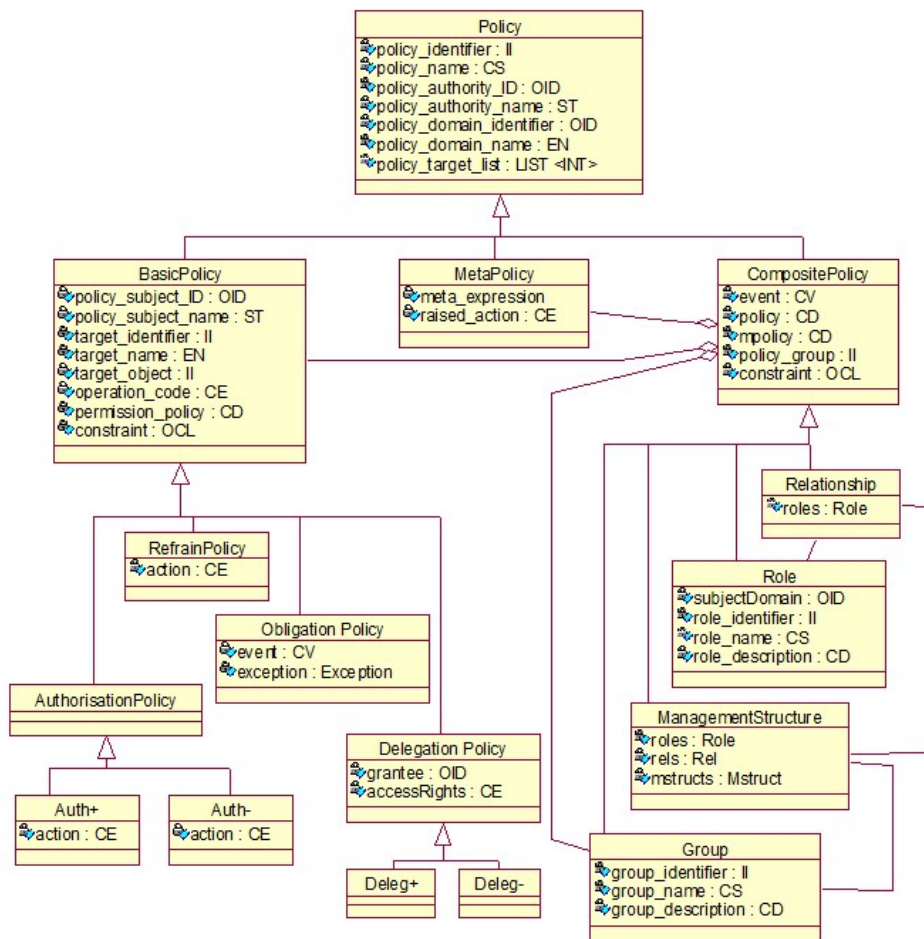


Figure 3. Policy domain components according to ISO 22600-2 [27]

The integration of that policy ontology in an ecosystem for managing security and privacy, using ISO 23903, has been performed in the HL7 Privacy and Security Logical Data Model, Release 1, June 2021 [28] (Figure 4).

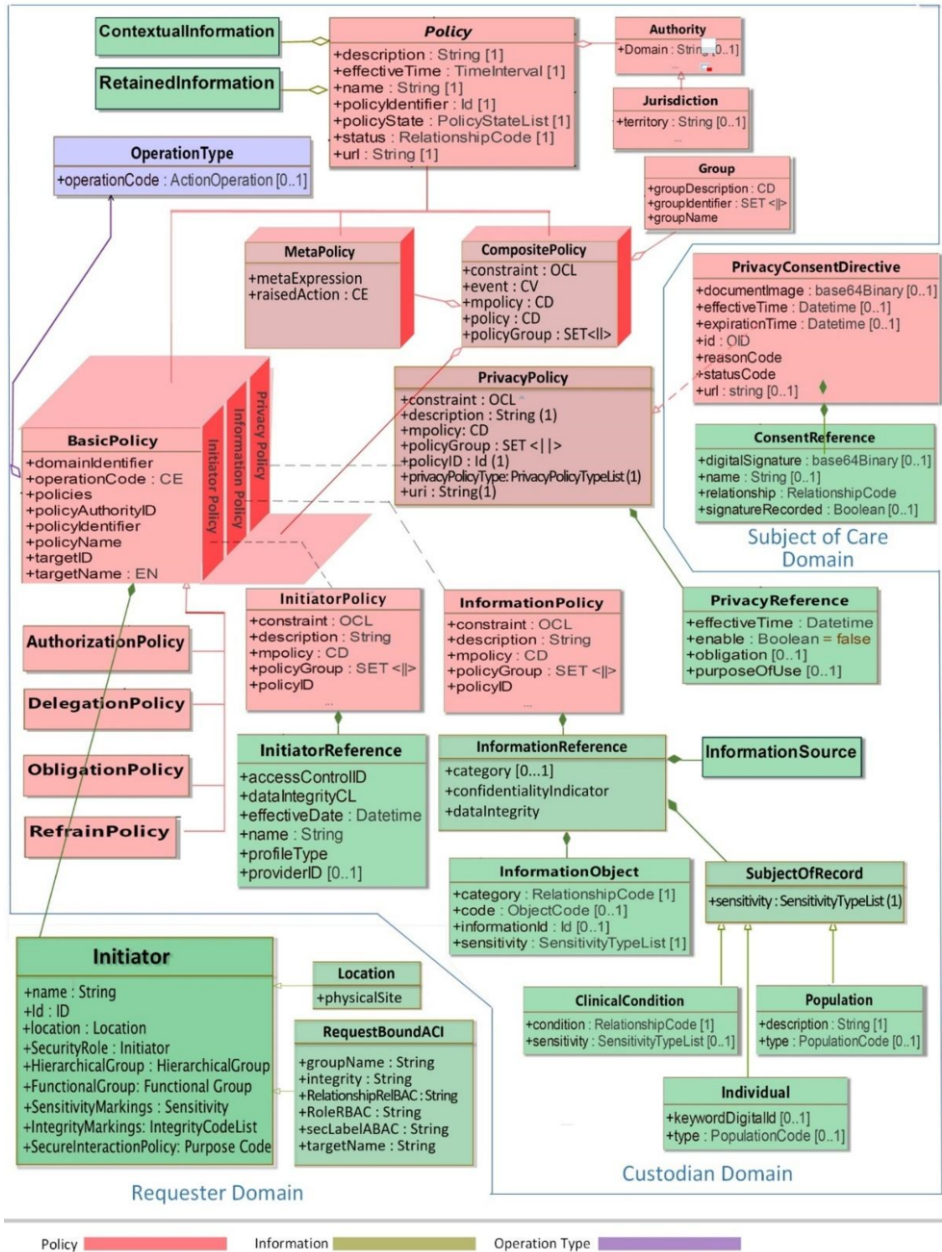


Figure 4. HL7 Privacy and Security Logical Data Model, Release 1, June 2021 [28]

The integration of ethical and trust aspects of autonomous and intelligent 5P medicine ecosystems has been developed at IEEE with a first global ontological standard for ethically driven robotics and automation systems (ERAS) [29].

For mapping and matching different ontologies to enable cross-domain communication and collaboration, the ontologies have to be represented or re-

engineered, respectively, as formal entities including their contexts, constraints and relationships by using attributes and relations according to ISO/IEC 21838:2021 Information Technology – Top Level Ontologies [16] (Figure 5).

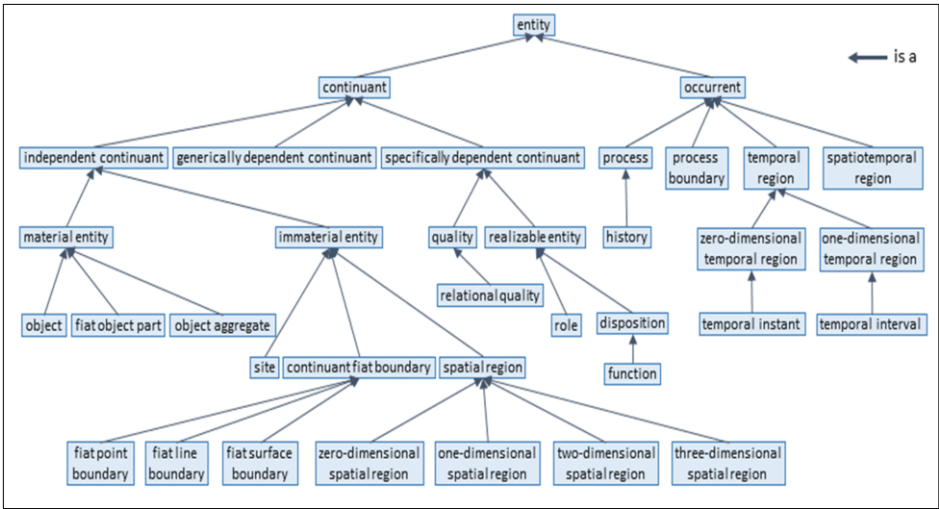


Figure 5. Basic Formal Ontology (BFO) is-a Hierarchy (after ISO/IEC 21838:2020) [16]

3. A Short Overview on Standards Classes and Related Specifications

Following, we present for the standards classes Architecture standards, Modeling standards, Terminology and ontology standards, Communication standards, Policy, security and privacy standards, Safety standards, and Identifier and identification standards some international specifications relevant in the context of P5 medicine ecosystems. Of course, the presented standards type and examples list is not intended to be complete.

Table 5. Standards Classifications and Related International Standards Examples

Standards Classification	Examples
Architecture standards	HL7 versions 2.x/3, OMG CORBA, OMG MDA, ISO 12967 Health informatics – Service architecture (HISA), ISO 7498-2:1989, Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture, ISO 13407:1999 Human-centred design processes for interactive systems
Modelling standards	OMG Unified Modeling Language (UML), ISO/IEC 19505-2:2012 Unified Modeling Language (UML), CEN 15300 CEN Report: Framework for formal modelling of healthcare security policies
Terminology and ontology standards	UMLS, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), Systematized Nomenclature of Medicine Clinical Term Ontology (SCTO), ISO 25720 Genomic sequence variation markup language, ISO/IEC 2382-8:1998 Information technology — Vocabulary — Part 8: Security, CEN-ENV 13608-1:2000 Health informatics — Security for healthcare communication — Part 1: Concepts and terminology, ISO 13940:2015 Health informatics — System of concepts to support continuity of care

Communication standards	HL7 v2.x/3, X12 EDI, UN EDIFACT, Odette FTP, CEN 13606 Electronic healthcare record communication, ISO/ IEEE 11073 Health informatics -- Point-of-care medical device communication, ISO 17113 Health informatics – Exchange of information between healthcare information systems – Development of messages, CDISC and DICOM specifications
Policy, security and privacy standards	ISO/IEC 2700 Information security management, ISO 22600:2014 Health informatics – Privilege management and access control, ISO 17090 Public key infrastructure, ETSI TS 101733 Electronic Signature Formats, ASTM E1987-98 Standard guide for individual rights regarding health information, CEN 13608 Security for healthcare communication, CEN 13729 Secure user identification - Strong authentication using microprocessor cards, ISO 25237:2017 Health informatics — Pseudonymization, ISO/IEC PDS Pseudonymisation Practices for the Protection of Personal Health Information and Health Related Services, ISO/IEC 27018:2019 Information technology — Security techniques — Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors, ISO/IEC 29151:2017 Information technology — Security techniques — Code of practice for personally identifiable information protection, ISO 21298:2017 Health informatics – Functional and structural roles, ISO/IEC 9594-8:2008, Information technology — Open Systems Interconnection — The Directory: Public-key and attribute certificate frameworks, ISO/IEC 9798-3:1998, Information technology — Security techniques — Entity authentication — Part 3: Mechanisms using digital signature techniques, ISO/IEC 10181-1:1996, Information technology — Open Systems Interconnection — Security frameworks for open systems: Overview, ISO/TS 17090-1:2013 Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services, ENV 13729:1999, Health informatics — Secure user identification for healthcare strong authentication using microprocessor cards, ISO 21091:2013 Health informatics — Directory services for healthcare providers, subjects of care and other entities, ISO/IEC 15408-1:2009 Information technology — Security techniques — Evaluation criteria for IT security — Part 1: Introduction and general model
Identifier and identification standards	LOINC, ASTM E1714-00 Standard guide for properties of a Universal Healthcare Identifier
Safety standards	CEN 13694 CEN Report: Safety and security related software quality standards for healthcare, ISO/DTS 25238 Classification of Safety Risks

4. Managing the Modeling and Development Process of 5P Medicine Ecosystems

4.1. Representation of 5P Medicine Ecosystems through Standards

When modeling and developing 5P medicine ecosystems, we have first to solve the mapping between the involved domains represented by domain ontologies to correctly and formally represent the considered multi-disciplinary business system use case. Thereafter, we have to perform the transformation into the ICT-specific views from the enterprise viewpoint down to the engineering viewpoint representing the implementable artifacts. Thereby, we have to deploy the related ICT ontologies from business process modeling through information modeling up to data modeling domain. While this process including the representation styles is clearly specified for the ICT domain perspective by using ISO/IEC 10746 Open Distributed Processing [10] and related specifications, the ontologies and representation styles in health informatics may be healthcare-specific and changing over the time. Healthcare-specific standards for representing domain-specific

business views are, e.g., the HL7 Domain Analysis Models or the ISO or CEN Health Informatics Functional Models (FM) or Services Functional Models (SFM). An example for the first group is the HL7 Composite Security and Privacy Domain Analysis Model (CSP-DAM), meanwhile replaced by the aforementioned HL7 Privacy and Security Logical Data Model, R1. Examples for the latter group are the HL7 EHR-System Functional Model, R2 (HL7 EHR-S FM), the HL7 PHR-System Functional Model, R2 (HL7 PHR-S FM), or the HL7 Service Functional Models like the HL7 Common Terminology Services 2 Functional Model or the HL7 Version 3 Standard Identification Service R1. Also, ISO 13940 System of Concepts to Support Continuity of Care [30] must be mentioned here. A newer example for representing health enterprise view components are clinical information models according to ISO 139722 Clinical Information Models [31] or the openEHR [32] and ISO 13606 Electronic Health Record Communication [33, 34] archetypes. Thereby, also some aspects of the business view as well as the informational representation (information view) are covered. Standards for healthcare-specific information view representations have been established in the HL7 Clinical Document Architecture (HL7 CDA) series [35]. Computational view representation examples are HL7 Implementable Technology Specifications (ITS), but also the meanwhile globally pushed HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) [36]. Figures 6 and 7 represent the different standards and representation styles in the ISO 23903 Interoperability and Integration Reference Architecture model and framework. Regarding FHIR, starting as implementable resource as expressed in Figure 7, 5 levels are meanwhile supported. The highest Level 5 covers knowledge-related aspects such as clinical reasoning, Level 4 process-related aspects, Level 3 semantic interpretations, Level 2 service implementations, and Level 1 technical representations.

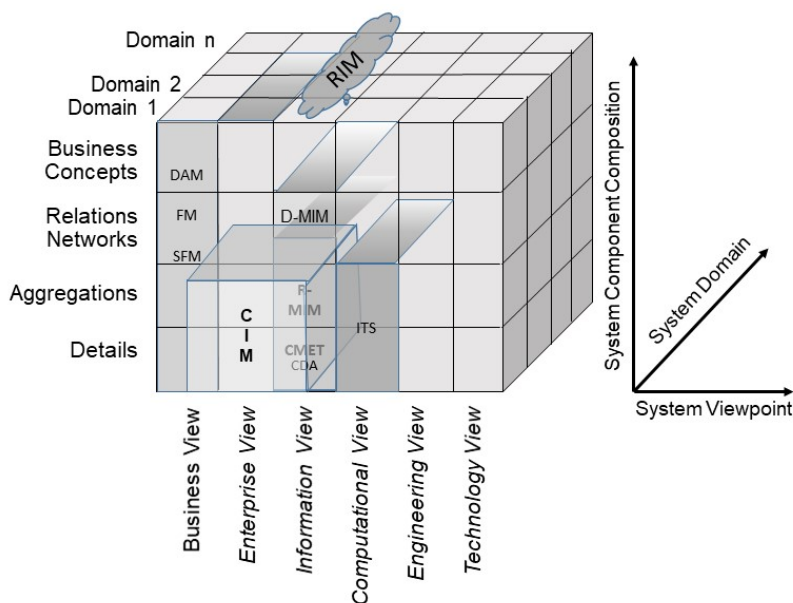


Figure 6. Healthcare-specific representations for different ISO 23903 views

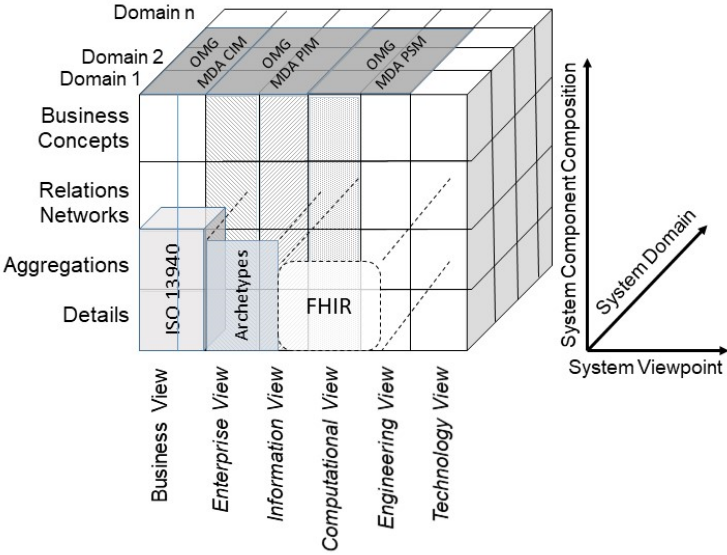


Figure 7. Healthcare-specific representations for different ISO 23903 views

4.2. Integrating Existing Standards in 5P Medicine Ecosystems

After discussing in some detail modeling and development of 5P medicine ecosystems, we will now address the challenge of mapping/matching or integrating existing specifications and artifacts using the model and framework of the ISO 23903 Interoperability an Integration Reference Architecture. For meeting this challenge, we have to understand perspectives, objectives, concepts, contexts, etc., the designer and developer of the component had in mind. Without that knowledge, any integration, mapping, or matching is not decidable. Therefore, we must re-engineer that missing knowledge. As the aforementioned conditions might change from use case to use case, the provided interoperability and integration outcome is specific for the considered use case or related classes of use cases, and the procedure has to be performed again for any new settings and contexts.

In the first step, components in question must be correctly placed into the ISO 23903 model regarding the domain, the granularity level and the represented development process viewpoint. Thereafter, the concepts represented by the considered components must be formally modeled in the business view using the corresponding domain ontologies as well as top-level ontologies for interrelating them. The concepts must be completed to correctly and operationally represent the real-world business system and business processes for the use case to be enabled or supported. The resulting business system representation must then be transformed into the views according to the development process up to the considered components' view. This includes a re-engineering of the components and relationships, i.e., classes, attributes, operations and relations needed to represent the full business use case must be added or modified. Figure 8 represents the described procedure.

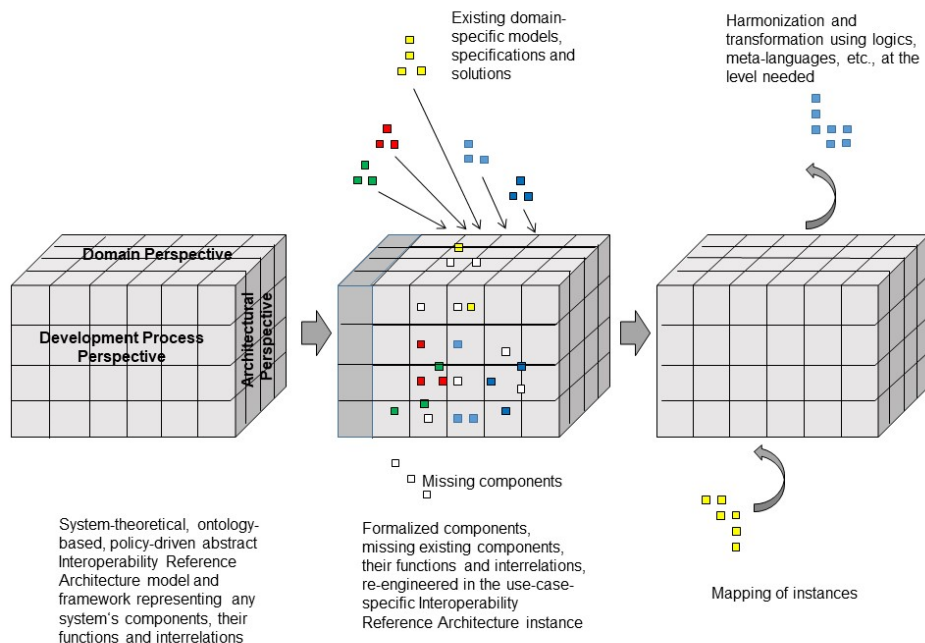


Figure 8. Integration of standards and specifications using the ISO 23903 Reference Architecture model and framework.

5. Discussion

Building on many years of work in health care with responsibilities for designing, implementing and using related information systems including necessary infrastructure services for interoperability, security, privacy, etc., but also for advancing health with telemedicine, pHealth and eHealth, the paper presents a model and framework for comprehensively and consistently representing and managing 5P medicine ecosystems using ISO 23903. The Generic Component Model (GCM), setting the basis for the approach dates from the early nineties of the last century and has successfully evolved over the time. Meanwhile, the Health Informatics TCs of ISO and CEN mandated the use of ISO 23903 for any project covering multiple aspects or domains, acknowledging the limitation of the data focus for specifying ecosystems. The described limitations of constraint representation language results in the need to advance from data sharing interoperability to knowledge sharing interoperability in dynamic and complex intercultural, interdisciplinary and inter-jurisdictional environments. By the way, this was the driving factor for replacing the EU Data Protection Directive [37] by the EU General Data Protection Regulation (GDPR) [38], i.e., advancing from a privacy-related data classification towards the detailed consideration of processes and contexts of creating, collecting, using, and sharing personally identifiable information (PII) [39]. Projects such as the European Health Data Space [40] are therefore more than questionable (see e.g. [3]). The nature of 5P medicine requires a concept- and context-based approach also for issues such as accompanying privacy and ethical aspects.

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A Socio-Technical Regime Transitions Model for Gerontechnology Service Design: Privacy, Information Security and Cyber Security in Focus

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Abstract. In this paper, we present on ongoing research to use a socio-technical privacy, information security and cybersecurity model to support the design, development and delivery processes of health care services for aging in place. The current research in gerontechnological services development is reviewed, and experiences from the use of serious games to evaluate the model are outlined.

Keywords: Socio-technical, Gerontechnology, Aging in Place

Introduction

The purpose of this paper is to outline a socio-technical privacy, information security and cyber security system (ST-PICS) modeling approach to support gerontechnological service design, that aligns with a proactive health care strategy of “aging or living” in place. The model attempts to go back to the origins of socio-technical systems analysis and design practices which starts by examining the work systems as a first step [1]. Starting with the primary work system, the next step is to examine the organizational structure and then the macrosocial systems or domains [2].

Even though the socio-technical systems analysis approach starts by analyzing the work systems, it often starts by framing the problem from a macrosocial perspective first. At the macrosocial systems level, the United Nations has declared an aging population as a global problem and the decade from 2021/2030 the decade of Health Aging [3]. Even though the United Nations points out that “No single discipline, perspective or method will achieve these goals”, Kolkowska et al. points out socio-technical issues are often ignored [4], and there is a strong technological determinism bias in current research efforts to deal with the health aging problem.

This paper is divided into 4 sections. After the introduction we outline terminology and concepts used to identify and frame the problem of health aging as a socio-technical regime transition issue. In this section we also briefly contextualize this paper as being part of a 4-year doctoral research project in applied socio-technical modeling, measuring, and managing of cyber crisis and cyber crisis prevention for the “civilian” sector in

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Norway. In the third part of the paper, we review some of the current research on applying socio-technical thinking and readiness measuring and modeling to manage socio-technical regimes. In the final section of the paper, we outline a preliminary research agenda for testing socio-technical readiness assessment tools with hybrid cyber range megagame called CS-Technopoly.

1. Framing the Aging Issue: Terms and Concepts

Gerontechnology is a combination of the two English words; gerontology and technology. Gerontology which can be defined as the study of physical and mental aspects of aging, as well as the social and societal implications of aging [5]. Technology has many definitions that have changed over time from being defined as “the useful art” to the use of science in industry [6]. Currently most gerontechnological research focus seems to be technological deterministic in nature and to a large extent are designed to support what Estes referred to as the “The Age Enterprises” which she defines as the

“Congeries of programs, organizations, bureaucracies, interest groups, trade associations, providers industries and professional that serve the aged in America.”[7]

This technological deterministic marketplace frames “old age” as “the problem” and uses the rhetoric of management by crisis to ignore key issues, which Kenner outlines as “the inadequacy of the social systems as structural inequalities and power asymmetries reproduced by the commodification and biomedicalization of aging become quite visible when elderly care becomes an elderly crisis.” [8]

There are those who acknowledge that gerontechnology approach is limiting and propose a new area of Socio-Gerontechnology [9]. However, it is the position of the authors that the current socio-technical “Age Enterprise” regime system model promotes technological determinism reactively and does not facilitate adequate socio-technical agency in the marketplace, in order provide sustainable products and services that meet all the stakeholder’s needs, wants and desires.

There are several different socio-technical models and methods, and tools used to understand, explain, prevent, and even predict, events, incidents, and crises in socio-technical systems. Clegg et al. have proposed the PreMiSTS method to predict and prevent malfunctions in socio-technical systems (PreMiSTS) [10]. Al Sabbagh has proposed an STS framework to design a cyber security warning system and to perform threat analysis of software supply chains [11]. A.L. Cassano-Pichea used the Rasmussen risk management framework and the AcciMap tool to do an ex-post analysis of seven predictions regarding the bovine spongiform encephalopathy (BSE) epidemic [12]. As part of her 4-year doctoral research program, Østby is developing within a hybrid cyber range platform a socio-technical cyber security readiness assessment tool to support training and education of civilian organization to prevention and proactively manage cyber security crises that can occur with the introduction of digital technology into civil (non-military) societal services and products. This readiness assessment tool was designed using several different socio-technical models [13, 14].

In the gerontechnology research community, several “assessment templates” and tools have been proposed in general to assess customers and users. But as Cozza et al. points out

"This nuanced uniformity is confirmed by the absence of explicit controversies between actors. Almost all the constructions see a trajectory of progress in which technology benefits all actors involved, and there is a general agreement in associating future ageing with an ever-increasing consumption of technology. In this sense, consumeristic ageing as well as technology-integrated ageing are the most explicit constructions. Positive effects of technology are projected both on caregivers – since it is expected that welfare technology reduces their working overload and time pressure – and, thus, on public sector organizations that are entitled to assess (i.e., civic ageing) and standardize (i.e., normalized ageing) welfare technology." [15]

This view, in combination with the notion of complex jobs, needs simple organizations as outlined by Walker et al. [16].

"Henceforth, we will use the concept welfare technology to refer to technologies which are usually clustered according to supportive, responsive, or preventive functions (Beech & Roberts, 2008). Supportive technologies help individuals to perform tasks that they may find difficult to perform on their own (e.g., medicine reminder/dispenser). Responsive technologies, based on detection and reaction, help individuals to manage risks and raise alarms (e.g., personal emergency alarms). Preventive technologies based on prediction and intervention mitigate dangerous situations and raise alarm (e.g., key systems for home nursing)."

These views direct systems researchers' attention to what people do with technology in their everyday practices, and how such use is structured by the rules and resources implicated in their work, rather than trying to understand why and how a given technology is more or less likely to be appropriated in various circumstances. These practical views focus on knowledgeable human actions. It makes the systems researcher focus on how recurrent engagements with a given technology constitutes and reconstitutes emergent structures of using the technology (technologies-in-practice). Thus, the research orientation is inverted — from a focus on given technologies, embodied structures, and their influence on the worker — to a focus on human agency and the enactment of emergent structures in the use of technologies.

2. Review of Current Research

As presented by Vasunilashorn et al. in [17], there has been an increase of academic literature (research) about aging in place over the last years (especially from 2000 – 2010). The mentioned literature, however, contain "a variety of topics pertaining to aging in place, ranging from housing and environment to health and technology" [17]. More recent systematic literature review on aging in place and quality of life [18] also reveals that assessment on quality of life is seldom performed, and that there is no consensus on definitions or domains structures. Additionally, an overview of systematic reviews of home care vs alternative locations of care [19] found "that home interventions that promote elder health and independence might be effective in helping elders age at home". They were however not able to make recommendations on alternative locations of care.

By using The Quality of Life Group of the World Health Organization's (WHOQLG) definition of quality of life as "individual's perception of his or her position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards and concerns" [20], Vanleerberghe et. al [18] suggests that

“Quality of life instruments for older people must be developed bottom up, with respect of the values and standards of the individuals of the population of our focus”. This bottom up-suggestion is aligned with the early motivation of socio-technical research [21], to improve industry-workers stationary and repetitive job situation.

However, gerontechnology as described in the introduction has previously focused on “ready-made” technologies driven by tech-companies “meeting” the problems of the increasing number of elderlies in society [22] which not necessary are in line with the elderlies’ expectations, standards and concerns. Thereby, “do-it-yourself” technologies have emerged, and elderlies see these as valuable alternatives, and purchase these from gerontechnology showrooms [22]. This can lead to troubles for the care-taker organizations and other care-takers to uphold knowledge and system-security and privacy requirements for all equipment involved [23], and to uphold check-lists [24]–[26] that follow agreed standards. These check-list assessments are so unique that no template fits all needs, so they create their own by collecting as much data as they can and populate it into a sample report which looks different depending on the focus of the modifications.

These issues can be referred to as technological determinism as initiated by Veblen [27]. The socio-technical approach, however, would not exactly have a top-down approach needed to meet the challenges but more of an holistic approach which means that technology, should not be the dominating factor when new work systems are developed [21]. In the terms of aging in place and gerontechnology, we suggest that all parties should be involved in discussions on what to implement and how. This may be referred to as a social constructivism approach [28], which is working in projects to discuss and determine decisions appropriate to meet all involved stakeholders’ needs, wants and desires. Often such initiatives have had the construct of a “paneling-board” which has a top-down assessment approach that is not appreciated by the elderlies and their next of kin. In this paper, we therefore suggest a combined bottom-up/top-down approach in a socio-technical escalation and de-escalation framework to meet the challenges.

Recent socio-technical research and studies [14, 29, 30] present escalation maturity models to assess the maturity of information security in organizations. These assessments are based on the ISACA framework [31], and the questions are modified for information security escalation risk assessment and treatment [32]. The escalation maturity model is presented in Figure 1.

Attribute Level	1 Awareness	2 Responsibility	3 Reporting	4 Policies and standards	5 Knowledge and education	6 Procedures and tools
0 Non-existent						
1 Initial						
2 Repeatable						
3 Defined						
4 Managed						
5 Optimized						

Figure 1. Escalation maturity model [29]

We suggest that this model can be used in to model the aging in place issue, including management, formal and informal caregivers and the elderlies themselves. Additionally,

a modified version of Wahlgren & Kowalski’s [33] escalation management model would work as a continuous risk assessment and risk treatment model in collaboration with the different stakeholders. The escalation management model is presented in Figure 2.

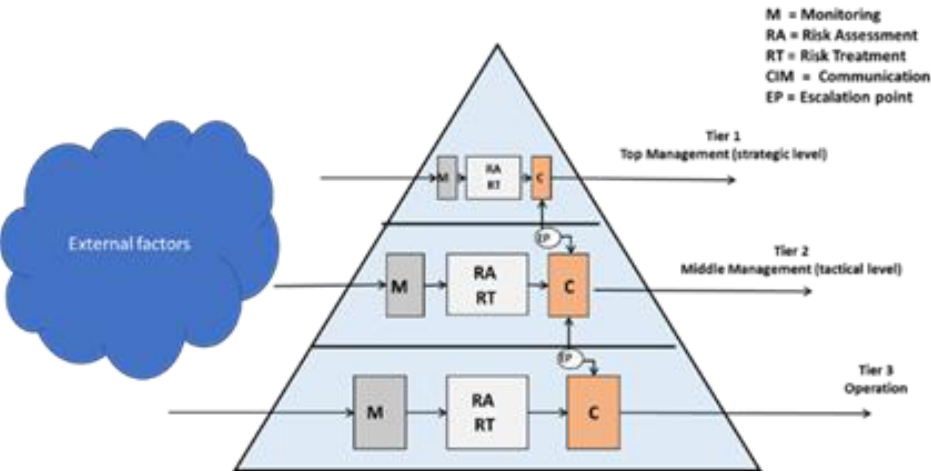


Figure 2. Escalation management model [33]

We suggest that the risk treatment as presented in Figure 2 is one of the core methods to meet the growing need for combining top-down and bottom-up approach in aging in place. Colnar et al. [34] suggests a risk mitigation model to meet the information security challenges in gerontechnology. The model is used to consider new appropriate risk mitigation measures in an appropriate time. In Østby et. al [14], a socio-technical maturity improvement process was suggested to enhance Colnar’s risk mitigation model. This process is presented in Figure 3.



Figure 3. Maturity improvement – a socio-technical lesson learned approach [14]

We suggest that the risk treatment process in gerontechnology would have to be implemented in a similar process, to mitigate risk at various steps of quality-of-life standards due to individual’s aging process. This can also be supported by risk matrixes [35], at the individual level, but also with other stakeholders who are involved in the delivery of care services.

The communication as presented in Figure 2 between the different aging in place stakeholders is important to meet the challenges. In a recent study, Nurgalieva et al. [36] have explored communication practices that tailor presentation of information to

improve the risk assessment of an elderly person fall injuries at home. This form of information sharing is comparable to crisis management escalation communication in SIEMS systems [37] and crisis management systems. We propose to transfer SIEMS and CIMS systems to support aging in place stakeholder communication.

In such communication-frameworks, organizational semiotics must be considered. Turoff et al. [38] present a dynamic emergency response management information system to improve information flow. However, as this is more a top-down approach, socio-technical semiotics as presented by Piccolo et al. [39] is better for considering information flow in the necessary communication. Many different stakeholders are involved, and a common set of semiotics is needed for the information flow to be effective and efficient. This can be managed by a social constructivist approach of FRISCO as presented in [40].

The doctoral research agenda is targeting societal structures and systems which should not exclude the societal implications of aging in place. The funding that would be necessary to integrate these two processes can come from national authorities (taxes) or from private initiatives. In a survey of program leaders representing 69 villages and 62 NORC programs in 2012, “key differences were found in the means through which villages vs NORC programs seek to achieve these aims (aging in place), as well as the populations likely to benefit from their efforts” [41]. Martens [42] conducted a similar analytical study of the Norwegian society. The study outlined funding responsibilities and presented how difficult it is to measure national and communal responsibilities for aging in place improvements.

“The Norwegian national government states that housing is an individual responsibility [25, p.7]. As many people as possible should live in their own homes and receive necessary home-care services there, and as many as possible should live in ordinary housing in ordinary surroundings with the possibility of living independent and active lives [41]. In the municipalities, the allocation of responsibility for housing is less explicit: Only 1 in 10 care plans and 3 in 10 housing plans state that housing is an individual responsibility. Among the municipalities that make this statement, several express the responsibility in very vague terms. This difference in how individual responsibility is emphasized can lead to different approaches to aging in place policies.” [42]

Socio-technical theories, however, suggest that socio-technical analysis should be done on each layer in society [28]. This theory could be an extension of the suggested escalation/de-escalation model. This would enable us to model who should be accountable for funding and improving aging in place. We consider dynamic socio-technical approaches like Leavitt [43], Kowalski [44] and Davis [45] as the foundation for socio-technical considerations for each stakeholder involved. The Kowalski model, which includes typical stakeholders, is presented in Figure 4.

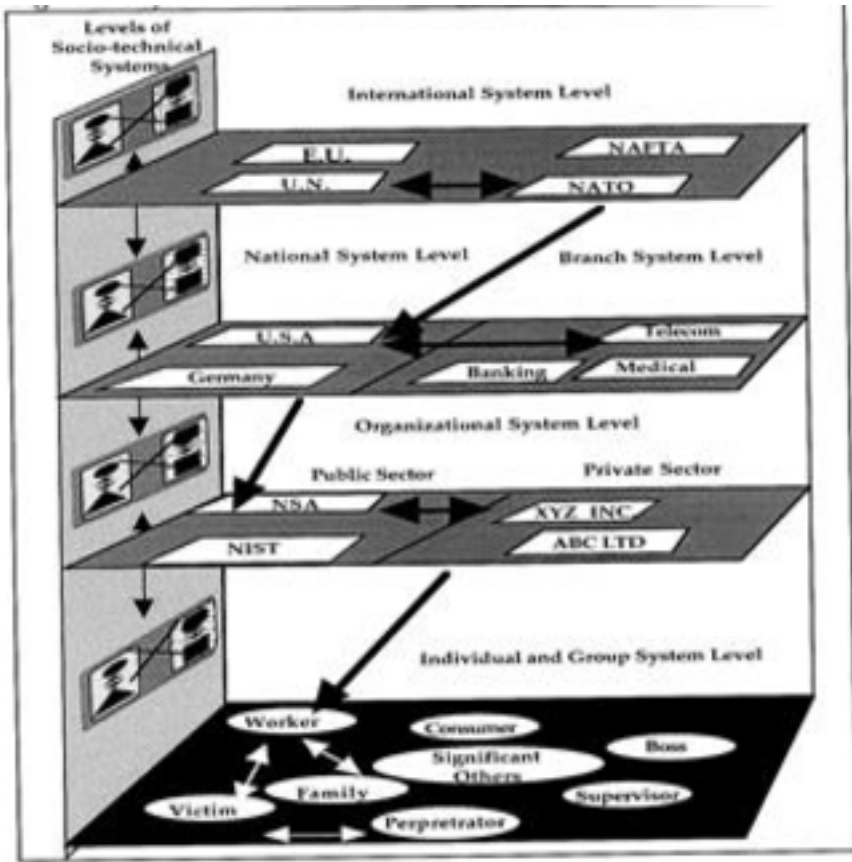


Figure 4. System of Socio-technical Systems [42]

To measure the societal readiness, one may use readiness-levels as presented by the Innovation fund in Denmark [46] in combination with risk management [47]. In other words, combining the level of readiness with the level of risk to outline socio-technical measures to improve aging in place for the system in focus [14].

3. On-Going and Future Research

To push for a more social constructivist approach and move away from a gerontechnological service design process that is less technological deterministic, we are developing and testing different serious games and exercises in the Norwegian Cyber Range. In these serious games and exercises, different stakeholders can play different roles based on specific experiences and experiment with discussions and negotiations [48] of how to move from one socio-technical regime to a new one.

For a classroom exercise, we extended the work done on socio-technical transitions canvases by Van Risjnsoever and Leendertse [49] and integrated it with the Kowalski security model [44]. In this exercise, we have information security master students performing a socio-technical analysis of a brain computer interface patent BCI [50] for

a long-term care facility that wants to use these interfaces to support health care delivery to their residents [51]. The students are tasked to identify socio-technical gaps in the systems and then required to debate if the brain computer interface health benefits outweigh privacy, information security and cybersecurity risk that this new brain computer interface creates. In the debate, the students are assigned different roles where one group of students represents long care facility service provider who is suggesting the introduction of the brain computer interface device to improve care, and the other the residents' council in the long care facility who is against the introduction of the brain computer interface device. Preliminary data collected from students on similar exercises [52] has shown favorable results. However, more longitudinal data is needed to evaluate the learning outcomes.

Megagames have been used in the health care sector to support stakeholders in their discussions on complex issues in health care service delivery [53]. We are currently developing and have beta-tested a megagame called CS-Technopoly [54]. The megagame is designed to model cybersecurity in society from a socio-technical perspective in general and will include the possibility to simulate and gamify the issue of aging in place so that stakeholders can have the opportunity to practice the negotiation of gerontechnology service design.

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Invited Papers

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Obstacles of eHealth Capacity Building and Innovation Promotion Initiative in African Countries

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Abstract. eHealth applications and tools have the potential to improve coordination, knowledge, and information sharing between health professionals as well as continuity of care. One of the main obstacles hindering its full integration and use, particularly in the healthcare sector in developing and low and middle-income countries is the lack of qualified staff and healthcare personnel. To explore obstacles that hinder capacity and innovation promotion initiatives, a survey was conducted among BETTEReHEALTH partners. A questionnaire was used to collect quantitative data from 37 organizations. Although there are different buckets of capacity-building and innovation promotion activities going on, the findings showed very few targeting policymakers and eHealth specialists. The findings found that obstacles to capacity building and innovation promotion include lack of finance, poor infrastructure, poor leadership, and governance, and these obstacles are context or region specific. Findings from our study concur with those from previous research on the need to identify practical solutions and simple interventions to address eHealth obstacles to capacity building in developing countries. As measures to mitigate these obstacles, our study proposed the need for adequate policies, strong political commitment, the development of academic modules to be integrated into existing educational programs, and the creation of more in-country and on-site capacity-building activities. While this study contributes to the discourse on eHealth capacity-building and innovation promotion initiatives among healthcare and public health professionals, the study has a limitation as data was collected only from BETTEReHEALTH partners.

Keywords. eHealth, ICTs, capacity building and innovation activities, BETTEReHEALTH

1. Introduction

The United Nations (UN) report on "global perspective human stories" reported that about half of the world's population does not have essential health services [1]. At the same time, more than 800 million people spend at least 10% of their household budgets on healthcare expenses. This forces people into financial hardship as many survive on only \$1.90 a day [2]. For example, many people are at risk of health conditions but have limited access to health services [3]. At the fifty-eight World Health Assembly (WHA), the Director-General (DG) of WHO challenged for those reasons developing countries

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to unlock the potential of eHealth, by integrating these tools and applications in the healthcare sector [2]. That way, they can improve access to and quality of health, which in turn supports the achievement of health-related United Nations Sustainable Development Goals (SDGs) [3]; otherwise, a third of the world's population will be underserved by 2030 [4].

eHealth is a common term that refers to “health services and information delivered or enhanced through the internet and related technologies” [5]. It refers to the use of digital technologies including information communication technologies (ICTs) and data to support and deliver health and healthcare [6], services provided by eHealth include physical and psychological diagnosis and treatment, telepathology, vital signs monitoring, electronic prescribing, and teleconsultation [7]. According to the World Health Organization (WHO), integrating eHealth services make healthcare delivery cost-effective and the use of ICTs to deliver healthcare services led to better healthcare [3]. In the past decades, eHealth tools and applications have emerged as a potential “game changer” enabling accessible, affordable and effective healthcare for all [8]. It is believed that eHealth tools and services are necessary for achieving the goals of Universal Health Coverage (UHC) [3], because they can improve individuals' health-related knowledge and behavior [9] and facilitate exchanging and sharing of information between health care provider and healthcare recipient [10]. Melchiorre et al. [11] added that eHealth applications can improve coordination and continuity of care between health professionals by enhancing opportunities for digital data sharing, communication and consultation at a distance which reduces healthcare utilization costs. It is presumed that in the long term, accelerated innovations in eHealth will transform the workflow in healthcare [12]. The increase in demand for eHealth tools has pushed global investment in eHealth innovations exponentially in the last five years to respond to market needs [3].

1.1. Factors Influencing the Integration and Use of eHealth

Despite the effects of eHealth services, WHO [13] indicates there are shortcomings that thwart the widespread of eHealth, especially in developing countries. This includes low or no budget for information and communication technologies (ICTs), poor infrastructure in the maintenance of health services, unreliable or erratic electricity supply, low level of human resources capacity to adopt eHealth, and resistance to change on the part of healthcare professionals. The findings of a study conducted in Tanzania to identify the challenges of integrating eHealth revealed eHealth is constrained by inadequate ICT skills, high cost of ICT, under-developed IT infrastructure including the lack of IT equipment, small proportion of internet users, and lack of information about suitable ICT solutions [14]. As explained by Anderson [15], though eHealth has the potential to positively influence the quality of care successful integration and use is hindered by several factors such as the high cost of acquisition of ICT, especially at the initial stage, and the lack of technical skills. Maintenance costs and costs of buying ICT equipment have also increased post-implementation costs of eHealth [16]. In a qualitative study on factors affecting the implementation of a standardized information system conducted in Cameroon, the findings showed that the centralized and bureaucratic organizational structure deters the allocation of finance to ICT-related activities, particularly at the lower level (district level) of the health system [17]. A study conducted by Staton et al. indicates that resistance to change on the part of healthcare professionals hindered eHealth and limited involvement in eHealth standard development [18]. Similarly, Adebisin et al, [19] attributed low integration of eHealth

to the inability of Health Information systems (HIS) to interoperate. Similarly, Stiawan [20] added that the inability of HIS to interoperate to distribute information concerning eHealth standards among the institutions in the healthcare sector is a major barrier to integrating eHealth. A survey on barriers and challenges to adopting eHealth in Africa using 200 questionnaires reveal that African countries' active participation in eHealth standards development is limited to the requirements of the International Organization for Standardization (ISO). Sluijs et al. [21] noted that poor strategic and lack of standards consume government budgets without reaching good results. Similarly, a study conducted by [22] found that the low adoption rate of eHealth has been attributed to both macro-level factors (e.g., supportive policies) from the perspective of the public healthcare organization and system, and micro-level barriers from the perspective of healthcare providers (e.g., physicians' perception of technological complexity). Other studies found as challenges to eHealth integration the non-existence of inadequate government policies that address a well-defined health system that incorporates eHealth [23], poor leadership and governance [24]. The lack of leadership and governance lead to no direction and coordination of eHealth initiatives at the national level, as a result, health goals in the country are poorly aligned with health strategies [24]. Luna et al., [25] added that in most LMIC, it is difficult to find clear policies and coordination between governance agencies and eHealth initiatives, which poses a huge challenge to integrating eHealth. In addition, unstable government makes it difficult to find long term policies as developing policies requires long term political term.

Other obstacles are the lack of hardware resources like phone lines, computers, and internet connections. The lack of computer resources hamper the widespread of eHealth services [22]. Another study conducted to explore technical factors hindering integrating electronic in referral hospitals indicated insecurity, inadequate funding for eHealth infrastructure, and lack of computer proficiency [26]. Alsahrani et al., [27] observed a significant number of physicians with poor skills and technical knowledge in dealing with eHealth tools resulted in resistance. Cardellino et al., [28] added that inadequate human resource capacity remains a threat to the integration of eHealth. According to a study on eHealth integration in developing countries, the authors found low adoption of eHealth to poor computing skills among clinicians [29]. A similar study by [30] opines low internet use among doctors in Pakistan to the unavailability of proper technology and lack of training. Asangansi et al., (2013) noted that lack of adequate ICT training could lead to health professionals' resistance to aversion to technology. In a similar vein, a study on eHealth adoption conducted by charitable organizations and trust groups concluded that eHealth applications cannot be fully integrated and used when the users lack basic IT skills. Studies from LMIC revealed that the lack of qualified health professionals is a chronic problem [32]; [33]. A scoping review and a qualitative case study exploring health professionals' ICTs skills in South Africa suggests that healthcare professionals struggle daily to keep up with technical developments in an ever-changing health environment [9].

eHealth services cannot tap their full potential if they do not fit the intended users' capabilities, and expectations. Thus, studies from LMICs suggest that education and training of health staff and professionals are essential to improve ICT skills [9]; [34]. Previous studies have examined the role of health workers in eHealth in Africa and LMIC but have focused on the availability of human resources rather than on their competencies and skills. Arguably, our review found few relevant articles on capacity-building activities among health professionals, hence the need for this study.

2. Objectives

The study explores constraints that influence eHealth integration and use among healthcare workers in developing countries. Empirical data was drawn from an online survey on capacity building and innovation promotion activities in Africa. Building healthcare staff in eHealth is critical because a well-trained workforce in eHealth will strengthen health systems and ensure adequate service deliver [35]. The findings will be used to guide the provision of eHealth-related information and resources to BeH partners and others.

3. Methods

The study adopted a survey design and data was collected using an online survey. The online survey was developed using Google Forms. Email invitations containing a brief explanatory text (informed consent) and a link to the online survey were sent to the four BeH partners, who then forwarded the survey to eHealth organizations/institutions in their respective region. The online survey was available in English and was open for participation for two months. Three follow-up requests for participation were sent each fortnight. Responses to the online survey was exported to an Excel spreadsheet, and all metadata on respondents was scrubbed from the file to safeguard the anonymity of respondents. Ethical clearance to conduct this study was obtained as part of a larger BeH project. A total of 37 organizations/institutions from 13 countries responded to the survey. One organization did not indicate the country's name and was excluded from the analysis. The online survey contained four sections:

1. eHealth capacity building and innovation promotion activities and target groups
2. Factors that hinder eHealth capacity building among health professionals
3. Health workers IT literacy
4. Proposed suggestions to build IT skills

Section 1: Survey responses to eHealth capacity building and innovation promotion activities. *Section 2:* Survey statements on factors hindering eHealth capacity building. *Section 3:* Responses to variables were grouped as 1= leadership support, 2=governance of eHealth, 3=resistance to change, 4=motivation, 5= time, 6=infrastructure, 7=financial support. *Section 4:* Proposed suggestion to build IT skills, open-ended questions, and content analysis were used to analyze the responses. Content analysis involves the subjective interpretation of text data through a systematic identification and coding of themes [36].

Pursuant to the online survey, four managers were randomly identified and informally interviewed to have a better perspective on eHealth capacity-building and innovation promotion activities in their respective organizations. Quotes from these interviews were used to substantiate the results. Content analyses was applied to analyze comments from the online survey. Finally, the results reported from the survey do not represent any organization apart from itself. Therefore, the parameters for generalizability from this sample to the larger population is limited.

4. Results

4.1. Characteristics of Respondents (Organizations)

Thirty-seven organizations from 13 countries responded to the online survey. The countries were grouped into four geographical regions: East, West, South, and North Africa. The list of countries is presented in Table 1. Thirteen (13) responses were from government organizations, 15 were from the institute of higher education, four were from non-governmental organizations (NGOs), three were from private companies, and two were from professional organizations. Of the 37 organizations, most responses came from South region and the least number of responses came from the North and West regions. See Table 1.

Table 1. List/description of respondents who participated

Names of country	No. of responses /countries	Regions
Malawi (Hub)	6	South
Tanzania	2	
South Africa	2	
Mozambique	4	
Ethiopia (Hub)	5	East
Kenya	3	
Uganda	1	
Ghana (Hub)	4	West
Togo	3	
Tunisia (Hub)	3	North
Mauritania	2	
Morocco	1	
Algeria	1	
Total = 13 countries	37	

The findings were categorized into the following criteria: capacity-building and innovation activities and target groups, factors that hinder eHealth capacity-building activities, health workers' ability to use a technology, health workers' IT literacy skills, and suggestions for building IT skills for health workers. The following sections provide descriptions of the respondents' capacity-building activities.

4.2. Capacity Building and Innovation Promotion Activities

The findings show that countries use diverse capacity building and innovation promotion activities, ranging from pre- and in-service education and training to the publication of training materials. However, "support from specialists from outside the workplace" was less used, as depicted in Figure 1. One of the managers had this to say. "...training support from specialists from outside the organization requires finances which most organizations do not have....".

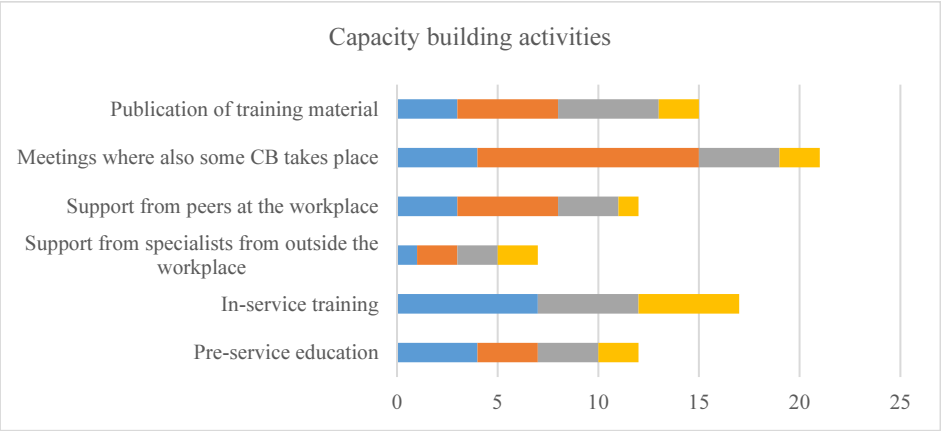


Figure 1. eHealth Capacity-building and innovation promotion activities

Those capacity-building activities were mostly organized for clinical health personnel and managers/administrative health personnel, while no policymakers and eHealth specialists have been targeted as presented in Figure 2.

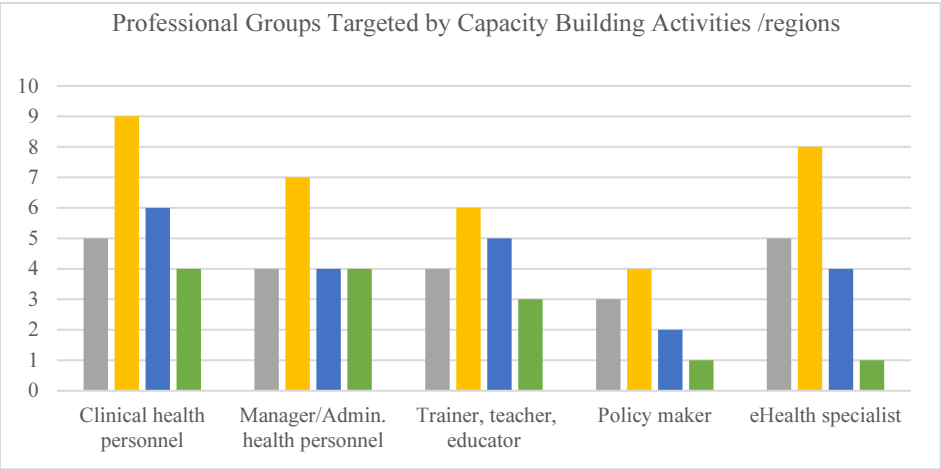


Figure 2. Professional groups targeted for capacity building

4.3. Obstacles to eHealth Capacity Building and Innovation Promotion Activities

There are numerous obstacles hindering eHealth capacity-building activities including financial, infrastructure, motivation, time, leadership support, and governance. The data was further analyzed regarding geographical regions, and the findings revealed that factors hindering eHealth capacity building in the North region are infrastructure and the lack of motivation. Lack of financial support and infrastructure constrain eHealth capacity building in the East and South regions.

4.4. Health Workers' Ability to Use Technology

While health workers use technologies (e.g., feature and smartphone, keyboard, and computer) for different purposes, however, the findings showed that in North, health workers' ability to use a feature phone for voice and text is low, and their ability to use a smartphone is high. In the East and South, health workers' ability to use a feature phone is high, but low to use a feature phone for the internet and to use the keyboard and computer. Then in the West, health workers' ability to use all four technologies is low.

4.5. Health Workers' IT Literacy

In this information age, health workers need to have the required skills and are willing to use eHealth tools. The study asked for the respondents' perception of the IT literacy of four cadres namely, clerks, primary health care staff, hospital managers, and health managers. The overall response was low literacy for all groups. There were, however, some differences across regions. In the North, IT literacy skills of clerks and primary healthcare workers are low, compared to those of hospital health workers and health managers. While in the East, the IT literacy skills of clerks and primary health workers are high, while those of hospital health workers and health managers are low. This is contrary to expectations, and may be due to the low number of respondents, but it might also indicate that IT is used more in the primary care in these countries. In the West, the IT literacy skills of primary healthcare workers are higher than clerks, while the skills of the hospital health manager are even lower. Then in the South, the IT literacy of all four groups of health workers was low, and those of primary healthcare workers are even lower. See Figure 3 for more details on health workers' skills.



Figure 3. Health workers IT literacy /Region

4.6. Proposed Suggestions to Build IT Skills of Health Workers

50% of the respondents suggested in-service training activities to build the IT skills. A responded added, “health workers should be trained on digital skills and visual presentation.” Another mentioned, “in my institution, there is need for more pre-and in-service training activities, especially in eHealth, to prepare users in the health sector to operate systems without any problems.” See Figure 4 for more suggestions.

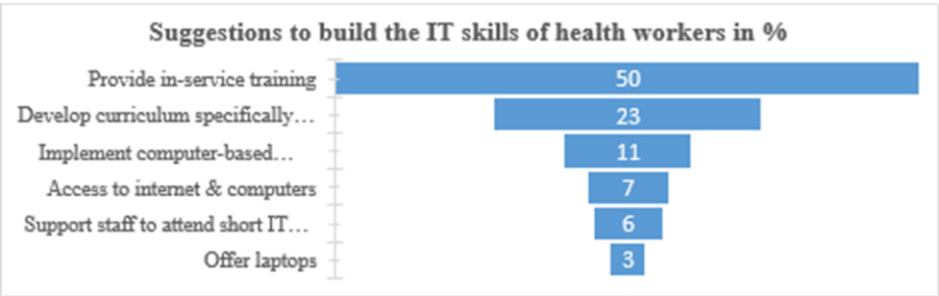


Figure 4. Suggestion to build IT skills of health workers

5. Discussions

The purpose of this study was to explore obstacles influencing capacity building and innovation promotion initiatives among BeH members and institutions. The findings from our study revealed that several obstacles hindering capacity-building and innovation promotion of eHealth initiatives, hence might thwart it widespread integration and use [4], especially in LMICs [37]. From the organizations studied, the findings showed they offer a wide range of eHealth capacity building and innovation promotion activities targeting various cadres of staff and healthcare professionals. However, few of the capacity building activities were for eHealth specialists and policymakers. There exist many obstacles which, are context/region-specific. Generally, the use of technology and IT skills of healthcare workers and professional, most particularly clerks and primary healthcare workers were low. The findings are consistent with earlier findings from other scholars who attributed low integration and use of eHealth to lack of computer skills among clinicians [26]. For a successful integration and use of eHealth, health professionals and staff involved must have at least basic computer skills. Addressing these obstacles is vital, whether related to lack of finance or staff’s ability to use ICTs this study provided suggestions. Provision of in-service training was top on the list. Looking at the list of proposed suggestions to develop IT skills there seemed to be a disjunction between these suggestions and those on section 4.3 (obstacles to eHealth capacity building. Although there are numerous potentials of integrating and using eHealth services, findings from our study revealed that several challenges.

The findings from this study reinforce previous evidence on the need to identify practical solutions and simple interventions to address eHealth obstacles to capacity building [9]; [32]. Our analysis showed that lack of finance, infrastructure, leadership support, and governance in eHealth are obstacles deterring eHealth capacity building and innovation promotion initiatives among BeH members and institutions. To mitigate these barriers, while the availability of finance is essential to develop infrastructure, purchase

technological equipment, pay for training, and recruiting qualified personnel, finance can only be effective and efficient when there are adequate policies, strong political commitment, and good leadership [32].

In addition, to addressing these challenges and creating sustainable capacity and capable healthcare staff and professionals, the American Medical Informatics Association suggested a system-wide approach where education and training should be offered. For instance, leaders/policymakers, health professionals, and eHealth specialists are taught in seminars, degrees, and certificate programs [9]. Other strategies emphasize on the importance of education including developing curricula and integrating them into existing training programs for health professionals to be taught both formally and informally. These are some of the activities BeH is focusing on. For example, in May 2022, the DEDICATED project (HISP Centre) has designed 10 eHealth modules in partnership with the following five universities: the University Eduardo Mondlane in Mozambique, the University of the Western Cape in South Africa, the University of Dar Es Salaam in Tanzania, the University of Malawi, and the University of Gondar in Ethiopia. The modules will be taught to undergraduate and graduate students in all five universities [38]. While this approach will target future eHealth professionals, research has shown the need of training initiatives from the national to the district levels for health professionals delivering care [39], which in most cases have limited resources. On-site training should be complemented with continuous support and mentoring. In-service training is wanted. It requires funds and infrastructure, and these two conditions are not met. One viable response that has shown promising results is on-the-job training, mentoring, and supervision by superusers or others in the workplace who are knowledgeable and have the time to help colleagues [40]. While training is still one of the most important approach to build the capacity of health professionals in eHealth, training alone cannot succeed without strong eHealth policies, committed leaders and good governance [24].

6. Conclusions

The healthcare sector is an ever-evolving sector requiring numerous staff and professionals with diverse skills. The staff and health professionals must have adequate skills and capabilities to respond to the evolving needs of the industry. As already mentioned above, eHealth education and training cannot be fully implemented without sufficient finance, adequate infrastructure, strong leadership, and governance [24]. The findings of this study reinforce the message from previous research [32] that IT training and education are essential for all practicing health professionals in the entire health sector, and more should be invested to staff at the district level who often need more. There is no doubt that integrating eHealth will increase efficiency the delivery of healthcare delivery, but on the other hand, there are many obstacles such as lack of IT skills, lack of finances, poor eHealth policies and governance, and lack of infrastructure that may thwart its adoption. Our study concludes that training of health workers and professional aimed at building eHealth skills and capacity should be versatile, to cater for diverse groups with different needs, and should adopt to the local context. The findings from this study may guide on aspect of obstacles to eHealth capacity building to address in to improve eHealth integration which will in turn improve health service delivery and the goals of achieving UHC. This study contributes to the discourse on eHealth capacity-building and innovation promotion initiatives among public health and

healthcare professionals. This study has a limitation as there was only 37 respondents from the 15 African countries. Future studies could extend the coverage of the sample. Nonetheless, our results are consistent with findings of previous studies.

7. Acknowledgments

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CTS2 OWL: Mapping OWL Ontologies to CTS2 Terminology Resources

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Abstract. The advancement of healthcare towards P5 medicine requires communication and cooperation between all actors and institutions involved. Interoperability must go beyond integrating data from different sources and include the understanding of the meaning of the data in the context of concepts and contexts they represent for a specific use case. In other words, we have to advance from data sharing through sharing semantics up to sharing clinical and medical knowledge. According to the Good Modeling Best Practices, we have to start with describing the real-world business system by domain experts using Domain Ontologies before transforming it into an information and communication technology (ICT) system, thereafter specifying the informational components and then transforming the system into an implementable solution. Any representation style – in the system development process acc. to ISO 10746 called system view – is defined by a related ontology, to be distinguished from real-world domain ontologies representing the knowledge spaces of involved disciplines. The system enabling such representational transformation shall also support versioning as well as the management of historical evolutions. One of such systems is the Common Terminology Service Release 2 (CTS2), which is a standard that allows the complete management of terminological contents. The main objective of this work is to present the choices we made to transform an ontology, written in the standard *Ontology Web Language* (OWL), into the CTS2 objects. We tested our transformation approach with the Alzheimer's Disease Ontology. We managed to map all the elements of the considered ontology to CTS2 terminological resources, except for a subset of elements such as the equivalentClass derived from restrictions on other classes.

Keywords. Ontology, CTS2, semantic interoperability, terminology resources, biomedical field

1. Introduction

Healthcare systems currently undergo a transformation towards integrated, interoperable, knowledge-based, policy-driven, highly dynamic, and fully distributed ecosystems according to the personalized, preventive, predictive, participative precision (P5) medicine paradigm [1]. This requires communication and cooperation of actors from multiple disciplines with specific perspectives, contexts, objectives, using their special methodologies, languages, knowledge, and skills. The challenge of P5 medicine

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ecosystems is the proper representation, mapping and matching of their domain-specific knowledge at any representation level from the real-world business system through the related IT systems, the information and finally the data used, deploying more and more constrained languages from natural languages up to computational ones. Thereby, mapping between elements from different domains or different viewpoint can only be performed at horizontal level, i.e., at the same level of granularity. To get there, components must be specialized or generalized, respectively. The corresponding representation of system-oriented, multi-domain, ontology-based, policy-driven P5 ecosystems using ISO 23903 [2] is shown in Figure 1.

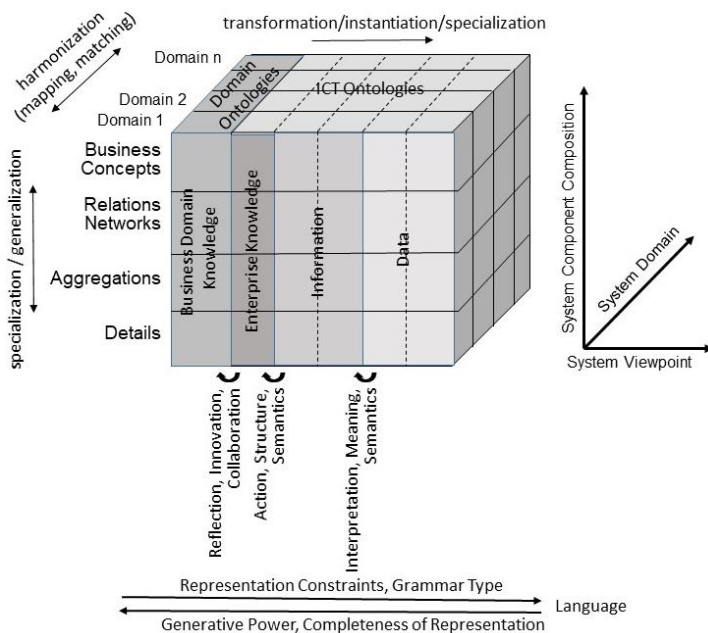


Figure 1. Model and framework for representing multi-domain, knowledge-based, ontology-based, policy-driven ecosystems.

While, from an ICT system development process perspective, that transformation into the viewpoint-specific representation style is clearly defined, e.g. in ISO/IEC 10746 Open distributed processing [3], the transformation of health systems based on existing standards is an open issue to be addressed in this paper. Thereby, we have to solve the mapping between domains represented by domain ontologies and the representational transformation between different viewpoints. Examples for the data view representation are database management system schemas or coding systems. Regarding the semantical representation, terminologies, thesauri, taxonomies, glossaries, data dictionaries, or vocabularies are used. The aforementioned semantical resources are collection of terms (entities) that are linked to a specific domain. They aim at creating a complete documentation that support the correct usage of such terms.

An ontology is *an explicit specification of a conceptualization* [4], going beyond terminologies by describing all the specific knowledge about its entities including their contexts, constraints and relationships by using attributes and relations [5]. Its main objective is to facilitate knowledge sharing unambiguously. Therefore, an ontology constitutes an efficient strategy to aggregate, standardize, represent and communicate

biomedical concepts and related information as well as, together with machine learning (ML) methods, it can be used for automatic reasoning [6] and predictions [7]. In the biomedical field, ontologies became particularly important for semantic interoperability and data integration [8,9] as they could be considered, for each medical concept, as the justification of the specification [10].

However, we should consider that the evolution of medical knowledge might cause changes both in the concepts and in the terms that are used to define them. So, it is necessary to use systems that allow versioning and management of the historical evolution of information and data [11]. As there exist many different types of ontologies, it is necessary to manage the challenge of creating, maintaining and mapping ontological concepts. Here, the ISO 21838 Top level ontologies [12] shall be used.

Many different tools were developed, in various languages and countries, to deal with the important problem of medical terminology management [13,14,15], but their usage was highly localized. In the following years, a more general and standard solution was widely adopted by the scientific community, the *Common Terminology Service Release 2* (CTS2) [16,17]. The CTS2 standard provides a universally implementable set of operations that can be used for the complete management of terminological contents. In particular, its functional profiles allow the creation, updating, deletion, reading, searching and versioning of terminology resources. CTS2 was created with the aim of providing a structure suitable for organizing information by using consistent and computable mechanisms. Therefore, it supports the improvement of information exchange quality.

The main objective of this work is to present the choices we made to transform the elements of one ontology presented in the standard *Ontology Web Language* (OWL) into CTS2 terminology resources. An ontology has a great descriptive ability, and the CTS2 helps in maintaining its integrity over the versions as it keeps track of all changes made on a specific version. To the best of our knowledge, this is the first work that reports this kind of transformation.

2. Methods

The purpose of our work is to document in detail all the choices we made in the process of transformation of an ontology into CTS2 resources.

2.1. Ontology Elements & Relations

A medical ontology is mainly characterized by the definition of a domain that comprises all the knowledge attributable to a given topic. Some examples of relevant medical ontologies, ranging over different areas, are: *Human Phenotype Ontology* (HPO) [18], *Infectious Diseases Ontology* (IDO) [19], *Epilepsy and Seizures Ontology* (EPSO) [20]. Within an ontology, the various objects are defined and interact with each other according to logical properties, reciprocal restrictions between and on objects, groups and semantic sets. The three main types of objects of an ontology are:

- **Class:** every single object belonging to the domain.
- **Annotation Properties:** further information purely attributable to the Class itself and independent of the others. Examples from the Alzheimer's Disease Ontology (ADO) are synonym, comment, label.

- **Object Properties:** A restriction, which places a limit on the values of a certain Class that respects a certain Property. In most cases, this Property is defined within the ontology, so it has logical value only within it.

The *rdfs:subClassOf* construct is implemented in OWL with the same logical value and meaning it has in the RDF Schema2, that is: if a Class C1 is defined as a subClassOf of another Class C2, then the set of elements that make up C1 they must at least be a subset of those that make up C2. A Class is therefore by definition a subClass of itself, as the subset can also be the whole set.

The *equivalentClass* construct, on the other hand, indicates that the set of elements of Class C1 are equivalent to those of Class C2, therefore the two sets must have exactly the same number and the same elements.

2.2. CTS2 Terminology Resources

CTS2 standard is distributed through the HL7 *Service Functional Model* (SFM) and the *Object Management Group* (OMG) *Service Technical Model* (STM), that respectively provide service interface specification at a functional level and technical requirements of the service3. Within this work, we will refer to the OMG model.

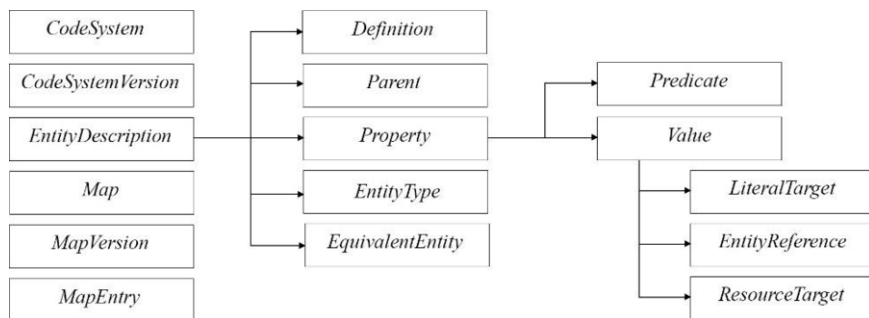


Figure 2. Hierarchical structure of the CTS2 resources that we used to map the ontology elements.

The CTS2 terminology resources summarized in Figure 2 are:

- **CodeSystem:** a classification system or a code system or an ontology or a thesaurus, etc. It includes information about publisher, release cycles, purpose, etc.
- **CodeSystemVersion:** a version of a CodeSystem. It includes information about release date, release format, contact information, etc.
- **EntityDescription:** a description about a class or a role or an individual within a specific CodeSystemVersion.
- **Map:** a collection of rules for transforming entities of a CodeSystem into entities represented in a second one. It includes information about creators, intended use, CodeSystem involved, etc.
- **MapVersion:** a specific version of a Map that maintains both the original and the destination CodeSystemVersion.

² <https://www.w3.org/TR/rdf-schema/>

³ <http://www.omg.org/spec/CTS2/1.2/>

- **MapEntry**: a definition of a set of rules that identifies how a single Entity that belongs to the original CodeSystemVersion maps to null, one or more target Entities that belong to the destination CodeSystemVersion.

The core CTS2 resource is the EntityDescription. It is the most complex but interesting item to investigate. Some of its metadata that we considered during the translation process are:

- **Definition**: An explanation of the intended meaning of a concept. An EntityDescription may have multiple definitions, each derived from a different source, represented in a different language or having a different purpose.
- **Parent**: The set of direct “parents” asserted by DescribingCodeSystemVersion. It is the responsibility of the service to determine what predicate(s) represent “parent/child” relationships.
- **Property**: Additional “non-semantic” (annotation) assertions about the entity being described that do not fit into the other categories.
- **EntityType**: The set of type(s) a resource can take and it should include owl:Class, owl:Individual, rdf:Property, or skos:Concept, although it may carry many other types as well.
- **EquivalentEntity**: An entity that has been determined to be equivalent to the about entity in the context.

The element we mainly focused on is **Property** and its two main components are:

- **Predicate**: The name or URI of the property predicate. It can be literal or an EntityDescription itself, so an Annotation Property or an Object Property.
- **Value**: The target(s) of the property. Note that this can only represent the literal format of the property. The details about the original property will be found in the *CorrespondingStatement* if the CTS2 implementation supports the statement profile. So, the attribute value of a property is of Class *StatementTarget* and it can be of three types:
 1. Literal Target: when the statement type is LITERAL. It can be used for properties like the entity “label” or “comment”.
 2. Entity Reference Target: the URI and optional namespace/name when the target type is ENTITY. It can be used when a property refers to another entity.
 3. Resource Target: when the statement type is RESOURCE.

An entity may have more than one value for the same predicate, so it is necessary to create a list of *StatementTargets* containing all the items and then assign the list to *Property.Value*, while *Property.Predicate* remains unchanged.

3. Results

The ontology we tested our mapping system on is the *Alzheimer’s Disease Ontology* (ADO) [21]. The list of CTS2 resources that we used in our translation process is composed by the following three main elements:

- **CodeSystem**. The functional profile involved is the *CodeSystem Catalog MaintenanceService*. Two of the input parameters that we provided were: *Uniform Resource Identifier* (URI), external link of the resource; *Name*, the local identifier of the catalog that we want to create.
- **CodeSystem Version**. The functional profile involved is the *CodeSystem Version Catalog Entry*. As for the CodeSystem one the input parameters is *Name*, a local

descriptor that uniquely identifies this version in the specific CodeSystem. Another input parameter is the *versionOf* which the name or URI of the code system that the version belongs to.

- **EntityDescription.** The functional profile involved is the *Entity Description Maintenance Service*. For each entity two important input parameters are: *EntityID*, the entity code and/or namespace identifier of the entity to be created; *Describing-CodeSystemVersion*, the URI or local identifier of the CodeSystemVersion that this entity belongs to. Once created, each entity can be updated to insert the information linked to each single ontology class or property. The components of an ontology element can be divided in two main categories: components that can be directly mapped to an element of the CTS2 EntityDescription and elements that need to be mapped into properties because they do not fit into any predefined item.

The first category includes the elements in Table 1. Among them, Example and Definition are lists that could have zero or more items, while at least one Parent is always present.

Table 1. Correspondence between elements of an ontology class that can be directly mapped to CTS2 EntityDescription components.

Ontology concept metadata	CTS2 resource metadata
Example	.Example
IsDefinedBy	.Definition
SubClassOf	.Parent
EquivalentClass	.EquivalentEntity

The elements that belong to the second category can be divided into the four main groups displayed in Table 2.

Table 2. Four cases to which all the elements, not contained in Table 1, of an ontology class/property can belong to: (a) predicate is a text and value is a text, (b) predicate is a text and value is an entity, (c) predicate is an entity and value is a text, and (d) predicate is an entity and value is an entity.

	Value is a text	Value is an Entity
Predicate is a text	The predicate contains the name and namespace of the statement predicate (<i>type: EntityNameOrURI</i>). The value element is a statement target of type LITERAL (<i>type: Opaque-Data</i>).	The predicate contains the name and namespace of the statement predicate (<i>type: EntityName-OrURI</i>). The value element is a statement target of type ENTITY (<i>type: EntityNameOrURI</i>).
Predicate is an Entity	The predicate contains the URI of the entity of type Annotation Property (<i>type: EntityNameOrURI</i>). The value element is a statement target of type LITERAL (<i>type: Opaque-Data</i>).	The predicate contains the URI of the entity of type Object Property (<i>type: EntityNameOrURI</i>). The value element is a statement target of type ENTITY (<i>type: Entity-NameOrURI</i>).

Figure 3 shows some examples of the translation applied to the selected ADO ontology.

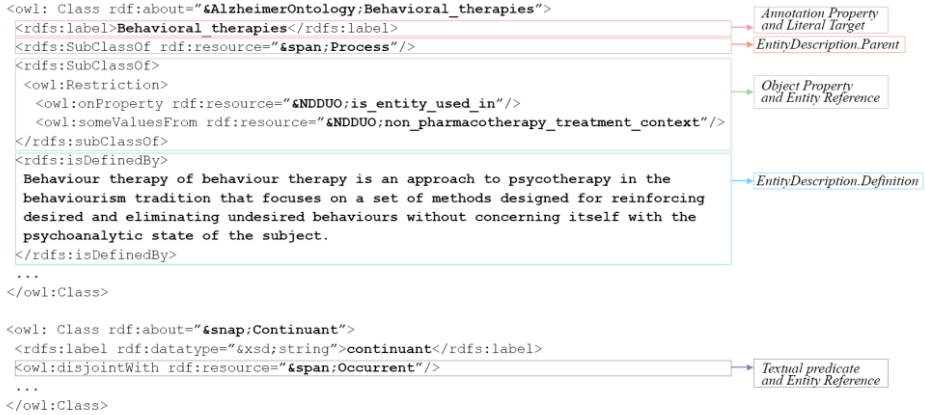


Figure 3. Examples of ADO elements translated into CTS2 terminology resources.

Label, highlighted in orange, belongs to case (c) as the predicate is an Annotation Property and value is text. *SubclassOf* with a restriction, highlighted in green, belongs to case (d) as the predicate is an Object Property (“*is entity used in*”) and the value is the entity “*non pharmacotherapy treatment context*”. *disjointWith*, highlighted in purple, belongs to case (b) as the predicate is textual and the value is the entity “*continuant*”. Figure 3 also shows two examples of elements that belong to Table 1. In particular, *SubclassOf alone* is the element that defines a hierarchical relation, so the element contained between the two tags is one of the entities of the ontology that constitutes the parent. On the contrary, *IsDefinedBy* presents a specific information about the entity and it is composed of free text.

4. Discussion

The development and usage of standard terminologies became extremely important in the scenario of data integration and improved the quality of the resulting outcome. However, terminologies evolve, new terms are inserted while others are withdrawn, so a system able to track all changes is necessary to maintain the integrity of the terminology resource. A standard solution that could be adopted is using the corresponding *Fast Healthcare Interoperability Resources* (FHIR) of HL7 Italy as shown in [22]. The major limitation of this approach is that only hierarchical relations are allowed, while extensions like important elements of the ontology could not be mapped, e.g. annotations and object properties. A non-standard solution is Protégé⁴, which is an open-source tool that supports the creation and management of ontologies. In particular, it keeps track of changes and makes the revision history available. The main advantage in using Protégé is that it is specifically built for ontologies, so the system can deal with all ontology components [5]. A limitation is that as far as we know there is no *Application Programming Interface* (API) available allowing a rich set of operation, e.g. the creation and update of an ontology. Users can interact with the database only through the web interface (WebProtégé), thus requiring a huge human intervention. In our work, we

⁴ <https://protege.stanford.edu/>

selected the Common Terminology Service Release 2 first because it is a standard solution and it is services-based, and second because we have already used it for the management of vocabularies in several scenarios [16,23,24]. The main advantage is that it provides a specification for the implementation of a set of operations that allow the complete management of all aspects of CTS2 resources. A limitation of this approach is however that there is a reduced subset of ontology relations, which we could not map into CTS2 resources, e.g., when *equivalentEntity* elements are obtained as restrictions on other entities.

In personalized medicine, it is essential to accurately describe the situation of a patient at all levels (from macroscopic [25] to molecular [26]) [27,28]. This kind of systems combines on the one hand the analytical nature of ontologies and on the other hand the systematic approach and rigor provided by standardized tools, such as the CTS2, to preserve the evolutionary history of the terminological systems. Therefore, we believe that it can be considered one of the enabling tools for the real implementation of the pHealth paradigms.

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Response Center Services: An Exploratory Study

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Abstract. The population aging has facilitated a growing number of welfare technologies and smart home solutions. These technologies enable clinical staff and health care professionals to provide health services in an intelligent way with the trend of patient-centric digital health platforms. As one of the health services, response center service is facing new challenges when connected with welfare technologies, such as false alarms, security threats, privacy leakage, etc. This paper introduces the mechanism of the response center and the role it plays in healthcare. We conduct an exploratory study to find out the benefits and challenges of the response center service from the results of a structured interview. Based on the findings, we identify the required services to improve the intelligent response center mechanism

Keywords. Welfare technology, smart home, privacy, response center, healthcare

1. Introduction

There is an increasing number of the elderly and patients in demand of health services in aging societies. Long-term care (LTC) has therefore been set as a key policy priority by governments in different countries to meet the growing care needs of population aging [1]. In Norway, health services, such as LTC, are provided according to the principle of the lowest and more effective level of care [2, 3]. As patients are provided with sufficient but no more than necessary services, long-term care service is offered to patients in their ordinary private homes prior to care homes or nursing homes. Also, patients in nursing homes are motivated to go back to their ordinary private homes [2]. Thus, long-term care service, a service supporting “aging in place” with a growing range of assisted living technologies (ALTs), constitutes an important part of LTC.

The response units, or response centers, play a significant role when providing long-term care services worldwide. To illustrate, there are various response centers providing different types of services today. For example, the Emergency Response Unit (ERU) deals with emergency situations including medical emergencies, firefighting [4]. Microsoft Security Response Center (MSRC) aims at protecting customers and Microsoft from privacy and security threats [5], Refugee First Response Center (RFRC) provides medical first aid and live video translation services [6], National Response Center (NRC) from the U.S. takes the responsibility of all reports on oil, chemical, radiological biological and etiological discharges as well as maritime reports of

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suspicious activity and security breaches [7], Health Response Center (HRC) provides family welfare services [8], disease control and prevention [9]. Some of the response centers have a combination of services like the Emergency Response Unit (ERU). However, we focus on the health related response center services in this paper. The health response centers, sometimes also called healthcare call centers or medical call centers [10, 11], can provide timely response services to patients and distinguish the emergency level. The health response center personnel will help handle the daily needs of the users and their family members and if necessary, deliver the message to health care providers for further medical aid and in this way help reduce their workload.

In Norway, municipalities take the responsibility of providing long-term care services, and the politicians and administrators plan and decide on local care services structures including the delivery of the services in different municipalities around the country [12]. The response centers are driven by local authorities in these municipalities [13]. They provide 24-hour care services for users continuously. Though the services provided by response centers vary among different municipalities, they have the following functionalities in general [14]: (1) Receiving incoming calls and inquiries and implementing necessary and effective follow-ups, (2) Taking the role of coordinating when emergency services are needed in addition to municipal services, (3) Technology-enabled remote monitoring and notify the users or vendors in time in case of technical errors or provide help when abnormal activities are detected. The welfare technologies used for remote monitoring include but are not limited to digital security alarms, image sensors, bed sensors, door alarms, global positioning systems (GPS), seizure or fall alarms, smoke alarms, electronic drug dosing, and electronic door locks [15]. These technologies enable more accurate assessments to be presented and more effective measures to be provided by the response centers. Meanwhile, they save the cost of health services.

Despite the benefits that the response centers and the welfare technologies bring, the service support mechanisms are faced with various challenges. According to the Norwegian explorative case study conducted date back in 2018 [16], response center personnel's concerns about the services they delivered include irregular reporting or under-reporting by patients, inappropriate support systems like lack of integration between different systems used at the response center, unexpected work demands like providing psychological support to those patients struggling with anxiety or depression.

However, the case study does not fit the development of smart home technologies and the growing need of long-term care services in the past few years. In the era of COVID-19 pandemic, the healthcare systems have been transformed worldwide with telemedicine and virtual healthcare integrated into the health delivery service [17]. Also because of the digitalization of the services, patients and their family members as well as the health care providers have shown more privacy concerns on welfare technologies. In the past two years, there are also growing trends of studies by researchers on patients' and bystanders' security and privacy concerns in different scientific databases (ACM digital library, PubMed, Semantic, etc.).

In this paper, we present the results of a exploratory qualitative, structured interview with response center personnel from four different Norwegian municipalities' response centers. The four representatives provide the views from the health care providers' perspective on the smart home technology-enabled response center services. A list of services provided by the response centers are identified by us from the benefits and challenges we collect according to the needs of the users (including the patients, the response center personnel, and the relatives of the patients). After that, we discuss the

room for improvement. The main contribution of the paper includes presenting the interview results and extracting core functionalities of the service system from the interview.

2. Method

We performed exploratory, qualitative, email-based, structured interviews to collect views of the health response center personnel on the response center services, complemented with a design method to identify and analyze the services as well as present the intelligent response center service mechanism.

Four response center personnel from different municipalities across Norway were contacted by us via email with attaching questions. The questions were sent directly to the interviewees without extra testing. The demographic characteristics of the interviewees were not required in the interview. After receiving their responses from email, content analysis was adopted to code data and generate categories. To be specific, the attaching questions in the email were classified into four categories by us (see tables 1 to 4 below): (1) Current status of the response center services, (2) Challenge 1 - Technology education and technical support, (3) Challenge 2 - Security and privacy concerns, (4) Challenge 3 - Efficiency and effectiveness of the service system. Each question in different categories has corresponding answers. Based on interviewees' answers to the questions, we summarized the competencies and problems of the current response center service in the next section.

Table 1. Current status of the response center services

Classification	Questions
Benefits	Q1: What do you think is the best value brought by the current response center services to users (patients and their family members, for instance)?
Requests distribution	Q2: Do you have statistics about the distribution of question types/requests from the patients? Q3: How does a typical first-line worker prioritize the questions/requests?
Challenges (in general)	Q4: What are the most frequent requests from the users? Q5: What do you think are the current and future challenges that the current response center service is facing (not well addressed and likely hard to address in the next decade)?
Emergency handling	Q6: Do you have any collaboration with the emergency medical communication centers particularly in coping with emergencies?

Table 2. Challenge 1 - Technology education and technical support

Classification	Questions
Backup solution	Q7: In case the care receiver or health professional does not know how to use or maintain the welfare technology, are there any backup solutions? (e.g., sending a technician, using phone calls or video communication to guide the users.)
Training program	Q8: Do you have any training programs or technologies aiding the users (care receivers or caregivers from municipalities) to learn and adapt to day-to-day changing care needs?

Table 3. Challenge 2 - Security and privacy concerns

Classification	Questions
Consent management	Q9: Do you/patients/patients' family members have any security and privacy concerns on the welfare technologies used in your services or difficulty in consent management?

Table 4. Challenge 3 - Efficiency and effectiveness of the service system

Classification	Questions
False alarms	Q10: Is false alarm a challenge to the operation of a response center?
	Q11: Are most false alarms from the phone call report from the phone calls or from the sensors applied (e.g., fall detection sensors, image sensors, etc.)?
Vague requirements	Q12: How to deal with the situation that patients' request from the phone call is unclear?
	Q13: Do you have technology such as data collection before or right in the phone call conversation to help you make better judgement?
Identification authentication	and Q14: How to make sure the phone caller is the correct patient (how to identify a patient in a remote way)?

3. Results

3.1. Benefits

The invited response center personnel list the benefits of the services they provide as follows (We mark the four interviewees as P1, P2, P3, P4 when presenting their opinions. The findings are all summarized by us from the interviewees' answers corresponding to each question. They are marked at the end of the sentence.):

- Equal treatment
For patients, they will be treated equally and get the same help regardless of where they stay in the country (Q1-P1). For operators (response center personnel), they will focus on each user so that they can provide services of good quality (Q1-P1).
- Security and competence
For patients, they are confident and feel secure as they know the professional personnel will guide them when they need help (Q1-P2, P4). For relatives (like patients' family members), they feel secure as they know users can call for help or report needs via the response center using various technologies (Q1-P1, P4).
- Quick contact and response
As the response centers enable patients to have quick contact with the health services, patients will be able to stay at home longer (Q1-P3). With welfare technology, response center personnel will be able to clarify what the patients need help with and send the right expertise to the patients (Q1-P3).
- Burden easement

It enables relatives to be confident when they are on holiday or during sleep because they are confident that patients will get the help they need in time (Q1-P2). Welfare technology enables response center personnel to send the right services, e.g., medicine dispensers will help with the correct medication at the right time instead of human intervention to deliver the health services (Q1-P3).

- **Emergency handling**

By easing the burden of the clinical staff, the response center services enable a more efficient emergency handling mechanism. At the same time, the response centers have close collaboration with other organizations, and the personnel can call the emergency medical communication centers daily when necessary (Q6-P1, P2, P3).

3.2. Challenges

Nonetheless, these benefits are brought together with a variety of challenges. When asked about the challenges that the current response center service is facing, the interviewees have more insights in addition to the challenges we have summarized in the previous section.

- **Increasing needs of response center personnel**

The increasing number of older people will add up the workload of the response center personnel and more qualified personnel are needed (Q5-P1)

- **Difficulty in adapting to the changing technology**

The updated and developed technologies and technical systems make it difficult for users and response center personnel to adapt to them (Q5-P1, P4). The fact is patients and response center personnel lack technical competence (Q5-P4, Q7-P1). Also, the changing work is time-consuming and there's not enough time to train qualified personnel (Q5-P4).

- **Lacking backup solutions for technology education and aid mechanism**

The technology education and aid mechanism are different among the response centers that the interviewees belong to. In general, the municipalities rather than the response centers take most of the responsibility for educating and aiding people with welfare technology (Q7-P1, P2). Though some municipalities have set up outpatient teams to assist with anything including equipment configuration, training, and troubleshooting (Q7-P2, P3), some do not have any technicians linked to the response center (Q7-P1). Even if some backup solutions have been made like having backup telephones in the event of loss of the response center reception, the response centers need better solutions with the increasing number of service recipients (Q5-P3).

- **Complex service processes, vague requirement identification, and inaccurate decision support**

With an increasing number of alerts from different technologies, and with different service processes for the response center personnel to follow up, the current decision support and the possibility of announcing or communicating

assignments can be a challenge (Q5-P2, P3). The use of an established decision support system is desired but not yet suitably developed for response center service use currently (Q3-P4). Moreover, response center personnel have difficulty in understanding patients' vague requirements, which adds up to the complexity of service processes and decision making. The solution that the response centers adopt now is integrating the service system with the electronic health records, so that the personnel can access the important information they need to help the patients and send health providers daily to the patients who have unresolved situations, if necessary (Q12-P1, P2, P3, P4). Mostly, the decision or judgment is made by the personnel relying on their experience. However, no technology is used to collect data right in the phone call conversation to help the personnel to make better assessments or decisions (Q13-P1). Also, in emergency cases when the response center personnel need to contact other organizations for help, it is pointed out that calls over the alarm box in some cases result in poor sound quality (Q6-P3). In all, it seems that more simplified technology solutions are needed to help personnel to make better decisions and ensure good communication quality between patients and personnel.

- Potential applications for incident assessment needed

It has been identified as a need for the personnel to communicate with the patients with an image in addition to sound (Q5-P3). Currently, it is the response center personnel who assess as accurate as possible the severity of the incidents (Q3-P1). As one of the methods to assist assessment, visualization of incoming incidents can help the personnel with prioritization of alarms or requests more accurately (Q5-P3).

- Difficulty in identifying false alarms (either from bystanders or technical dysfunction) and repeated alarms (from patients' phone call reports)

One of the interviewees regards the false alarms and repeated alarms as challenges as they are time-consuming (Q2-P1, Q11-P1). Another interviewee also identifies the false alarms caused by technical dysfunction and admits the possibility of the sensors being triggered accidentally but does not consider false alarms as big challenges themselves (Q11-P3).

- Identification and authentication risks

Among the four response centers that our interviewees work for, one of the response centers has a more developed identification and verification mechanism for both patients and the health personnel compared to others. The measurement it takes includes asking for the name of the patients rather than saying the name of the patient to get a confirmation, linking the identity from the sensors to the identity from the electronic health records, and recording the follow-up of the care services via electronic health records (Q14-P3). However, not all the response centers regard the mechanism they adopt as a challenge (Q14-P1, P2), which can cause information security risks consequently. The technical suggestion put forward by personnel is to get a video connection to the user so that they can have visual contact (Q14-P2).

- Security and privacy concerns

Though the risk and vulnerability analysis [18], as well as data protection impact assessment, has been conducted in the response centers (Q9-P2, P3) in compliance with the legal requirements (the patient and the user's rights act [19]), there are still some security and privacy concerns from the patients and their family members (Q9-P2, P3, P4). There are some cases where patients can be skeptical as their family members are being monitored at the same time (Q9-P1). It increases municipalities' and response centers' difficulty in managing multi-users consent when being monitored.

- Specific solutions needed for different types of requests:

Because of the frequent requests from patients, more categories of solutions are needed for better services. The personnel list respiratory distress, pain, malfunction on various nutrition pumps, nausea, falling, elimination of produced body fluids, displacement of the patient (in bed or to toilet chair), psychological support, etc. (Q4-P3)

3.3. Service Identification

With the challenges above, we extracted the services required in an intelligent response center service system. We split the services into services currently available and planned for improvement (though some of them are also available by now, they remain to be improved) in the future (Table 5). The proposed solutions aim to reduce the current burden. For example, image visualization will help health providers to identify incidents or vague requirements, which have been raised by the interviewees as a challenge, so as to provide appropriate health services. Furthermore, in some cases, multi-users needs should be considered at the same time. Therefore, both service recipients and providers' needs were considered. After that, the detailed support solutions were analyzed corresponding to each service.

Though more intelligent solutions and software services can be integrated into the current response center system design with the emerging technology management solutions, more services provided by other organizations or platforms should be linked to the response center system in support of professional consultation, such as mental health disorders or feeling of isolation (online social media and mental health center). In the meantime, external technical center as well as cloud storage are linked to provide backup solutions. To ease the burden of the personnel and save medical resources, more incidents need to be classified and handled on a machine level before being escalated to the human level.

With the aspects considered, the mechanism of the system is visualized in Figure 1. In general, the solid lines represent the internal information system of the response center, while the external platforms or organizations in support of the response center services are marked with dashed lines. The machine-level incident processing with optimized video analytics and incident assessment algorithms are expected to not only help reduce the burden of response center personnel but also service providers from external organizations.

Table 5. Service Identification

Service	Currently available	Planned for improvement	Based on patient's needs	Based on response center personnel's needs	Based on other users' needs	Corresponding support
Daily living assistance	X		X	X		Medical devices, sensors, smart wireless network, disease management systems
Daily contact	X		X			Medical devices, sensors, smart wireless network, backup telephone
Incident assessment	X		X	X		Self-report and shared decision-making system
Emergency handling	X		X			Incident audio/video recording
Technology education	X		X	X		Technology training
Technology aid	X		X	X		File/data automated backup, automated technical incident report, remote support
Requirement identification and clarification		X	X	X	X	Access control, Video enabled communication
Psychological support		X	X			Online social media
Identify false alarms		X		X		False alarm filtering - AI video analytics [20]
Identify repeated alarm		X		X		Fatigue management system - repeated alarm scheduling and clustering [21]
Security and privacy protection		X	X		X	Consent management platform (CMP), privacy preserving technology

4. Discussion

Despite the improvement of the system, privacy is one of the barriers to the proposed functionalities. Better automated services are brought with more privacy leakage possibilities during electronic health records and video data processing. Being linked with external services raise the possibility of privacy leakage regarding information sharing as well. In other scenarios, like when family members are living with patients, or when daily health service or emergency aid is delivered, the privacy-preserving dilemma also exists. The fact that different user roles (patients, bystanders like family members or health care providers) have different duties and privacy concerns has led the users to make different decisions under the same scenarios. For instance, medical help will be highly prioritized by clinical staff when an emergency happens despite considering patients' privacy concerns. Meanwhile, when different users are being monitored, the privacy-related consent management become more complicated so as to monitor all the users legally. In the proposed mechanism (highlighted in red), a shared decision-making mechanism which enables different parties to make decisions together,

as well as the consent management system, should be integrated to synchronize different parties’ decisions and privacy concerns.

As one of the limitations, the figure has not covered detailed solutions for different types of incident identification. In falling accidents, for example, the alarms can be sent either by the sensors automatically once the event is detected or sent by the patients manually. Under some circumstances, the alarms can even be sent by the sensors to the health care providers with more details reported by users. Thus, the final reports that will be sent extremely rely on the urgent level of the incidents. Also, we are faced with the same challenge when applying privacy-preserving technology to different types of incidents as users have different privacy concerns in different incidents.

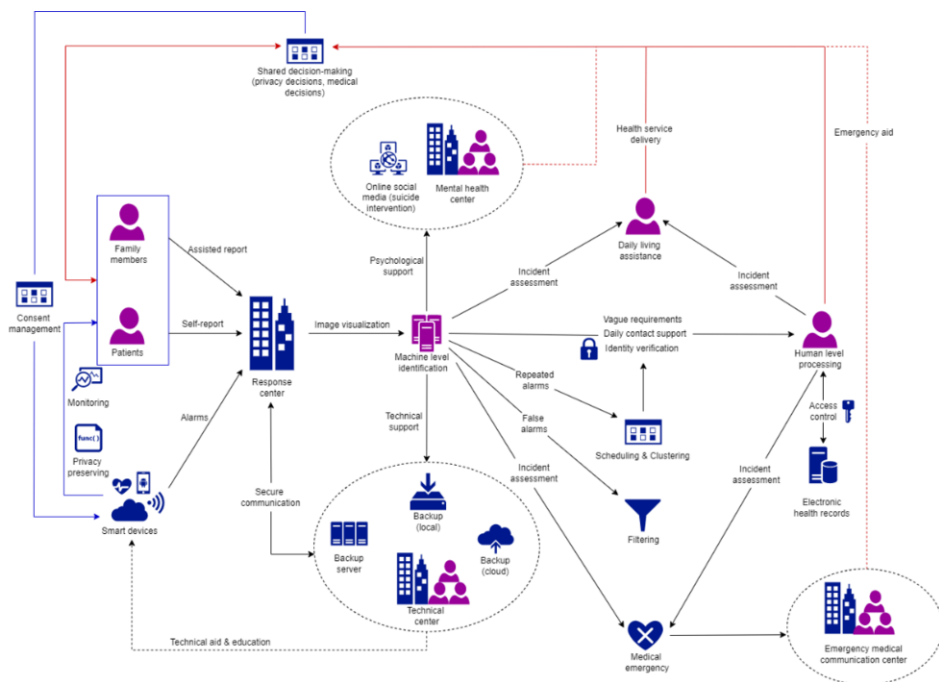


Figure 1. Intelligent Response Center Service Mechanism

5. Conclusion

In this paper, we conduct an exploratory study that will help improve the intelligent response center service. We identify and analyze the services in the technology-enabled response center system from a structured interview with four representatives of the response center personnel. Based on the views we collect, the benefits and challenges with current response center services are extracted. According to the findings, we identify the required services to improve the response center systems. The results and analysis are presented from the technical perspective, with privacy and security leakage and different technology platforms considered. Finally, we emphasize the core efforts that need to be made for improving the system.

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Risk Factors for COVID-19: A Systematic Mapping Study

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Abstract. Introduction: COVID-19 has affected people in several countries around the world. They experience respiratory symptoms that can be mild, moderate, or severe. Several reviews that characterize the risk factors of COVID-19 have been performed, but most address only risk factors associated with medical conditions, ignoring environmental and sociodemographic-socioeconomic factors. Objective: This study aims at characterizing different risk factors in the published literature that influence contagion by COVID-19. Methods: The review consists of three stages, including a systematic mapping with studies found in the Scopus database, an analysis of results, and finally the identification of relevant COVID-19 risk factors. Results: A map of studies id provided considering two main groups: the type of research and context. Most studies consider risk factors associated with medical conditions, while research on other factors is scarce. Conclusions: Medical conditions such as diabetes, obesity, cardiovascular disease, hypertension, and factors such as age and sex, appear to be the ones that increase the risk of contracting COVID-19. Further research is needed on environmental, sociodemographic, and socioeconomic risk factors.

Keywords. Covid-19, environment, health, risk factors, sociodemographic, socioeconomic

Introduction

COVID-19 is the disease caused by a new coronavirus called SARS-CoV-2. It was first learned on December 31, 2019, following a report of a cluster of ‘viral pneumonia’ cases in Wuhan, People’s Republic of China [1]. It was characterized as a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO) on January 30, 2020 [2]. On March 11, 2020, the WHO characterized COVID-19 as a pandemic [3].

Most infected people have respiratory symptoms which can be mild, moderate, or severe. Other symptoms vary from person to person depending on different factors. It has also been reported that older people and those with underlying medical conditions are more likely to present severe afflictions [4].

Although possible symptoms have been described and the vaccines have reduced the mortality rate, the long-term effects are still unknown. Furthermore, due to COVID-19’s novelty, long-term studies are not possible. For this reason, and because of the population at elevated risk, COVID-19 is still a serious public health issue.

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Confirmed testing rates for COVID-19 provide critical information to understand its full impact and identify ways to decrease morbidity and mortality. Nevertheless, a lack of testing, especially in low/middle-income countries, impacts the detection of its prevalence. In addition, hospitalization rates offer an indirect measure of local outbreaks and mortality. Still, these rates are generally affected by sociodemographic and socioeconomic factors such as insufficient funds or limited knowledge about COVID-19.

All the previous factors add up to the necessity of identifying risk factors that aid healthcare entities in making decisions to reduce COVID-19 cases.

The motivation of this study is to characterize the distinct types of risk factors present in the published literature that influence contagion by COVID-19. Accordingly, the authors performed the following stages: a) a systematic mapping, b) an analysis of results, and c) identifying relevant factors.

1. Related Work

Due to the profound impact that the COVID-19 pandemic has caused worldwide, many studies in the literature characterize risk factors, most of which address only one type of risk factor. We present some of the reviews that have been made.

Reviews [5-18] mention both Human (HM) and Sociodemographic-Socioeconomic (SD-SE) risk factors. Common factors include age, sex, obesity, hypertension, and diabetes.

Environmental (EV) risk factors are referenced in reviews [19-23]. They mention multiple types of factors where air contamination stands out. Unlike HM risk factors, the reporting of these types factors is not extensive.

HM risk factors alone are found more frequently like in [8], [19], [20], [24-44]. The most frequent HM factors are hypertension, diabetes, obesity and cardiovascular diseases.

The SD-SE risk factors found in [8], [25], [33], [35], [38], [39], [41], [42], [45-48] show that age and sex have been cataloged as risk factors that may increase the complications when diagnosed with COVID-19.

Finally, reviews [20], [49-52] are some of the few ones that present the three types of risk factors, HM, SD-SE and EV, at the same time.

Considering the reviews found in the literature, this article aims to characterize the risk factors that affect the morbidity and mortality of COVID-19. We cover all three types of risk factors. Furthermore, this study differs from other reviews that include the three groups of factors without having geographical limitations or focusing on a specific risk factor. The results can be useful for health professionals and public health agencies to implement strategies in response to COVID-19. They can also be useful for any implementation based on technology that aims to support COVID-19 predictions and decisions.

2. Methodology

Our methodology consisted of three stages: 1) *Systematic mapping*, 2) *Analysis of results*, and 3) *Identifying relevant factors*. In particular, the systematic mapping stage was derived from the “Guidelines for performing Systematic Literature Reviews in Software Engineering” [53].

2.1. Systematic Mapping

Systematic mapping is a type of systematic review with a broad scope, designed to cover and provide an overview of a research area, classifying and counting contributions according to predefined categories. It is based on selecting, reading and classifying abstracts through 5 main phases, culminating with a results map.

2.1.1. Scope and Research Question

The research question led this study to discover works that described different risk factors for COVID-19. Therefore, having this goal in mind, the research question for the systematic mapping was: What risk factors are found in the COVID-19 literature?

2.1.2. Information Search

The problem at hand guided the selection of the main search terms. As a result, the chosen keywords generated the search string: "RISK FACTORS" AND "COVID". The next step allowed us to select the Scopus database, considering it has broad scientific research coverage. Finally, the query was applied to the title, abstract, and keywords.

Specifically, the selected search string covered a larger number of studies. The search was conducted between August 9 and August 22, 2021, obtaining 1,786 studies. Most of them are presented in English.

2.1.3. Inclusion/Exclusion Criteria

The goal of this section was to define the inclusion/exclusion criteria to filter potentially relevant papers retrieved from the search. Table 1 shows the selected requirements.

Table 1. Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
IC1: the paper should include at least one of the risk factors of interest. They are SD-SE, EV, and/or HM.	EC1: Papers were published before 2015 to construct a clear trend of publication
IC2: the paper is review-type. Other studies were analyzed allowing for a much broader vision of the subject	EC2: papers with a theoretical approximation to the problem
IC3: the paper has performed a study of the risk factors for COVID-19	EC3: papers do not mention risk factors for COVID-19
	EC4: papers published as notes, editorials, or letters

The authors ensured that the reviewed papers mentioned the problem to be addressed. Furthermore, any duplicate papers were removed. Finally, no restriction was applied regarding the country of publication, country of study, results, or the language of publication.

2.1.4. Classification Scheme

During the initial review, we looked for ways to classify and order the information on the studies. Thus, considering the three identified groups of risk factors, we identified two main classes among the papers. These two classes grouped the type of review and the factors covered. It should be noted that the number of studies in the database increased daily. The classes were:

- *"Type of research"* It refers to the type of review that had been conducted. It was a result of scanning over the abstracts.
- *"Research context"* It refers to the types of factors found and their combinations. It was generated once the papers were organized and reviewed more deeply.

2.1.5. Data Extraction Strategy

To standardize the data extraction and reduce the bias of results and the informality of the process, we created a spreadsheet to follow during the examination. This template was adapted from [53]. First, authors in charge of examining the papers extracted the title of the document, authors, year of publication, type of research, research context and summary; this last information was compiled in a document containing the identified risk factors by each document. The resulting document is in Spanish and can be found in [54].

2.2. Analysis of Results

After analyzing the selected documents, we sorted and characterized each of them. The classification allowed us to identify the risk factors present in the papers. Extracting this knowledge gave us a sense of the importance of different risk factors for COVID-19 and the papers that have been made around them.

2.3. Identification of Relevant Factors

After structuring the data from the studies selected, we identified relevant factors, which are the most frequent factors mentioned in the studies. Initially, from the factors found in the review, we established a standard writing format so that similar terms were written equally. Then, the factors that were mentioned more than once were entered into the template. Finally, a function was applied to count the times that each factor was determined as a risk factor in all the studies. A table was created for each type of risk factor. Their combinations were not considered because the purpose was to establish how many times a factor was classified as a risk factor.

3. Results

From the 1,786 returned documents, 564 were related to the objective of the work and met the inclusion and exclusion criteria. Table 2 shows the derived classification scheme.

Table 2. Classification scheme

Classification “Research context”	Classification “Type of research”
“Environmental factors.” These factors involve environmental variations	“Review and experimentation” Reviews that perform their own studies
“Human factors.” These factors are related to people’s health conditions	“Review” Documents that reach the goal of a review but did not perform their own studies
“Sociodemographic and Socioeconomic factors.” These factors involve the characterization of people	“Non-formal review” The document’s abstract did not indicate if the study considered databases or the number of documents that they examined
“Environmental and Human factors”	
“Sociodemographic and Socioeconomic, and Environmental factors”	
“Sociodemographic and Socioeconomic, and Human factors”	
“Sociodemographic and Socioeconomic, Environmental and Human factors”	

The main result was the map of studies shown in Figure 1, which relates the classes and indicates the number of articles found for each of them with their proportions.

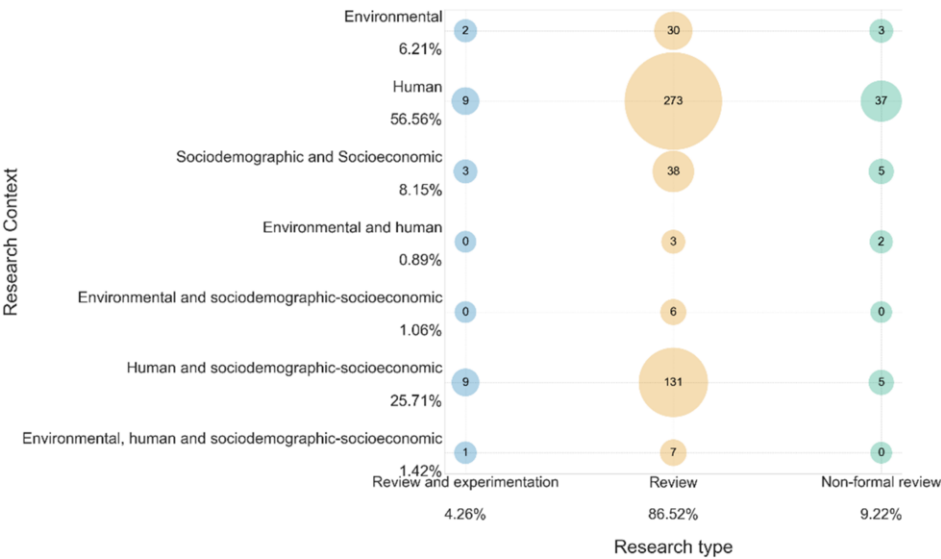


Figure 1. Bubble graph mapping and associating the type of research with the research context. The percentages are calculated per each axis.

3.1. Analysis

The map shows that the largest number of documents corresponds “review” type and only addresses HM risk factors. The second largest number of papers, also being of “review” type, study HM and SD-SE factors. On the opposite side, the “review and experimentation” documents have the least dominance in the mapping.

The papers that address EV risk factors have the least representation among all combinations. In addition, among all categories of “type of research,” very few results were obtained for documents that addressed the category of EV and HM risk factors.

“Non-formal review” type has lower dominance in the mapping, and in terms of the research context, HM risk factors were the most prevalent for this category.

Finally, it should be noted that the risk factors with the most presence in the documents were comorbidities such as diabetes, hypertension, obesity, and cardiovascular diseases, as well as factors such as age and sex.

3.2. Relevant Risk Factors

The risk factors for COVID-19 were classified into the three initially proposed groups; HM risk factors, EV risk factors, and SD-SE risk factors.

Human risk factors. Table 3 shows that HM risk factors have the greatest presence in the studies, where diseases related to mental and physical health were found. Some diseases with the greatest presence were diabetes, obesity, cardiovascular and hypertension. Some documents that cover a large number of these factors were: [8], [9], [37], [41], [42], [44], [50], [55-64].

Table 3. Number of times that Human risk factors were mentioned in the documents

Human Risk Factor	Count	Human Risk Factor	Count
Diabetes	107	Tuberculosis	6
Obesity	102	Coronary	6
Cardiovascular	90	EPOC	6
Hypertension	82	Genetic	5
Chronic disease	30	Cytokine storm	5
Cancer	26	Depression	4
Smoking	24	Alcoholism	4
Pulmonary	24	Sleep	3
Renal	24	Physical inactivity	3
Fatty liver	23	Anxiety	2
Respiratory	21	Epilepsy	2
Mental	18	Malnutrition	2
Cerebrovascular	16	Sclerosis	2
Asthma	15	Stress	1
HIV	10	Dementia	1
Inflammatory	10	Alzheimer	1
Blood	9	Addiction	1
Vitamins	9	Diet	1
Heart disease	6		

Environmental risk factors. Table 4 shows the EV risk factors, which are the ones that have the lowest representation among the studies. The EV factors with the greatest presence were the environment, air quality and pollution. Some documents that cover at least two of these three factors were: [21], [22], [50], [65-67].

Table 4. Number of times that Environmental risk factors were mentioned in the studies

Environmental risk factors	Count	Environmental risk factors	Count
Environment	16	Particulate Matter	4
Air	14	Surface	3
Contamination	11	Humidity	3
Aerosol	10	Wastewater	3
Weather	5	Meteorological Phenomena	2
Respiratory droplets	4	NO2	1
Temperature	4	Solar light	1
Radiation	4		

Sociodemographic and Socioeconomic risk factors. Table 5 presents the found SD-SE risk factors. Age is the most mentioned factor in the documents, followed by sex and race. The documents covering at least two of the three factors were: [8], [35], [41], [44], [59], [64], [68-76].

Table 5. Number of times that Sociodemographic and Socioeconomic risk factors were mentioned in the documents

Sociodemographic and Socioeconomic risk factors	Count	Sociodemographic and Socioeconomic risk factors	Count
Age	399	Education	5
Sex	81	Lifestyle	3
Race	27	Public health	2
Ethnicity	16	Geographic	2
Economic	16	Transport	2
Job	14	Immigrants	1
Income	10	Social networks	1
Housing	5	Overcrowding	1

4. Discussion

It was found that most of the publications have been made from 2020, the year in which the disease was considered a pandemic. Figure 2 shows the number of studies published per type of risk factor’s group since the pandemic started.

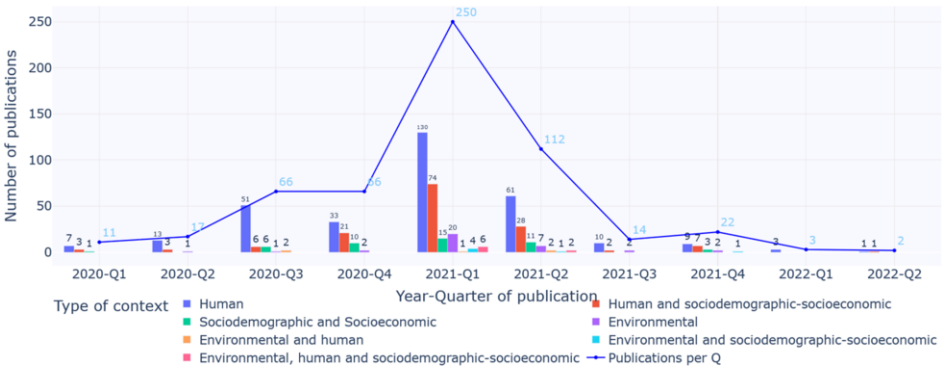


Figure 2. Number of studies per type of context published in each quarter since the pandemic started

Most of the studies around COVID-19 risk factors were published in the first two quarters of 2021, reflecting the great effort made in 2020 to understand the new disease. This temporality, however, also shows the low amount of research on risk factors in recent quarters. Furthermore, this decreasing trend contributes to the lack of exploration of other risk factors, such as the EV type.

From the included studies, we determined three groups of risk factors: HM, SD-SE, and EV. Some studies mention elements belonging to more than one group, so possible combinations between them were also considered. Most identified risk factors belonged to the HM type, followed by SD-SE. Few studies have identified EV risk factors, which the recent appearance of the disease can explain.

As stated before, the most frequent factors belong to the HM class. The possible reason is that it contains clinical factors, the most common ways to diagnose a disease. In general, for the characterized HM risk factors, it was determined that they could be classified into two large groups; factors related to mental health such as depression, stress, and sleep disorders, among others; and factors that refer to the diseases present in people who have been infected with COVID-19. On the other hand, EV risk factors were the least studied and, among the outstanding factors are the environment, air quality and pollution. Finally, for SD-SE factors, we identified factors such as: age, sex, race, ethnicity, economic income, and type of work.

Regarding the *practical and research implications*, this review makes it possible to explore the risk factors of COVID-19, which would allow an in-depth study and thus help health organizations in their decision-making process. In addition, this study identifies factors that generally increase vulnerability to other diseases. Moreover, the study allows us to identify gaps for future research, such as that a few documents mention the three types of risk factors.

In addition, thanks to the map of the studies, it is recommended that novel studies focus their research on type “review and experimentation,” in conjunction with EV and SD-SE risk factors. It would be beneficial to consider combining the mentioned factors with other factors, since there is little research around them.

5. Strengths and Limitations

This study includes all the risk factors found for COVID-19, regardless of the study type. It helps readers to know the factors that influence the presence of the disease. However, since only review articles were considered for the systematic mapping, other factors were likely excluded. While Scopus is one of the largest indexing digital libraries for health literature, this study did not include other digital databases. Also, the initial filtering of papers was focused on the title and abstract, which could lead to excluding relevant papers. Finally, other classification criteria might be appropriate for extracting further study information.

6. Conclusions

This study presents the systematic mapping of risk factors for COVID-19. Human risk factors are the ones that most influence the presence of the disease, highlighting diseases such as diabetes, obesity, hypertension, and cardiovascular diseases. In addition, most of the studies have considered these factors since the start of the pandemic. Regarding EV

factors, very little research is found in the literature, even though risk factors such as air, pollution and the environment are evident. As to SD-SE factors, the risk factors most closely related to the disease are age, sex, race and ethnicity. More research on EV and SD-SE risk factors is required to define what other factors can influence COVID-19. It is expected that this study will help to formulate future work around risk factors for COVID-19. In particular, this mapping lays the groundwork for the future research project entitled "Multidimensional machine learning model to determine a COVID-19 vulnerability index" on which the authors of this article are currently working. The objective is to characterize the risk factors that explain the vulnerability of COVID-19 and to build and evaluate a machine learning model that allows the calculation of a COVID-19 vulnerability index considering the most relevant variables, mainly those available from public datasets.

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The Causal Plausibility Decision in Healthcare

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Abstract. The explosion of interest in exploiting machine learning techniques in healthcare has brought the issue of inferring causation from observational data to centre stage. In our work in supporting the health decisions of the individual person/patient-as-person at the point of care, we cannot avoid making decisions about which options are to be included or excluded in a decision support tool. Should the researcher's routine injunction to use their findings 'with caution', because of methodological limitations, lead to inclusion or exclusion? The task is one of deciding, first on causal plausibility, and then on causality. Like all decisions these are both sensitive to error preferences (trade-offs). We engage selectively with the Artificial Intelligence (AI) literature on the causality challenge and on the closely associated issue of the 'explainability' now demanded of 'black box' AI. Our commitment to embracing 'lifestyle' as well as 'medical' options for the individual person, leads us to highlight the key issue as that of who is to make the preference-sensitive decisions on causal plausibility and causality.

Keywords. Artificial Intelligence (AI), black box, machine learning, unsupervised, causality, explainability, causability, clinical decision support, individualisation, personalization

Preamble

In 2019, Caroline Kramer and colleagues from the University of Toronto Mt Sinai Diabetes Center published the results of a meta-analysis of an observational data set [1]. A meta-analysis is a relatively 'shallow' form of machine learning, not seen as warranting the 'black box' characterization of the 'deep learning' forms of Artificial Intelligence (AI) now flourishing. In her acknowledgements, Caroline thanked Romeo Kramer, her miniature Schnauzer dog, for inspiring the meta-analysis, which examined the association of dog ownership with all-cause mortality, with and without prior cardiovascular disease.

"Ten studies were included yielding data from 3 837 005 participants (530 515 events; mean follow-up 10.1 years). Dog ownership was associated with a 24% risk reduction for all-cause mortality as compared to non-ownership (relative risk, 0.76; 95% CI, 0.67–0.86) with 6 studies demonstrating significant reduction in the risk of death. Notably, in individuals with prior coronary events, living in a home with a dog was associated with an even more pronounced risk reduction for all-cause mortality (relative

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risk, 0.35; 95% CI, 0.17–0.69; I2, 0%)... Dog ownership is associated with lower risk of death over the long term, which is possibly driven by a reduction in cardiovascular mortality.... A possible limitation was that the analyses were not adjusted for confounders” [1, p. 1].

As one might expect, especially in the light of this last limitation, a critical response followed. Eventually, the editor of the journal was moved to publish a set of commentaries, making valid, albeit entirely predictable, comments [2]. A response from the authors [3] included some sensitivity and confounder-adjusted analyses in support of their conclusion, but importantly (from the point of view of the present paper) they also introduced a biological rationale for the meta-analytic findings.

“... Specifically, dog ownership has been shown to increase owner’s physical activity, lower blood pressure, reduce physiological indices in response to stress, and improve mental health among others positive effects beyond the cardiovascular system. In addition, the existence of a special human-dog bond was demonstrated in an experiment published in *Science*⁷ in which an oxytocin-gaze positive loop was observed between dogs and their owners that was similar to the hormonal response observed when mothers interact with their infants. In conclusion, while we recognize that the current evidence consisting of mostly observational data cannot establish any causal association between dog ownership and survival, we disagree that dog ownership is solely a marker of increased physical activity. Given the growing body of evidence, we speculate that such positive interspecies interaction promotes greater adherence to a healthy lifestyle, improves cardiophysiological indices, improves overall well-being, and promotes the activation of a hormonal loop associated with positive emotions that are likely beneficial to human health [3, p. 815].”

We do not need to go further into the various and valid methodological concerns in this case, because we take the multiple uncertainties they give rise to as the given normal in healthcare decision making. (This applies even when high quality interventional studies have been undertaken.) For the researcher, the ultimate conclusion is typically that more research is needed. But, also typically, and perhaps a tad gratuitously, they will add the injunction that the present results should be *used* ‘with caution’.

1. Introduction: Individual Decision Support

Our work is exclusively on decisional use, so we do not have the luxury of retaining the scientific purity of the researcher, remaining agnostic as to whether a link is causal or not. Having read Kramer, and being fully cognizant of all the issues raised in the ensuing debate, we are faced by an individual, with or without a prior coronary event. What should we do about dog ownership in our decision support tool? Should it be included as an option, along with, as we do for medication options, a performance rating on the all-cause mortality criterion. Or not? Of course, beyond this specific question lies the general one that has nothing to do with any particular intervention, such as owning a dog. That general and unavoidable decision as to whether a *causal* link between interventions and outcomes exists - has been given new and heightened exposure by the arrival of ‘deep learning’ AI. So, while this paper is prompted by the recent excitement about the potential for AI to improve healthcare, the issue addressed is eternal.

Our interest is in the improvement of all *individual* health decisions, taken inside or outside a healthcare system, and anywhere within it, but we use primary care as our exemplar ‘inside’ setting, usually without great loss of generality. We also approach the

topic in the specific context of providing decision support to both professional and person (including patient-as-person), the latter being regarded as the *decision owner*.

We need to establish our position on individual decision support right away. (We interpret individual decision support to embrace clinical decision support). We define the best possible decision support as that which both maximally *individualizes* and maximally *personalizes*. Maximal individualization is achieved by obtaining and inputting the best available estimates for the option *performance ratings*, i.e. how well each of the adoptable causes of actions, including doing nothing, performs on each of the harms and benefits that matter to the specific person (i.e. their criteria). Maximal personalization is achieved by eliciting and inputting the specific person's criteria, along with their criterion *importance weightings* for each harm and benefit (i.e. their preferences). Given that they are fundamentally distinct ontologically, these two sets of inputs (performance ratings and importance weightings) must be produced independently, only subsequently being integrated into the necessary overall assessment ('score') for each option. Individual decision support tools which achieve these objectives facilitate, perhaps virtually ensure, care that meets the legal 'reasonable patient' standard for informed consent [4].

2. Artificial Intelligence (AI)

Our focus on improving decisions rather than adding to knowledge has important implications for our response to the AI literature. It means immediate attention is required to the distinction between teleological and causal explanations.

The explanation for professionals and persons undertaking decision making - and deciding whether or not to engage with an individual decision support tool in the process - is teleological, not causal. As agents, neither is *caused* to engage in decision making, but do so in pursuit of a goal (Greek *telos* purpose, end), being assumed to be seeking the best means of achieving it. However, in pursuit of that goal (*effect*) and, under inevitable uncertainty, they will be interested in determining what means may *cause* it and with what *probability*. It is in facilitating the best estimates of causal probability, and only in such facilitation, that we believe AI can make a major potential contribution to improved individual healthcare and health. This contribution is limited by failure or reluctance to accept that it can be manifested - 'add value' - only in the teleological setting of decision making, not simply by 'adding knowledge' to a research depository.

There are two noteworthy features of the seriously reflective literature on AI in healthcare, which we will take to be exemplified in the survey article by Eric Topol [5]. One is its almost total absorption with AI applications in relation to medical techniques (such as scans) and medical treatments (such as drugs). There is relatively little AI interest in 'lifestyle' databases, partly, perhaps mainly, a knock-on effect of the failure to invest in collecting 'hard big data' about lifestyles, as compared with devices and drugs. Second, there is almost exclusive concern with the quality of the AI-based information that would potentially be passed to decision makers, and a taken-for-granted assumption that the acceptable quality threshold for passing is to be set by researchers, not decision makers/owners. It is never suggested or contemplated that the appropriate quality threshold should be determined in the context of the individual decision. We demur, and will be returning to this point at length, since it is crucial for our work in developing *individual* decision support tools. Tools that must include non-medical

options, such as pet ownership, where we believe the issue of *whose* causality thresholds are to be applied is likely to become more and more prominent and contentious.

Finally, by way of background, we take the view that all data production, collection, exploration, and processing is conducted on the basis of some implicit or explicit *model*, i.e. a constructed ‘small world’. All empirical results and interpretations are produced within a ‘small world’ model and reflect underlying conceptual constructions and methodological preferences. The single most important motivation for all data activity in this small world is to *somehow* improve *something*. In the case of healthcare, including our decision support, that something is a construction of ‘health’. We find all-cause mortality to be an uncontroversial component of most health constructs and so focus on this for the present purpose, albeit it is only one of the multiple criteria relevant in most health decisions.

3. The demand for ‘trustable AI’

There is now a vast literature on the enhanced techniques for the centuries-old activity of data exploration, developed and implemented under the umbrella term AI. As ‘machine learning’ (ML) from observational data becomes more and more technically sophisticated - and incidentally profitable - concern with what is going on in ‘deep learning’ programs has increased in parallel. It has now reached the point where the orthodox position has become a demand for ‘*trustable* AI’. The 2022 MIE conference had this in its title and theme and it is useful to note for future use, how the issue was presented as one of control, with the problems - and solutions - located solely in the AI system.

“... new machine learning methods...promise to improve the accuracy of diagnosis and screening, support clinical care, and assist various public health interventions such as disease surveillance, outbreak response, and health system management. Naturally, as these new AI systems emerge, concerns arise concerning the level of control that should be conceded when reviewing the pace at which AI methods are introduced. One concern in particular arises from the fact that these new AI systems often work as “black boxes”, and are unable to explain their results. Explainability is critical, however, to respond to patient and practitioner narrative exchanges, and the fact that practitioners, who are responsible for their decisions, cannot easily follow the proposals of AI systems that they disagree with is also a problem [6, p. v].”

Before addressing the central issue of what is to constitute ‘explainability’, it is important to reaffirm our position that AI can only improve decision support through improving the *individualization* (of the option performance *ratings*). To do so, AI exercises must, of course, have addressed the well-known problems of confounding that arise in non-interventional sources; but since they invariably seek to do so, to the extent possible, we do not need to spend time on this. However, in line with what was said earlier, the use of AI results must avoid trespassing into *personalization* and/or *decision making* conceptualized as the final *integration* of individualized ratings and personalized weightings. Such trespassing will inevitably occur when the data exploited in the AI exercise reflect the *preference* judgements embedded in the decision that generated each datum in the data set. This is likely to be particularly important when the data reflect patterns of practice, based on the trade-offs among outcomes *assumed* to be appropriate by guideline bodies. Here, unfortunately, we can do little more than call attention to this neglected, non-epidemiological confounder, perhaps more serious than many of the

recognized epidemiological and biophysical confounders of which AI researchers are well aware.

The call for ‘trustable AI’ is a call for an *explanation* of what is going on inside the AI ‘black box’. It is not necessary to delve deeply into the many possible constructions of the terms ‘explanation’, and closely associated ones, such as ‘explainability’ and ‘explainee’ exhaustively documented by Carvalho and colleagues [7]. We need only to make clear that any conclusions emerging from these conceptual exercises, can only inform, not determine, the appropriate requirements (standards) for ‘explainability’, in a specific context and for a specific decision owner. This follows from the fact that setting these standards are *decisions* and therefore logically involve value judgments and preferences, above all and inevitably, judgments on the trade-offs made among the main types of possible error. This logic is perfectly captured in Ken Hammond’s brilliant subtitle to his *Human Judgment and Social Policy: Irreducible Uncertainty, Inevitable Error, Unavoidable Injustice* [8].

The orthodox demand, as in the MIE quote above, is for ‘explanations’ that go beyond technical *procedural* accounts, such as ‘we conducted a Bayesian network analysis’. It is maintained, correctly, that such accounts will not be ‘understandable’ by many, perhaps almost all explainees and lead to their characterization as ‘black boxes’. Such *procedural* accounts will also not provide the *declarative* information - about *what* has been found to be causing *what*, and to what extent - which is desired/required by professionals and patients. To anticipate, we will argue that thinking these two demands can be met within a single ‘explanation’ is based on a serious conceptual confusion.

In response to these demands a number of ‘Explainable AI’ (eXAI) programs have been developed to delve into deep machine learning programs [9]. Programs such as SHAP are able to extract the feature/category/attribute importance (coefficients) detected by a deep learning program and present these *declarative results* in visually effective ways - undoubtedly making them more ‘understandable’ and ‘interpretable’ to a much wider audience of explainees. One of the many data sets used in teaching about AI techniques and eXAI programs is one relating to the predictors of survival on the Titanic. It contains eight passenger categories and in most exercises the prediction coefficients (in SHAP, the ‘Shapley values’) for sex and class of passage emerge as the most important, with being female and travelling first class ‘explaining’ increasing survival to the extent and in the direction indicated by these values.

Two things about such eXAI programs require emphasizing. Firstly, their impressive accomplishment in presenting these ‘causal coefficients’ must not distract from the fundamental point that they do not in any way actually *explain the process* by which these findings were arrived at. They simply present a summary plot of these findings in a visually communicative and hence more interpretable and useful way (including useful for us in our pursuit of performance ratings). The supply of the (demanded) declarative information about *what* the program has found to cause *what*, and to *what extent*, is widely confused with an explanation of *how* the program found these. That latter explanation can only be a *procedural* one, of the sort which most people find hard to understand and therefore characterize as a ‘black box’. Secondly, eXAI programs can only produce findings in relation to the features/categories /attributes entered into the analysis, and not those which were not; in other words, findings in relation to those features/categories/attributes which met some threshold for causal plausibility and were included. We do not know whether data relating to the pets accompanying Titanic passengers does not exist, or was regarded as lacking in causal plausibility, and was therefore not processed in the ML application or the SHAP interrogation of it.

In some cases causality may be ‘beyond reasonable doubt’ to all (reasonable) observers. This will be particularly the case with biophysical causes (e.g. trauma, poison). At the other extreme, the impossibility of causality may be beyond reasonable doubt, except in some ‘placebo’ sense (e.g. snake oil). (For the record, we do not question the evidence on the effectiveness of placebos; however, we see the cause of the placebo effect as the prescriber, not the prescribed). In between these extremes, there are the vast range of *possible* causes which have to be assessed for whether they meet some standard for causal plausibility, or ‘causability’ in Holzinger’s term [10].

In the case of Judea Pearl’s campaign for ‘strong AI’, in *The Book of Why* [11], this assessment determines whether the category/feature/attribute is entered into the causal diagram that he insists must be drawn *prior* to any AI exploitation of a data set. This causal model will therefore determine (as ‘supervisor’ of the ML program) the scope of the processed set, often confining it to a subset of the fuller set that could be explored unsupervised (e.g., excluding information about the pets of Titanic passengers, if this was readily available.) And so the findings of ML programs will, by definition, be restricted to those attributes selected *ex ante*. Pearl therefore rules out the ‘weak AI’ in which causal plausibility is assessed *ex post* in order to determine whether the outputs of an unsupervised exercise are to be accorded causality.

We can find no reason to disassociate ourselves from this reviewer’s summary of *The Book of Why*.

“One of the book’s central claims, re-asserted again and again, is that data on their own are “dumb,” and cannot be causally interpreted until one draws a diagram, representing a set of assumptions about the reality behind the data. In Pearl’s view, the assumptions in a causal diagram live in some separate, a priori realm, completely distinct from “data.” He never tells us where the diagrams are supposed to come from, if not from empirical observations about the world; the book contains scattered references to “background knowledge” or “common sense”, but these never coalesce into a general statement about what sort of information is allowed to inform our choice of diagram. We are only told that whatever this information is, it must not be “data.”

So, in Pearl’s version of causal inference, you must first choose a diagram before you see the observational data at all. You are not allowed to change this diagram once you see the data, since diagrams do not come from data... Although he never says as much... the entire subject of Pearl’s book [is] no more and no less than estimating the coefficients for a pre-specified, fixed diagram... we are adrift in [a] strange world where one makes certain causal assumptions (encoded in a diagram) for the sake of assessing others, never sure whether any given arrow is an inviolable assumption or a testable hypothesis, or what makes the difference [12].”

But our inference from this, and weaker versions of this argument, should not be misinterpreted. Our fundamental point is not that we should avoid intermediate binary categorization of a category as ‘plausibly causal/not plausibly causal’ for a target outcome (Titanic survival, All-Cause Mortality). Nor that we should avoid final categorization of it as ‘causal/not causal’. In decision making we cannot. At some point, ‘drawing a causal diagram’ - constructing a causal model - is unavoidable and should be undertaken very seriously. The basic assumption and rationale of this paper is that all such models of causation must be seen as constructs produced by *preference-sensitive decisions* of human beings. Under unavoidable uncertainty, assigning causality involves setting a threshold on a scalar variable of causal plausibility. In any such threshold-setting exercise, the possibility of type 1 and type 2 errors arises, with a false positive resulting from assigning causality to a category which (according to a *constructed* gold

standard/'ground truth') has none, a false negative resulting from denying causality to a category which is causal. Any threshold setting can therefore only be done on the basis of error trade-off *preferences* - how serious are the consequences of a false positive relative to those of a false negative?

These preferences can have no basis in 'science', 'knowledge' or 'expertise'. The type 1/type 2 trade-off appropriate when seeking the *truth*, in scientific research, is completely different from that appropriate when seeking the *best option* in the individual decision, *now, under uncertainty, in practice*. This trade-off will depend on all the circumstances of the case and should reflect the individual decision owner's preferences, not those of the professional - nor the profession [13] - and certainly not that of any expert group of researchers.

In the provision of individual decision support in healthcare we see the consequences of human decisions on inclusion or exclusion from the intermediate 'plausibly causal' set and hence the final causal model as potentially substantial. Few advocates of 'trustable AI' see that the elephant in the room is *whose* preferences are to be entered in setting the decision threshold. The (unwritten) Book of Who is more important than *The Book of Why*.

4. The Data Sets

It may help if we present a simplified filter taxonomy for the data sets that might be used in machine learning (ML) to contribute to healthcare.

“1 Data for a category (characteristic/attribute) which *is not* produced/collected/ 'cleaned', but only because of excessive practical difficulty and/or expense.

2 Data for a category (characteristic/attribute) which *could be* produced/collected/ 'cleaned', without much practical difficulty and at acceptable expense, *but is not*

- A. because of its universally perceived irrelevance to any healthcare evaluation
- B. because its collection is prohibited by some legal, political, or professional authority on ground/s unconnected with its causal plausibility
- C. because it lacks causal plausibility in the eyes of an 'expert' group and would therefore be excluded *ex ante* from a 'supervised' ML exercise – so there is no point

3 Data which can be collected without practical difficulty, is indeed collected, but is excluded (*ex ante*) from a 'supervised' ML exercise as lacking causal plausibility.

4 Data which can be collected without practical difficulty, is indeed collected, but is subsequently dismissed (*ex post*) from a 'supervised' ML exercise as lacking causal plausibility.

5 Data which remain - those for a category (characteristic/attribute) which are deemed to reach some causal plausibility threshold.”

An empirical illustration of filtering is provided by a Danish research group that used AI techniques to identify the predictors of ‘acute critical illness’ in the electronic health record of all residents of four mixed rural and urban municipalities (18 years or older in 2012–2017) [14]. The potentially vast data set was

“... limited to include 27 laboratory parameters and six vital signs. The parameters were selected by trained specialists in emergency medicine (medical doctors) with the sole purpose of simplifying the model to enable a better discussion of the model explanations of its predictions [of ‘acute critical illness’]. While a deeper model with more parameters might lead to better performance, it would also have made the discussions between clinicians and software engineers difficult. Therefore, the scope of this article is not to obtain the best performance at all costs but to demonstrate how clinical tasks can be supported by a fully explainable deep learning approach [14, p. 5].”

Their final comments (below) are in line with the group signing up to the orthodox assumption that simply fails to question whether clinicians have the competencies required to understand what they need to understand in order to understand.

“Clinicians must be able to understand the underlying reasoning of AI models so they can trust the predictions and be able to identify individual cases in which an AI model potentially gives incorrect predictions. Consequently, a useful explanation involves both the ability to account for the relevant parts in an AI model leading to a prediction, but also the ability to present this relevance in a way that supports the clinicians causal understanding in a comprehensible way. An explanation that is too hard to perceive and comprehend will most likely not have any practical effect [14, p. 1].”

This hubristic assumption is dangerous in itself, apart from its restriction to ‘medical’ causes and explanations. Moreover, like most of the eXAI literature, the Danish study falls prey to the fallacy that *displaying* the causal findings of an AI program constitutes an explanation of how it arrived at these causal findings. It does not. The latter requires the deep *procedural explanation* that has already been proclaimed to be too difficult to understand!

With its comprehensive unique personal identifier system, Denmark is the perfect setting for an unsupervised ML exercise on a massive population-wide database. Among the large number of non-zero coefficients that might emerge for predicting all-cause mortality is that for dog ownership. We will never know, if we don’t undertake it.

5. Judging Probable Cause

If humans are to judge causal plausibility and causality in the absence of an interventional experiment, as we routinely have to, what do we know about how we do this, as experts or non-experts of all kinds? In an early seminal paper of 1986, Einhorn and Hogarth proposed an ABC by which we judge probable cause - using Alternatives, Background, and Cues:

“... judgments of probable cause are affected by a causal background, probabilistic cues-to-causality, and a discounting process for dealing with specific alternatives... these general ideas can be summarised by a perceptual analogy in which causal candidates are differences-in-a-background (figures are seen against ground), good explanations arise

from internally consistent patterns of cues (good figures form a gestalt), and good explanations have few plausible alternatives (as do good figures) [15].”

The go-to paper on causality in the psychological literature is now the Sloman and Lagnado 2015 review of *Causality in Thought* [16]. Given our entirely practical interest in developing individual decision support tools to be used in decision making practice, we confine ourselves to this central question they ask:

“Can human causal inference be captured by relations of probabilistic dependency, or does it draw on richer forms of representation?”

In answering this *descriptive* question, they reviewed research in reasoning, decision making, various forms of judgement and attribution, and concluded:

“We endorse causal Bayesian networks as the best normative framework and as a productive guide to theory building [about causal thinking]. However, it is incomplete as an account of causal thinking. On the basis of a range of experimental work, we identify three hallmarks of causal reasoning—the role of mechanism, narrative, and mental simulation—all of which go beyond mere probabilistic knowledge... causal inference is not merely a way of representing and updating probabilities; it is not merely Bayesian inference. Human causal inference involves the construction of narratives that unfold over time and determine the focus of attention, narratives that reflect knowledge of the specific mechanisms that drive effects...the causal Bayes nets framework has not offered a silver bullet that answers all questions about human thought. We have seen that it is not always clear whether a choice should be modeled as an intervention [16, pp. 223, 236, 240].”

We fully acknowledge all the descriptive points made by Sloman and Lagnado, though point out no one has ever suggested that the causal Bayes nets framework answers *all questions about human thought*. However, it *may* answer or contribute significantly to answering the question in which we are interested. As established earlier, we decided that our *practical* individual decision support tools, designed for use, not theorizing, should incorporate and display the best available estimate of the degree to which (in many cases, probability) treatment options will produce (cause) a specified effect (criterion). So, in contrast to Sloman and Lagnado we find ourselves satisfied with ‘mere probabilistic knowledge’. We do not even begin to consider how ‘mechanism’, ‘narrative’ and ‘mental simulation’ could be incorporated, *along with probabilistic dependencies*, in our individual decision support tool. And, for the avoidance of all doubt, this individual decision support tool is designed to support choice, modelled as a set of possible interventions to address the question ‘what should we do, now?’ We would be happy to trial our type of individual decision support tool against one in which ‘mechanism, narrative and mental simulation’ are embodied, on a level playing field. Examples of our individual decision support tools can be found at <https://easybest.org.uk>, with introductions in [17, 18].

6. Why is CI Treated Differently from AI?

The blackness of a black box is in the eye of the beholder; the transparency of an AI program is in the mind of the ‘explainee’. What the output of a black box is telling the ‘explainee’, with great clarity if supplemented by a program like SHAP, is not an explanation of how it came to arrive at that output. Holzinger’s example of the application of his System Causability Scale [19] (see Appendix), developed in the context of his call for a *discipline* of causability [10] illustrates this very well. A doctor is asked to assess

the Framingham Risk Tool on this 10 item 5 level Likert Scale. This doctor scores it at .86. However, he has been asked nothing about the procedure by which the Framingham tool arrives at its cardiac risk score.

The clinical encounter is a classic illustration of another ‘black box’ in operation. However, a clinician is never expected to have to explain their ‘clinical judgement’, a term for which we substitute Clinical Intelligence (CI) to emphasize the contrast with AI. Clinical Judgement-as-CI is, by definition, differentiated from any explicit reasoning process or analytical account and invariably constructed as an holistic intuitive process. Its assumed existence is exemplified in the NICE statement that precedes every guidance it issues [<https://www.nice.org.uk/guidance>]. The clinician *must* exercise their judgement in every case, and

“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 or the people using their service.”

In contrast to the calls for the ‘black box’ of AI machine learning process to be opened up and examined for their ‘explainability’, ‘interpretability’ and ‘understandability’, clinicians are never faced by similar calls in relation to their CI process; the process which enables them, inter alia, to ‘take this guideline fully into account, alongside the individual needs, preferences and values of their patients’. The call is wisely not made, because it could not be answered, except as a *theory* of the process, constructed *ex post*. Geoff Hinton, head of Google Brain, and renowned for his work with Artificial Neural Networks, is very clear:

“People can’t explain how they work, for most of the things they do... People have no idea how they do that. If you ask them to explain their decision, you are forcing them to make up a story [20, p. 3].”

Process tracing by psychologists and ‘expert systems’ researchers long ago established that expert clinicians are unable to provide a procedural account of their decisions as IF-THEN production rules, or indeed within any other analytical framework. The source of holistic CI (which we agree is undoubtedly possessed, though to varying degrees, by clinicians) is generally assumed to reside in the intuitive skill of ‘pattern recognition’ acquired through experience. Here, our point is that, *as a procedural explanation*, ‘pattern recognition’ is unlikely to satisfy anyone other than possibly other clinicians - or those who ‘trust’ them to the extent that no demand is made on them for causal plausibility or ‘explainability’. Since pattern recognition is an important basis for machine learning, whether or not it becomes an acceptable ‘explanation’ of findings in the world of AI will be interesting to observe.

7. The Lost Opportunities

The Marshall-Warren discovery of the effectiveness of antibiotics in treating stomach ulcers is perhaps the most famous - notorious - example of how professional resistance to accepting even *plausible causality* can hinder healthcare progress [21]. It parallels the well-documented reluctance of the clinical community to accept the outcome of the clinical vs actuarial debate on *predictability* [22].

There are manifold examples of ‘opportunistic’ findings in healthcare research leading to confirmatory research and improved treatment. Liraglutide for bile acid diarrhea is a recent one [23]. But such findings need not be opportunistic. Unsupervised deep learning programs set to work on massive databases should be seen as abductive

generators of plausible causes, to be followed by unbiased *independent* assignment of causal plausibility *in a defined task*. At the moment the ‘raw’ individual data collected in health research of all kinds is both defined and processed in accordance with a discipline-based study protocol.

In the current research set-up/industry these protocols invariably specify the aim of the study as being to evaluate/assess/describe, ‘quantitatively’, ‘qualitatively’ or both, some way or ways of improving something or some things. The something could be 10 year fracture risk for people with chronic obstructive pulmonary disease, or ‘shared decision making processes in primary care’. It doesn’t matter what it is. It could and should be exploring *all* the possible causes within the data set in relation to generic outcomes, all-cause mortality and all-cause morbidity being the main candidates. The opportunity is lost through the targeted framing of the research and silo-based ‘ring-fencing’ in terms of what data is collected, how it is processed, and what happens to it subsequently. These restrictions mean that gigabytes of potentially exploitable data are simply being left unexploited, either silently or with various justifications. Justifications which include that they are ‘commercial in confidence’, but more often ones that reflect the non-financial material interests of researchers and their corporative organizations.

We are deliberately using ‘silo’, in order to stress that the compartmentalization of research has massive downsides, as well as the upsides which lead to its existence. These downsides are swept under the carpet by unspoken/taken-for-granted agreement among all disciplines that such compartmentalization (‘specialization’) is in their individual and collective material interests, in terms of growth in funding, jobs, publications, and kudos.

Characterizing generic unsupervised exercises pejoratively, as ‘trawling’ or ‘fishing expeditions’, is in line with the material interests of silo-based research groups.

What can be done? Individuals are perhaps the most likely agents of change. In line with the spirit of mydata.org (<https://www.mydata.org>) they could insist that their data, even when it is being collected for a cause-specific purpose, be inserted into unsupervised machine learning programs targeted at generic outcomes. Individuals could be encouraged to agree to participate in research only on the condition that their contributions (their *raw* data, quantitative or qualitative) are made available in pseudo-/anonymized form for ‘OPEN’ unsupervised AI learning, independent of its silo origin, within x years of its collection. At an institutional level, research protocols could be approved by Ethics Committees only when it is shown how data inputs provided *pro bono* by voluntary participants will be fully exploited in relation to *all* health benefits and harms.

8. Postamble

Should Caroline have acquired her dog and should she be proud of owning Romeo, a miniature Schnauzer, as she states. The answers, arrived at by simple logical human reasoning, is that it all depends on (a) the things that matter to her - her multiple criteria - and their relative importance - the weights she attaches to ‘health’ and ‘non-health’ criteria such as all-cause mortality and feeling proud; and on (b) how having a dog and ‘being proud’ effects (performs on) each of these criteria. We cannot support her in this decision if some group of people have pre-emptively decided that there will be little or no information available on (b), because possessing a dog has not met *their* standards for causal plausibility and causality. Such pre-emption should not be in their power, since the necessary error trade-offs should be the preferences of Caroline, the decision owner.

The core fallacy, perpetrated in evidence-based medicine and evidence-based guidelines, is that the error trade-off appropriate in setting a threshold for admittance to the status 'true', has some legitimate connection with the error trade-off appropriate in a decision about what should be done now, under whatever uncertainties exist. While our focus is on the individual, this actually applies in group level decisions, such as in public health, where the issue of causation within epidemiology has built on the pioneering work of Bradford Hill, but notably without attention to the error trade-offs necessary in decision making [24]. The WHO statement on AI is similarly free of attention to the preference-sensitivity of decisions [25]. Whose preferences are the key issue in all decision contexts. The cognitive sources of flaws in decision making both group and individual, have been brilliantly summarized and illustrated in NOISE - A flaw in human judgment [26]. Unfortunately, addressing them will not necessarily have any impact on the motivational and political biases embedded in the power structure of the status quo. It is these that will determine the preference basis of decisions - including whether or not to address them. We should be wary of allowing the medical research tail to wag the health decision maker dog [27].

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Appendix: System Causability Scale (SCS) [19, P. 196]

The purpose of our SCS is to *quickly* determine whether and to what extent an explainable user interface (human–AI interface), an explanation, or an explanation process itself is suitable for the intended purpose. [Likert scale, 10 items with 5 levels from ‘strongly agree’ to ‘strongly disagree’]

1. I found that the data included all relevant known causal factors with sufficient precision and granularity.
2. I understood the explanations within the context of my work.
3. I could change the level of detail on demand.
4. I did not need support to understand the explanations.
5. I found the explanations helped me to understand causality.
6. I was able to use the explanations with my knowledge base.
7. I did not find inconsistencies between explanations.
8. I think that most people would learn to understand the explanations very quickly.
9. I did not need more references in the explanations: e.g., medical guidelines, regulations.
10. I received the explanations in a timely and efficient manner.

As an illustration, SCS was applied by a medical doctor from the Ottawa Hospital to the Framingham Risk Tool (FRT). FRT was selected as a classic example of a prediction model that is in use today. FRT estimates the risk of coronary artery disease in 10 years for a patient without diabetes mellitus or clinically evident cardiovascular disease, and uses data from the Framingham Heart Study. FRT includes the following input features: sex, age, total cholesterol, smoking, HDL (high density lipoprotein) cholesterol, systolic blood pressure and hypertension treatment. The [doctor's] ratings for the SCS score are reported in Table 1. [Total score was 86/100].

Study of the User Behaviour Caused by Automatic Recommendation Systems Call to Action

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Abstract. Diagnostics accuracy and usability of symptom checkers have been researched in several studies. Their ability to set a correct diagnosis especially in the urgent cases is questionable. There is one aspect of symptom checkers that has not been deeply studied yet. It is their ability to motivate patients to follow up after receiving a direct recommendation and to decrease a load on the health care professionals. The goal of this research is to study how patients behave after receiving a recommendation from a symptom checker and motivation of this behavior. We studied how patients react on the symptom checker recommendations and the motivation behind this behavior. In total we invited 3615 patients to have a symptom checker screening; 2374 of them agreed to run a symptom checker screening; 867 of them agreed to participate in the study. The proportion of the patients who agreed to have a symptom checker screening. So, we can clearly see that symptom checker screening doesn't result in a significant decrease of the load on healthcare professionals. This is supported by the quantitative study results. The patients emphasized the ease of use of the tool and clearness of the recommendations it gives. However, they perceived it as rather a second opinion tool or a tool that helps to prepare to the doctor's visit.

Keywords. symptom checker, user acceptance, follow-up rates

Introduction

The World Health Organization (WHO) stated in 2013 that the world was short of 7.2 million healthcare professionals of all disciplines. This number will likely increase to 12.9 million by 2035 [1]. Primary care is particularly [2] affected, with severe lack of health care professionals in most of the countries [3–5]

Large countries with remote areas face another problem: Transporting patients to the points of care.

This has several consequences for the healthcare systems. One of the main and most problematic issues are a reduced access to health care, growing inequity, long waiting times [6], increased load on the emergency services [7,8]. This all lead to the late diagnostics and not optimal treatment. Traditional doctors oriented clinical decision support systems could reduce a workload on the doctors. This was not enough to solve all the listed problems. Machine learning (ML) and Artificial Intelligence (AI) methods

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in data-driven decision support systems helped to reduce healthcare professionals workload, allowed more efficient management of clinical resources and help patients access medical services [9,10].

Online and point of care symptom checkers are becoming a tool that is supposed to be patient oriented and solve the problem of initial screening and help people in remote areas to have a first medical contact [11].

Diagnostics accuracy and usability of symptom checkers have been researched in several studies. Their ability to set a correct diagnosis especially in the urgent cases is questionable [12]. There is one aspect of symptom checkers that has not been deeply studied yet. It is their ability to motivate patients to follow up after receiving a direct recommendation and to decrease a load on the health care professionals.

The goal of this research is to study how patients behave after receiving a recommendation from a symptom checker and motivation of this behavior.

1. Methods

1.1. Symptom Checker

A symptom checker that is being studied is a general-purpose diagnostic symptom checker that is based on the Bayesian classifier. It asks multiple choice questions (figure 1), suggests 3 most probable diagnosis after a conversation (figure 2), and offers a call to action (figure 3) to follow up with a doctor or not. The average number of questions in one patient interaction was 11. There were 3 types of call for action messages: You need to see a doctor urgently (red), it would be good to see a doctor soon if you feel worse (yellow), there is no need to see a doctor now (green)

← Назад

27%

✕ Отмена

Есть ли у вас увеличение лимфатических узлов?

Да

Нет

Не знаю

Продолжить

Figure 1. Question example. Translation from Russian: Do you have enlarged lymph nodes? Yes, No, Not Sure; Continue

99% вероятность	96% вероятность	84% вероятность
Острое респираторное заболевание (ОРЗ)	Хронический тонзиллит	Острый тонзиллит

Острое респираторное заболевание (ОРЗ)

Группа инфекционных заболеваний с преимущественным поражением верхних дыхательных путей и бронхов.

- У 9 из 10 человек с такими же симптомами было диагностировано это заболевание;
- диагностику и лечение проводит врач-терапевт;
- **внимание!** Симптомы заболеваний дыхательной системы могут быть характерны для COVID-19. При подозрении на коронавирусную инфекцию обратитесь по телефону горячей линии 8-800-2000-112. Узнать о бесконтактной сдаче анализа на COVID-19 вы можете на сайте [сдайнакоронавирус.ру](https://sda.nakoronavirus.ru)

Я подозреваю, что у меня острое респираторное заболевание (ОРЗ), что делать?

- 1. Соблюдать рекомендации**
 - Пить больше жидкости;
 - Отказаться от курения;
 - При отсутствии лихорадки или системных симптомов для ускорения выздоровления вернуться к привычному образу жизни.
- 2. Сдать анализы**
 - Клинический анализ крови с лейкоцитарной формулой и СОЭ.

Figure 2. Diagnosis suggestions

Translation from Russian:

Acute respiratory disease

A group of infectious diseases that mainly affects the upper respiratory tract and bronchi.

Nine out of 10 people with the same symptoms have been diagnosed with this disease.

Diagnosis and treatment are carried out by a general practitioner;

Warning! Respiratory system symptoms may be characteristic of COVID-19. If you suspect a coronavirus infection, call the hotline at 8-800-2000-112. To learn about noncontact testing for COVID-19, visit [сдайнакоронавирус.ру](https://sda.nakoronavirus.ru)

Результат оценки симптомов

Обратитесь к врачу в ближайшее время

Ваши симптомы могут потребовать внимания врача, запланируйте консультацию в ближайшие дни. Если вы чувствуете себя значительно хуже чем обычно, а симптомы длительно сохраняются или усиливаются - обратитесь к врачу сегодня.

Figure 3. Call to action. Translation from Russian: Result of symptom screening

It would be good to see your doctor soon.

Your symptoms may need your doctor's attention, schedule a consultation in the next few days. If you feel significantly worse than usual and your symptoms persist or get worse, see your doctor today.

1.2. Recommendations Follow Up

The first part of the study was dedicated to calculation of a follow-up rate.

The patients were offered to work with a symptom checker before a doctor's visit. Facilitators, who were not healthcare professionals supported patients with the symptom checker operation. The patients were motivated by a gift voucher that they could use for the medical services in the clinic.

A proportion of patients who accepted the offer was calculated by the research team. After the patients have completed a symptom checker session, we invited them to participate in the study.

Inclusion criteria were:

- Age > 18
- Purpose of visit: primary visit
- Completed a symptom checker session

Exclusion criteria were:

- Age < 18
- Secondary visit scheduled by a doctor

Those who had agreed were offered to sign a consent for that contained the purpose and the details of the study. They were also asked to fill in a short questionnaire that contained basic demographic information: age, gender, education and contact details.

After the consent form and a questionnaire were submitted to the research team, the patients were asked to provide the results of the symptom checker session.

The patients were asked if they would like to have a follow up visit with a doctor or not. We calculated the proportion of patients who wanted to have a follow up and those who didn't for the following groups of the patients:

- Green call to action (No need to see a doctor)
- Yellow call to action (Self-observation and may be see a doctor later)
- Red call to action (Urgently see a doctor)

The study was performed in a private outpatient clinic in March-April 2021. The study got the approval by the local ethics committee.

1.3. Motivation Study

For understanding the motivation to follow up or not on the symptom checker recommendations, we invited all the patients to take part in the interview. All the patients invited to interview were notified of the objectives of the study and of the purpose of the interviews in written.

The study was designed as a series of semi-structured interviews based on a topic guide, which was developed by the study team and reviewed by the local ethics committee.

Interviews had the following agenda:

1. Was the symptom checker user friendly and easy to use?
 - 1.1. Did you understand the recommendations?
 - 1.2. Did you understand the diagnosis that the symptom checker provided?
2. Did the symptom checker influence your decision to follow up with a doctor?
3. Why did you decide to follow up or not after a symptom checker session?

The guide included open questions to provide good understandings of the patients' opinion, without influencing from an interviewee. We applied a probing approach [13] during interviews to encourage patients to express openly.

Table 1. Demographic details of the study population

Gender	Average age	Age > 60	Education		
			Higher	Secondary	Below secondary
346 Males	42.6	106	98	238	10
521 Females	43.1	134	125	384	12
Total 867	42.9	240	223	622	22

The interviews were performed by two members of the research team. Each interviewee was in written assured of anonymity and confidentiality of the study participation. They were informed of their right to revoke personal data from the study at any time. The interview duration was 10 to 20 minutes and all of them provided sufficient information for the study. A combination of thematic analysis and a grounded theory approach was used to analyze the interviewees' responses [14,15].

2. Results

2.1. Recommendations Follow Up Results

In total, we invited 3615 patients to have a symptom checker screening; 2374 of them agreed to run a symptom checker screening; 867 of them agreed to participate in the study. The proportion of the patients who agreed to have a symptom checker screening. Table 2 contains the details of the patients' acceptance rates.

Table 2. Study population.

Patients approached	Agreed to the symptom checker screening	Agreed to participate in the study
3615	2374 (65,67%)	867 (23,98%)

Table 3 provides a classification of the study participants into groups.

Table 3. Distribution of the patients according to the call to action

Gender	Green	Yellow	Red
Male (346)	65 (18,79%)	213 (61,6 %)	68 (19,65%)
Female (521)	101 (19,38%)	341 (65,45%)	79 (15,16%)
Total (867)	166 (19,15%)	554 (63,9%)	147 (16,96%)

Table 4 presents follow up rates for each group of patients.

Table 4. Follow-up rates

Gender	Green	Yellow	Red
Male	46 (70,8%)	204 (95,8 %)	68 (100%)
Female	74 (73,3%)	329 (96,5%)	79 (100%)
Total	120 (72,3%)	545 (96,2%)	147 (100%)

2.2. Behavior Motivation

We have interviewed 48 patients, who agreed on this part of the study and signed a consent form.

The thematic analysis identified 4 core topics related to the patients’ responses, namely: (1) usability, (2) intention to use, (3) trust, and (4) data protection. The first core topic highlighted the usability and clearness of the questions and recommendations. The second core topic demonstrated that the patients have strong wish to use the symptom-checker for screening. The core topic number 3 identified the issue of trust. The topic 4 identified personal data security and protection awareness. Table 5 present selected responses to support the obtained results.

Table 5. Selected answers

Core topic and Code	Selected responses
Usability Time	It doesn’t take much time to do a screening [A1]
Usability clearness	The questions were clear to me, I could answer them easily [A2]
Usability Time	This tool can save my time [A3]
Intention to use	I think this tool can be best used as a second opinion [A4]
Second opinion	
Intention to use	I can use it to better prepare to the doctor’s questions [A5]
Second opinion	
Intention to Use	The portal allows to quickly update It can help me to be better
Second opinion	informed on my health conditions [A6]
Intention to Use	I still want to talk to a real doctor [A7]
Second opinion	
Trust Explanation	The system explains the results clearly, so I can make an informed decision [A8]
Trust Explanation	I can see the logic behind the decision, so I can base my decision on what the system recommends [A9]
Trust User enthusiasm	The recommendations are clear, so I can rely on them when deciding to follow up [A10]
Data protection	It’s good that no personal data is collected [A11]
Privacy	
Data protection	The session is anonymous, so I can trust the system [A12]
Privacy	

3. Discussion

As we can see from the follow up rate results, the urgent recommendations cause a 100% follow up rate. A red message always resulted in the doctor’s visit. Yellow messages with a recommendation to visit a doctor soon if the health conditions do not improve also

resulted in almost a 100% follow up rate with actual number of 96,2%. The only recommendation that filtered some of the patients and prevented some of the not required visits was a green message with 72,3% follow up rate. So, we can clearly see that symptom checker screening doesn't result in a significant decrease of the load on healthcare professionals. This is supported by the quantitative study results. The patients emphasized the ease of use of the tool and clearness of the recommendations it gives. However, they perceived it as rather a second opinion tool or a tool that helps to prepare to the doctor's visit.

Our results add a discussion point to the efficiency of the symptom checker in terms of being able to decrease a load on the healthcare professionals or even replace them in some situations. We didn't observe any behavioral difference between males and females.

3.1. Limitations of the Study

In this study we did not assess the accuracy and other efficiency characteristics of the symptom checker. This will become a subject of a further study. The second limitation of the study is that we didn't research how the screenings affected the length of the actual doctor's visit, which will also become an objective of the further studies.

4. Conclusion

Our findings suggest that automatic symptom checkers don't significantly decrease a load on healthcare professionals, as they are mostly perceived as a second opinion tool.

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Assessing Human Mobility by Constructing a Skeletal Database and Augmenting it Using a Generative Adversarial Network (GAN) Simulator

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Abstract. This paper presents a neural network simulator based on anonymized patient motions that measures, categorizes, and infers human gestures based on a library of anonymized patient motions. There is a need for a sufficient training set for deep learning applications (DL). Our proposal is to extend a database that includes a limited number of videos of human physiotherapy activities with synthetic data. As a result of our posture generator, we are able to generate skeletal vectors that depict human movement. A human skeletal model is generated by using OpenPose (OP) from multiple-person videos and photographs. In every video frame, OP represents each human skeletal position as a vector in Euclidean space. The GAN is used to generate new samples and control the parameters of the motion. The joints in our skeletal model have been restructured to emphasize their linkages using depth-first search (DFS), a method for searching tree structures. Additionally, this work explores solutions to common problems associated with the acquisition of human gesture data, such as synchronizing activities and linking them to time and space. A new simulator is proposed that generates a sequence of virtual coordinated human movements based upon a script.

Keywords. OpenPose, Rehabilitation, Generative Adversarial Network (GAN), Siamese twins Neural Network, Simulator, Human body movements

Introduction

Remote medicine utilizes human gestures to conduct real-time medical treatments (1) (2). For example, The COVID-19 pandemic demonstrated the importance of remote diagnosis and treatment. In the modern age, it is now possible to utilize a camera video stream to collect, analyze, and interpret human emotions in a remotely located 3D environment by using artificial neural networks (3). Vocabulary Lexicon's purpose with this Research work is to present an indexing system for our predefine body movements that will enable us to recognize and describe physical actions using machine learning algorithms. As an outcome of this research, developers will transform posture into text

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and vice versa. Our objective is to characterize human motion by using neural network architectures such as Autoencoder (4), Siamese twins (5), and DWT-NN (6) in conjunction with OpenPose (7) and Mediapipe (8). Remote therapy may be used when many patients recuperate after hip, knee, elbow, or shoulder surgery (9) (10). A variety of non-contact medical treatments might be developed by utilizing a family of neural network designs resulting from this research.

1. Literature Review

This research work dissertation proposes a solution to enrich and enhance skeletal data veracity, by providing accurate and specific data tailored to research requirements using the GAN deep-learning method (11). In the articles (12) (13) (14), some databases contain video clips of human movements divided into a variety of classes. To begin with, they process the data through the OpenPose software, translating the video frames into skeletal pose sequences, which are then analyzed. A three-dimensional matrix represents each skeletal pose. To preserve the relationship between the skeleton joints, the authors reordered every pose as part of Deep First Search (DFS). Our movement generator is based on skeletal data that provide spatial and temporal information. Several studies have investigated the issue of recognizing human movement using skeleton-based neural networks (CNNs) (12) (15) (16). Therefore, Deep Convolutional Generative Adversarial Networks (DC-GANs) use CNN layers as their generator and discriminator [8]. It is proposed in (12) (14) (16) (17) to use an image format (TSSI - Tree Structure Skeleton Image) to generate a tree structure skeleton image based on the collection of N tree structure sequences. Therefore, we utilized Deep First Search (DFS) to restructure and create tree structure skeletons.

2. Patients Data Base

There are six basic physiotherapy exercises in the database, which have been carefully selected to be suitable for analyzing and processing with a single camera (two-dimensional processing), see (2). There are 30 participants in the database, who each perform six exercises. Ten cycles comprise each exercise (e.g. rotating the right arm). Exercises are performed once with a right tilt and once with a left tilt (for example, once with a right foot rotation and once with a left foot rotation). A total of about 7500 motion cycle videos have been tagged and timed in the database. This study included healthy subjects (volunteers - students) with no disability identified during tests to control postural stability. The subjects group comprised of 4 men and 26 women with an average age of 21.1 (SD 1.2) years, body weight 64,8 (SD 9,4) kg and body height 170 (SD 9) cm. One single measurement of each subject was taken during the session. The study was performed in accordance with the Helsinki Declaration and the study protocol was approved by the local Ethical Committee, by the Faculty of Biomedical Engineering, Czech Technical University in Prague. The entire database has been encoded as skeletons - a skeleton in every frame (Figure 1).



Figure 1. database has been encoded as skeletons - a skeleton in every frame

Performing exercises creates skeletal structures. The human body is represented by 25 vertices in each skeleton. The vertex has three components: Coordinate X, Coordinate Y, and Coordinate C, which indicates the level of certainty about each point in the skeleton on a scale from 0 to 1 (1-absolute certainty, 0 absolute uncertainty).

3. Gesture Generator Using Generative Adversarial Network

AI (artificial intelligence) is a revolutionary technology that is finding applications in a wide range of products and services that we use on a daily basis. An amazing application of AI technology is Deep Learning, which is based on neural networks. Deep learning-based application development requires a large dataset with a sufficient number of training examples. In the absence of such databases, researchers and data scientists use synthetic data to circumvent the problem. Through the use of synthetic data as an augmentation strategy, our research offers to demonstrate a solution for a particular database containing a limited number of video clips of human physiotherapy workouts. Using a gesture generator, skeletal gestures are generated from the videos (see Figure 2). OpenPose is utilized for creating a representation of this existing database. OpenPose is the world's first real-time collaborative system for identifying the human body in images and videos. Raw images of the human body are converted into three-dimensional skeleton vectors in Euclidean space using skeletal algorithms such as OpenPose, AlfaPose, and Mediapipe. The vector represents one position of a human being. In order to produce new samples and to govern the generated motion type, we will demonstrate in this research how to utilize a Generative Adversarial Network (GAN) as a generator.

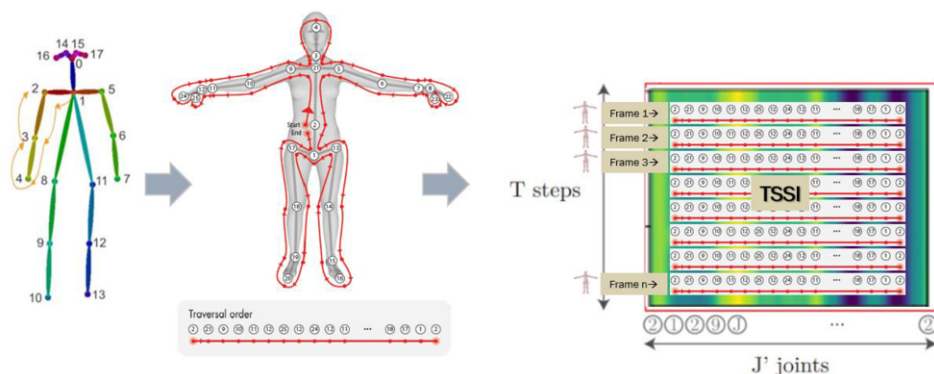


Figure 2. Tree Structure Skeleton Image (TSSI)

3.1. Network Architecture

Our system creates samples using a generator (Figure 3). A sequential layer model is designed using deep convolutional generative adversarial networks (DC-GAN). The input to the first layer consists of random noise ($1 \times 1 \times N$) which is subsequently concatenated to the ($1 \times 1 \times C$) class which controls our output movement type. Topology structure combines DC-GAN generator layers architecture and adaptation [3][8]. The discriminator in our system is responsible for distinguishing between the fake generator output and the true skeletal pseudo-image. The result is a value that lies within the interval $[0,1]$ that gives the probability as follows, 0 for a phony pseudo-image and 1 for a real pseudo-image. It is suggested in papers (12) (18) that the DC-GAN discriminator might take a layered architecture. In this research we are using the Depth-First Search (DFS), a search technique for tree structures. We changed the order of joints in our skeletal model to highlight the connections between them. The samples will consist of only the gesture frames without any additional frames that are not essential.

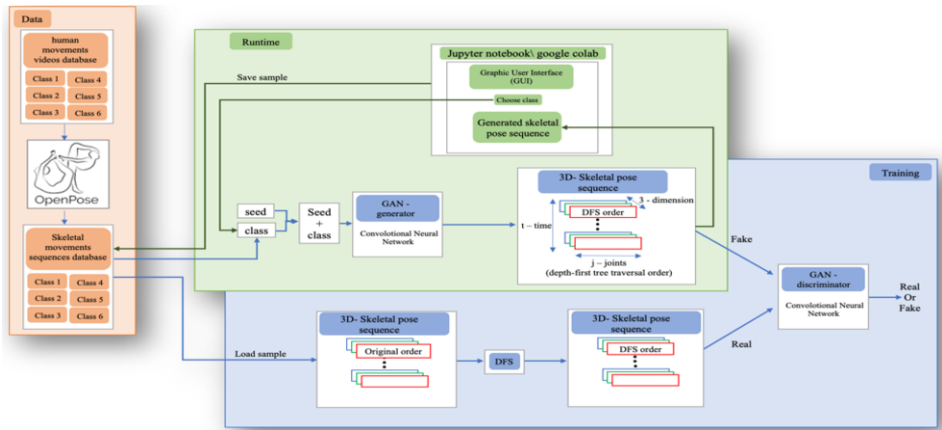


Figure 3. GAN Concept Design

4. Demonstration of How to Measure Gesture Mimics via the Siamese Neural Network

The neural network chosen for this project is the Siamese neural network (5). The reason for selecting the Siamese network is its one-shot learning capability. The result is that once the network has been properly trained, it is possible to classify a new image into a class that was not included in the initial training. Integrated Pose Estimates (IPEs) images were developed to train the network. Using this new technique, we were able to capture all the motion of the human body in one image. It is not necessary to use all of the frames within a time window to create a good representation of IPE. We conclude that different gestures require different time windows for optimal IPE representation.

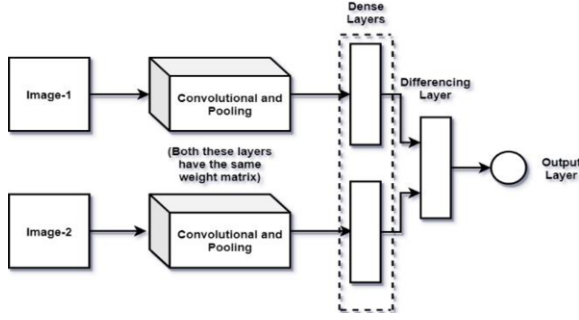


Figure 4. Siamese Network Layout

The input to the network (see **Figure 4**) consists of a pair of IPEs with dimensions of 105x105 pixels each. Inputs are fed into the same convolutional and pooling layers and the output is a tensor with 4096 elements for each input, which can be considered as a type of code or latent of the IPE. These codes are fed into the differentiation layer, which computes their L1 distance, i.e.

$$D = \text{flatten}(|T_1 - T_2|) \quad (1)$$

where T_1, T_2 are the tensors obtained from the convolutional and pooling layers, respectively. There is only one neuron in the final dense layer that has a sigmoid activation function. We can model this layer mathematically:

$$y = \sigma(\text{bias} + \sum_i w_i D_i) \quad (2)$$

where:

- σ is the sigmoid function: $\sigma(x) = \frac{1}{1+e^{-x}}$ (3)
- D_i is the i 'th element of D
- w_i is the corresponding i 'th weight

Accordingly, the output of the network is a number between 0 and 1, which correlates to the degree of similarity between the two inputted IPEs. The closer the output value is to zero, the higher the level of similarity predicted.

N-Way is a method of validating the one-shot learning process (5). We used a random subset of IPEs for every activation of a single N-Way evaluation. As part of a single N-Way evaluation, a specific IPE is randomly selected to function as the reference IPE, and its movement is considered to be the reference movement. Moreover, N other IPEs are selected at random with the constraint that only one belongs to the reference movement, while the remaining $N-1$ IPEs each belong to a different movement. Each of these N IPEs is paired with the reference IPE to create N pairs. Using the Siamese network, each of these pairs is converted into a corresponding output value. For an N-Way prediction to be considered accurate, the unique pair of movements must produce the minimum output value. By repeating the 'N-Val' process a number of times, the accuracy will be computed as follows:

$$\text{Accuracy} = 100 \cdot \frac{\# \text{ of correct predictions}}{N_{\text{val}}} [\%] \quad (4)$$

5. Results

Over 4000 movements were generated for the Neural Network database and testing using a synthetic movement simulator. Through the simulator, the user is able to create choreography by combining seven predefined movements (see example in Figure 5). Synthetic movements were classified according to seven predefined categories in our system. There are five hidden layers in our classification network, which is a Siamese network. The classification of real data produces 86% accuracy, while the classification of our simulated data produces 91.82% accuracy.

Movement: pick up

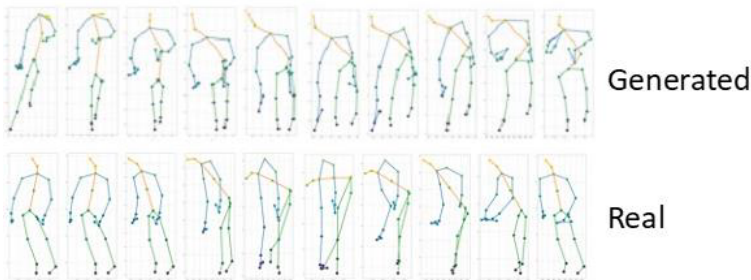


Figure 5. Results

6. Conclusions

We build a GAN simulator to feed a Siamese Network that measures, classifies, and infers human movement. The simulator produces video footage of actual physiotherapy treatment sessions. The video footages contain vectors representing skeletons, thus allowing us to recreate human movement sequences. We present the idea of how a Generative Adversarial Network (GAN) works and how we used it as a tool that makes it possible to create and control human body motion parameters. We reorganized the joints of our skeleton model in a tree structure search approach reorganized using DFS to emphasize their connections. Data collection of human gestures is usually fraught with challenges, such as maintaining synchronization between activities over time and space. The research investigates some of these and other standard stumbling blocks. It is interesting to note that a by-product of our study can be a virtual dance simulator that choreographers can use to translate choreographic sequences into dance steps.

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Privacy and Trust in pHealth - Past, Present and Future

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Abstract From beginning to today, pHealth has been a data driven service that collects and uses personal health information (PHI) for personal health services and personalized healthcare. As a result, pHealth services use intensively ICT technology, sensors, computers and mathematical algorithms. In past, pHealth applications were focused to certain health or sickness related problem, but in today they use mobile devices, wireless networks, Web-technology and Cloud platforms. In future, pHealth uses information systems that are highly distributed, dynamic, increasingly autonomous, multi-stakeholder data driven eco-system having ability to monitor anywhere person's regular life, movements and health related behaviours. Because privacy and trust are pre-requirements for successful pHealth, this development raises huge privacy and trust challenges to be solved. Researchers have shown that current privacy approaches and solutions used in pHealth do not offer acceptable level of privacy, and trust is only an illusion. This indicates, that today's privacy models and technology shall not be moved to the future pHealth. The authors have analysed interesting new privacy and trust ideas published in journals, and found that they seem to be effective but offer only a partial solution. To solve this weakness, the authors used a holistic system view to aspects impacting privacy and trust in pHealth, and created a template that can be used in planning and development future pHealth services. The authors also propose a tentative solution for future trustworthy pHealth. It combines privacy as personal property and trust as legal binding fiducial duty approaches, and uses a Blockchain-based smart contract solution to store person's privacy and trust requirements and service providers' promises.

Keywords Privacy, Trust, System view, Fiducial Duty, Privacy law, Smart Contract

Introduction

While being focused on personal health and services as well as personalized health and health care, pHealth presents a horizontal view to health care, eHealth and mHealth. Real life pHealth services and applications vary in size and interest. It can be a single sensor-based monitoring solution (e.g., heart rate monitoring), or it has a multi-dimensional view to person's health problems (e.g., support for independent living). From

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technological point of view, pHealth can appear as person's health problem focused application or as personal health system (PHS) that collects personal health information (PHI) using body sensors and wearables. Currently, it is increasingly part of a multi-stakeholder eco-system focusing on health management.

From past to today, information systems for healthcare and health have performed a meaningful development at conceptual, technological and information system levels. An important driver for this development has been the paradigm shift in health care, i.e., the transition from hospital centred and reactive healthcare to person-centred preventive and even predictive care [1]. In the past, health care information systems (e.g., hospital information systems) were institutional, local, siloed and static. In today, health care and health information systems are increasingly cross-organizational, communicative, networked ecosystems with data sharing capability.

During last 15 years, pHealth has underwent similar transition as health care. In the past, many of pHealth applications were local, focused on the use of certain body sensors and wearables to measure and analyse person's health and sickness related body functions. The goal was to support the management of person's health or illness, self-care and independent living. Nowadays, pHealth services use different kind of artifacts such as sensor, mobile devices, wireless networks, Web-technology and Cloud platforms for collecting, storing and processing PHI to support on-line personalized care and health management. Current pHealth services are also increasingly part of a multi-stakeholder eco-system.

At present, the collection of personally identifiable information (PII) takes place every day and everywhere when we are using networks, personal computers, smart phones and wellness devices. Our behavioural health related activities are tracked by the browser, and our e-mails can be read by applications or cookies invisibly injected by applications [2, 3]. Furthermore, PHI is not collected and processed only by regulated healthcare organizations and professionals, but also by commercial non-regulated health service providers, web service providers and social web applications. PHI is also shared and sold between them [4-7]. Researchers have observed that digital information systems are seldom designed with privacy in mind [8].

This situation has raised huge privacy and trust concerns. In today's health information systems, it is difficult or even impossible for a person to know what PHI is collected, used and disclosed by whom for what purposes, which privacy laws are deployed by the service provider, and how to maintain privacy in distributed ecosystems [7, 9-11]. In real life, it is almost impossible for the service user to prevent unnecessary data collection and to know to whom data is disclosed. Furthermore, security-based solutions widely used in current information systems are ineffective in privacy protection. Therefore, the assumption that a person can control the use of his or her personal information in the Internet and ecosystems is just an illusion. In fact, we simply do not have privacy [12].

Concerning trust, the situation is not much better. From past to today, it has been expected that people blindly trust in service provider and in technology used (e.g., computers, mobile phones networks Clouds and data storages, and applications). According to Mc Knight et al. it is expected that a service user believes (typically without any proof) that structures such as guarantees, regulations, promises, legal recourse and procedures are in place (i.e., structural assurance), and that the environment is in proper order (i.e., situational normality) [13]. According to Ruotsalainen et al., this is unfortunately a wrong assumption, because in distributed and multi-stakeholder environments such as pHealth, it is almost impossible to know to whom and why to trust

[14]. Researchers have observed that in today's digital information systems not only privacy is an illusion, but also trust is only a belief [15].

In the future pHealth, the situation can be even more serious, because information systems used by pHealth will be highly distributed, dynamic, increasingly autonomous, data-driven multi-stakeholder ecosystems. Those systems have the ability to monitor anywhere person's regular life, movements and health related behaviours using smart sensors and surveillance systems, and to combine this multi-source information to personal Big Health Data that can support 5P medicine and pHealth in many ways. Personal Big Health Data can be used for different analysis, to calculate detailed personal health profiles, detect of changes in personal health and disease, to support continuous health management, and for the development of personal health devices and services. It can be also easily misused for other purposes. Researchers expect, that future pHealth will rely on Internet of Things (IoT) based data collection, advanced computer methods such as machine learning (ML), artificial intelligence (AI) and deep learning (DL) [11, 16]. They all need the availability of Big Data. Future pHealth applications and services can also empower to better understand causes of diseases [17]. The development of pHealth does not stop with the collection and intelligent use of PHI. In the future, mobile manipulators will be also part of the pHealth ecosystem. As those manipulators have ability to navigate in space and manipulate objects, communicate with person and networks, and have autonomous capabilities, they have the potential to assist people in everyday tasks, for example in home [18].

In spite of the big promises of the future pHealth, the development can lead to a situation where for a person as the source of PHI and at the same time user of pHealth service, there is no privacy, and she or he has to trust blindly in technology providers' goodwill in the environment of insufficient regulations [11]. To find a way from the current unsatisfactory situation to future trustworthy and privacy-enabled pHealth, the authors have studied both privacy and trust challenges existing in today's pHealth services and information systems, and new privacy and trust approaches and solutions proposed by researchers. Based on findings got, the authors have formulated a summary of principles, architectural models, rules and technological artefacts which, when used as hole, have power to make future pHealth ethically acceptable, trustworthy, and at the same time support person's privacy needs.

1. Privacy and Trust Approaches and Challenges

As discussed in the introduction chapter, pHealth is sensitive, health data driven service or application. Therefore, high level of privacy and trust is a prerequisite for successful pHealth. Because pHealth applications and services are typically build over general ICT technology and services (e.g., the Internet, mobile networks and Cloud services), their privacy and trust challenges can be used as proxy for pHealth.

Information privacy and trust are dynamic, situational, context-depending and vague concepts without globally accepted definition [7, 19]. This makes it challenging to conceptualize them and to perform them by computer programs. Privacy is human and constitutional right [20], but not an absolute policy. In principle, privacy addresses the question "what would we like others to know of us". Privacy is also a regulatory concept. In western countries, privacy is for long understood as a personal right to protect individuals against something (e.g., against other's manipulation, control or surveillance),

and to prevent others from harmful actions. Widely used privacy models include privacy as control, privacy as a commodity, privacy as property or contextual integrity, privacy as a concern and legal construct, risk-based privacy, and privacy as behavioural concept and social good [21, 22].

The principle of autonomy is one of cornerstones of privacy, i.e., to control when and by whom PHI is collected, and for what purposes it is used [22]. The concept of privacy as a commodity understands privacy as economic good that can be traded for other goods or services [23]. Privacy as a concern refers to individuals' anxiety regarding data collectors' and processors' practices in collection, using and sharing data. Privacy as a regulative (legal) construct tries to regulate the disclosure and use of information in a context, and to protect individuals [24]. The risk-based approach to privacy focuses on risk such as harm, caused by unnecessary data collection, misuse and disclosure, surveillance and behavioural manipulation [25]. The nature of privacy and the lack of availability of reliable information make the measurement of actual (objective) privacy challenging [26]. Therefore, different proxies such as perceived risks, service level agreements, external third-party seals, service provider's privacy policy documents, reputation, direct observations, and degree of compliance with laws or standards are widely used instead [7].

Despite privacy is a fundamental right, there is always a tension between public and commercial interest to collect and use of PHI on one side and person's need for privacy on the other side. According to Ruotsalainen et al., nowadays, industry sees increasingly personal information as raw material for products and services, and society as public good. Therefore, there exist conflicting interests between individual's need for privacy on one hand and the use of PHI for meaningful public benefits or for making profit on the other hand [11].

A big privacy challenge is that today's ICT technology enables the collection, use and storage of extremely sensitive health-related information about person's life, health problems and behaviour. Modern sensors, microchips and computer technology, wearables and consumer level devices such as smart wrists have the ability to measure not only blood pressure, heart rate, quality of sleeping and social activities, but also personal training, emotions, mood, voice profile and daily life health behaviours. Furthermore, person's sweat, urea, breath gases, faces, or saliva can be measured and analysed as well. Smart-video-based facial recognition applications have the ability to analyse our emotions such as joy, sorrow and smiling. Furthermore, video surveillance systems in public spaces can monitor our social and health related behaviours. In the Web, there are tens of thousands health apps collecting and using PHI, and many people also self-disclose their personal health problems in social networks [19]. Currently, all this data is typically stored in the Web (e.g., in Clouds and platforms), and this enables the creation of a virtual personal Big Health Data repository. An additional privacy concern is that person's behavioural health data is systematically and hidden tracked by Web service providers, health apps and Web platforms. According to Dobkin et al., at least 77.4% of Websites globally track visitors' data and behaviour [27]. Zuboff has noted that behavioural tracking is not only used to measure body signals, but it covers also our physical and social behaviours and how we use information systems [28].

A big privacy concern is that PHI is increasingly used outside the regulated health care domain and by personal health wellness applications in the Web. Nowadays, PHI is not only used for health services, but also for social control, crime prevention, prevention of antisocial behaviours, to control humans' social life and behaviours, and to manipulate person's decisions.

Trust exists in the relationship between a trustor and trustee. It is widely understood as a social norm, subjective feature, psychological state, personal trait, and willingness to be vulnerable to other party's expected or unexpected actions without the ability to monitor or control them [29]. Trust is needed in situations, where the trustor has insufficient information about the features and trust behaviours of the trustee [30].

Thrust can be a disposition, attitude, belief, expectancy, feeling willingness to trust, and perception based on own previous experiences or others' recommendations. It takes place between persons, but also between a person and a technical artifact (e.g., computer application or information system). Trust is necessary in situations where the trustor has insufficient information about the features and behaviours of the trustee [31]. Disposition (propensity) to trust is the tendency to trust others. Perceived trust is often only an opinion. Thrust can be also computational, i.e., based on measured features of the trustor and used information system [29]. Computational trust imitates the human notion of trust, and it is widely used to substitute mental trust models [30].

The lack of trust is a big problem when we are using computers, mobile phone networks, digital information systems, or the Internet and Web services. This environment is also a problem in pHealth, because its services are built over commercial digital technology. The user of pHealth service has not only to trust in a service provider, but also in invisible computer technologies, applications and algorithms. According to Mc Knight, trust in technology is often a belief that technology used is reliable, secure, and protects information privacy, and appropriate governance is established and enforced [32].

Currently, service providers and platform managers often expect that the level of privacy the service user needs is a result of the balancing person's privacy needs against service provider's business objectives and requirements. Because the service provider is in real life often the stronger actor, this balancing means that the service provider's business benefits regularly override person's privacy needs. Therefore, the most practical solution for a person to maintain privacy is to reject the service, filter the amount of PHI he or she has willingness to disclosure or add noise to data [33]. In real life, stakeholders' privacy and trust features are seldom available, and the person has limited or no power for negotiation with the service provider to force her/him taking into account personal privacy needs. Instead, the service user is forced to accept service provider's privacy promises (policy) and trust manifesto in the form of a take-it-or-leave-it approach [27].

There are many other challenges. One is, that service providers are increasingly monetarizing personal information by selling collected PHI to other actors. Another problem is that the number of applications using PHI for secondary purposes is rapidly increasing. Examples of that include job recruiting, credit checks, the justice system, predictive policing, and determining health care for people. Furthermore, ML, AI and DL are used to analyse Big Health Data for providing personalized life style related proposals, health predictions, and context-aware profiles.

International organizations, regulators and governments have established both general and privacy laws, norms, standards, Golden Rules and health care specific acts to enable meaningful use of personal data, and to restrict unnecessary secondary use of PHI. Current privacy laws and guidelines are built on the principle of privacy as legal right, and a control as well as notice-and-choice approach [22]. From the person's point of view, privacy laws and Golden rules seem unfortunately to be weak compromises and in real life ineffective and not widely implemented by industry [24]. Laws also offer poor privacy in public spaces, and behavioural privacy is not protected [28].

A big problem from data subjects' and pHealth service users' point of view is that commercial service providers have low incentives to enforce strong privacy policies, and often they do not keep their privacy trust promises. Instead, they often fail to provide even basic privacy protection [34, 35]. Furthermore, researchers have shown that current security and control-based solutions have failed to guarantee privacy in distributed and dynamic digital environment, and many big Web actors and service providers simply do not worry of privacy laws [26, 37]. The result is, that the lack of reliable information of service provider's, networks and applications' privacy and trust features has led to situations where feeling or opinion is the only measure of privacy and trust in pHealth.

From a personal point view, the current situation concerning privacy and trust in digital information systems is unsatisfactory, and when thinking of future highly distributed, dynamic and increasingly autonomous pHealth, the situation will be even more challenging. The use of AI, ML and DL, especially if raw PHI is used, generates privacy challenges such as the possibility of data reconstruction, and difficulties to support person's privacy policies, erasing of data and realizing the right to be forgotten [38]. Extensive collection of detailed PHI, health tracking and the creation of Big Health Data repositories can lead to total loss of autonomy and increased behavioural, social and political control, behavioural manipulation and discrimination, routinely monitoring of personal health and wellness in work and public places, and finally the commodization of PHI [11]. The authors state that better privacy and trust solutions than what is used now are indispensable for future pHealth. They should take into account person's and service user's privacy and trust concerns and enable them to know what PHI is collected, used and shared? Furthermore, persons need reasons to trust in the implementation and efficiency of laws and regulations, in service providers' and technology providers' privacy policies, features and behaviours, and in information systems as a whole. In the future pHealth, it should be clear, who is the owner of our PHI in different contexts, and what is the impact of data collection, and how data is used and shared by different apps. The data subject shall also have the possibility to measure (or estimate) using reliable data, what is the actual level of privacy and trust in pHealth information system.

2. New Privacy and Trust Approaches and Technological Solutions

Researcher have not only studied privacy and trust challenges existing in today's pHealth, but also proposed new approaches and solutions for privacy and trust to be used in future distributed information systems. Some of them are quite radical and require a paradigm change and new laws, but others rely on currently used privacy and trust models, and propose only architectural, mathematical and functional solution, Table 1, [29].

Balkin has proposed a concept of information fiduciary [39]. According to Balkin, a fiduciary (person or organization) has special obligations of loyalty and care toward another person and the responsibility not to do harm. Fiduciaries must also act in the interests of another person. This means, that for example a fiduciary must accept and implement person's privacy needs. Because powerful organizations, such as online service providers and cloud companies, regularly collect, analyse, use, sell, and distribute personal information, Balkin suggested that they should be understood as information fiduciaries toward their customers and users of their digital services [39]. According to Barret, an information fiduciary model can strengthen protections for privacy, equality, and autonomy in the digital age [40]. According to Dobkin, the principle of information

fiduciary should be a legally imposed as duty [27]. Fiduciary relationship as legal duty is also a trust builder. For Mayer, trust in fiduciary relationships is based on the professional's competence and integrity [41].

Table 1 Examples of new privacy and trust models and solutions

Concept of information fiduciary as duty	New concept
Privacy as trust	New way to understand privacy
Personal information as property Privacy as intellectual property	Defines data ownership and new property rules A radical philosophical approach
Privacy as trust and legal binding fiducial duty	Expands trust as legal binding duty model
Computational privacy and trust	Uses available information and mathematical methods
Person controlled use of PHI	Proposal based on the use of cryptography
Cryptographic models	Blockchain Smart contract Patient controlled use of PHI
Data protection by encryption	Differential privacy Homomorphic
Privacy risk analysis-based approach (EU-GDP)	Part of the EU-GDPR act
New information architecture	Edge architecture

For Waldman, privacy in information sharing context is a social construct based on trust [22]. He has proposed a new way to understand privacy as Privacy as Trust approach that is not bound to the concepts of control, choice, autonomy, or seclusion. It is a radical concept that presents a principal movement from the right to privacy to trust. According to Waldman, privacy as trust creates a fiduciary relationship between data subject and users. In this approach, a private context is also a trusted context [22].

Ritter et al., have proposed regulating digital information as a new class of property under current legislation. In this approach, rights of ownership for digital data establishes control of its use [42]. According to Samuelson, current laws do not give individuals the full right to control the use and disclosure of personal data. The informational property rights approach empowers individuals however to negotiate with organizations and firms the ways data is used [43]. Ruotsalainen et al. have proposed to use the Privacy as Property approach in such way that it enables a person to define personal privacy policies [11].

It is also possible to combine approaches and solutions shown in Table 1. Ruotsalainen et al. have made a solution that combines privacy as personal property model, trust as fiducial duty, legally binding smart contract, and Blockchain-based repositories for contracts [7]. In this approach, legally binding duties prevent big companies to set their own privacy standards. Instead, it defines a digital service level agreement the service provider must follow [11].

In the case, reasonable information of service providers' and information systems' privacy features is available, the data subject or service user can use mathematical methods to calculate the level of privacy and trust in an information system. Ruotsalainen et al., have used a Fuzzy Linguistic method to calculate the Merit of Service (Fuzzy attractiveness rating) for the whole ecosystem, where PHI is collected, processed, and shared [30].

The model of person-controlled use of PHI is based on the idea that a person has full control over operations with own PHI (e.g., the person grants or rejects granular access to the record storing PHI in a context). For access control, the person has to generate a private-public-key pair. The encrypted data is typically stored using Blockchain technology [44]. Yue et al. have proposed a Blockchain solution that enables the patient to own, control and share own data securely without violating privacy [45].

Cryptographic techniques such as encryption, differential privacy, or k-anonymity are widely used for anonymous communication and in data analysis. New encryption methods such as fully homomorphic encryption and differential privacy can be used to anonymize data. New homomorphic encryption allows calculations with the data without decryption, that way offering a strong solution for privacy [46].

A contractual agreement such as service level agreement (SLA) is one of strongest methods to guarantee service level and quality. Legally binding SLA is typically made performed between organizations, but it is not offered to pHealth customers [47]. Smart contracts are computer programs that automatically execute the terms of a contract in transparent and auditable manner. One of its features is that it can be executed by a network of mutually distrusted nodes without the need of a trusted authority [48]. For integrity, availability and non-repudiation of the contract, the content of a smart contract can be stored in a Blockchain. That kind of smart contract can be used by a person to publish personal privacy policies for all users of his or her PHI [29].

A Blockchain is a time-stamped series of records that is managed by a cluster of computers not owned by any single entity. In it, data blocks are bound to each other using cryptographic technology [49]. Blockchain offers advantages such as anonymity, decentralized trust, confidentiality and integrity of documents, authentication and non-repudiation of data. To enable control of actions, data transactions are signed by the owner using a private key [49]. For privacy, encryption is needed. Blockchain technology is increasingly used not only in commerce but also in health care.

In Edge Computing, cloud services are moved to the network edge [50]. Edge consists of human-controlled devices such as PCs, smart phones, IoT devices, personal health devices and local routers [51]. From a privacy point of view, its benefit is that sensitive personal data is located in the edge, and the control of trust and secure data flow belongs to it.

3. System View to Privacy and Trust in pHealth

As discussed in earlier chapters, future pHealth is increasingly part of a highly distributed and dynamic multi-stakeholder information system that uses intensively AI, ML and DL for detailed personal health analysis. It can also share PHI and results with other partners across contexts and jurisdictions. Stakeholders of the network have typically different business and privacy policies as well as trust features. These features of next generation pHealth indicate, that traditional control- and protection-based privacy solutions are insufficient, and belief or promises based trust will not work. Researchers have proposed

a big variety of solution from encryption to new privacy approaches (Chapter 3), but none of them is a silver bullet. The authors state, that instead of a single method or solution (e.g., encryption of PHI) for privacy and trust a holistic system view is needed. It takes into account privacy and trust models used by stakeholders, features of the environment, stakeholders', information systems and applications' privacy and trust features, sensitivity of data collected and used, and data subject's or service user's personal privacy and trust needs. Based on findings made by researchers, the authors have developed a template with seven views, that can be used in developing trustworthy and privacy enabled information system for next generation pHealth (Table 2). For each view, actions and tentative solutions are also shown. While the representation of an ideal system meeting all the aforementioned requirements has been developed by the authors and meanwhile standardized as ISO 23903 [52] as well as in related security and privacy standards such as ISO 22600 [53], ISO 21298 [54], or HL7 Privacy and Security Logical Data Model – Release 1 [55], the establishment and enforcement of the related governance is still an open issue.

Because ethics is the cornerstone of information privacy and privacy laws, it should be the starting point for the template. Ethics tries to explain what is good or bad behaviour in a situation. The authors proposed for future pHealth the use of a combination of consequentialism that is focused to consequences to a person caused by the collection, use and disclosure of PHI, and utilitarianism that means that PHI should available to improve population's health [7].

To be successful, future pHealth seems to require new legislation. The authors propose that the ownership of PHI, information and personal health behaviours must be defined unambiguously at the level of law. Furthermore, the authors state, that a person should be the owner of his or her PHI. All stakeholders in pHealth (e.g., service providers, data collectors and users) should have legal duty to publish reliable information concerning their privacy and trust features and behaviours, as well as privacy and trust features of their information systems. It is also necessary to strengthen the position of a person in such a way that it can always be aware of what, how and by whom PHI is collected and used.

Table 2 Privacy and trust views and solutions for future pHealth

View	Details	Proposed Action	Possible solution
Concepts	Ethics, privacy and trust model	Analysis of ethical principles, privacy policies and trust promises used by participating stakeholders (e.g., in Business models)	-Consequentialism -Privacy as personal property -Trust as fiducial duty -Computational privacy
	Consequences of the use of PHI	Analysis of consequences of data collection to the DS	
Environment	Laws, standards, golden rules	-Regulatory analysis - Creation of new laws	-Law to force service providers and IS developers to publish their privacy and trust features

			- Law to strengthening the role of a person -Law to restrict hidden collection of PHI
Stakeholders	Business and privacy policy Privacy and trust features	Policy analysis	Disclosure of stakeholder's privacy and trust features in standardized form
Information system	-IS Architecture - Privacy and trust challenges information systems -PHI retention	-Selection of suitable architecture -Regulatory compliance analyses -Analysis of security and privacy risks	-Edge computing -Blockchain architecture -Federated computing -Communication privacy by encryption -Privacy and trust agents
Service or application	-Design methods -Privacy and trust tools	-Use of privacy as default method -Implementing of privacy and trust services	-Access limitation (attribute-based access control), audit trails - data minimization and filtering, adding noise to data -Data vanish method -Notification to the DS of PHI collection -Federated data analysis -Federated learning
DS (in the role of service user)	-Person's position and power -Person's privacy needs -Reason to trust -Benefit and harm -Level of privacy and trust	-Creating own privacy policy -Collect privacy and trust attributes -Decision why to trust	-Service/application to -measure level of privacy and trust - Calculate the actual level of privacy and trust - Make a Smart contract
Data and sensors	-Integrity and reliability of sensors and data -Privacy management	Point-to-point raw data encryption at sensor level	Lite encryption methods

The person should be also be aware and informed of personal behavioural data collected in public places and hidden by applications. Furthermore, a person as the owner of PHI should have tools to define own privacy policies and rules. Here, the aforementioned standards could come into play. Organizations offering “free of charge pHealth applications”, which collect PHI and behavioural data, should also have the responsibility to offer similar paid application without health data and behavioural tracking.

Federated learning (FL) is a learning model that tries to address the problem of data governance and privacy by enabling ML from non-co-located data. ML offers a way to preserve user's privacy by decentralizing data from the central server to end-devices [56]. In an FL solution, the data controller not only defines its own privacy policies, but also controls data access and has the ability to revoke it [57]. Those features make FL a good tool for future pHealth. It is also necessary that pHealth applications (especially AI, ML and DL applications) support the principle of forgetting and enable data erasure. Encryption as default principle should be used everywhere where it is possible (e.g., homomorphic encryption or differential privacy). The authors state, architectural

solutions such as Blockchain-based information systems, Edge architecture and Federated Learning offer and strong encryption offer increased privacy compared to in today widely used Cloud based solutions, and therefore they are proposed to be used in future pHealth.

4. Discussion

Researchers have shown that, despite information privacy and high level of trust are prerequisites for successful pHealth, current privacy approaches and solutions do not offer acceptable level of privacy, so trust is just an illusion. This means that current privacy models and technology used cannot be moved to the future pHealth. According to the authors, to make future pHealth trusted and supporting privacy, a holistic system view is needed. In this paper, the authors have presented a seven-view privacy and trust template, and new privacy and trust concepts, architectural and technological solutions for future pHealth.

The authors state that without adapting new ways to understand privacy and trust, and creating new laws, which strengthen the position of a person, it is almost impossible to guarantee privacy and trustworthiness in future pHealth. The authors see, that current laws such as the EU-GDPR, that rely on privacy as notice and choice concept (aka consent) as well as on privacy risk analysis will no work in future environment [58-60]. Furthermore, according to Kerasidou et al., until today, policy-makers and technology developers have failed to provide people reasons to trust and left users of digital networks and services vulnerable. People are simply expected to blindly trust in companies' fairness and promises [61]. Thinking the future, the worst solution is only to wait for new laws and regulations, fair industrial self-regulation, and global harmonization of ways privacy and trust are understood. Instead, developers of next generation pHealth information systems, applications and services should create a holistic view on the system of systems based on a system-theoretical, context-aware, architecture-centred, ontology-based and policy-driven approach as standardized in ISO 23903, start to use the privacy and trust as default principle, and privacy and trust approaches and solution discussed in this paper.

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Management of Cancer Patients in the COVID-19 Crisis Using Telemedicine: A Systematic Review

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Abstract. *Background:* Telemedicine can provide a solution for disease management during the COVID-19 pandemic. This literature review aims to explore the role of telemedicine during the COVID-19 pandemic for management of cancer patients. *Method:* A comprehensive systematic search was conducted in PubMed, Science Direct, EMBASE, and Web of Science databases for the papers published until April 2021. Studies were included in case they had practically used telemedicine in the management of cancer patients during the COVID-19 crisis. *Results:* After screening 2614 titles and abstracts and reviewing 305 full-texts, 16 studies were found to be eligible. The results indicated that most of the patients contacted by telemedicine services mostly used to interact with patients breast cancer (n=4, 25%). The most common use of telemedicine was the provision of virtual visit services (n=10, 62.25%). Besides, communication was most frequently provided by live video conferences (n=11, 68.75%). *Conclusion:* Telemedicine can provide continued access to necessary health services in oncology care and serve as an important role in pandemic planning and response.

Keywords. Telemedicine, Tele-oncology, COVID-19, Cancer

Introduction

Cancer has imposed a major burden on the whole world for a long time [1]. In the event of any crisis or epidemic outbreak, the treatment process for this group of patients is faced with many challenges, and the novel Coronavirus (COVID-19) pandemic has not been an exception. Studies have indicated that the incidence of COVID-19 was higher in patients with cancer and that these patients were at an increased risk of mortality [2] and developing severe life-threatening complications [3]. Increased transmission and poor outcomes among cancer patients infected with COVID-19 have called for social distancing and quarantine so as to minimize contact with infected individuals [4]. On the

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other hand, care delivery for cancer patients has been disrupted or delayed at least partially during the peaks of the pandemic due to the prioritization of resources, and physicians have become concerned about the recurrence of cancer prognosis. During such periods, health professionals take different measures to protect their patient groups. Telemedicine is one of the methods used by oncologists. Considering the fear from contagion during the COVID-19 pandemic, telemedicine has been regarded as a savior. In this context, telemedicine has been shown to be a reliable tool that distantly guarantees a proper surveillance [5, 6] and clearly outweighs the setbacks by minimizing the need for referring to healthcare facilities [7]. In fact, telemedicine has provided an opportunity to bring patients and physicians together digitally [8] without the need for physical contact and to prevent the further risk of infection [9, 10]. To the best of our knowledge, there are not comprehensive, study that investigating the application of telemedicine among oncology patients during the COVID-19 pandemic. Identifying these experiences is the first step of moving toward adopting and usage of telemedicine in pandemic planning and response, so this literature review aims to explore the role of telemedicine during the COVID-19 pandemic for management of cancer patients.

1. Methods

This systematic review was conducted based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [11].

1.1. Search Strategy

A search was performed in PubMed, Science Direct, Web of Science, and EMBASE databases for the relevant articles written in English between 2019 and April 2021. A combination of keywords and Medical Subject Headings (MeSH) were used as follows: COVID19, COVID-19, Coronavirus, 2019-nCoV, Tele*, Telemedicine, Tele-medicine, Tele oncology, Telecare, Virtual care, Remote care Cancer and Neoplasm. To combine the terms, use was made of the Boolean operators (AND, OR, and NOT). The applied search strategy is presented in Table 1.

Table 1. The search strategy of the study

Databases: PubMed, Science Direct, EMBASE, and Web of Science	
Limits: language: English, in title/abstract (keywords), full-text available, document type: article	
Publication date: 2019 up to April 2021	
#1	COVID19 OR COVID-19 OR Coronavirus OR 2019-nCoV
#2	Tele* OR Telemedicine OR Tele-medicine OR Teleoncology OR Telecare OR virtual care OR Remote care
#3	Cancer OR Neoplasm OR Malignant
Search strategy	#1 AND #2 AND #3

1.2. Selecting and Refining the Studies

All full-text articles that practically investigated the role of telemedicine in the management of cancer patients during the COVID-19 crisis were taken into

consideration. The papers in the formats of letters to editors, short communications and in other languages than English, and those with English abstracts published in languages other than English were excluded. During this step, it was attempted to inquire about the related gray literature or the studies that were not included in the search process by reviewing the reference lists of the selected studies or by contacting some experts or the authors of the articles. This complementary search was based on the titles of the related articles in the reference lists of the selected articles and was conducted in Google Scholar. After searching for studies in all databases and eliminating duplicates, the studies were independently reviewed and screened by two members of the research team (FS and ZE) in three phases (titles, abstracts and full texts). At each phase, the final decision for including the article was made based on the agreement between the two members. In case of disagreement, the opinion of the third member (LA) was asked. After selecting the final articles based on the desired inclusion and exclusion criteria, the data on the role of telemedicine in the management of cancer patients during the COVID-19 crisis were extracted and included in data extraction forms using Microsoft Excel 2016. The extracted data included the year of publication, study location, intervention type, study population, study objectives, methodology, and main findings. The articles meeting the inclusion criteria were critically reviewed using the summative analysis method.

2. Results

In total, 2614 articles were retrieved after searching the databases. After removing the duplicates, screening, and applying the inclusion and exclusion criteria, 305 studies were eligible for further full-text review. Thereafter, 16 articles were selected for the final analysis (Figure 1).

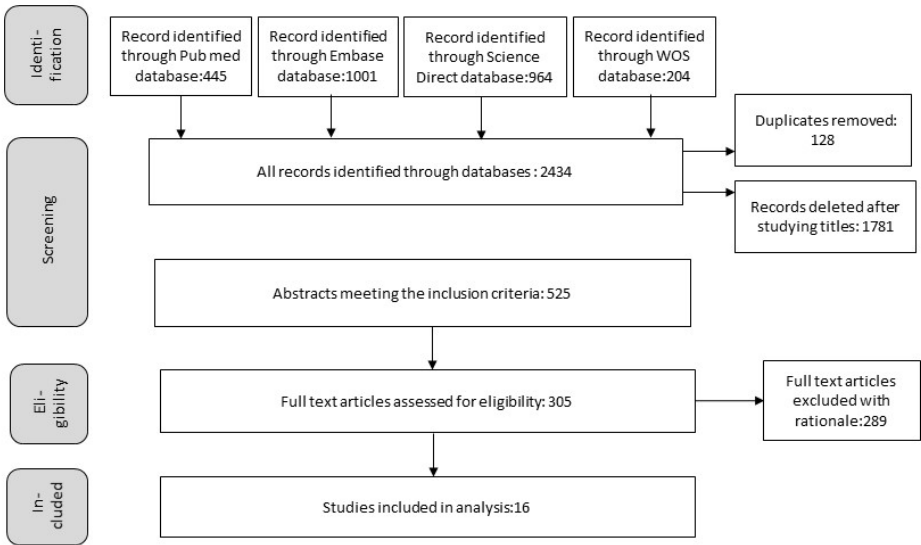


Figure 1. PRISMA Flow Diagram for the systematic review process

The summary of the characteristics of all included studies is shown in Table 2.

Table 2. Description of the included studies

Author &Ref	Publication date	Country	Study design	Participants in the intervention	Number of patients	Reasons telemedicine appointment
Rajasekaran [12]	2021	England	Cross sectional	Patient/provider/ other team personal	Not mentioned	Treatment and follow up
Nahm [13]	2021 Jan	USA	Case report	patient and provider	1	Treatment and follow up
Loneragan [14]	2020	USA	Cross sectional	Patient/provider/ other team personal	2281	Treatment and follow up
Christian [15]	2020 Feb	Canada	Multi Method	Patient/provider/ other team personal	12	Rehabilitation
Umar [16]	2020 Oct	USA	Cross sectional	Patient/provider/ other team personal	871	Screening
Sonagli [17]	2020 Nov	Brazil	Cohort study	Patient/provider/ other team personal	77	Screening
Berlin [18]	2021 Jan	Canada	Cohort study	Patient/provider/ other team personal	2207	Treatment and follow up
Olshinka [19]	2020 Oct	Canada	Cross sectional	Patient/provider/ other team personal	251	Triage and management
Lee [20]	2020 Apr	China	Cross sectional	Patient/provider/ other team personal	3800	Treatment and follow up
Klain [21]	2020 Sep	Italy	Cross sectional	Patient/provider/ other team personal	445	Treatment and follow up
Yildiz [22]	2020 Oct	Turkey	Cross sectional	patient and provider	421	Treatment and follow up
Daggubati [23]	2020 Jul	USA	Cross sectional	Patient/provider/ other team personal	Not mentioned	Treatment and follow up
Guerra [24]	2021 Mar	USA	Cross sectional	Patient/provider/ other team personal	45	Palliative care
Kang [25]	2020 Sep	USA	Cross sectional	Patient/provider/ other team personal	Not mentioned	Treatment and follow up
Kenney [26]	2021 Feb	USA	Cross sectional	Patient/provider/ other team personal	81	Treatment and follow up
Reddy [27]	2021 Feb	USA	Cross sectional	Patient/provider/ other team personal	1744	Treatment and follow up

As shown, the included studies were published in journals between January 2020 and April 2021. Most studies had cross-sectional designs ($n=12$, 75%) and half of them were conducted in the USA ($n=8$). Our findings show that the reasons for telemedicine appointments among cancer patients during the outbreak of COVID-19 were treatment and follow-up ($n=11$, 68.75%), screening ($n=2$, 12.5%), palliative care ($n=1$, 6.25%), rehabilitation ($n=1$, 6.25%) and triage and management ($n=1$, 6.25%) respectively (Figure 2). It should be noted that most number of studies that evaluated the telemedicine services based on cancer types of patients contacted by telemedicine suffered from breast cancer ($n=4$, 25%) (Figure 2). The results demonstrated that the most common usages of telemedicine during the COVID-19 pandemic were provision of virtual visit services ($n=10$, 62.25%), consultation ($n=5$, 31.25%), palliative care ($n=2$, 12.5%), and nurse visits ($n=1$, 6.25%) (Supplementary E). Based on the study findings, communication was most frequently provided by live video conference ($n=11$, 68.75%), phone call (50%), and Email ($n=7$, 43.75%) (Table 3).

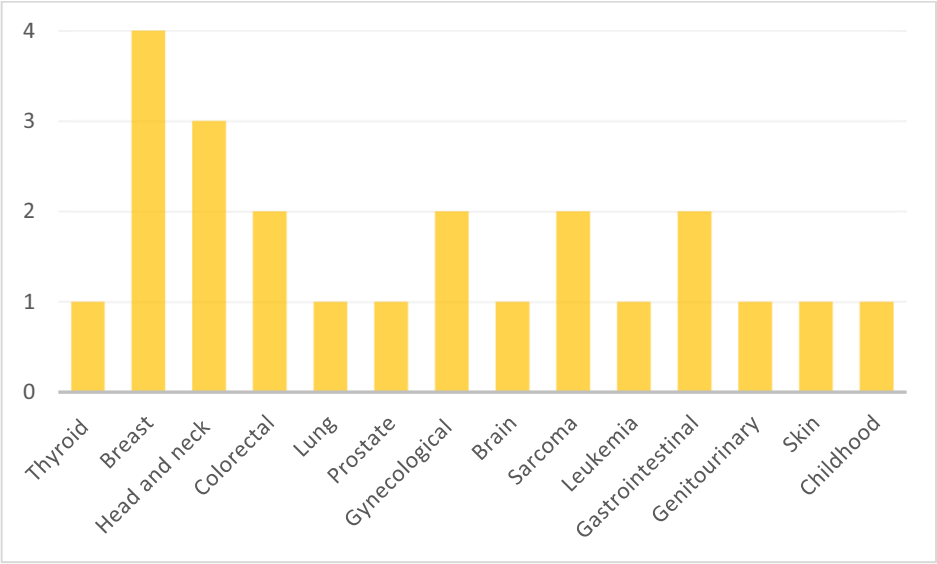


Figure 2. The number of studies that evaluated the telemedicine services based on cancer types of patients

Table 3. Types of telemedicine service

Type of telemedicine service	Frequency (%)	Reference
Clinical visit	10 (62.25%)	13, 14, 15, 16, 17, 18, 22, 23, 26, 27
Palliative care	2 (12.5%)	24, 26
Nurse visit	1 (6.25%)	26
Consultation	5 (31.25%)	12, 19, 20, 21, 25

3. Discussion

This study aimed to explore the role of telemedicine in management of cancer patients during the COVID-19 pandemic. In other words, this study explained the experiences of the used telemedicine services for improving the management of cancer patients during the COVID-19 pandemic.

The results indicated that the virtual visit service was the most common telemedicine service used during the COVID-19 pandemic. Studies have demonstrated that virtual visits did not decline the quality of care and were as effective as in-person visits [28]. Evidence has also revealed that substantially more telemedicine visits were made during the COVID-19 pandemic [29]. A previous study estimated that 42% of individuals in the US had an avoided or delayed care during the COVID-19 pandemic [30]. Nonetheless, the role of virtual visits in improving outcomes in cancer has been vastly reported [31]. During the COVID-19 pandemic, for instance, telemedicine visits reduced disease exposure among staff, patients, and family members, eventually preserving the scarce supplies of personal protective equipment and reducing patients’ demands for facilities

[29, 32]. Moreover, telemedicine could offer unparalleled flexibility; care partners could be either at the patient's side or physically distant and easily take part in voice or video conference visits [32]. Although telemedicine has been well-accepted by patients and oncologists [33, 12], in some cancer types, virtual visits might not be appropriate for some patients based on the level of accuracy or the necessity to conduct diagnostic tests or physical examinations. The current study findings indicated the following reasons for telemedicine appointments among cancer patients: treatment and follow-up during the COVID-19 pandemic, cancer screening, palliative care, and rehabilitation. Follow-up care has been recommended for all patients suffering from cancer in order to manage cancer-related health issues and provide training about the future health risks. These methods have also been reported to reduce morbidity and mortality during the pandemic [34]. Despite the great advantages of telemedicine, its implementation in resource-limited settings might be challenging. In this context, the most common barriers reported by studies were policy issues, concerns regarding malpractice-related issues, lack of formal organizational structures and reimbursement mechanisms, technological barriers including poor internet connection and low technology awareness, prescription issues, and social/cultural limitations [35-37]. The present study results showed that communication through telemedicine was most frequently provided by live video conferences. In order to control the spread of COVID-19, video consultations and telephone follow-ups have been possible in multiple settings for breast, lung, endometrial, colorectal, and prostate cancers [38]. Synchronous platforms allow patients and the neurosurgery team (physicians, advanced practice clinicians, nurses, residents, and/or fellows) to connect at the real time. Asynchronous forms of telemedicine, including Email and SMS have been also commonly used, but the rapid expansion of video conferencing capabilities and smartphones have paved the way for the synchronous forms of telemedicine [39]. Yet, there have been significant differences in demands for these two forms of telemedicine, which have to be considered in the development of any telemedicine system. To the best of our knowledge, this is one of the most comprehensive studies investigating the application of telemedicine among oncology patients during the COVID-19 pandemic. Like other studies, the present research had certain limitations. Firstly, it only included papers and reports published in English, and gray resources (unpublished reports and proceedings of conferences) were excluded. Secondly, the authors did not have access to some other databases, such as CINAHL and PsycINFO.

4. Conclusion

Telemedicine can provide continued access to necessary health services in oncology care and serve an important role in pandemic planning and response. Telemedicine is in fact an excellent method to maintain care continuity for cancer patients while limiting the risk of contagion for both patients and providers and maintaining social distancing. Yet, further studies are required to explore the factors that may enhance the quality of virtual care for both survivors and providers.

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An Overview on Security and Privacy of Data in IoMT Devices: Performance Metrics, Merits, Demerits, and Challenges

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Abstract. The Internet of Medical Things (IoMT) emerges with new trendsetter device applications, where it defines the incorporation of medical devices with the Internet of Things (IoT). The healthcare sector continues to encounter challenging obstacles that have an impact on the quality of treatment provided to patients. To get rid of this problem, IoMT is being deployed to achieve the high reliability and efficiency of the health system. The IoMT devices are superimposed with clinical information as they contain the details of patient health data, address, and other patient identifiers. By containing such amount of sensitive information, it becomes cumbersome to preserve data privacy and security. Due to inadequate security and privacy precautions, patient health data is susceptible to leakage, which has a direct impact on the patient's life. In addition, the majority of medical devices are susceptible to cyberattacks, putting patient information at risk. Inadequate control of life-support equipment can have a devastating effect on patient outcomes. Thus, this survey intends to review the various security models of IoMT devices using standard techniques to support health care systems. It provides a wide range of literature reviews regarding IoMT systems and compares them with traditional methodologies. This review work exhibits the motivation for current technologies to maintain the security and privacy of patients' data with IoMT devices. The systematic review entails background on security in IoMT devices, techniques for security, usage of diverse validation measures, and also discusses the problems and motivation for future research work.

Keywords. Internet of Medical Things; Security and Privacy of Data; Encryption; Blockchain; Authentication; Performance metrics

Introduction

Nowadays, IoMT has become the emerging technology to manage the patient's health information [1]. It is mainly used for various applications in hospitals, body sensors and homes. The IoMT environment is built with the collection of enormous medical devices, sensors and so on [2]. These efficient devices also have the potential to wear over the individual body surface. Due to the rapid development of the IoMT system, the medical industry can easily handle the medical information [3], where the practitioner aids in early detection of disorders and diagnosing effectively.

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Though the evolutionary growth of IoMT applications is observed in recent years [4], it confines with the two concerns as privacy and security. Over the IoMT infrastructure, it is critical to administer the health data as it contains myriads medical data [5]. Owing to the illustration of IoMT network, several attacks can be easily intruded and degrades the performance. Thus, it fails to preserve the significant data [6]. The system becomes vulnerable with respect to inadequate authorization or authentication of medical devices or sensors, lack of knowledge [7] about encrypting the data, insecurity of device interface, etc. The foremost technique to build the effective [8] IoMT system is authentication mechanisms to secure and privacy preserve the patient's data. Also, encryption techniques like Elliptic Curve Cryptography (ECC), Diffie-Hellman technique, etc. are employed to generate the cipher [9] text data that defends from malicious threats. Over the recent years, blockchain technology [10] has been immensely involved in the IoMT applications, where it enhances the security performance. However, all the aforementioned techniques restricts with few shortcomings [11] to protect the medical information. The main contribution of survey is as follows as (i) to demonstrate the various methodologies used for secure and privacy preserve of data in IoMT that belongs to recent developed paper, (ii) to categorize the algorithms used for IoMT application with its future scope and (iii) to discuss the chronological analysis for IoMT devices and its performance measures used for validation and (iv) to provide the research gaps and challenges for secure and privacy of data in IoMT devices.

The remaining section of the paper is follows. Section II explores the existing works based on 20 reference papers and its chronological review. Section III provides the basic introduction of IoMT along with performance measures. The merits, demerits, research gaps and future challenges are discussed in Section IV. Section V brings the closure of survey paper.

1. Literature Review

1.1. Related Works

Kumar and Tripathi [12] have proposed the consortium based blockchain network in terms of smart contracts for preserving the data in IoMT platform. It has integrated with the Inter Planetary File Systems (IPFS) cluster node, in which the authentication was needed to access the patient's clinical data by smart contracts. Furthermore, the cluster layer was also used for storage purpose. After authentication, the data was securely transmitted with the aid of consortium blocks. On the contrary of other implemented works, the suggested method has illustrated that it has achieved higher security level. Ogundokun et al. [13] have explored the concept of Crypto-Stegano method for securing the medical information over the IoMT infrastructure. This model was developed by inferring the methodologies of both cryptography and steganography. Finally, the valid information was acquired, which was used to evaluate the performance. Thus, the outcome has ensured that it has delivered better effective results in terms of data loss, security and capability and perceptible quality, thereby, it has proved an efficient model. Mohan et al. [11] have developed the private blockchain technique to maintain medical information securely. It has created a decentralized network, where the data was to be stored significantly. Here, in order to provide the data confidentiality, the Elliptic Curve Integrated Encryption Scheme was employed to do double encryption process. Thus, the performance was assessed, and it has achieved as less transaction time, thus, it has

obtained the more security for privacy preserving the data. Abbas et al. [14] have investigated the novel approach of Blockchain-assisted Secure Data Management Framework (BSDMF) in IoMT platform. It has performed the secure data management that was happened among the personal and cloud servers as well as utilized medical equipment's and personal servers. In addition to this, the blockchain model was taken for guaranteeing the data transmission over IoMT environment. Finally, the experimentation was carried out, and its results were validated using different measures as more accuracy and precision rate and trust factor and also reduced the response time. Wang et al. [15] have described the "Efficient Privacy preserving outsourced Support Vector Machine (EPoSVM)" for IoMT sector. In order to securely train the SVM network, it has deployed eight various secure-based computation protocols. Therefore, the trained data was obtained as secure manner and it has proved the privacy of the medical information while testing the model. Hence, the evaluation was elucidated that the recommended method has achieved the high security and privacy rather than former approaches. In 2021, Sun et al. [16] have presented the hybrid model for securing and preserving the data over IoMT. Here, the novel hybrid model was developed by the combination of both "Medium Access Control (MAC) and Enhanced On-Demand Vector (EAODV)-enabled routing". Initially, the registration process was carried out for devices in the offline phase. Therefore, it has blocked the illegitimate devices into the network. After this process, when the device has initiated the process, its corresponding server has to send the mutual authentication procedure. Over the sessions, the data integrity and reliability were maintained by influencing the encryption and decryption process. Finally, the simulation results have declared that it has enhanced the efficiency.

Egala et al. [17] have proposed the hybrid technique of preserving the data in IoMT platform, named as blockchain-based Distributed Data Storage System (DDSS). It has the main objective of diminishing certain constraints with the parameters like latency and storage cost. In order to perform a better authentication of entering the device into the network, the Selective Ring based Access Control (SRAC) was utilized. Finally, the performance was measured and thus it has obtained the impressive results to deliver the effective process of preserving the data. In 2021, Aslam et al. [18] have utilized the ANFIS model in the manner of blockchain based security management for IoMT applications. The main aim of this model was to aid the individuals to do the daily activities and also protect from the infected person. Here, the K-Nearest Neighbor (KNN) was also employed to analyze the performance in terms of accuracy measure. Li *et al.* [19] have presented the novel framework of Mutual Authentication and Key Agreement (MAAKA) by the characteristics of Provably-Secure and Lightweight (PSL), named as PSL-MAAKA for IoMT. The authentication process was carried out that has assisted by XOR and Hash operations, correspondingly. Furthermore, a security analysis was made through the concept of random oracle model. Finally, the experimental results have elucidated that the proposed scheme has obtained less overhead complexity. Ding et al. [20] have introduced the Deep learning approach of Encryption and Decryption Network (DeepEDN) for securing medical information. Here, it has taken the medical images for experimentation. In order to learn the image related data, Cycle-Generative Adversarial Network (Cycle-GAN) has been deployed. Further, the "Hidden Factors" of the learning technique were used to do the encryption phase, which could be restored while doing the decryption. Finally, the performance was validated, and its respective outcome has ensured to improve the system efficiency and better performance. Guan *et al.* [21] have enhanced the model of Efficient Differentially Private Data Clustering scheme (EDPDCS). Here, the K-Means clustering was employed to choose the initial centroid

data point and optimized the allocation of budget for increasing the accuracy. Over the iteration, the minimum and fixed value were considered for privacy budget. Owing to the clustering approach, the efficiency and accuracy were improved. Finally, the performance was analyzed and proved that it has acquired the better data preserving performance. Saba *et al.* [22] have framed a secure and efficient network over IoMT platform. The prime intention of this work was to mitigate and evade the overhead problem among the biosensors that it has employed. It has also required to secure the patient's medical data. Hence, the enhanced mechanism has appropriately ensured the integrity of the network, energy consumption of biosensors, less delay and low packet loss ratio.

Sowjanya *et al.* [23] have explored the lightweight authentication based Elliptic Curve Cryptography for IoMT platform. It was implemented in AVISPA tool and standard protocols were utilized to secure the medical information. Hence, the formal and informal way of approach was employed for security performance analysis. Comparative analysis was made to ensure the proposed scheme has increased the robust efficiency of IoMT devices. Alsubaei *et al.* [24] have recommended the ontology-oriented IoMT Security Assessment Framework (IoMT-SAF) for IoMT sector. Based on the customer prerequisite, it has identified the best solutions that were aided to make the better decision for securing the information. Finally, it has outperformed with its performance improvement. Chen *et al.* [25] have framed the asymmetric based encryption and authentication process over the IoMT environment. Here, the transmission mechanism has also involved for storage purpose, which was governed by distributed symmetric encryption. Along with this, authentication and authorization were carried out. Hence, the extensive outcome has demonstrated that it has acquired desired performance. Aghili *et al.* [26] have presented the novel lightweight authentication process for securing the medical information. Here, the proposed framework was termed as Lightweight Authentication, Access Control and Ownership (LACO). The major concern was considering the ownership transfer, where the server could modify the patient clinical data. Further, LACO mechanism was introduced against such attacks like insider attacks and Denial of Service (DoS). Hence, the performance results were validated and measured. Yi and Nie [27] have demonstrated the Multivariate-Quadratic-Equations (MQ) public-key cryptography and rainbow model of cryptographic scheme for IoMT applications. This algorithm was employed for end-to-end service that has resisted to such threats. Hence, certain countermeasures were considered to evaluate the performance. Thus, outstanding results were acquired to provide the better performance. Rani *et al.* [28] have influenced the Hybrid Teaching and Learning Based Optimization (HTLBO) for rendering the optimal results. Here, the Chinese Remainder Theorem (CRT) was developed to determine the security and authentication process. Finally, the extensive results have revealed that it has achieved less energy cost and computation time. Garg *et al.* [29] have suggested the "Blockchain Enabled Authenticated Key Management Protocol for IoMT (BAKMP-IoMT)" for managing the medical data securely. It was implemented in Automated Validation of Internet Security Protocols and Applications (AVISPA) tool, where it has significantly resisted to several attacks. Finally, the simulation was performed and its results were validated via diverse measures. Hence, the extensive results have proved it has mitigated computational and communication burden. Elmisery *et al.* [30] have developed new IoMT devices with respect to fog nodes. The prime aspect of this model was to manage the privacy and confidentiality of patient's data. With an integration of such models, the proposed scheme was measured, and its outstanding results have proved that the efficient performance.

1.2. Chronological Review

Figure 1 depicts the chronological analysis of existing secure and privacy of data using various methodologies. Here, it takes the recently implemented papers for obtaining the features and challenges of security in IoMT applications. Thus, 10%, 20%, 30% and 40% of literature works considered for the year 2018, 2019, 2020 and 2021, respectively.

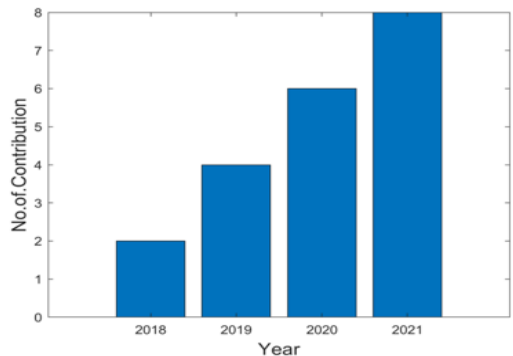


Figure 1. Chronological review on the traditional models of secure and privacy of data in IoMT

2. Introduction to Medical Devices in IoT with Algorithms for Security and Privacy of Data along with Performance Measures

2.1. Introduction to Medical Devices in IoT

IoMT is comprised with medical smart devices, which is all connected to other over the Internet. The prime objective of IoMT application is to handle the medical information. Hence, the Figure 2 represents the general diagram IoT devices along with servers, medical devices and IoT devices.

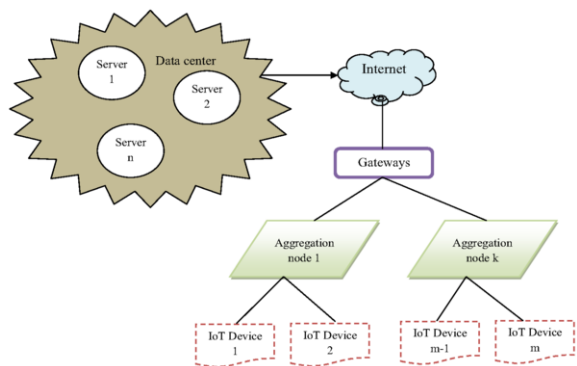


Figure 2. General diagram of IoT network with medical devices

The IoMT communication is another factor to deliberate the data transmission in four ways such as “Body Area Networks, Home Area Networks, Neighbourhood Area

Networks, and Wide Area Networks”. Recently, the body area network has become the emerging way of communication with IoMT devices. Some health records of individuals are gathered through the wearable body sensors, which is then transmitted via Internet and presented in the IoMT application. The diagrammatic illustration of body area network is depicted in Figure 3.

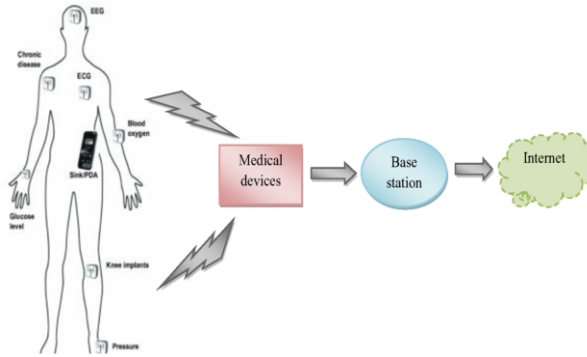


Figure 3. Diagrammatic representation of body area network with IoMT Devices

2.2. Algorithmic Categorization on Security and Privacy of Data

This section elucidates the algorithmic categorization for data security and privacy over IoMT platform. Various standard approaches have been utilized to increase the system efficiency. It is mainly focuses on the methodologies of authentication process, encryption and decryption algorithm, and blockchain based techniques. Thus, the Fig. 4 shows the algorithm categorization for privacy preserving the data in IoMT sector.

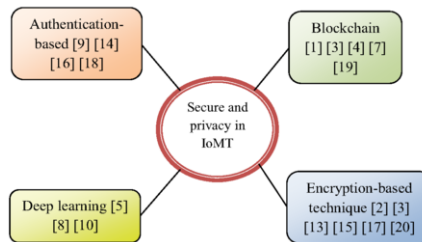


Figure 4. Secure and privacy preserving algorithm for IoMT data

2.3. Performance Measure

In order to validate the efficacy of the model, diverse number of performance measures is taken. Here, the validation ensures the efficiency and robustness of the system and reduces also the overhead complexity in terms of computation, storage and communication. Table 1 illustrates the performance measure that is used for analyzing the various techniques.

Table 1. Diverse performance Metrics taken for validating the security and privacy of data in IoMT applications

Article	Communica- tion overhead	Computation overhead	Storage cost or overhead	Response time	Accuracy	PSNR	Throughput	Miscellaneous measures
[1]	-	-	-	-	-	-	-	Scalability, security, privacy, storage size, execution time
[2]	-	-	-	-	-	✓	-	SSIM, RMSE, MSE and time complexity
[3]	-	-	-	-	-	-	-	Power consumption, transaction speed, scalability
[4]	-	-	-	✓	✓	-	-	Latency ratio, precision, trust
[5]	✓	✓	-	-	-	-	-	-
[6]	✓	✓	-	-	-	-	✓	Delay, packet delivery rate
[7]	-	-	✓	✓	-	-	-	-
[8]	-	-	-	-	-	-	-	ROC curve
[9]	✓	✓	✓	-	-	-	-	-
[10]	-	-	-	-	-	✓	-	Entropy, SSIM
[11]	-	-	-	-	✓	-	-	Running time
[12]	-	-	-	-	-	-	✓	Packet loss ratio, energy consumption, delay, link breaches
[13]	✓	✓	-	-	-	-	-	Running time
[14]	-	-	-	-	✓	-	-	Precision and recall
[15]	-	-	-	-	-	-	-	Authentication and key agreement security
[16]	✓	✓	-	-	-	-	-	-
[17]	-	-	-	-	-	-	-	-
[18]	-	-	-	-	-	-	-	Energy security level
[19]	✓	✓	-	-	-	-	-	-
[20]	-	-	-	-	✓	-	-	Running time, key generation

3. Features, Research Gaps and Future Challenges for Security and Privacy of Data for IoMT Devices

3.1. Features and Challenges on Existing Works

Table 2 elaborates the advantages and disadvantages related to existing works of secure and privacy of data in IoMT applications. Over the past few years, different expertise deploys distinct approaches to analyze the security performance.

3.2. Challenges and Further Research

This section explains the challenges related for security and privacy of data from IoMT. Over IoMT applications, some challenges are prominently visible that degrade the performance, efficiency and robustness. The prime challenging issue [31] is lack of

standardization for medical devices. Some of the most constraint factors that degrade the efficacy of the systems are scalability, reliability, insecurity, data integrity, consistency and efficiency. The challenges are listed as below while deploying the IoMT devices.

- **Revealing the patient information:** The reputation of healthcare institutions and the well-being of their patients are both severely compromised.
- **Data insecurity:** Due to the fact that these tools are being used in a diverse set of locations, including in hospitals, care homes, and remote care and the poor competence of patients in regards to security, there is a great chance that in home care and remote care, the patient's data would be targeted by hackers. In similar way, the patient's health data can be easily leaked [32] from the hospital from the insiders too. Thus, the challenge is to develop the efficient authentication and authorization mechanism in future perspective.

Table 2. Merits and demerits noted from literature works on security and privacy of data in IoMT devices

Author Name	Algorithm	Merits	Demerits
Kumar and Tripathi [12]	Consortium blockchain	• It enhances the decentralization of the system. It improves the scalability measure to preserve the data.	• Being usage of distributed cluster, it limits with computation time complexity.
Ogundokun <i>et al.</i> [13]	Cryptography and steganography	• It becomes feasible as it improves the robustness of the system. It reduces the time complexity	• It does not support the data related to audio or video formats. It suggests using learning approach for further improvement.
Mohan et al. [11]	ECC and blockchain	• It increases the scalability and mitigates the power consumption.	• Software application is not supported for this model.
Abbas et al. [14]	Blockchain	• It attains the impressive results regarding distinct measures.	• It may fails with structural and computation issues.
Wang et al. [15]	SVM	• It enhances the system efficiency by achieving less cost effective	• It is not applicable for real-world applications.
Sun et al. [16]	Routing	• It reduces the computational overhead for both encrypting and decryption the information	• It is suggested to include advanced techniques to achieve higher results.
Egala et al. [17]	Blockchain	• It exploits the low latency value	• It does not consider some QoS constraints for performance improvement
Aslam et al. [18]	KNN	• It improves the predictive results.	• The usage of ANFIS tends occurring the structural complexity.

- **Data flaws:** By having enormous number of medical data, data handling becomes another challenging factor as it has the chances to misplace the data to

another patient [33]. Hence in the future, it is motivated to develop computer-aided and security-based IoMT device AI models to handle the data efficiently.

- ***Accuracy and privacy:*** Over the IoMT environment, medical data can be accessed by various malicious actors as it presents huge security concerns regarding confidentiality, integrity, and accuracy. Due to attack intrusion [34], the medical data may get lost or altered. Therefore, a well-developed method, such as an intrusion detection system, must be implemented to maintain the accuracy and privacy of data.

The protection of the patients' confidentiality and safety is the primary emphasis of IoMT's contributions to healthcare system. Security measures, such as authentication and authorization schemes, are essential to prevent unauthorized access to confidential healthcare information. That's why it's crucial to find a cutting-edge approach that can ensure data is secure during its entire journey. Review findings show that many documented techniques exist to secure IoMT devices. However, traditional cryptography and machine learning based security techniques cannot be implemented on these smart devices because of a number of limitations, including power, size, implantability, and wearability. Therefore, an effective new solution is needed that can fulfil all the security requirements and extend throughout the medical space to assure the security, privacy, and trust of these smart devices. The examination of the surveyed data also shows that the ECC algorithm, lightweight authentication, and the blockchain technique provide the highest levels of security. Therefore, future studies should concentrate on creating effective lightweight cryptography, intrusion detection systems to protect and safeguard data from IoMT devices, making it possible to construct power-efficient and sustainable IoMT devices.

4. Conclusion

This survey has illustrated the different methodologies used for security and privacy of data of IoMT devices. The basic introduction along with contribution has given, which was followed by providing the literature works. The chronological analysis was done by the recent deployed works related for the security and privacy of IoMT data. Consequently, the survey work has been analyzed with diverse performance metrics, algorithm implementation, merits and demerits. Finally, the insights of survey have rendered the challenging concerns that lead to future development.

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Systems Interoperability

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FHIR Based ContSys Ontology to Enable Continuity of Care Data Interoperability

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Abstract. In the midst of a global pandemic, perspectives on how digital can enhance healthcare service delivery and workflow to address the global crisis is underway. Action plans collating existing digital transformation programs are being scrutinized to set in place core infrastructure and foundations for sustainable healthcare solutions. Reforming health and social care to personalize the home care setting can for example assist in avoiding treatment in a crowded acute hospital setting and improve the experience and impact on both health care professionals and service users alike. In this information intensive domain addressing the interoperability challenge through standards based roadmaps is the lynchpin to enable health and social care services to connect effectively. Thus facilitating safe and trustworthy data workflow from one healthcare systems provider to another. In this paper we showcase a methodology on how we can extract, transform and load data in a semi-automated process using a Common Semantic Standardized Data Model (CSSDM) to generate personalized healthcare knowledge graph (KG). CSSDM is based on formal ontology of ISO 13940:2015 ContSys for conceptual grounding and FHIR based specification to accommodate structural attributes to generate KG. CSSDM we suggest enables data harmonization and data linking. The goal of CSSDM is to offer an alternative pathway to speak about interoperability by supporting a different kind of collaboration between a company creating a health information system and a cloud enabled health service. This pathway of communication provides access to multiple stakeholders for sharing high quality data and information.

Keywords. EHR, FHIR, Ontology, Interoperability, Healthcare System

Introduction

The global crisis caused by the ongoing pandemic, has largely altered the functionality of various service based industries. High on this agenda has been the health and social care industry. The impact on which has been unprecedented. As a consequence, national health and social care programs are progressing action plans to integrate digital as a foundation in future planning of health and social care systems by 2025 *National Health Service (NHS), 2022*. As digital platforms mature in society, people are increasingly cognizant of the potential that technology driven home based solutions can offer. Demand for digital in health and social care is therefore on the increase, both at the service level and service user level. Some examples include convergence of lifestyle products through smart technology, scheduled interactions online, remote monitoring of health conditions and sharing information with health and social care professionals to address unmet needs. For implementing an efficient care plan management system, sole

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analysis of acute hospital summary and clinical care's Electronic Health Records (EHRs) is no longer sufficient. Other core components like individual user needs and social settings should adequately be considered for inclusion. For example the individual living conditions and biography, as well as healthcare information flow, from one healthcare setting (primary care) to another healthcare setting (home care). From a technology perspective evidence of urgent requirements include a patient-centric approach, defined access and control, healthcare data models, and integrated reference architecture models and frame-works. All of the above are reported in the evidence as essential in order to progress action plans for scalable digital solutions to support health and social care. This has been emphasized for example at the proposed *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT* by the US government, Office of the National Coordinator (ONC).

From a standards perspective in Europe the, '*Rolling plan for ICT standardization*' (2020) by the European Commission prioritizes on healthcare interoperability, cross-border treatment, and involvement of societal stakeholders in the development of EHR systems. Standards such as ISO 23903-Health informatics — *Interoperability and integration reference architecture — Model and framework* focus on ecosystems which offer a harmonized representation to realize interoperability, and advance systems that are flexible, scalable, and which can follow a systems-oriented, architecture-centric, ontology-based and policy-driven approach [4].

At the global level the International Organization for Standardization (ISO) 13940:2015-*System of concepts to support continuity of care* provides a conceptual framework to connect patient needs in their complete spectrum of the care journey. Whereas Health Level 7 (HL7) Fast Healthcare Interoperability Resources *FHIR* provides a detailed specification of the various types of resources that can be used to store data in order to address queries on a wide range of healthcare related problems. Less evident in these resources is a semantic data model which can be used for integrated data from across different care settings. Recent studies have shown various advantages of knowledge graphs for the utilization of EHR data and the provision of explicit explainable results to address healthcare queries over time. Knowledge graphs represent the knowledge, relationship and data entities in a formal ontological structure so that the healthcare concepts in the knowledge graph are explicit [10]. In this paper we are providing a fusion model and subsequent steps to demonstrate how OWL 2 Web Ontology Language *OWL2* ontology model can enable data integration from different existing legacy systems using a semi-automated mapping. Our proposed Common Semantic Standardized Data model (CSSDM) aligns with ISO 23903:2021 Health informatics — *Interoperability and integration reference architecture — Model and framework* [4].

The CSSDM can align with the reference model scenarios such as: An organization working with healthcare and workflow related data, a public healthcare data controller (e.g., Health Service Executive (HSE)/National Services Scotland (NSS)/electronic Data Research and Innovation Service (eDRIS)), or a service which needs to optimize their data preparation pipelines for more efficient use when preparing data for research experiments. A core related issue across these various examples is the need to address data heterogeneity and the tedious processes associated with tackling data heterogeneity in the daily work of the data analysts (e.g., repeated solving of similar heterogeneity issues in order to maintain an acceptable quality of service to clients). Wider related issues include tackling the interoperability challenge with data from external sources and interfacing with clients not familiar with local conventions and practices. The

remainder of this paper sets in place research conducted on addressing heterogeneity by describing the related work and current challenges in healthcare data modelling, in Section 2. In Section 3 we present our overall methodology and implementation approach, and conclude in Section 4 with a discussion on future work plans and an example of a generated knowledge graph from our initial development work.

1. Related Works

As part of the development of a standards-based roadmap to enlighten our research, a number of standards were critiqued to inform our decision making and development plan. For example *ISO/AWI TR 24305* Health informatics - Guidelines for implementation of HL7/FHIR based on ISO 13940 and ISO 13606 was reviewed. However it was noted that neither of these resources have to date modified the existing ISO 13940 model, nor included any semantic formalism in their initial work [7]. Earlier work completed by us offered a formal ontology for continuity of care *ContSonto*[3] using a top-level ontology DOLCE as an upper-level ontology [2] and using OWL as a formal language is cited for background reading.

Key challenges of subsequent work also highlight limited involvement of healthcare professionals in designing and implementing the healthcare information model. For the most part, the health care models are designed by the ICT professionals with very minimalist's involvement of healthcare professional thus such models are ICT-driven rather than domain driven for the context of use [5]. Non-standardized and self-defined data models can therefore more often face adoption problems for scaling diverse EHR datasets [11]. FHIR as a resource does not also provide any specific implementation guidelines for context of use or functionality. Examples from different countries such as the USA, which have their own FHIR profile published contrary to a FHIR profile in use by an Indian hospital, indicate that the two FHIR profiles are not interoperable. This supports our review of the evidence that there is no published native FHIR OWL specification which can be used as part of a semantic model. Just a small number of ongoing projects exist that attempt to develop a transformation schema in order to transform FHIR JSON to JSON-LD and then convert it into a Terse RDF Triple Language (Turtle) format. In our view, they are however not fit for data integration as they neither followed any ontological principle as suggested by the OntoClean methodology [6], nor clearly make any distinction between the structured attributes and classes. In this paper, we therefore mainly focused on the adoption of a collaborative approach to address these aforementioned gaps. Working with the ISO Health-informatics Technical Committee (ISO/TC 215) and based on experience gained from EU Horizon 2020 *interopEHRRate* project, we provide in the following section a summary of the results of our selected methodology.

2. Methodology

We instigate our proposed methodology with two key assumption. The first assumption is not to create another new ontology or create a New Working Item Proposal for another draft standard, but rather use the existing standards and emerging road map to provide solutions to the existing healthcare system issues raised in the introduction section.

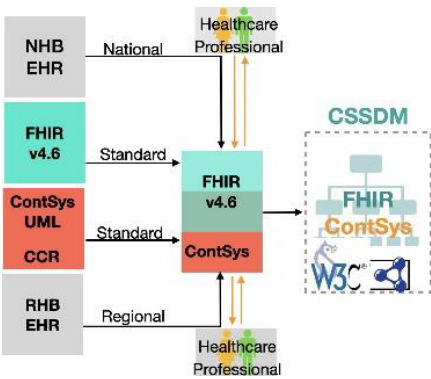


Figure 1. CSSDM Process

The second assumption is re-usability. Our rationale to choose [RDF/XML](#) is based on the following rationale: The syntax of RDF/XML was the first RDF format created by W3C and it is therefore considered in the evidence as the standard format. This means that most RDF libraries and triplestore DBs deliver RDF in this format by default. If you therefore want to work with legacy RDF systems or would want to use XML libraries to manipulate your data (as RDF/XML is valid XML), then RDF/XML is the most practical format to use.

ContSys Concept	FHIR Resources
SubjectOfCare:healthcare actor with a person role, who seeks to receive, is receiving, or has received healthcare	FHIR:Patient: Demographics and other administrative information about an individual or animal receiving care or other health-related services.
ObservedCondition: health condition observed by a healthcare actor	FHIR:Observation: Measurements and simple assertions made about a patient, device or other subject.
Request: demand for care where a healthcare professional asks a healthcare provider to perform one or more healthcare provider activities	No one to one Mapping available
MedicationRequest (New Subclass)	FHIR: MedicationRequest:An order or request for both supply of the medication and the instructions for administration of the medication to a patient.

Table 1. ContSys FHIR mapping

We have analyzed and accommodated view point of ISO 23903:2021—Interoperability and integration reference architecture [4], Care Coordination Measures Atlas [8], and Inference model for future [9] for modelling patient centric view and put foundation to reach the ISO/TS 22272:2021 target state. Overall process of CSSDM shown in Figure 1. In Step 1, we have created a Formal Ontology for Continuity of Care details of which are available in our previous work [3]. In this step we considered and consulted existing available resources relating to information models which we identified as relevant in the context of continuity of care. These included national EHRs, regional EHR models, FHIR resources and Continuity of Care Record (CCR) models, which were then mapped with each other and translated into a formal OWL model. In Step 2, we have presented, discussed and disseminated information about our formal OWL model with the national and international technical committees, which we are engaged with in order to agree and to map concepts based on their meaning. This included exploring concepts such as subject of care and its equivalent to *FHIR:Patient*, and observed condition, which was subsequently mapped with *FHIR:Observation*. In case of *FHIR:Medication Request*, we couldn't find exact mapping in the ContSys resource. We therefore opted to create a subclass of request. The mapping table is presented in Table 1.



Figure 2. FHIR:Patient attributesinclusion in *Subject of Care*

In Step 3, we have provided a summary of the enriched formal OWL model with the attributes specified in the FHIR resources. Figure 2 shows a snapshot from the editor. On the right, it provides the location of the particular concept in the class hierarchy, i.e., subject of care is a subclass of role. And on the right side, it reflects *all attributes* which are borrowed from FHIR resources.

3. Results and Discussion

We defined Healthcare data interoperability as not a one-time task to solve, but rather a continuous process to deal with in this rapidly changing ICT environment. In this paper, we have provided how to achieve a step in addressing the interoperability challenge by adapting existing model and techniques rather than creating a new model the way it fits the requirement of the Linked Data approach in order to generate an interconnected knowledge graph. In approaching the development using GraphDB, pattern matching can be used to develop a graph as demonstrated in the following Figure 3. Knowledge graphs help in performing complex queries, which are more efficient than join operation in typical relational database.

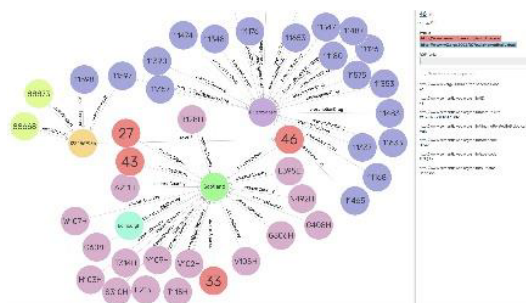


Figure 3. FHIR: Medication Request attributes inclusion

In a number of instances, it is obvious that different organizations when mapping their data to optimize interoperability and address the heterogeneity challenge do not distinguish between the various attributes at the schema level. There are three distinctions to be considered at the schema level 1.

The Common Schema 2. The Core Schema 3. The Context Schema [1]. Lack of a distinction between the different schemas as listed above creates challenges as the core and common attributes more often are the same, however the context of use is not.

Therefore when designing information models it is important to map the ontology based schema for Core and Common only. It is very important to omit the con-text specific attributes, which therefore do not apply to the wider context of use outside of the system under development. The example listed above demonstrates this scenario in the case where both the Indian and USA FHIR profiles which are designed for specific use in the context of the organization. They cannot be applied for reuse in other organizations as their profile has implicit meaning which is not interpretable by the machine. As a rule of thumb, we suggest future semantic schema development should only include what is common and core, thus leaving the context-specific attributes to be locally modified based on local needs. In this way advancing interoperability on approx. 80% of the data fields developed using a FHIR based *ContSys* semantic schema available at Github [ConstsysFHIR2022.owl](https://github.com/ConstsysFHIR2022.owl).

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Electronic Health Records at People's Hands Across Europe: The InteropEHRate Protocols

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Abstract. Sharing of personal health data could facilitate and enhance the quality of care and the conduction of further research studies. However, these data are still underutilized due to legal, technical, and interoperability challenges, whereas the data subjects are not able to manage, interact, and decide on what to share, with whom, and for what purposes. This barrier obstacles continuity of care across in the European Union (EU), and neither healthcare providers nor data researchers nor the citizens are benefiting through efficient healthcare treatment and research. Despite several national-level EU studies and research activities, cross-border health data exchange and sharing is still a challenging task, which is addressed only under specific cases and scenarios. This manuscript presents the InteropEHRate research project along with its key innovations, aiming to offer Electronic Health Records (EHRs) at peoples' hands across the EU, via the exploitation of three (3) different protocol families, namely the Device-to-Device (D2D), Remote-to-Device (R2D), and Research Data Sharing (RDS) protocols. These protocols facilitate efficient, secure, privacy preserving, and General Data Protection Regulation (GDPR) compliant health data sharing across the EU, covering different real-world use cases.

Keywords. Health Information Exchange, Research Data Sharing, D2D protocol, R2D protocol, RDS protocol, InteropEHRate

1. Introduction

Personal health data are not currently utilized at their widest potential, for research and healthcare in the European Union (EU). There exist several challenges, such as legal or technical, with the major ones dealing with the way that these data could be unleashed [1]. Despite the evolution of research technologies, EU citizens still have limitations in accessing and controlling the health data they are producing, especially in cases when they must travel in different EU countries. Citizens' right to obtain an electronic copy of their data, established by Art. 15 of the General Data Protection Regulation (GDPR) [2], is not always implemented. Healthcare digitization in EU is progressing rapidly, however,

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personal health data can be found split across different healthcare providers and siloed in different data environments, shrinking their overall ability to lead healthcare research and innovation activities. There also exist barriers related with the different semantics. Hence, it is not always feasible for EU citizens to understand, access and share their clinical history, ensuring efficient healthcare treatment.

Some initiatives in national levels are targeting towards increasing citizens' access and control over their own data, to facilitate health data sharing and exchange. These include the example of MyData [3] that aims to accelerate transformation for ethical and human-centric data sharing and use, as well as Carequality [4] that provides a national-level interoperability framework to enable data exchange among health data sharing networks. With Cloud fax services [5] digital documents and reports can be efficiently routed into folders and organized in a larger document solution, while KONFIDO [6] aims towards secure cross-border health data exchange. However, these solutions are tailored to work under specific national-level cases, supporting a short list of real-world use cases. At the EU level, the paradigm of Health Information Exchange (HIE) follows an approach being healthcare centered. In detail, for national-level health data exchange, patients' health data are maintained and controlled by healthcare providers through the Electronic Health Records (EHRs) paradigm. The latter are centrally connected to EHRs being regional or national, providing the ability to citizens themselves, as well as to external research centers and healthcare organizations to access these data. To achieve this, the HIE is controlled through connected entities' networks or central EHRs. On the other hand, for achieving health data exchange in the cross-border context in the EU, this is enabled by the MyHealth@EU [7] services, for exchanging ePrescriptions and Patient Summaries utilizing the analogous services, via eHealth National Contact Points (NCPs).

However, these solutions have limitations into data sharing with citizens. Specific rules are missing in the form of protocols as data sharing means, compliant with data governance and protection regulations, to provide the citizens the ability to receive a copy of their own data and control them. In this manuscript, the InteropEHRate [8] project and its main results are presented, for releasing locally siloed health data and providing citizens' control into managing their personal health data among multiple countries and healthcare providers, through mature data exchange protocols.

The remaining paper has the following structure. Section 2 provides the different InteropEHRate protocols that have been specified for health data exchange and sharing. Section 3 includes a description of the evaluation scenarios on top of which these protocols are exploited, while Section 4 includes a discussion of the security and privacy challenges, as well as the overall stakeholders and offerings, concluding to our next steps.

2. InteropEHRate Protocols & Methods

The solutions of the InteropEHRate protocols adopt a citizen-centric approach, complementary to the healthcare-centered one, giving the ability to citizens to use, share, and manage their health data, utilizing their mobile devices. This is facilitated through the Smart Electronic Health Records (S-EHR) mobile application, which gives the capability to its users to locally manage and store health data in smartphones. Hence, citizens can control and share their data with stakeholders (i.e., research centers, healthcare providers), fully compliant with their own requirements and the GDPR.

InteropEHRate specifies five (5) different open protocols (Figure 1) that give the ability to S-EHR application owners to securely share health data, controlling what to

share, when to share, as well as with whom to share. The protocols are organized in three (3) families called *Device-to-Device (D2D)*, *Remote-to-Device (R2D)* and *Research Data Sharing (RDS)* protocols, being structured upon the Health Level 7 (HL7) Fast Healthcare Interoperability (FHIR) standard [9], utilizing the electronic Identification, Authentication and Trust Services (eIDAS) [10] network for authentication purposes. Each protocol can be used alone or in synergy with the others, therefore the developers of S-EHR applications can choose what to offer to the users and the users are free to choose which ones to use. All the protocols exploit specific HL7 FHIR interoperability profiles to structure the managed data, and use local-language and terminology translation services, for a common health data interpretation. All the protocols, except for the R2D Emergency (part of R2D family), are peer-to-peer, offering data exchange between the citizen and another party, without intermediary parties.

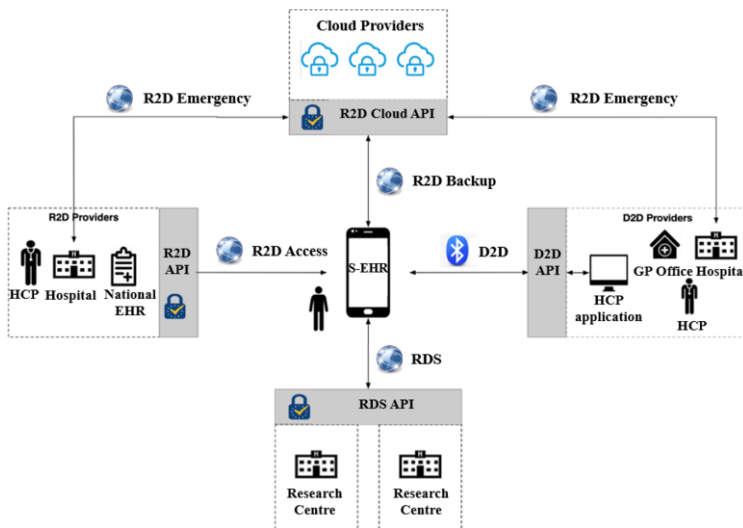


Figure 1. The InteropEHRate protocols.

2.1. Device-to-Device (D2D) Protocol

The D2D Protocol [11] specifies the means, the messages, and the health-related data to be exchanged between two devices in a close-range distance, avoiding the usage of internet connection. Data transfer takes place through the Bluetooth v4.0 short range distance communication protocol, where the citizens owning a S-EHR application can communicate and exchange data with Healthcare Practitioners (HCP) owning an HCP application (i.e., a secure for the HCPs, for instance an EHR frontend, also supporting the D2D protocol). Exchanged data may include both unstructured and structured data that can be transferred through Bluetooth, extending it for supporting HL7 FHIR data. The D2D protocol has high genericity, specified as a non-vendor specific solution.

2.2. Remote-to-Device (R2D) Protocols

The R2D Protocols is a family of three (3) communication protocols, exploiting the Hyper Text Transfer Protocol (HTTP) and the HL7 FHIR standard for health data exchange across interacting parties from different EU locations. These protocols are the:

- *R2D Access Protocol* [11]: It specifies the way for EU citizens to securely download health data from a remote repository of health data to their S-EHR application. It specifies a set of standardized rules for importing health data from any supporting provider, such as a clinical care provider (e.g., general practitioner, hospital) or a regional/national health system. It uses eIDAS so that citizens use the same credentials to download the data from any provider.
- *R2D Backup Protocol* [12]: It specifies the way for EU citizens to automatically backup and manually synchronize their HL7 FHIR encrypted health data that are already stored in their S-EHR application through the R2D Access Protocol, to any cloud storage service [13] and retrieve them on demand. The encryption key is not shared with the Cloud provider, for data subject privacy.
- *R2D Emergency Protocol* [12]: It specifies the way for authorized health providers to retrieve health information from a citizen's cloud storage service and enhance the health data of the patient at the case of an emergency scenario. The citizen can enable access to the health data that is stored (i.e., backed up through the R2D Backup Protocol) on the chosen cloud storage service, and data access can be provided to a qualified HCP with an HCP application, having a special Quick Read (QR) code provided by the data subject.

2.3. Research Data Sharing (RDS) Protocol

The RDS protocol [14] provides the way to citizens to share their health data for research purposes. Citizens are fully controlling and deciding how, when, and for what research studies their HL7 FHIR structured data will be utilized. Data are anonymised on the mobile device of the citizen before sharing them with the specific research study. The RDS protocol also provides the ability to citizens to remotely participate in research studies being prospective, giving the needed data via their S-EHR applications. The RDS protocol can address interoperability, privacy, and security gaps of citizen-driven data sharing, thanks to cross-border data integration and market-ready security paradigms.

3. Planning for Real-World Evaluation

As it has been stated, the current research is part of InteropEHRate, aiming to support patient-centered exchange of health records. The planning is to validate the protocols in countries hospitals' belonging to the project's consortium (e.g., University Hospital Center of Liege, Gabriele Monasterio Tuscany Foundation), providing a proof-of-concept of the protocols, via a specific validation plan [14] regarding the below scenarios.

3.1. Healthcare Visit Abroad Scenario

This scenario exploits the D2D protocol facilitating the case where a patient, while abroad, refers to a local physician, for a visit related to his/her health situation. The patient is admitted to the healthcare facility and communicates with the HCP exploiting the D2D protocol. The patient authorizes the HCP to access, through the HCP application, elements of his/her health data which have been already downloaded locally to the S-EHR application exploiting the R2D Access protocol or previous D2D protocol usages.

3.2. Emergency Access Scenario

This scenario exploits the R2D Backup and R2D Emergency protocols when a patient is abroad and has an emergency. The patient is driven to a hospital's emergency department for treatment. The patient had already backed up his/her data in the preferred cloud storage exploiting the R2D Backup protocol. Following, the R2D Emergency protocol is exploited by an HCP via the HCP application. The HCP verifies the patient's identity and gives access to the cloud storage where the emergency data are stored which may be downloaded to the HCP application. At patient's discharge, a Discharge Report is generated on the HCP application and uploaded to the citizen's cloud. The S-EHR application synchronizes with the cloud, to store this health data on the patient's device.

3.3. Research Data Sharing Scenario

This scenario exploits the RDS protocol to allow patients to share health data to support health research. A research center is conducting a research study for a medical condition's risk factors. It is required the prospective collection of health data for a specific period after a citizen's study enrolment, and the retrospective evaluation of the patient's data for a different (extended) period. Thanks to the RDS protocol, the S-EHR application automatically verifies if the citizen satisfies the enrolment criteria of available research studies, and the citizen may explore more details regarding this research and the types of requested data. The citizen can approve the research study invitation, signing through his/her smartphone a specific consent, authorising the S-EHR application to automatically provide the requested data in an anonymised format.

4. Discussion & Conclusions

With EHRs evolution, it is urgent to deploy techniques enabling health data encryption and access control in mobile applications towards protecting the security and privacy of clinical information. All InteropEHRate protocols are equipped with security mechanisms for achieving data integrity and confidentiality, as well as privacy preservation. These schemes follow the standards defined by ENISA's Minimum Security Measures for Operators of Essentials Services [14] and the healthcare domain needs, while credential management is based upon the use of Public Key Infrastructures (PKIs) [14]. All the protocols are exploiting the concept of standardized infrastructures deriving from a Certificate Authority (CA) [14] or from eIDAS regulations, including other EU services like the CEF eID [14]. Data integrity and confidentiality is achieved via encryption mechanisms based on trending solutions and Key Derivation Functions (KDFs) [15]. To satisfy data security as defined under Art. 32 of the GDPR [16], it is considered the use of advanced encryption, pseudonymization, and identity management. For privacy preservation, there are utilized variants exploiting cryptographic primitives, being aligned with the adopted techniques currently utilized by the final users. For GDPR compliance, the included legal perspective and privacy-by-default approach facilitates personal data treatment. Consent is required at several stages of use, and more specifically when (i) the applications are being installed, (ii) data are being exchanged, (iii) data are being stored in the cloud storage, and (iv) users are taking part in sharing of research data. Such actions provide the end user with control over data processing, ensuring adherence to the GDPR principles of transparency, fairness, and lawfulness.

InteropEHRate unlocks siloed health data and provides the citizens with the ability to manage their health data across different countries and health providers, boosting the efficiency and concept of health. The beneficiaries can be the: (i) Citizens taking advantage of better health services, (ii) Healthcare providers accessing health profiles and determinants from broader citizens, (iii) Health researchers accessing additional data and performing participatory clinical trials, (iv) Supply/demand side stakeholders being facilitated with advanced data protection, portability, and health data access, (v) Healthcare organizations and authorities enhancing care continuity, and (vi) Digital health start-ups, mobile health developers, and EHR vendors, offering features for interoperability and added value. The principles of InteropEHRate are user experience, security, privacy, and standardization, based on CAs and EU regulations. Semantic and technical interoperability is achieved via HL7 FHIR profiles, knowledge management tools and implementation guides. Next steps include the protocols' validation within real-world scenarios, user-experience enhancements, and comparisons with patient-centric commercial services (e.g., digi.me), and products (e.g., HealthVault, Google Health).

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ETL Processes for Integrating Healthcare Data - Tools and Architecture Patterns

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Abstract. Improving the interoperability of healthcare information systems is a crucial clinical care issue involving disparate but coexisting information systems. However, healthcare organizations are also facing the dilemma of choosing the right ETL tool and architecture pattern as data warehouse enterprises. This article gives an overview of current ETL tools for healthcare data integration. In addition, we demonstrate three ETL processes for clinical data integration using different ETL tools and architecture patterns, which map data from various data sources (e.g. ME-ONA and ORBIS) to diverse standards (e.g. FHIR and openEHR). Depending on the project's technical requirements, we choose our ETL tool and software architecture pattern to boost team efficiency.

Keywords. Health Information Exchange, ETL tools, Architecture patterns, HiGHmed, Software Design

Introduction

German Medical Informatics Initiative (MII) aims to achieve semantic interoperability of clinical data for reuse in patient care and biomedical research [1, 2]. For this clinical data integration and internal data retrieval, at the University Hospital Schleswig-Holstein (UKSH) Medical Data Integration Center (MeDIC) and as partner of HiGHmed Consortium [3], we require ETL (Extract-Transform-Load) processes to extract valuable clinical data and convert them into international exchange standards, e.g. Fast Healthcare Interoperability Resources (FHIR) and openEHR. Clinical data information is extracted from various data sources originating from our hospital information systems, such as exporting data from ORBIS as HL7v2 messages. Before embarking on any software development project, one of the first questions to ask relates to our choice of tools and architecture.

1. State of the Art

ETL stands for extract, transform, and load [4]. It aims for sorting, cleansing and standardizing data from multiple heterogeneous data sources to single or multiple sources. In this way, it improves productivity and data accuracy in data warehouses. In Business Intelligence (BI), ETL processes are particularly used to collect data from various

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sources and information systems and process it syntactically and semantically; thus, making it valuable for users. In recent years, studies [4–7] have analyzed ETL tools related to business intelligence. [8–12] demonstrate the development of ETL processes for healthcare data transformation. However, there is a literature gap in comparing the ETL tools and software architecture with practical healthcare examples.

Common healthcare data exchange formats are: 1) FHIR, 2) OpenEHR via 3) Integrating the Healthcare Enterprise (IHE) profile Cross-enterprise document sharing (XDS).

- 1) Fast Healthcare Interoperability Resources (FHIR) organizes information into discrete and independent data elements and using the REST approach, Resources (individual information packets) can be created and shared rapidly and easily.
- 2) openEHR [13] describes the management and storage, retrieval and exchange of health data by using archetype-based Electronic Health Records (EHRs). Archetypes provide semantic modelling by referencing particular Reference Models (RMs) defining possible arrangements of data that correspond to logical data points and groups for a domain topic.
- 3) XDS [14] exchanges any kind of document by separating document content (e.g. unstructured PDF documents) from metadata (structured and searchable object characteristics) and specifies the use of SOAP and SOAP with Attachments for communicating between actors.

2. Concept

For the conceptual design of data transformation, we show common ETL tools for healthcare data. In addition, we choose three ETL processes within our MeDIC as practical examples and investigate from where our data originates, to which system/ data formats they have to be converted and published.

2.1. Common ETL Tools for Healthcare Data

Generally, ETL tools can be divided into two categories [4, 5]: *tool-based* and *source-code based*. Tool-based ETL processes facilitate creating workflows of ETL activities and automating the execution with a graphical user interface (GUI). Among them, several open-source data integration tools achieve high levels in terms of maturity and performance in healthcare use cases as follows:

- Talend [7] is an open-source tool but not a full BI suite. It uses a code-generating approach. Besides high data connectivity, it allows writing more customized SQL queries and Java from its own GUI.
- Apache NiFi supports scalable data routing and automates the data flow between systems. It has a web-based user interface. Additionally, it allows for extending the core functionality by developing customized processors. For example, data science platform [8] uses NiFi to route data flow
- Pentaho Data Integration (PDI) is an open-source application for Business Intelligence with reporting, analysis, dashboard, datamining, and ETL capabilities. Loma Linda University Health care, Remedy Partners and

University of Oklahoma Tulsa conduct numerous projects [10,11] that use PDI to process healthcare data.

- CloverDX (CloverETL) [12] provides also visual control and automation of data flows.

On the contrary, the advantage of source-coded ETL solutions is that they give developers the flexibility to handle new requirements and create unit tests. However, they require a certain level of programming and maintaining skills in the development team and cause burdens on the overall project. Java and Python are common languages for ETL developers: Java is a general-purpose, object-oriented programming language. It is generally faster and more efficient, because it is a compiled language. Spring Boot is an open-source Java-based framework that supports the creation of stand-alone, production-grade applications easily. Conversely, Python is a dynamically typed and interpreted language. Python is considered to have less learning curve than Java

2.2. ETL Processes

We collect three ETL processes with different technical requirements:

- ETL Process 1: Mapping MEONA database export in CSV to FHIR
- ETL Process 2: Mapping ORBIS HL7 to Template Data Documents (TDDs)
- ETL Process 3: Constructing SOAP envelopes with encoded TDD to openEHR via IHE XDS.b

Source Systems: Our data originates from 1) MEONA and 2) ORBIS:

- 1) MEONA [15] is a clinical software, which supports the entire medication treatment process. MEONA offers: Safe medication prescription and administration, and efficient documentation of measures and reports at the push of a button.
- 2) ORBIS [15] is a solution for workflows in medicine, administration and management of healthcare facilities. UKSH currently uses a customized version of HL7 v.2, which is the most widely implemented healthcare standard for electronic data exchange in the clinical domain, to exchange data to and from ORBIS.

Target Systems: HAPI FHIR JPA server [16] is a FHIR server that uses relational databases and handles all storage and retrieval logic. Apart from HAPI FHIR, there are other different FHIR servers in the market: Blaze, Firely Server, IBM FHIR Server, etc. Additionally, Better Platform is a commercial Clinical Data Repository (CDR), which is designed to store and manage EHRs based on openEHR specifications.

In case of ETL Process 1, we aim to map information from the MEONA database as exported CSV files into FHIR R4 resources. As part of the MMI use case POLAR_MI, we detect medication problems and use medical data to optimize clinical care. The data are exported as CSV files. The result is loaded to a self-hosted HAPI FHIR server and later will be evaluated by analysis scripts from the POLAR_MI consortium. By ETL Process 2 (part of the HiGHmed use case Cardiology [2]), we attempt to detect decompensation in heart failure patients by mapping a mixture of standard HL7 messages (ADT and BAR) and customized ORU reports into Template Data Documents (TDDs) [11]. These TDDs can be consumed by the ETL process described in ETL Process 3. In ETL Process 3, we construct SOAP envelopes with encoded TDDs to “IHE XDS.b Affinity Domain in conjunction of openEHR clinical data repository [13]”.

3. Implementation

ETL Process 1 is developed with Java and Spring Boot. Its ETL components are organized within a three-layered pattern [17]: the application layer, domain layer and data access layer. Each layer provides services to the next higher layer. The application layer executes the desired thread. In the domain layer, we define the source entities and the mapping processes with help of the HAPI FHIR library. The infrastructure layer is responsible for the data access and delivery of FHIR resources.

To fulfil the mapping of ETL Process 2, two ETL tools, Nifi and Talend, are connected as a “broker pattern [17]” using the streaming platform Apache Kafka. Nifi, due to its extendable customize feature, is in charge of receiving pipe-formatted HL7 messages, aggregating a unique identifier in the form of a Master Patient Identifier (MPI) [3] and converting the HL7 format to XML-based. Subsequently, Nifi pushes the messages to Kafka for distributing messages on different topics, whereas the Kafka topics are named after the HL7 message type. Finally, each Talend job reads from its corresponding topic, maps the HL7 data into openEHR templates and enriches it by querying and adding terminologies from a terminology server.

In ETL Process 3, we construct SOAP envelopes with Talend in a pipe-filter pattern [17]. We divide our process into multiple “filters” e.g. querying the XDS Value Sets from the terminology server and encoding the result TDDs from ETL Process 2. Talend’s GUI offers a more visible way to map multiple XDS metadata and create “filters” here.

4. Lesson Learned

Three important components in a general ETL process in healthcare data integration are introduced: the ETL tools, the data origin and common healthcare data exchange formats. Besides giving this overview of the current healthcare data exchange area, we demonstrate three ETL processes, using different ETL tools to satisfy the data conversion requirements of our MeDIC into the resources in introduced formats.

Data from different sources and the target output formats strongly affect the decision of the correct ETL tools. Not all the requirements can be handled by a single ETL tool, every ETL tool has its advantages and limitations. For instance, ETL Process 1 utilizes the Java library *HAPI FHIR Structures FHIR R4* to create the expected output classes of FHIR resources. Similarly, ETL process 2 can be implemented in the same way using Java. Using Talend to map from HL7 to openEHR proved to be complex. In that context, we encountered during the development of ETL Process 2 the problem that the target XML templates can be too large for the Talend engine to handle.

Another problem we faced was the uneven skill disparity in the team. The challenge for our developers was the understanding of both fields, software development and healthcare data. For instance, some clinical experts are more familiar with standard terminologies like SNOMED CT and LOINC. On the other hand, technical experts focus more on infrastructure communication and software engineering. This problem can be also solved by choosing and combining the right tools. For the non-source code analysts and developers, the graphical components of Talend, like *tXMLMap*, provide visible and easy-to-understand pipelines. At the same time, Nifi is a good medium point, as it allows us to extend its functionalities by creating new source-code-based custom processors flexibly; while having a relatively simple graphical interface to manage the ETL pipelines. Hence, we use both Talend and Nifi together in ETL Process 2. We use

Talend to handle complex healthcare data transformations without source code and develop additional functionality with Nifi.

In addition to choosing the right ETL tools for developers, well-designed architecture patterns can also increase the level of abstraction and thus the team efficiency and workload management. ETL Process 3 shows the strengths of a pipe filter pattern by reusing “filters” to query “Value Set” from a terminology server and be able to process incoming TDD files from multiple processes.

In summary, the decision on the appropriate ETL tools and architecture patterns can save laborious work and time; however, it depends on the project purpose and skill of the development team.

5. Conclusion

Appropriate ETL tools and architecture patterns enable the development of healthcare data exchange efficiently, thereby advancing medical informatics research in general. Choosing the right tools and architecture pattern is critical, because once an architecture is in place, it is very hard (and expensive) to change. The shown implementations with tools and architecture patterns are adaptable for further ETL projects with a similar purpose. Nevertheless, further topics like data provenance, virtualization, unit tests and evaluation should also be in consideration for ETL processes.

6. Contribution of Authors

KC and SP developed the approach and drafted the manuscript. BS designed the high-level MeDIC architecture and gave methodological input. All authors read and approved the final manuscript.

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Decentralized EHRs in the Semantic Web for Better Health Data Management

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Abstract. Electronic Health Record (EHR) systems currently in use are not designed for widely interoperable longitudinal health data. Therefore, EHR data cannot be properly shared, managed and analyzed. In this article, we propose two approaches to making EHR data more comprehensive and FAIR (Findable, Accessible, Interoperable, and Reusable) and thus more useful for diagnosis and clinical research. Firstly, the data modeling based on the LinkML framework makes the data interoperability more realistic in diverse environments with various experts involved. We show the first results of how diverse health data can be integrated based on an easy-to-understand data model and without loss of available clinical knowledge. Secondly, decentralizing EHRs contributes to the higher availability of comprehensive and consistent EHR data. We propose a technology stack for decentralized EHRs and the reasons behind this proposal. Moreover, the two proposed approaches empower patients because their EHR data can become more available, understandable, and usable for them, and they can share their data according to their needs and preferences. Finally, we explore how the users of the proposed solution could be involved in the process of its validation and adoption.

Keywords. Distributed electronic health records, FAIR principles, HL7 FHIR, bio-data management, ontology

1. Introduction

Burnout in healthcare takes a toll on physicians and their impact on patient health they could have without it. We believe that overly complicated healthcare institutions are part of the problem. According to Clayton Christensen's work, "The Innovator's Prescription," these institutions mix three separate business models. Our goal is to research and validate a decentralized electronic health record (EHR) that would be optimized for the "solution shop" business model. Solution shops are designed to diagnose patients, meaning to solve unstructured problems with the help of experts who have the appropriate tools and resources.

Centralized electronic health records (EHRs) are established digital solutions that are part of hospital systems and outpatient clinic software. It may not be realistic to replace them. Therefore, decentralized EHRs must operate in synergy with established systems, focus on relevant patient problems that can be documented more efficiently in

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a decentralized cooperative way, and add significant value to diagnosing. In other words, decentralized EHRs must provide more FAIR (Findable, Accessible, Interoperable, and Reusable) bio-data that can be created efficiently and analyzed in the complex healthcare ecosystem and contribute to faster and better diagnosis in solution shops.

2. Methods

Because the availability of high-quality data is the key to better diagnostic processes, we consider a decentralized EHR a data-driven application. It can operate on a diverse set of harmonized data collected from various environments. However, this feature poses significant challenges to the underlying data model. Firstly, it must evolve more flexibly than a schema for a relational model. Secondly, it must accommodate different levels of sophistication in data modeling - from flat tables up to formal ontologies expressed in RDFS / OWL [1]. Thirdly, it must be easy and practical to compile this data model to other frameworks used by different experts (e.g., clinicians, data scientists, terminology curators, developers). The promising approach that addresses these challenges is the LinkML framework. It already has traction in successful applications such as cancer and environmental microbiome data harmonization and biological knowledge graph integration [2]. LinkML (linkml.io) is a data modeling language for describing the structure of an instance collection. Each instance instantiates a class from the LinkML metamodel depicted in Figure 1.

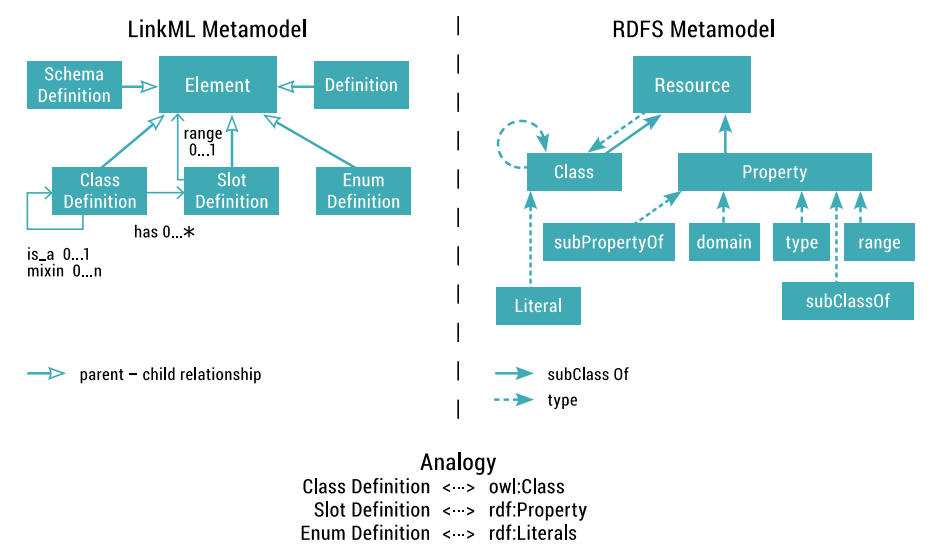


Figure 1. The LinkML Metamodel for data-driven applications and its analogy to the RDFS Metamodel.

Furthermore, the LinkML framework provides developer and curator-friendly tools for working with data, such as data validators, data converters, compatibility tools, and schema inference. Data models are created in simple YAML files, optionally annotated using ontologies. Furthermore, this data model can be compiled to other frameworks such as JSON-LD contexts, JSON schema, and Python data classes. One could argue that the LinkML metamodel is too simple to accommodate any clinical model that is the

foundation of a well-designed EHR. However, we will show in the Results section that even with this simplified modeling, we can store and process clinically relevant data. The added value is the availability of more FAIR data because this approach can easily integrate data from various sources that differ in the sophistication of their data model.

Two promising technology stacks appropriate for the decentralized EHRs have been researched. These stacks represent two competing advancements of the World Wide Web (WWW), namely blockchain within Web3 [3] and Solid - a decentralized platform for social Web applications within the Semantic Web or Web 3.0 [4]. Table 1 summarizes the main features and limitations of both.

Table 1. Main features of two promising technologies for decentralized EHR

Feature comparison		
Feature	Blockchain	Solid (CSS)
Advancement of WWW	Web3	Semantic Web or Web3.0
Data privacy and security	Data widely accessible but patient identity is a secret via cryptography	Data not available without an access grant to a pod
Data sharing	Smart Contracts	Consents (Verifiable Credentials)
Patient identification	Unique patient identifier	WebID
Data safety	Many decentralized copies	Centralized locations of providers
Interoperability in general	Lack of open standards	W3C standards, conformance tests
Data interoperability	HL7 FHIR and other standards only in off-chain data	HL7 FHIR and other standards
Information findability	None defined	Link traversal based queries [5]
Data integrity	Immutable ledger	End-to-end encryption
Auditability	Systematic examination of blocks and network	None defined
Semantic data modelling	RDFS / OWL or LinkML only in off-chain data	RDFS / OWL or LinkM
Data representation	Transaction blocks with references. Graph data - JSON-LD off-chain	Graph data - JSON-LD
Data storage challenges	Blockchain size is a limit but pointers to off-chain data possible	Graph size influences the performance of queries and analysis
Ways of data monetization	Bitcoin and other cryptocurrencies	None defined

We argue that a new approach to decentralization that could have a potential to transform the diagnostic processes within the healthcare system must make use of both technology stacks to overcome all limitations mentioned in Table~1. Our proposed technology stack in the Results section is therefore mainly based on Solid due to its high potential to apply FAIR principles of data sharing and to support data-driven applications.

3. Results

We used the LinkML framework to show how clinically relevant data can be modeled, represented, and stored in a decentralized EHR. Firstly, we show how to easily integrate data from various sources. We model data as events with their time frames and we use the Simple Event Ontology [6] as the basis for the LinkML framework (Figure 2). As described in the Methods section, the LinkML framework makes this data model more accessible to various experts and scenarios. We show its application on an example of

EHR data that can be in the HL7 FHIR RDF format combined with data from wearables in CSV in the following Python implementation². Solid pods have several containers where data can be stored according to different data models. Alternatively, one user can have many Solid pods. This possibility allows the original HL7 FHIR RDF dataset to be stored in a separate container or pod. It can be queried anytime for additional information or unclear clinical context resulting from the simplified LinkML model.

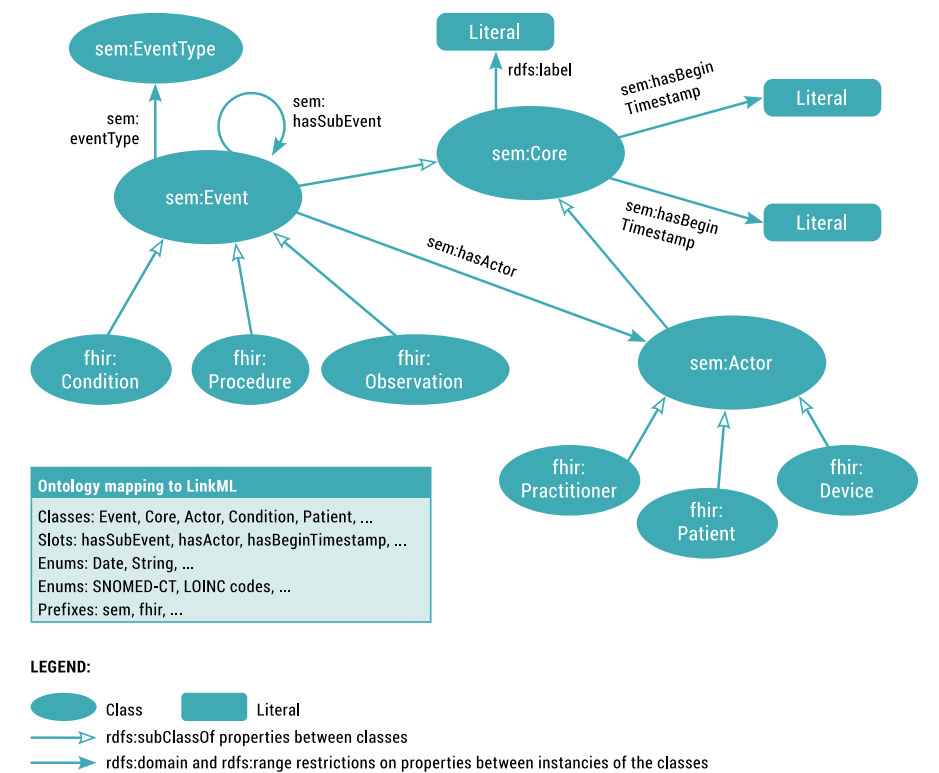


Figure 2. The proposed ontology for the EHR data integration and its mapping to the LinkML Metamodel

Secondly, we explored how the phenotype information can be stored in decentralized EHRs. Currently, EHR systems record virtually no phenotype information. We show how an event in the form of a condition from the HL7 FHIR RDF data can be easily transformed into the Phenopacket Schema (phenopacket-schema.io) with the help of the created LinkML model. A phenopacket links detailed phenotype descriptions with a disease, patient, and genetic information. How to correctly convert all relevant EHR data in the HL7 FHIR RDF format to a phenopacket and enrich it with more data in the LinkML framework is a topic of ongoing research. With the help of our proposed decentralized EHRs, sharing these phenopackets as FAIR data is effortless. Increasing the sharing of FAIR phenopackets will support large-scale computational disease analysis using the combined genotype and phenotype data.

Furthermore, we propose the infrastructure for the decentralized EHRs based on the Community Solid Server (CSS)². To overcome its limitations mentioned in Table 1, this

² <https://github.com/CommunitySolidServer/CommunitySolidServer>

technology stack needs to be extended by Web3 features, especially for data integrity and auditability. Nevertheless, based on the features mentioned in Table 1 and our experimentation, it can significantly contribute to the following FAIR principles:

1. It can make use of the proposed data modelling in the linkML framework to support interoperability.
2. It implements many W3C standards that support data linking and findable data such as W3C Linked Data, SPARQL for query and W3C Link Data Platform.
3. It can be easily connected to terminology services for concept alignments – the same information can be presented to different audiences.
4. It is based on mydata.org principles, therefore users can grant consents for specific personal data usage and data sharing such as data donation to research. This approach to data sharing is in line with the [General Data Protection Regulation](#).
5. It can be the underlying infrastructure for data intermediaries participating in the European Health Data Spaces (EHDS).

As mentioned in Table 1, data stored in Solid pods are without an access grant private. Privacy hinders findability and accessibility of the data, therefore safe mechanisms on how to share data in an anonymized or pseudonymized way must be researched. One way of ensuring the user's privacy while making data accessible is by allowing for selective disclosure of only those attributes that are necessary for authentication and authorization like in [7]. Another approach are methods for answering SPARQL queries through zero-knowledge link traversals that are being researched, for example in [8].

Moreover, data-driven applications can be developed on top of this Solid technology stack, because:

1. There is no crucial data storage challenge of potentially large personal health knowledge graphs [9].
2. Personal data stored in pods can be linked to external knowledge graphs and organized according to various data models such as the mentioned phenopackets.
3. It supports cooperation of several users on data stored in a particular pod.
4. It is an enabler for analytic services based on querying, reasoning, graph analysis and graph neural networks. These services could be used for more advanced clinical decision support systems and for smart guidance for patients.
5. Linked Data Shapes, Forms and Footprints³ are defined to further support data entry, retrieval, and user interface in data-driven applications.

4. Discussion and Conclusions

The technology stack based on the Community Solid Server, as discussed in the Results section, can be extended by the components of the Blockchain stack:

- An immutable ledger for enhanced data integrity: It may not be used for all data stored in pods but only for a subset for which a high level of integrity is required

³ <https://www.w3.org/DesignIssues/Footprints.html>

by the clinical processes (for example, the blood type, current allergies, selected prescribed medications such as narcotics).

- A way of data monetization based on Bitcoin or other cryptocurrencies for data sharing: This feature can reward physicians for sharing part of their records to the decentralized platform or creating unique entries in the decentralized EHRs, thus motivating them to contribute. It can also be used to pay patients for donating their data, for example, to research.

A decentralized EHR could become an authoritative source in areas where some form of a decentralized record exists and where patients, pregnant women, or parents usually proactively collect data. The examples include a pregnancy health record, a newborn and toddler progress note, immunization records, and medical history or anamnesis from the patient narrative.

Moreover, the data integration at the patient's side supports the mentioned "solution shop" business model for better diagnosis. This business model requires multidisciplinary cooperation. The proper bio-data modeling and management based on the LinkML framework and the resulting data representation that can be easily shared via the proposed decentralized technology will significantly contribute to this multidisciplinary cooperation and FAIR Health Data Sets for further research and analysis. The initial data modeling can be simplified to the event-based model, as presented in Figure 2. The model of the actual events of various types can be further elaborated to match the best approaches to clinical modeling. Finally, the potential of proposed approaches to save time, improve diagnosis and increase sharing of FAIR data must be validated by a properly designed study in the future.

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Safety, Security, Privacy and Trust Challenges and Solutions

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Information Security Risk for Welfare Technology and Personal Healthcare Devices

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Abstract. Welfare technology is expected to become a larger and more important part of the healthcare sector. This creates a need to understand, which information security risks welfare technology and affiliated devices are exposed to. In a scoping review, we present an extensive overview of relevant threats. Furthermore, some key vulnerabilities in health technologies like IoMTs and welfare technology devices are highlighted. In the conclusions, the risks relevant for welfare technology is discussed, where four top risks are emphasized as a result of the findings.

Keywords. Information security, risk, threats, vulnerabilities, welfare technology, healthcare devices

Introduction

In the years coming, countries around the globe and especially European countries will be facing a demographic shift towards an aging and multi-diseased society as well as a massive resource scarcity in healthcare [1]. An example is the look at the Swedish population, where the part aged 80 is expected to increase from 5.3% in 2020 to 23% in 2030 [2]. In this context, it is argued that technology will become a solution to meet some of the predicted care-needs. New and innovative technological solutions can help taking over some of the care-work, especially related to less complicated medical tasks such as providing medication, home-based assistance, monitoring of vital signs, just to name a few [3]. For a long time, the healthcare sector has been dependent on technology to provide necessary care for patients, especially in hospitals and increasingly in home-based care. Medical devices in healthcare are not a new phenomenon, but the increasing amount of new solutions, systems, application and devices is changing how healthcare services are delivered. An increasing trend in the healthcare sector is the use of the Internet of Medical Things (IoMT), welfare technology and remote, distributed care solutions.

Research Motivation and Research Question

The integration of new technological solutions in healthcare imposes new risks. The IoMT industry alone is predicted to contain over 21 billion devices by 2025. From an information security and privacy perspective, there are risks that must be addressed to ensure the security and safety of health data, and ultimately of the patients. This paper

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explores the following question: *Q1: Which information security risks are relevant for welfare technology?*

Welfare technology is a term coined in the Nordic countries, and is similar to assisted living technology, ambient assisted living technology and IoMT to name a few. When exploring which risks that are relevant for welfare technology, one should also explore which threats and vulnerabilities welfare technologies and similar devices can be exposed to. This will help strengthening the understanding of how and which risks that can materialize.

1. Method

To complete this scoping review, a six-step method has been completed as suggested by [4]. The suggested steps is a straight-forward approach, where we searched through previous research that were using different methods, such as qualitative, experimental and mixed methods. A scoping review aims at understanding what current research exist related to the chosen topic [4]. When completing these six steps, suggestions by [5] on how to conduct a literature review was also included where appropriate. In step 2 of the approach suggested by [4], the Boolean logic as explained in [5] was used. Further, in step 3 of “selecting studies”, we established inclusion and exclusion criteria as a guide to include relevant studies. In this paper we did not consult with stakeholders or relevant interest groups, but it is desired to do so in extension of this research.

To generate findings, searches were conducted in the following databases Science Direct, IEEE digital library, ACM digital Library, PubMed, Web of Science and AIS electronic library. The following search words were used to generate findings: “welfare technology”, “telecare”, “telemedicine”, “IoMT”, “assisted living technologies” AND “security”, AND “Risk”, AND “security risk”. A total of 9 searches was performed, resulting in an total number of 2193 findings. Literature relating to the importance of information security for welfare technology is scarce. To include papers relevant for welfare technology, inclusion and exclusion criteria were established. These are presented in Table 1.

Table 1. Inclusion and exclusion criteria

Inclusion	Exclusion
Peer reviewed journal or conference paper	All other excluded
Published in English or Norwegian	All other languages excluded
Topic focusing on information security risks, threats or vulnerabilities relevant for welfare technology	Papers focusing on specific security mechanisms e.g. biometric solutions, blockchain
Research object healthcare sector	All other sectors excluded
Healthcare technologies suited definition of welfare technology[6]	All other technology excluded

A large number of findings were identified in the first search (N=2193). Through the first screening, this number was reduced to 58 papers. Following the first screening, a second screening was performed, where the inclusion and exclusion criteria’s were

used. During the second screening every paper was read back-to-back, resulting in 5 additional papers being identified as relevant through the snowballing method. When the first screening, second screening and the snowballing method was completed, a total of 22 papers were included in this review.

2. Results

In this section, relevant findings will be presented. We will start by presenting relevant threats, attacks and vulnerabilities. Thereafter, identified risks will be discussed.

2.1. Threats and vulnerabilities

According to [7], IoMT devices can be divided into four categories: wearable devices, implantable devices, ambient devices and stationary devices. Devices operate at different layers of the system architecture, where each layer is exposed to threats in different ways, and can be subjected to different types of attacks. Further, [8] refers to the FDA stating that for every 1000 connected device, roughly 164 attacks threaten them. [9] found devices depending on wireless personal area networks through Bluetooth-low-energy to be more exposed to Man-in-the-Middle attacks, replay attacks and network communication decryption as a result of insufficient encryption schemes. Thus, [9] uses information security principles by first reviewing how DDoS may jeopardize availability of implantable devices, and second how replay attacks can compromise confidentiality and integrity. Similarly, [10] refers to security principles when reviewing relevant threats for personal medical devices, where [11] identified over 50 different threats related to the security principles, mapped against different stages of data transmission. Threats towards confidentiality were evaluated to be the most serious.

In [12] several known attacks are highlighted. Similar to [7] and [9] the different layers of the IoMT system architecture is considered, as layers have different impacts on the data collection, transmission and storage. [12] highlight IoMT system risks and specific attacks that can threaten IoMT devices, such as physical attacks and network attacks. The most frequently mentioned network attack is DDoS, MITM, replay attack and brute force attack [12, 13, 14, 15] reviews the threat and vulnerability landscape for IoMT, where cardiac devices, implantable brain devices and pacemakers are examined. The authors stress the potential of blind and targeted attacks. When [16] explores living-labs it is emphasized that threat actors may be more inclined to attack these environments as it is a low-risk and high-reward attack. Thus, the vulnerabilities in these digital ecosystems are argued to be many. IoMTs have less security mechanisms than a laptop, which makes them more vulnerable of attacks. [17] divides telemedicine security threats into seven specific areas, where each threat area represents a point where threat actors can compromise assets through common vulnerabilities – resulting in multiple risks for telehealth care systems.

[18] states that the healthcare sector is more vulnerable of attacks due to the high value of data being processed. This is supported by [14] who found threats towards IoMT devices to be much higher when health data was processed. Further, [14] finds several easily exploitable vulnerabilities in sensors, as security measures are light-weight due to constraints such as small storage space and low battery capacity. Another factor that introduce vulnerabilities is network connectivity. When connecting devices to a network, both the attack surface and potential vulnerabilities increase [14]. Similarly, [19]

emphasize that devices connected to network increases vulnerabilities as they become endpoints or access points for attacks.

2.2. Information security risks

In [20] it is highlighted that downtime in healthcare devices can lead to patient harm or in worst case death. [13] refers to solution providers to provide security, and argues that though providers offer similar security mechanisms, they differ in the protection they provide. Besides, it can contribute to increase complexity of the device landscape, as different devices serve different purposes, offer different functionality and ultimately have different needs for security. As stated in [13] “each type of device poses its own security risk”. This is supported by [21] who expresses a great concern that welfare technology will be a security risk for patients.

[22] explores sensors and smart homes for elderly in healthcare, where one of the key concerns of using devices is related to security. Alike [7, 8] find that the most common risk for IoMTs can be associated with complexity and inconsistency of devices. Similar to [22], the use of welfare technology for elderly in a homecare setting is examined in [23]. A risk that prevailed in this study was the dependency of healthcare workers to perform certain tasks such as charging devices, turning on alarms, sensors and so forth. Third-party risks are also mentioned, especially in cases when dependent on assistance from vendors/suppliers [23]. [24] stresses risks related to supply-chain, network security and privacy. Further, [10] highlights device security, connectivity security and cloud security as three security areas with higher risk exposure.

In [25], the authors stress the security of mobile devices in telehealth systems. Further, the current trend in software development related to increased connectivity and an exponential growth in medical data contributes to a high risk exposure for the telehealth system and affiliated devices [25]. Specific risks associated with hacking and remote monitoring, data availability, unauthorized access, unauthorized traffic monitoring and third-party intrusion were identified by [26], who views the risks related to IoMT as high. In [27] risk is connected not only to technology, but also to human factors such as how humans interact with technology, their knowledge and their competence. Hence, [17] finds that ICT competence have effect on security, which ultimately makes telemedicine highly prone to cyberattacks.

3. Discussion

Several threats, vulnerabilities and risks has been identified in this review. There is an inherent risk in welfare technologies as they are exposed to different risks by serving different purposes. Especially considering that compromise of welfare technology have different consequences for patients depending on the function of the device [14][16]. In the following, four top risks identified as relevant for welfare technology will be discussed.

Literature demonstrates the once technology is connected to internet, the potential risk increases due to an increase in attack surface. Meaning that devices that are connected to either share or transfer information through network connectivity can be more vulnerable towards cyber threats [12, 14, 15, 16, 18, 19, 20, 22]. In a future scenario where healthcare services rely on welfare technology, the consequences if a risk materializes increases [28]. Also, imagining a closer interconnectivity between welfare

technologies, IoMTs and medical devices will introduce new risks [15, 16]. Currently, there are several known risks related to medical devices, like those for pacemakers, implantable cardiac devices and insulin pumps [9, 14, 19]. These risks exist even though medical devices are regulated. For welfare technologies and affiliated devices, there is no standardization framework nor regulation to ensure the security of devices [16].

In the field of security, the human factor is often viewed as the weakest link as they can be manipulated. In several papers, the human factor is of importance when it comes to information security breaches and use of technology [7, 11, 23, 28]. [28] claims that during the Covid-19 pandemic, 86% of the attacks was affiliated with phishing, i.e. humans being exploited. [23] stated that training healthcare workers AND users (e.g. elderly using welfare technology) will increase a sense of safety and mitigate the chance of patients getting hurt due to errors. Meaning that if the training and awareness is sufficient, the information security risk can actually be reduced.

Several different manufacturers, producers, developers and so forth is a common factor for different health technologies, IoMTs, welfare technologies and personalized devices. There can be multiple third-parties involved, with varying focus on security. Both [14] and [16] emphasize that there is a lack of insight into the consequence of security risks, as they can lead to disruption of normal operations. Further, a concern expressed in several papers related to the inadequate security at the device level, such as insufficient encryption schemes [27]. This poses a serious risk for welfare technologies [10, 13, 23, 24]. Many different third-parties can be challenging to manage and follow-up to ensure sufficient security, which in turn can result in higher risk exposure.

Complexity is the forth risk and is addressed in several papers, as it can create a intertwined technological ecosystem which can be difficult to manage [7, 20, 22, 23]. This is relevant for welfare technology, especially when viewing available technologies and potential threats towards different devices. Complexity in the technological ecosystem-, available devices-, number of manufactures-, number of devices being used interchangeably-, and interconnectivity between devices, is a risk that based on this review, is likely to increase. Therefore, complexity is evaluated to be a highly relevant risk for welfare technology.

4. Conclusion

Information security risks will likely continue to exist for welfare technology. Some would even argue that without risks - we are not progressing. However, one must understand the risk, especially in the healthcare sector where risks may have fatal consequences. This paper has identified threats, vulnerabilities and several information security risks relevant for welfare technology. The top four relevant risks identified is network connectivity, human factors, third-party risks and complexity.

There is an inherent risk in the unregulated, free-marked devices, as there is not a guarantee for their security and henceforward safety for patients. Several more questions should be researched further to ensure security and trustworthiness of welfare technology and devices. Currently, lacking eligibility criteria and standardization of the free market, allows unserious actors to produce devices with insufficient security and possibly at risk of attacks. This contributes to a urgency to gather and disseminate knowledge about information security risks relevant for welfare technology and related devices. Thus, it demonstrates a need for standardization and focus on built-in security mechanisms.

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Provenance and Dynamic Consents for the Management of Medical Data

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Abstract. Medical data describe patient health information, both in healthy and disease conditions. In any case, health institutions need to ask for patient consent in order to provide their services. Patients usually give consent on a one-time basis, for a specific usage. Afterwards, if medical data usage is research, original patient consent does not apply and further consents should be required. On the other hand, provenance of medical data to verify the origin of health procedures is desirable, as digital health is increasing. We propose HIPAMS modular architecture to provide both provenance and dynamic consents for medical data as described in this paper.

Keywords. Dynamic consents, provenance, modular architecture, HIPAMS

Introduction

Provenance of medical information and dynamic consents from patients are some desirable features for a Health Information System (HIS) that are currently not widely supported.

In this paper, we propose the use of a modular platform, Health Information And Management System (HIPAMS), derived from MIPAMS (“M” for Multimedia) [1] and GIPAMS (“G” for Genomic) [2], [3], to provide support for managing and storing provenance information and also to manage dynamic consents.

It is worth noting that HIPAMS is content agnostic, and it may apply to any health information format. Information for provenance and consents will be independent from the format itself, managed by specific modules, accessed via clear Application Programming Interfaces (API’s) in order to provide low coupling between them.

This paper describes the proposed HIPAMS architecture, focusing on how dynamic consents and provenance metadata can be implemented and included in the system. Afterwards, we discuss different issues on provenance, dynamic consents and their integration. Finally, we present conclusions and future work.

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1. Methods – HIPAMS Description

The architecture of the developed platform is an evolution of our original Multimedia Information Protection And Management System, MIPAMS [1], [4] and also of the Genomic Information Protection And Management System, GIPAMS [3]. As it now deals with health information, we have called it Health Information Protection And Management System, HIPAMS.

It must be pointed out the modular nature of these architectures, which provides several advantages, like the possibility of reusing modules for different kinds of content and the facility to add more modules with the same foundational principles to support new functionalities.

Figure 1 depicts its structure. Most of the modules were already described in [3], so we only describe the functionality of the new modules and those that have been extended (in alphabetical order):

- Authorization Service: Module for authorization rules *and consents* validation.
- Health Content Service: Module in charge of health information management, both in reading and writing operations.
- Metadata Service: Module in charge of handling metadata of medical documents, which may help in identifying and finding them.
- Policy / Consent Service: Module in charge of the creation of the authorization rules, which are organized into policies and consents.
- Provenance Service: New module in charge of adding and managing provenance information for health digital content supported by the platform.

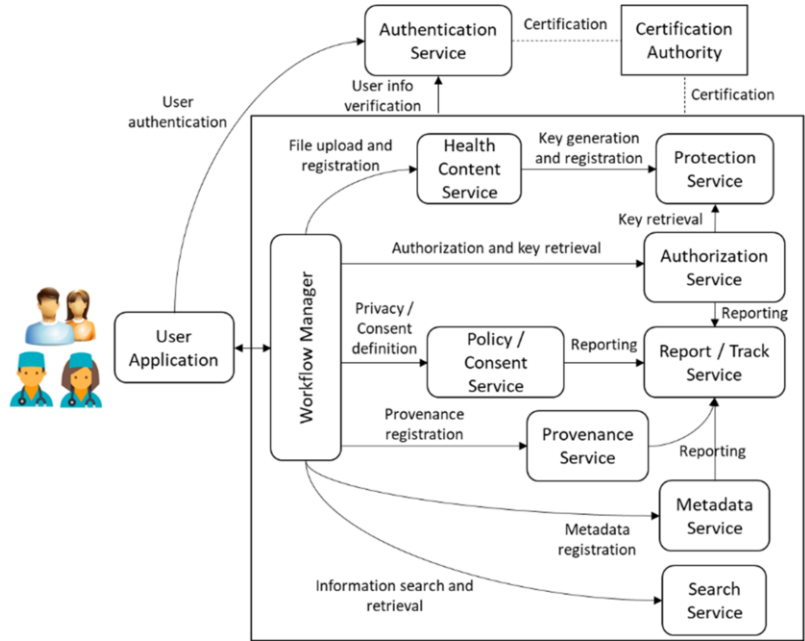


Figure 1. HIPAMS Architecture.

The communication between the modules in HIPAMS architecture is based on Representational State Transfer (REST) [5], which makes use of the HTTP protocol methods to communicate clients and servers.

Each module provides one or more REST operations that can be invoked by the Workflow Manager (WM) or other module(s). The User Application cannot directly invoke any module's operations. User Application requests' can only be done through the WM. Moreover, we make use of JSON Web Tokens (JWT) [6] to guarantee that the user that wants to call an operation is authenticated and has the corresponding permission to do so.

2. Results

The first part of this section on results analyses our approach to, and considerations on, dynamic consents, mainly in relation to static consents and policies and their authorization process. Then, the issue of data provenance is presented, where one of the possible alternative approaches is selected as a starting point.

2.1. *Dynamic Consents, Policies and Authorization*

Health institutions require patient's consents. They have to request them in order to be able to provide their medical services to patients, who give these consents for specific purposes, usually related to the clinical practice and in a one-time (or a period of time) basis. Therefore, if some medical information can be useful later on, for instance, for research or educational purposes, the initial consent given by the patient may not be enough.

In some cases, consents may change over time (dynamic consents) due to several reasons, but this feature cannot be easily represented and managed in current health systems.

In order to provide a possible solution to the current consent rigidity, we are exploring the dynamic consent concept, using privacy protection policies and its corresponding authorization algorithms. Our proposal is to give the patient, possibly through the Hospital Information System (HIS), the ability to be informed, for example, that her medical information could have a secondary use for research, so a change in the consent is needed. It should be noted that research is not the only possibility. Once the mechanism is established, any use can be informed and requested to the user.

The first step to achieve dynamic consents is to decide the best way of representing the information. Our proposal is to define them as policies and rules for two reasons: 1) there are already expertise and tools available on that, including for example previous work on GIPAMS [3], and 2) authorization mechanisms for policies and rules are in place. Then, dynamic consents could be implemented by creating a new rule (or a policy) with the modified conditions approved by the patient (e.g. usage, timing, health professional, etc.). The system should look for the latest consent when authorization is required.

In any case, to be able to take this approach, we should consider how to integrate it with existing standardized consent formats, like the one currently under development by HL7 FHIR (Health Level 7 Fast Healthcare Interoperability Resources) [7]. This consent format already considers the possibility of computing consents using policies, as it includes a policy element, which may contain a policy expressed in a well-known policy

language, like eXtensible Access Control Markup Language (XACML) [8]. Then, as GIPAMS uses XACML to express policies and rules to authorize access to genomic information, it seems a good starting point to use this language to implement the Policy / Consent Service in HIPAMS (see section 2), including policies into consents following FHIR specifications. Afterwards, when dynamic consent authorization is required, the Authorization Service will be used for this task, as it already supports XACML authorization mechanisms.

2.2. Provenance Information

There are different technical approaches for the digital management of provenance information, or provenance metadata. The approach may vary depending on the kind of information to which provenance metadata is attached. In our case, we are dealing with health information. Provenance requirements for health are not necessarily the same that for multimedia content, such as images, as an example.

In order to obtain the best solution for provenance metadata management, we have analyzed several approaches. These include:

- W3C model [9], which is the basis for several other solutions.
- Specific provenance metadata for images to help controlling fake content, as being considered by the JPEG standardization working group [10].
- The new work in ISO/TC 276 (Biotechnology) for biological samples [11] and its relationship with genomic standards such as ISO/IEC 23092 (Genomic Information Representation, MPEG-G) [12].

Our first solution consists in trying to adapt for health information the work we are doing on a proposal for JPEG provenance metadata [4]. Therefore, a Provenance Service is to be developed for HIPAMS. Although images and health information are different, the structure of the associated provenance metadata and the mechanisms to generate and process that metadata may be rather similar.

3. Discussion

There are many initiatives for the definition and provision of digital consents, like FHIR Consents [5], ONC eConsent Toolkit [13] or the electronic Informed Consent concept [14], [15].

They have in common the concern about how informed consent should be managed electronically, facilitating tools and guidelines to do so. Taking some of these initiatives as a base point, they may facilitate dynamic consent, as they already consider electronic means for managing consents.

However, dynamic consent is also already considered in the literature, mainly related to biobanks and other institutions where long term relationship with patients and participants is of utmost importance, as presented in [16].

The initiatives indicated are a small sample of an existing problem, that there is a large number of solutions to address electronic and dynamic consents, as there is not a common universal electronic format to represent and manage consents.

In summary, dynamic consent is a desirable feature when managing consents, but, as briefly stated in this section, there is not a unique way to provide a solution. Our approach is to implement dynamic consents using a modular architecture like HIPAMS. Then, this could be combined with other existing initiatives. Finally, we should always consider the associated legal aspects, restrictions and obligations.

With respect to provenance, the discussion covers different questions, such as: how much detailed provenance metadata is needed, how is these metadata to be expressed and created, which level of protection (security and privacy) is needed? Our first results go in the line of reusing and adapting other existing solutions, many of them still under development.

Finally, we should keep in mind that we are aiming at an integrated approach for handling health information (the HIPAMS architecture described in section 2). Therefore, dynamic consents and provenance are key aspects for this integration since they are usually considered independently.

4. Conclusions and Future Work

The work we have introduced focuses on an integrated and modular architecture for health information management system that is interoperable and secure. HIPAMS is our implementation of such a system. However, there are still a few specific aspects that could be included to improve the system. Two of them have been addressed in this paper, namely the management of dynamic consents and the creation and use of provenance metadata associated to the health information.

For the first aspect, we propose to use privacy rules and associated mechanisms, while for the provenance aspect we want to consider adapting newly defined approaches for other kind of content, such as images or even genomic information.

We would like to stress that we are working on a Spanish Government funded Project (GenClinLab-Sec, PID2020-114394RB-C31), where we are developing the GIPAMS architecture, already mentioned throughout the paper, to support the secure interchange of genomic information applied to the clinical practice in the genomic laboratories. We planned several scenarios to support interchange of information within the same lab and between different labs. We expect that lessons learnt in the implementation of this project could also be applied to health information.

With respect to future work, apart from refining and implementing the 2 new HIPAMS modules, we are considering to contribute these ideas to the just started standardization work on a Personalized Digital Health Framework (PDH-F), taking place in the new working group WG11 of ISO/TC 215 (Health Informatics).

Acknowledgements

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Characteristics and Subjective Evaluation of an Intelligent Empowering Agent for Health Person Empowerment

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Abstract. Empowerment is a process through which people acquire the necessary knowledge and self-awareness to understand their health conditions and treatment options, self-manage them, and make informed choices. Currently, few stand-alone applications for patient empowerment exist and people/patients often go on the Web to search for health information. Such information is mainly obtained through generic search engines and it is often overwhelming, too generic, and of poor quality. Intelligent Empowering Agents (IEA) can filter such information and assist the user in the understanding of health information about specific complaints or health in general. We have designed and developed a first prototype of an IEA that dialogues with the user in simple language, collects health information from the Web, and provides tailored, easily understood, and trusted information. It empowers users to create their own comprehensive and objective opinion on health matters that concern them. The paper describes the IEA main characteristics and presents the results of subjective tests carried out to assess the effectiveness of the IEA. Twenty-eight Master students in Digital Health filled an online survey presenting questions on usability, user experience and perceived value. Most respondents found the IEA easy to use and helpful. They also felt that it would improve communication with their doctors.

Keywords. Digital Health, Patient Empowerment, Intelligent Agent, Tailored Health Information, Artificial Intelligence

Introduction

Although digital transformation in healthcare is accelerating, there is still a disconnect between current healthcare, that is focused on disease management, and a more holistic approach that looks at the health and wellbeing of the whole person [1]. The latter approach aims at empowering people by improving their comprehension of their health so that they can manage it better [2, 3, 4]. To be empowered people/patients must:

1. have the necessary knowledge and self-awareness to **understand** their conditions and treatment options;
2. be able to make informed and conscious health choices (i.e., **decide**);

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3. actively manage, with or without advice from medical professionals, their health and well-being (i.e., **act**).

Currently few stand-alone applications for patient empowerment exist [1] and people often go on the Web to search for health information [5]. However, Web information is mainly obtained through generic search engines and it is often overwhelming, too generic, outdated, and of poor quality [3, 5, 6]. Although Artificial Intelligence (AI) could play an important role in health empowerment, it often empowers machines rather than people (e.g., self-diagnosis apps tend to be substitute doctors and keep patients as passive recipients) [7, 8].

By combining the potential of AI with the vast amount of health information available on the Web, we sought to facilitate the person/patient empowerment process by providing the user with tailored health information taken from the Web that is trustworthy and easily understood [9]. This is realized through the creation of an Intelligent Empowering Agent (IEA) that interacts with users to understand their information needs, retrieves and customizes health information from the Web (by means of an AI algorithm), and presents the user with a tailored, intelligible, and trustworthy output that facilitates his/her comprehension, thus empowering wise health decisions.

This paper describes the main characteristics of the IEA and reports a subjective assessment of an IEA prototype made by 28 students of a Master on Digital Health. This assessment has been performed to evaluate the usability, user experience and perceived value with the IEA and receive feedbacks on how to improve it.

1. Methods

1.1. IEA Description

The components of an IEA are:

a) User query

The user selects a complaint from a list or directly enters it as free text.

b) User profile

The user profile is constructed from each user's current health status (e.g., symptoms and/or conditions), background health status (e.g., sex, age, gait, BMI, comorbid illness, etc.), and lifestyle information (e.g., sleep, drugs, meal composition, etc.).

c) Search engine

The search engine retrieves health information from the World Wide Web and Semantic Web (e.g., health-lifesci.schema.org), other health information repositories, and internal information coming from previous searches (anonymized).

d) AI algorithm

The AI algorithm takes the health information collected by the search engine and chooses the most relevant one by using machine learning and decision tree mechanisms. The information is selected according to the following criteria [10, 11, 12]:

- **Language complexity**, to provide users with information that they can easily understand.
- **Information quality**, to provide users with current, accurate, trustworthy, and unambiguous information.

- **Custom information**, to provide users with tailored content (considering the user query and user profile).
- e) **Output presentation**

Tailored relevant health information is provided on complaints (definitions of and related elements), diseases (definitions of and related elements), tests (descriptions of and related elements), and external information sources. A “traffic-light” coloring coding (i.e., red, amber, or green), that implies the need for an urgent consultation with a healthcare professional, is also provided.

1.2. IEA Implementation

A first IEA prototype, the Conversational Health Agent for Person Empowerment (CHAPE) has been developed. It can be accessed at <http://cohealth.ivi.ie/chape>. Once the user inputs age and sex, CHAPE provides a list of possible complaints that can be easily understood by a non-health literate user. Depending on the complaint selected and the user’s profile characteristics, a further sub-list of possibly related complaints is presented, to help define the primary complaint more precisely (Figure 1).

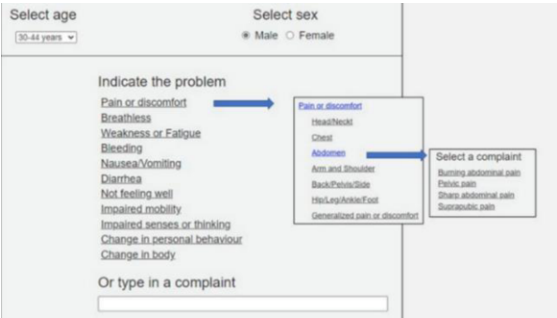


Figure 1. CHAPE interface allows users to specify their complaints in an easy and natural way.

The IEA then uses the information retrieved from the Web and organized by the AI algorithm to provide the information window shown in Figure 2.

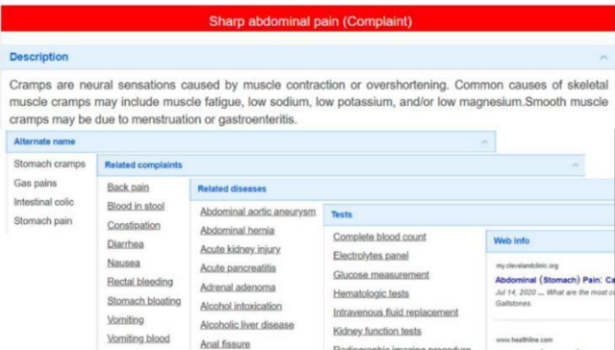


Figure 2. Output window with tailored, trustworthy, and simple information about the searched element.

1.3. IEA Subjective Tests

We have run some subjective tests to evaluate the effectiveness of CHAPE and determine features that need to be improved, ethical approval for which was obtained from Maynooth University. CHAPE was presented to a workshop of employees of the Irish Health Service Executive Agency studying for a Master on Digital Health. These students were asked to use CHAPE and fill an anonymous online survey (https://ec.europa.eu/eusurvey/runner/Chape_initial). The survey had four sections: 1. non-sensitive user-profile information, 2. questions on the usability, user experience and perceived benefit of the system, 3. desired additional features, and 4. other feedbacks. Agreement with specific questions in the survey was expressed in a 1–5 Likert-type scale as follows: 1= strongly disagree, 2= disagree, 3= undecided, 4= agree, 5= strongly agree.

2. Results

Participants

Overall, 28 responses were obtained from 20 females and 8 males, 6 with an age range 19-40 years and 22 with an age range 41-60 years. For what concerns the medical knowledge, 1 had none, 3 had basic knowledge, 4 had average, 14 had good and 6 excellent. For what concerns the computer skills, 1 had basic skills, 6 had average, 14 good, 6 excellent and 1 did not answer.

Responses:

In terms of usability, most respondents found CHAPE interface clear and helpful in identifying health information about complaints, diseases, and tests (Table 1). In terms of user experience, most respondents could better understand their complaints and related diseases and tests (Table 2). In terms of perceived value, the majority of respondents found that CHAPE would improve communication with their doctors (Table 3).

Table 1. Responses to “How easy to use do you find CHAPE?” question.

Statements	No of respondents (and %) who agree or strongly agree
I find the CHAPE interface clear and easy to understand	23 (82.1%)
CHAPE helps me to identify my problem/complaint	18 (64.2%)
CHAPE helps me to identify diseases related to my complaint	21 (75%)
CHAPE helps me to identify tests related to my complaint	22 (78.5%)
CHAPE helps me to identify web information related to my complaint	23 (82.1%)
I think that CHAPE is simple and can be used without priorknowledge	17 (60.7%)
I find that CHAPE is fast in responding to my input	24 (85.7%)

Table 2. Responses to “How helpful do you find CHAPE?” question.

Statements	No of respondents (and %) who agree or strongly agree
After using CHAPE I understand my complaints and diseases better	17 (60.7%)
CHAPE helps me to understand tests related to my complaint	21 (75%)
CHAPE helps me to improve my overall comprehension of complaints and diseases	20 (71.4%)
The websites that CHAPE provides me to explore further health information are useful for me	23 (82.1%)
I consider the information provided by CHAPE trustworthy	15 (53.5%)
I consider the information provided by CHAPE relevant to me	18 (64.2%)

Table 3. Responses to “Which of the following statements apply to you?” question.

Statements	No of respondents (and %)
CHAPE encourages me to take a more active interest in my healthand wellbeing	14 (50.0%)
CHAPE helps me to improve communication with my doctor	17 (60.7%)
CHAPE helps me to improve my health	12 (42.86%)

In terms of additional features and other feedbacks, six respondents recommended to expand the user profile with others health parameters and improve interaction with the system by adding a graphical or tactile interface, photo recognition, and a choice history. Three respondents suggested to add clinical terminology like SNOMED and extracting insights from the gathered information such as population health. Some concerns were expressed on the lack of complaints details (1 respondent), an overly simplified problem section (1 respondent), and the used language not suitable for users with a low level of medical knowledge (1 respondent).

3. Discussion

CHAPE has been designed and implemented to provide relevant, trustworthy, and easy-to-understand health information about complaints and diseases to facilitate people/patients’ empowerment.

The literature presents few studies that link person/patient empowerment to intelligent agents and these are quite different from CHAPE: Issom et al. [13] present a chatbot that focuses on the self-care of Sickle-Cell Disease without addressing the comprehension step; Macedo et al. [14] present a chatbot that provides information, created by healthcare professionals, to people with Parkinson’s Disease; Iatraki et al. [15] present a health information recommender (with manually created information) for cancer patients; Yadav et al. [16] present an AI-driven mobile application that predicts cases of anemia and thalassemia, designed for use by healthcare professionals and not by patients. All these above applications focused on specific diseases and provided manually edited health information. In contrast, CHAPE allows the user to choose from different complaints and diseases, and automatically collects information, appropriate to the user’s needs, from the entire Web. Furthermore, the subjective test have shown CHAPE’s effectiveness in terms of usability, user experience and perceived value.

4. Conclusions and Future Work

This paper has presented the characteristics and subjective evaluation of an Intelligent Empowering Agent (IEA) that provides relevant, trustworthy, and easy-to-understand health information to facilitate people/patients’ empowerment. Subjective testing showed that the IEA is easy to use and helpful, and the majority of respondents considered it would improve their communication with healthcare professionals.

To test it on a wider demographic, the user interface is being redesigned to be more conversational (chatbot like) and include more user profile information, such as gait, body type, nutritional status, comorbidities etc. Complaints and diseases are being associated with Concept Unique Identifiers (CUI) of the Unified Medical Language SystemTM to map them to standard terms taken from medical-term classifications such

as ICD-9, ICD-10, or SNOMED. How information is gathered and filtered out will be explicitly explained to improve trustworthiness. Although user input is anonymous, users will be provided with an option to grant or withdraw informed consent to use their data.

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Personality Traits and Security Motivation

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Abstract. Security awareness training has long been considered a critical element in organizational cybersecurity preparedness and a mandatory activity in many laws and regulations as well as cybersecurity management standards such as ISO 27001. Organizations approach the issue with different methods, but many rely on online training as a cost-effective way to reach a large number of employees at a low cost. When this training is delivered as a voluntary measure, it is essential to have knowledge about the factors contributing to motivation to participate. This study uses the theoretical concepts from Protection motivation theory (PMT) as well as looking into how individual personality traits might affect the willingness to participate. A survey was conducted in a large Norwegian municipality and the data analyzed with PLS-SEM. The study found support for the concepts of Cost and Effectiveness affecting Motivation, but not Vulnerability and Severity. The personality traits of Extroversion and Agreeableness was found to have some moderating effect

Keywords. Security awareness, protection motivation theory, personality traits

Introduction

The human element of cyber security has long been a focus of research [1] and according to the 2021 Verizon data breach report[2] 85% of breaches involved a human element and 36% of all breaches involved phishing. For this reason, user education and awareness is seen as a crucial element of cyber security programs in organizations, also demonstrated by its inclusion in many security management standards, such as ISO 27001. In the health care sector, where frontline workers continually manage highly sensitive information while under continuous pressure of medical emergencies and other stressful situations, the human aspects of cybersecurity come to the frontline. Security awareness training in organizations ranges from simple education on security policies (password strength and reuse, rules for sharing of information etc.) to more complex themes such as increased understanding of threat actors, how to spot phishing emails or understanding privacy concepts such as personally identifiable information (PII) that are critical to the security of organizations. In line with the increased digitalization of health care services, awareness training methods have also moved from classroom/lecture-based or distribution of written policies to more interactive digital solutions, increasing the possibility of adapting the training to personal preferences and learning styles.

Research has highlighted the problem of employee motivation toward security awareness programs and the need for a better understanding of how employees perceive

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such training[3]. While there have been many studies of security awareness, awareness training and its effects on security compliance and security behavior in organizations, see [1] for a review, few have looked into how personality traits affect attitudes to security compliance or actual behavior. While [4] considered personality effects on security compliance and [5] on risk-taking behavior, the present study focuses on motivation and addresses this by using a survey that combines concepts from the security awareness literature and scales for the measurement of personality traits, as well as participation in voluntary security awareness training.

A large municipality in Norway with interest in the success of their security awareness training activities was selected as the case for this study. The municipality has conducted semi-yearly security awareness campaigns. The training has so far been conducted voluntarily and this presented an interesting opportunity to investigate factors contributing to motivation and how traits contribute to motivation and participation that would not be possible in a mandatory setting.

From a research perspective this study contributes to better theories and understanding of how individual psychological traits affect cybersecurity behavior. From a practical perspective, the research can contribute to better awareness training systems by adopting the training to individual parameters, thus supporting better training outcomes. In the study, a questionnaire was constructed based on theories of security awareness and protection motivation theory, as well as a short-form personality scoring scale, and the results were analyzed quantitatively with PLS-SEM.

1. Theoretical background

1.1. Security awareness training

The authors of [3] describe several challenges with security awareness training in organizations, such as the gap between the understanding of security professionals and ordinary employees, the need to adapt to the receiver's knowledge level, advice fatigue where employees fail to adapt to security requirements due to the stressful nature of the amount of advice, policies and requirements, the employee's perception of the advice as superficial and unsystematic, or the monotonous nature of the training programs.

1.2. Theories of protective behavior

Many theoretical frameworks have been applied to the study of security awareness in organizations, or more specifically, how attitudes and beliefs contribute to security behavior, for example compliance with security policies. The authors of [1] identified four major theories most frequently used in studies that all try to explain either behavioral intention or actual behavior, Theory of reasoned action/theory of planned behavior (TRA/TPB), General deterrence Theory (GTR), Protection Motivation Theory (PTM) and Technology acceptance model (TAM). (TRA/TPB), developed by Aizen [6] seeks to explain intention and behavior by *attitudes*, *subjective norms* and *perceived behavioral control*. GTR [7] rooted in criminology, focus on the individual's choice not to commit a crime by evaluating the risk of sanctions. In PMT [8] the individual's "protection motivation" – understood as the intention to perform some protective behavior (for example, stop smoking) is calculated based on a threat appraisal taking into account the perception of severity and one's vulnerability to a threat, and a coping appraisal taking

into account one's perception of how effective the response will be and how likely one is to succeed. Lastly, in TAM [9], behavior (specifically the adoption of technology) is influenced by the perceived usefulness and ease of use.

The protection motivation theory (PMT) concepts were considered the most relevant for this study. The studied behavior is voluntary, and GTR is more appropriate in a non-voluntary context. TRA/TPB and TAM are more generic models less concerned with threat evaluation as a driving factor in security assessment and choices concerning cybersecurity behavior. PMT has been applied in many studies in information systems research with sometimes inconsistent findings, but the authors of [10] have conducted a meta-analytic study of 92 published studies utilizing PMT. Their findings suggested that the PMT relationships are stronger in a personal context but that the intention-behavior relationship was most robust in a workplace relationship. Their study also found good support for response- and self-efficacy, but no support for response cost.

In our study, we choose to keep all variables from PMT theory to contribute to data for the general model – except for self-efficacy. Self-efficacy is generally in PMT understood as the individual's evaluation of their ability to perform the protective behavior – in this instance, the behavior is rather simplistic – participating in online training – for this reason, we consider self-efficacy in this specific context less relevant.

1.3. Personality traits

The Five-Factor Model of personality traits is the leading framework for theorizing around psychological traits of personality, understood as cross-situationally consistent and relatively enduring patterns of thoughts, feelings and actions [11]. The FFM consists of the five dimensions Extraversion (E), Agreeableness (A), Conscientiousness (C), Neuroticism (N) and Openness to Experience (O). As these traits signify consistent thought patterns, it is reasonable to assume they will also affect decisions concerning individual cybersecurity behavior.

For example, [12] studied the effect of personality traits on the adoption of security tools. The study found that Conscientiousness and Agreeableness moderate the relationship between behavioral intent and extent of use, conscientiousness was found to have a moderate moderating impact, and Agreeableness had a small to medium moderating effect.

In [13], the moderating effect of personality on factors influencing the intention to violate security policies in organizations was studied. The study combined the threat and coping appraisal from protection motivation theory with deterrence theory, where a person is deterred from performing policy violations by the threat of sanctions (severity and likelihood of receiving the sanction). They found that more agreeable persons would be more affected by their evaluation of self-efficacy, that is, their ability to adhere to the policies, more conscientious persons would be more affected by their evaluation of the severity and possibility of sanctions. In contrast, the more neurotic persons were most affected by their evaluation of the Cost of performing the correct behavior.

The FFM is traditionally measured using extensive questionnaires, the most comprehensive being the 240-item NEO Personality Inventory, Revised (NEO-PI-R), but shorter versions have been developed - in this survey the ten-item TIPI scale of [14] was used – comprising only ten questions the personality scale takes only 1 minute. The individually validated Norwegian translation of TIPI was used [15].

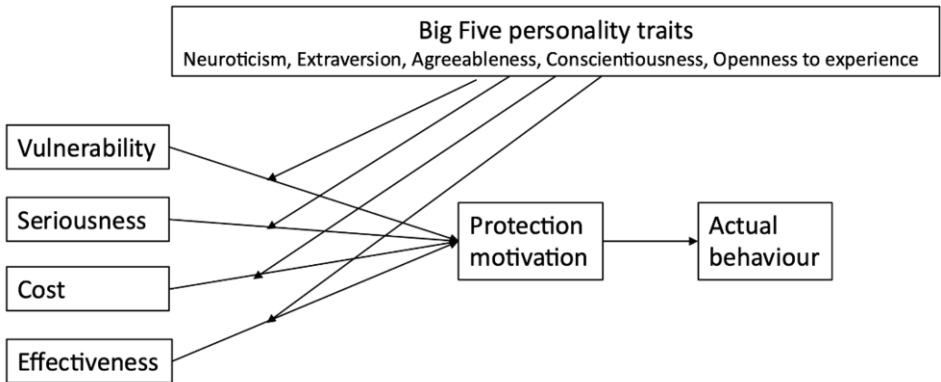


Figure 1- Research model and hypothesizes

2. Methodology

A questionnaire was developed based on the theoretical concepts from PMT to reflect the concepts of *Perception of vulnerability*, *Perception of seriousness*, *Response effectiveness*, *Cost*, and *Protection motivation* when it comes to participating in online security training. In addition, the TIPI scale was included to give a measure of personality for the respondents. A pilot of the questionnaire was performed with a subset of respondents (excluded from the final survey) to validate language and scales. An overview of the research model is presented in figure 1.

The questionnaire was distributed to two groups of employees – group A was selected from employees that had chosen to participate in the voluntary awareness training, and group B from employees that had chosen to abstain – this allowed the combination of actual participation in the training with the questionnaire responses while maintaining full anonymity for the participants. Responses were collected through the service Nettskjema.no, configured not to collect personally identifiable information.

3. Findings

Of the 1500 respondents invited to participate, a total of 126 responses were received, giving a total response rate of 8,4%. For group A (500 invited), 115 responded, with a rate of 23%, for group B (1000 invited), 11 responded, with a rate of 1,1%. While the response rate was low, the total number of respondents are sufficient for the ten-power criterion for using PLS-SEM (a sample number a minimum of ten times the number of in-going relations to the endogenous variable). To verify internal validity and composite reliability, Cronbach's alpha, Rho_A, composite reliability and Average variance extracted were calculated for the PMT concepts. Composite reliability and Cronbach's alpha for all constructs were over 0.7, and AVE as a measure for convergent validity is greater than 0.5 as recommended by the literature. A bootstrapping with 5000 samples was then conducted in SmartPLS to establish p-values for the relationships to check of significance of the relationships

Of the relationships investigated from the PMT theory, only Cost and Effectiveness was found to be significant with a p-value < 0.05. Of these Effectiveness had a 0.5

positive effect while Cost had a -0.33 negative effect. From the personality moderation effects, the moderating effect of Agreeableness on Cost (effect 0.13) and Extraversion on Effectiveness (-0.18) was found significant. All other relationships were not found to be significant. For the model in total, the included variables gave a R-score of 0.827 signifying that the included variables contributed to 83% of the variance in Motivation.

A multi-group analysis was planned to investigate difference between participants and non-participants. Due to the low sample size, it was impossible to perform this analysis on the full model. In an analysis on just Cost and Effect no significant group difference was found (likely due to the low sample size for non-participants).

4. Discussion

The data analysis did not support the evaluation of Seriousness and Vulnerability as motivating factors for participation. While this differs from other studies utilizing PMT, it is in line with other studies finding that the coping appraisal (Cost, effectiveness) have stronger effect than fear appraisal (seriousness, vulnerability). The coping appraisal process has much in common with other technology acceptance models where effectiveness and usability play a greater role, such as the technology acceptance model (TAM) [7]. The reason may be that the respondents do not see security awareness training as a direct protective measure, but consider participation more abstractly focusing on utility and Cost (is it useful, do I have time...).

The significant moderating relationship of Agreeableness on Cost signifies that respondents with a higher score on Agreeableness is less likely to let evaluation on Cost affect Motivation. In [9] agreeableness is described by "forgiving attitudes, belief in cooperation, inoffensive language, reputation as a pushover". This may be interpreted as respondents with a higher belief in cooperation being more likely to accept and participate in voluntary training measures, trusting the organizations evaluation of the value of the measure than their own evaluation. The significant negative moderating effect of Extraversion on Effectiveness signifies that respondents with a higher score on Extraversion are less likely to let their evaluation of the measure's effectiveness contribute to their motivation to participate. In [9] extraversion is described by "social skills, numerous friendships, enterprising vocational interests, participation in sports, club memberships". This may be interpreted as the respondents placing higher value on external valuations of usefulness, such as managers and peers, than own evaluations.

While there is some evidence from the analysis to assume that personality does have a moderating effect on participation in voluntary awareness training, the relationships are not large, with effects of 0.13 and -0.18. Caution is therefore advised to when it comes to placing too much reliance on the use of personality measures in the design of and recruitment to voluntary measures. While the concepts of Severity and Vulnerability have been found significant in other PMT-based studies [8], they seem to have less effect in relation to more abstract concepts such as security awareness training in general. The significant difference in response rate for participants and non-participants is also notable. While the direct reasons was not studied directly, in practice, this might signify that email-based awareness training is not the optimal way of reaching or motivating a large proportion of the organization's employees, especially for employees who are not typical office workers, such as in the health care sector. While inexpensive, the effectiveness is questionable when large groups of employees do not participate. Further studies of how to reach these groups should be performed, for example, through qualitative interviews

with non-participants. The current study also has other limitations, for example, other important factors such as individual differences in stress levels, age, sex, and cultural differences were not considered.

5. Conclusion

Our findings suggest that participation in online security training is affected more by pragmatic usefulness/usability evaluations than by threat evaluations, so further studies should focus on methods to improve actual and perceived usefulness and ease of use. From a practical perspective, employing organizational social pressure to participate, and focusing on the personal advantages of the training can also be suggested to improve participation.

Acknowledgements

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Learning Systems and Artificial Intelligence

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Nonalcoholic Steatohepatitis Diagnosis - A Model-Related Personalized Medicine Approach

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Abstract. Nonalcoholic fatty liver disease (NAFLD) is a clinical syndrome, and pathologically characterized by diffuse macro-vesicular fatty change in the hepatocytes. NAFLD includes simple nonalcoholic fatty liver disease, nonalcoholic steatohepatitis (NASH) and hepatic cirrhosis. NASH is a disease evolving under the influence of various stimuli still poorly understood, but where insulin resistance is prominently. In this paper, we present a new diagnosis model to predict NASH.

Keywords. Nonalcoholic fatty liver disease, liver disease, clinical decision support system, knowledge representation, artificial intelligence, fuzzy logics

Introduction

Non-alcoholic fatty liver disease (NAFLD) is one of the most common causes of chronic liver disease in the world [1]. NAFLD is a clinical syndrome and pathologically characterized by diffuse macro-vesicular fatty change in the hepatocytes. NAFLD includes simple nonalcoholic fatty liver disease, nonalcoholic steatohepatitis (NASH) and hepatic cirrhosis [2]. NAFLD is a recently recognized entity related to modern lifestyle and with expanded clinical importance because of the rising incidence of obesity and diabetes. NAFLD is an increasingly recognized cause of liver-related morbidity and mortality, and it is frequently associated with insulin resistance. While insulin resistance and hyperinsulinemia are, in large part, metabolic consequences of obesity, the basis of diversity in severity and progression of inflammation and fibrosis is not known [3].

The presence of fat in the liver means the accumulation of triglycerides. This accumulation determines the evolution of the disease. Infiltration of 30% of hepatocytes is an incipient form, the moderate form means that 60% of hepatocytes were infiltrated, and the severe form induces over 60% of infiltration hepatocytes [4]. NASH is a disease evolving under the influence of various stimuli still poorly understood. However, in this disease, it is well known that insulin resistance is largely implied [5]. Risk factors for NASH/ Fibrosis are: Age over 45 years; Obesity; Diabetes/Insulin resistance; low platelets; low albumin; AST > ALT; and imaging signs of hyper portal hypertension.

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Several biological Nash prediction tests have been developed [6-7]. The evolution of NAFLD and NASH is variant for each patient, and it is important to use all relevant information to diagnose the disease such as clinical information, biological test, genomic information, and imaging. In this paper, we describe a new diagnosis support system based on validated knowledge from scientific literature and clinical practice guidelines (CPG) to diagnose NASH. We tested our diagnostic model with database of 36 patients generated randomly.

1. Methods

We have developed a framework for interacting with patient’s heterogeneous data (omics, clinical and biological information) and formalizing medical knowledge.

1.1. CPG Formalization:

In the present work, we used not only clinical practice guideline [8] CPGbut also scientific literature as sources of knowledge. We have developed a Fuzzy Semantic Web Reasoning approach using the RDF/N3 language to express the rules from the knowledge sources [9]. This approach was previously tested for Infectious diseases diagnosis decision support [10].

1.1.1. Case Based Fuzzy Cognitive Maps (CBFCM)

Case Based Fuzzy Cognitive Map (CBFCM) is a hybrid decision-making computing technique [9]. CBFCM is represented as nodes (concepts) that illustrate the different aspects of the system’s behavior. Concepts may represent variables, states, events, inputs and outputs, which are essential to model a system. The value of each node (concept) is represented as Fuzzy Set. Figure 1 is a graphical representation of CBFCM method. A patient N is described by a set of clinical parameters (C1, C2, and Cn). Those clinical

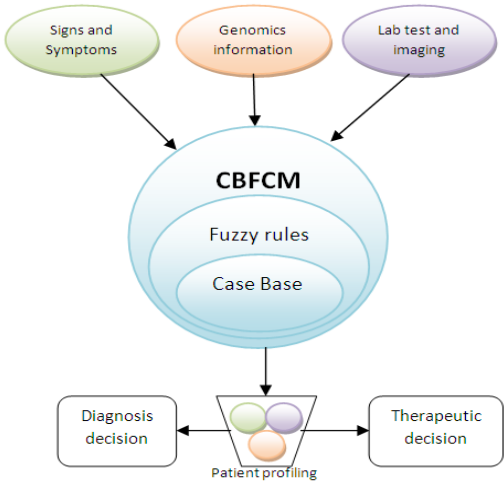


Figure 1. Diagram representing the CBFCM method

parameters can be clinical signs, age, gender, genetic profile, or biological results. D_i represents the decision concept, here the diagnosis of NASH, and W_{ij} represent the strengths of the relationships between concepts.

The construction of CBFCM [10] is consisting of three parts: (a) to determine concepts and (b) to determine the strength of cognitive relationships between concepts (c) to explicit fuzzy control rules.

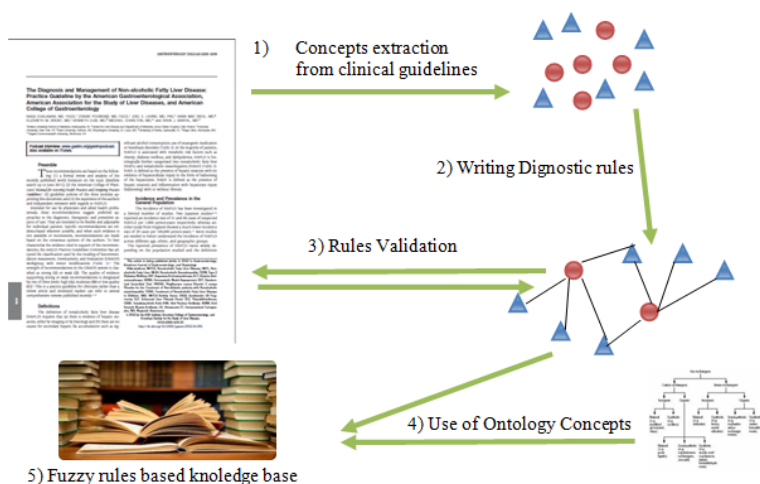


Figure 2. CPG fuzzy formalization method

In the Semantic Web N3 formalism, the weights W_{ij} are in the range (0,1), each weight (concepts' influences) presents a degree of influence from 0 to 1 [10, 11].

1.1.2. Information Model

The Semantic Web framework based on CBFCM integrate heterogeneous data: Clinical data (signs, symptoms, ...); Biological data (lab test, ...); Imaging and omics data. To create a patient clinical profile, we need to use all these types of data. These data are annotated with SNOMED CT concepts. We extracted a related part of SNOMED CT using UMLS.

2. Results

We extracted 18 clinical concepts and these concepts are annotated with SNOMED CT concepts (Table 1).

Table 1. Clinical concepts of NASH diagnosis model

Clinical concepts	Label Description	SNOMED CT Concepts ID
C1	Hyperglycemia	80394007
C2	Hypertriglyceridemia	302870006
C3	HDL	9422000
C4	Hypertension	38341003
C5	BMI	60621009
C6	Waist circumference	276361009
C7	Fasting insulin	252251004
C8	Index HOMA-IR	237650006
C9	Alcohol consumption	160580001
C10	ALT	250637003
C11	AST	250641004
C12	Apolipoprotein	259599001
C13	GGT	60153001
C14	Haptoglobin	85294008
C15	α -fetoprotein	16236008
C16	Adiponutrine gene profil	413451007
C17	Old-Age	70753007
C18	Sex	263495000
D1	NASH	197321007

We tested our diagnostic model with database of 36 patients. We have a performance of 91%. Figure 3 is an example of result rules. The output are N3 triples: PatientIdxxx is the ID of our patients, snomedct:266468003 is a decision concept (NASH), and fl:pi is the confidence degree of the rule.

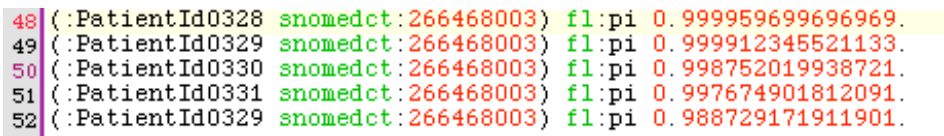


Figure 3. Example of decision rules

3. Discussion and Conclusion

The CBFCM approach allowed us to integrate heterogeneous clinical data to perform a personalized patient profile. This method can identify causal relationships between clinical, biological, genetic concepts and decision concept (Diagnosis of NASH). The use of CBFCM enables to incorporate several sources of knowledge (several CPGs, knowledge from literature), which is of great advantage since all knowledge is rarely

embedded in a unique CPG. Indeed, knowledge of a medical field is usually broad, complex and closely related to other areas so that several knowledge sources are needed to cover and modeled the medical domain in question.

We have implemented the knowledge bases, rules and databases in the same environment (RDF, N3, Euler...) without compatibility constraints; this is one of the advantages of using Semantic Web tools. The success rate of 91% shows the functionality of the model and its future usefulness in clinical practice.

The conducted study allowed us to test cognitive approaches reasoning to enable personalized medicine. The advantage of this approach is to enable the sharing and reuse of knowledge and simplify maintenance. This work represents a preliminary step in developing a CDSS and we'll use a clinical database to test this system and to compare it with others statistic reasoning methods.

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Development and Implementation of the Data Science Learning Platform for Research Physician

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Abstract. Data analysis and their application are the unavoidable factors in the activities analyses in health care. Unfortunately, the acquisition of data from large available medical databases is a complex process and requires deep knowledge of computer science and especially knowledge of tools for data management. According to the European General Data Protection Regulation, the problem becomes much more complex. Recognizing these problems and difficulties, we have developed a Data Science Learning Platform (DSLPL) that primarily targets practitioners and researchers but also the computer science students. Using our proposed tool chain together with the developed graphical user interface, data scientists and research physicians will be able to use available medical databases, apply and analyze different anonymization methods, analyze data according to the patient's risk and quickly formulate new studies to target a disease in a complex data model. This article presents a clinical research discovery toolbox that implements and demonstrates tools for data anonymization, patient data visualization, NLP-tools for guideline search and data science learning tools.

Keywords. Healthcare, risk prediction, Natural Language Processing, Fuzzy logic

Introduction

Data analysis and their application are becoming an essential aspect in the domain of health care, especially in the field of intensive care. The developed data analytic tools can provide a basis for classification problems in health care, e.g., the classification between normal data and anomalies. These tools will be furthermore useful to identify sub-groups of patients in a given population. Due to the large amounts of data, medical doctors are facing challenges to recognize symptoms and to identify disease in early stage as well as to choose optimal treatment [1].

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The data is often very complex and exists in different medical systems and the doctors need a fast access to the right information at the right time. Even with very experienced physicians, this can be a complex task. It is essential for researching physicians to have available test data that they can easily statistically analyze and combine. Moreover, the results provided by machine learning, e.g., disease prediction or risk, could also help them to build more efficient models by adjusting patients parameters on one side, and to combine it with guideline recommendations on the other side. In the recent years, there are a lot of studies that use the power of Artificial Intelligence for the design of risk prediction models [2], [3][4]. The Risk Based Toolbox was created following systematic literature review and recommendation as well as survey of clinical trial units [5]. A detailed review and the principles of anomaly detection algorithms in the different types of medical problems are described in [6]. Each of these algorithms work well on special types of data and computer scientist and statisticians were in the most cases the targeted user group for this type of research. There are furthermore numerous published examples of powerful computational tools - clinical decision support systems - installed in hospital, that can for example identify critical values automatically and help clinicians in decision [7],[8]. The semantic CDSS systems based on ontology and application of fuzzy ontological reasoning in the medical guidelines are presented in recent studies [9], [10]. The different anonymization methods are earlier presented in [11][12][13] and implemented in anonymization tools [14]. We recognized the lack of integration of the mentioned models into a useful research and discovery tool that will be primarily intended for analyzing, learning, researching and testing the results.

Our goal is that the proposed model and toolbox primarily target learning clinical researchers who are newcomers to the two areas; artificial intelligence and medicine. The computer science students and data scientists will also find this toolbox helpful with their studies to understand and analyze the results provided by AI algorithms, to understand the process of anonymization, machine learning, NLP and fuzzy logic and to be able to use and to easier analyze big data. To ensure that the data, which is continuously collected, can also be used by researching physicians in an appropriate manner to their tasks, a Graphical User Interface (GUI) is developed that can also be operated efficiently and effectively by this user group.

1. Material and Methods

According to the European General Data Protection Regulation (GDPR), the health data are treated "as a "special category" of personal data which is considered to be sensitive by its nature" [15]. For demonstration purpose, we used the MIMIC-III 100 patients database provided by [16][17]. As the MIMIC-III patients' data are already anonymized, in our application we used synthetic tool [18] to generate patient data and to test and to improve the anonymization methods.

The enclosed program was created in the object-oriented C# programming language using the .NET framework, where windows are GUI controls of the .NET Framework. Microsoft Visual Studio 2019 was used as the development environment. For testing data, the open-source synthetic data generator Synthea was used [18]. The software is integrated with Python code where the model for risk prediction [19] is investigated. PostgreSQL as open-source object-relational database and the Matlab Fuzzy rule database are used for the primary data management. The code for our tools can be found at <https://gitlab.rlp.net/l.begic899724/dslp>.

2. Methodology and Design

We developed a graphical user interface that consists of the four-parts anonymization tool, patient simulator tool, risk prediction tool and guideline tool (Figure 1).



Figure 1. Data Science Learning Toolbox.

The first anonymization tool contains five different parts as it is presented in Figure 2. The first functionalities (No. 1 and No. 2 in Figure 2) represent the data import process, where the files' format can be a CSV-file generated from the various data sources. The properties of the attributes of the data are displayed in No. 3 in Figure 2.

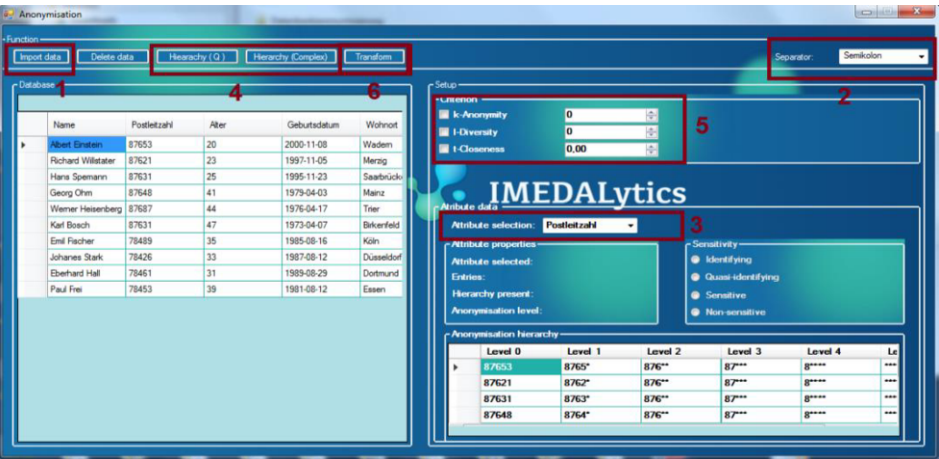


Figure 2. Anonymization toolbox

To anonymize the data, a hierarchy is required for each quasi-identifying attribute (No. 3 and No. 4 in Figure 2). At this stage, the application offers the different

anonymizations' algorithms: k-Anonymity [11], Distinct l-Diversity [12] and t-Neighborhood [13] (No.5 in Figure 2). The button marked as No.6 in the same Figure is used to transfer the input data and the specified information to the next level, in which the individual created nodes are checked via the OLA algorithm [20]. The patient simulator toolbox simplifies the procedure of formulating complex SQL queries to get patients' results for different parameters like lab events, vital signs or the parameters that integrated more data to construct an event e.g., mechanical ventilation or medication treatment. The users in a simple way pick up and match the patient data according to the desired criterion and have the statistical analysis and visualization for every available parameter over the different time interval. The guideline tool represents a recommendation engine where over 1020 different recommendations from 45 guidelines [21] are stored in a database and can be used by different search criteria.

Additionally, using our recently published NLP-FUZZY algorithm [19] we created a procedure for automatic recommendation extraction from guidelines and insertion of recommendations from guidelines to the database. The proposed NLP-FUZZY algorithm combines capabilities of Natural Language Processing (NLP) and Fuzzy Logic approaches. In the first step, the NLP-FUZZY performs a semantic extraction of medical guidelines using a bi-directional Long Short-Term Memory (LSTM). Subsequently, using the extracted semantic, it creates fuzzy rules, which are able to recognize new cases in a learning domain while predicting and extracting the grade of recommendation.

The last toolbox (Figure 3) brings together the results of merged waveform patient's data from the patient simulator toolbox, the risk prediction algorithm based on Dynamic Time Warping- Dynamic Barycenter Averaging (DTW-DBA) [4] approach and the medical guidelines engine. In the learning phase of the DTW-DBA algorithm, a statistic approach in combination with DTW is used to merge all patients in "positive on disease" and "negative on disease" classes and create a Dynamic Time Warping Barycenter Averaging analysis for each feature [19]. In the second classification phase, validation data sets are used to validate the precision of classification (No.1 - No. 2 in Figure 3). Additional adjustments such as frequency and positioning in the graph gives to user an opportunity to analyze the graph and risk results in selected segments as well as in chosen time slots (No. 3 in Figure 3). In the risk simulation, the stable vital parameters are presented with the blue line, and in the moment where risk is recognized, the graphs' lines change their color in red. When the risk is recognized, the risk percentage is shown and in the same moment the recommendations connected with the disease are offered to the clinician (No. 4 in Figure 3). Here the complete statistical analysis over the patients with the most similar symptoms are done and according to it, the most appropriate recommendation is singled out (No. 5 in Figure 3). Expected results for vital sign parameters after the suggested recommendation (based on previous statistical analysis over the most similar patients) are also presented to the researcher. The information about the recommendation strategy and the statistical analysis over the patients with the similar patient condition gives the young physician the opportunity to analyze different risk patterns and possibly find out some hidden properties in patients states. The developed tools in this paper are prototypes and research demonstrators for training purposes and showing the work process of a future research tool chain. However, further research is needed especially in the field of the clinical applications and use-cases.

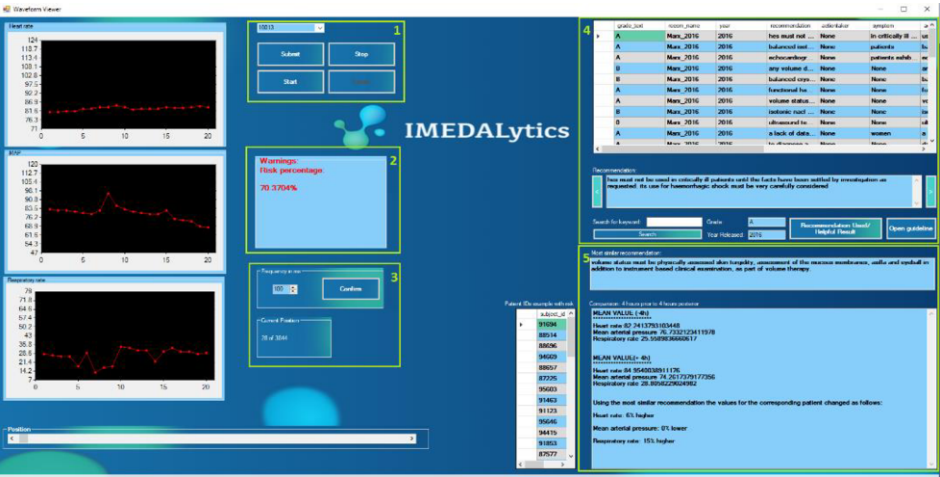


Figure 3. Risk prediction toolbox.

Here especially knowledge from medical experts is required to identify/classify, e.g., anomalies in the time series and to connect them with a real medical event. This solution represents a useful tool to connect experts from the computer science with health experts and to evaluate upcoming novel data analysis approaches and algorithms.

3. Conclusion and Future Work

In our work, we presented the development and implementation of the Data Science Learning Platform (DSLPP) for research physicians. The first purpose of the DSLPP is to offer research physicians the possibility to simplify the data acquisition from Healthcare Big Data without knowing complex SQL queries and other computer science techniques. The combination of Natural Language Processing and Fuzzy logic is demonstrated in real guideline examples and the automatic extraction and insertion of the guidelines are provided for research. The last tool in our DSLPP is an integrated risk prediction algorithm based on DTW-DBA approach. Here, the physicians have an opportunity to analyze the patient's risk, analyze suggested recommendations as well as estimated vital sign parameters after recommendation application. The next step in DSLPP will be to implement synthetic data platform using ML techniques. Here the research physician will have opportunity to generate synthetic data to match sample data, where the important properties of sample data are reflected in synthetic data.

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Ab.ai – A Novel Automated AI Tool for Reporting Antibigrams

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Abstract. Anti-Microbial Resistance is one of the greatest threats that mankind faces right now due to the inappropriate use of antibiotics. Institution of appropriate antibiotics in right dose for the right patient at right time is the “gamechanger” in fighting AMR. Antibiotic Sensitivity Testing (AST) or antibiogram is done to ascertain the sensitivity profile of the organism. The most widely used method in laboratory practice in India is the Kirby-Bauer’s disk diffusion test. There are few shortcomings in the manual interpretation of antibiograms in the form of high inter-operator variability, mandatory requirement of trained microbiologists – which is difficult in low-resource settings and high degree of interpersonal bias due to various factors like stress, workload, and visual acuity. We propose the Ab.ai tool for automating the AST procedures in laboratory. The Ab.ai tool comprises of 3 phases: first for data collection, second for data processing and the third for generation of antibiotic sensitivity reports. Various software packages like OpenCV and EasyOCR are used for the development of the Ab.ai tool. A total of 50 antibiograms of both GPC and GNB are interpreted both by manual and automated method. The manual method is considered the “gold-standard” and the performance of Ab.ai tool was compared against the manual method. The Ab.ai tool achieved an agreement of 98.4% on susceptibility categorization of GPC antibiotics and 97.6% on that of GNB antibiotics against the gold standard manual method. The proposed Ab.ai tool serves as a perfect candidate for automating AST procedures and would prove to be a “game-changer” in battling AMR.

Keywords. Antibiogram, Antibiotic Susceptibility Testing, Anti-Microbial Resistance, Artificial Intelligence, Automated Tool

Introduction

Anti-Microbial Resistance (AMR) is one of the major threats looming in patient care globally [1]. It refers to the development of the adaptive mechanism by the microbes through which it negates the detrimental effects of the antibiotics used to treat the infections caused by them. Antimicrobial Susceptibility Testing (AST) or Antibiogram is a laboratory procedure done to ascertain the susceptibility profile of the microbe i.e., to which antibiotics the microbe would respond. The most widely used method in laboratory practice in India is the Kirby-Bauer’s disk diffusion test.

Briefly, the procedure of antibiogram is as follows: the isolated organism is lawn cultured over the Mueller Hinton Agar (MHA) and the commercially available antibiotic

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disks are placed over the MHA with equal spacing between the disks. The culture plates are then incubated overnight. The zone surrounding the antibiotic disks where there is no growth of bacteria is known as the Zone of Inhibition (ZOI) is formed. This is interpreted by a microbiologist according to the Clinical and Laboratory Standards Institute (CLSI) guidelines.

Artificial Intelligence (AI) has revolutionized health care sector in several ways. AI has proved to be an efficient tool in fighting AMR. Potential of Machine Learning in various aspects like predicting resistance from genome data, utilizing this data to frame the antimicrobial stewardship policy and developing newer antibiotics in the long run [1]. An offline mobile application-based AST interpretation system was developed and achieved good performance in terms of overall agreement with susceptibility categorization [2]. AntibigramJ, an open-source software for automatic interpretation of antibigrams provides an efficient and cost-effective solution for automating the laboratory procedures. This model achieved an impressive agreement of 87% with trained microbiologists [3]. A next gen solution to combat AMR has been proposed in Robotic Antimicrobial Susceptibility Platform (RASP). The RASP was able to perform superiorly than the human technicians in terms of throughput, data resolution and cost parameters [4].

A supervised machine learning based AST automation software, Antilogic was developed for interpretation of AST. Antilogic achieved an impressive agreement against the validation set [5]. An innovative Automatic Identification Algorithm (AIA) has been developed for automating the process of reporting of AST. Various antibiotics were tested through this automated tool. However, several challenges were faced in this trial like imperfect seeding of microorganisms, partial action of antibiotics, overlapping zone of inhibition, formation of secondary halos, etc. [6]. Machine Learning models were developed to predict the antibiotic resistance of bacteria causing primary and secondary pyoderma infections. Various antimicrobial families used to treat Skin and Soft Tissue Infections (SSTIs) were analyzed and a non-linear relationship is found to exist in predicting the antimicrobial resistance [7]. The key factor for incorporation of these AI technologies in clinical practice is its “explainable” nature. The scientific basis of usage of AI and Machine Learning Technologies in battling AMR should be demonstrated with clear evidence, paving way for its incorporation into clinical practice and public health measures [8].

Gaps identified in the manual AST procedures are as follows: high inter-operator variability, mandatory requirement of trained microbiologists – which is difficult in low-resource settings and high degree of interpersonal bias due to various factors like stress, workload and visual acuity.

1. Methods

The proposed architecture of the automated Ab.ai tool is depicted in Figure 1. The study was approved by the Institutional Ethics Committee (Reg No. 199(5)2022). Various software packages like OpenCV and EasyOCR are used for the development of the Ab.ai tool.

OpenCV: Computer Vision Library, a software library used for applications pertaining to computer vision which is available as open source.

EasyOCR: An Optical Character Recognition package based on Python.

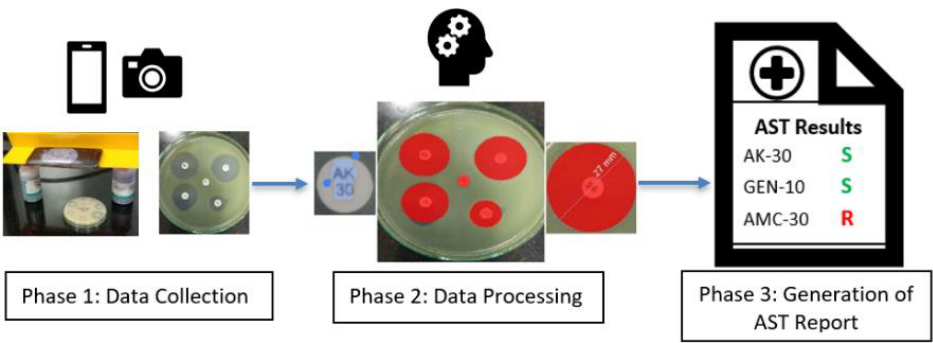


Figure 1. Architecture of the proposed automated Ab.ai tool

The Ab.ai tool comprises of 3 phases: first for data collection, second for data processing and the third for generation of antibiotic sensitivity reports.

1.1. Phase 1: Data Collection – Capturing of Antibigram Images

The data collection phase deals with the capturing the images of antibiogram plates. The organism which was streaked in the culture plate would also be provided as input. Images of 50 antibiogram plates which consists a total of 250 antibiotics (25 plates streaked with Gram Positive Cocci (GPC) and 25 plates streaked with Gram Negative Bacilli (GNB)) were captured using Redmi Note 8 smartphone which possess a Quad camera with resolution of 48 Mega Pixel. The GPCs used in this study are Staphylococcus aureus and Enterococcus species (Enterococcus faecalis and Enterococcus faecium) and the antibiotics used are Penicillin G, Cephalexin, Cefotaxime, Co-Trimoxazole, Erythromycin, Cefoxitin, Ciprofloxacin, Clindamycin, Vancomycin and Linezolid. The GNBs used in this study are Pseudomonas aeruginosa and Escherichia coli and the antibiotics used are Amoxycillin Clavulanic Acid, Amikacin, Gentamicin, Ciprofloxacin, Cephalexin, Cefotaxime Clavulanic Acid, Ceftazidime Clavulanic Acid, Piperacillin Tazobactam, Imipenem, Tetracycline, and Cefepime. The images were taken at a standard distance of 15 cm from the culture plates. These images are then transferred to the Personal Computer for further processing.

1.2. Phase 2: Data Processing – Analysis of Antibigrams

This data processing phase revolves around analyzing the antibiogram images. The images of the antibiogram plates were processed using the OpenCV and EasyOCR packages. The main aim of this phase is to identify the antibiotic disks and to measure the diameter of the Zone of Inhibition (ZOI).

Recognition of the Antibiotic Disks: The antibiotic disks along with the ZOI were segmented from the antibiogram images using segmentation techniques. This segmented image was then processed using the EasyOCR package. The symbol of the antibiotic and its disc concentration were read from the segmented images. The symbols were then compared with the database to find the full antibiotic name.

Measurement of the diameter of the Zone of Inhibition (ZOI): The AI model was trained to delineate the ZOI from the adjacent zones with microbial growth. The diameter of the ZOI was then measured.

1.3. Phase 3: Generation of Antibiotic Sensitivity Report

This phase deals with the assimilation of the data gathered from Phase 2. The Zone size interpretative chart for the Antibiotic sensitivity testing based on the CLSI guidelines is maintained in the MySQL database. The antibiotic, its disc concentration and the diameter of the ZOI for the particular organism would be matched with the database and the report is then generated.

2. Results

The data processing phase identified the various antibiotics and their respective ZOI. The sample image of antibiogram plate streaked with *Pseudomonas aeruginosa* is shown in Figure 2 (A). The output showed segmentation of the ZOI, identification of the symbol, disc concentration of antibiotic and measurement of its diameter as in Figure 2 (B).

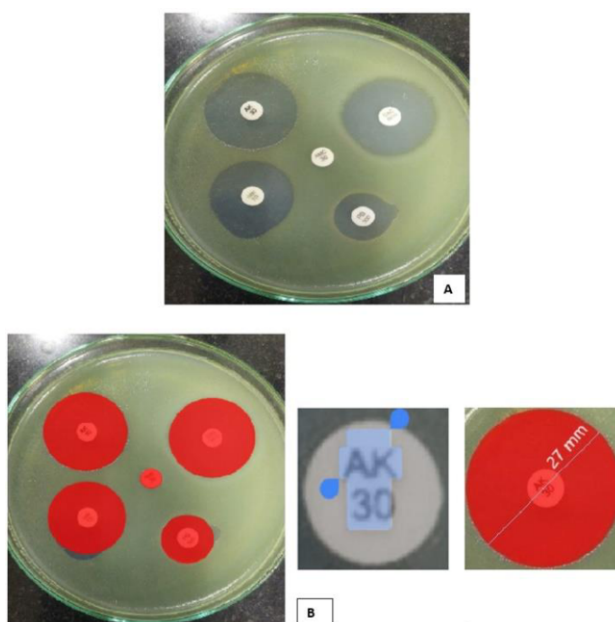


Figure 2. (A) Image of antibiogram plate streaked with *Pseudomonas aeruginosa* (B) Segmentation of ZOI, Identification of symbol and disc concentration of the antibiotic and measurement of diameter of ZOI

Analysis of performance of the Ab.ai tool

The 50 antibiogram plates which consists a total of 250 antibiotics were interpreted by 2 microbiology trainees and each of them individually interpreted the susceptibility of the antibiotics as Sensitive, Intermediate or Resistant according to CLSI guidelines. Discrepancies between the interpretations of the trainees were further resolved by a

senior microbiologist. Thus, the interpretations provided by the microbiologist through manual method are considered to be the gold-standard. The performance of the Ab.ai tool was compared against the manual method and the results shown in Table 1. The sample antibiotic sensitivity report generated by the Ab.ai tool is shown in Figure 3.

Table 1. Performance evaluation of the automated Ab.ai tool against the manual method. Interpretation of 125 antibiotics for GPC and GNB each by trainees, manual and automated method are shown.

	Gram Positive Cocci (GPC)			Gram Negative Bacilli (GNB)		
	Sensitive	Intermediate	Resistant	Sensitive	Intermediate	Resistant
Trainee 1	48	24	53	50	26	49
Trainee 2	49	22	54	52	24	49
Manual (Trainees + Sr. Microbiolo- gist)	49	24	52	51	25	49
Automated (Ab.ai)	48	24	53	53	24	48

Department of Microbiology - Sample Antibiotic Sensitivity Report*

Method: Automated Ab.ai Tool

Symbol	Antimicrobial Agent	Disc Content – Conc.	Diameter of ZOI	Grading – Sensitive /Intermediate/Resistant
AK-30	Amikacin	30 mcg	27 mm	Sensitive
GEN-10	Gentamicin	10 mcg	23 mm	Sensitive
CAC-30	Ceftazidime/Clavulanic Acid	30 mcg	28 mm	Sensitive
AMC-30	Amoxycillin/Clavulanic acid	30 mcg	6 mm	Resistant
PB-300	Polymyxin B	300 units	15 mm	Sensitive

*Only for research purposes, not used in routine laboratory practice

Figure 3. Sample antibiotic sensitivity report for the sample shown in Figure 2.

3. Discussion

The Ab.ai tool has proved to be successful in interpreting the antibiograms. The AI model has been able to accurately identify the symbol and disc concentration of the antibiotics. Figure 2 (B) shows an example of accurate segmentation of the ZOI. However, it is found that in some instances the AI model hasn’t accurately segmented the region. This has been attributed to the irregular margins of the ZOI and streaks of growth presenting over the ZOI.

Interobserver variability is evident from the difference in interpretations of antibiotics by the 2 trainees for both GPC and GNB groups as depicted in Table 1. The interpretations of automated Ab.ai tool is compared with the manual method. The Ab.ai tool achieved an agreement of 98.4% on susceptibility categorization of GPC antibiotics and 97.6% on that of GNB antibiotics against the gold standard manual method. Hence, the Ab.ai tool is found to perform superiorly than AntibiogramJ [2]. These results point out towards the success of the Ab.ai tool.

4. Conclusion

AMR is a major clinical hazard. Institution of appropriate antibiotics in right dose for the right patient at right time is the “gamechanger” in fighting AMR. The proposed Ab.ai tool serves as a perfect candidate for automating AST procedures. The key pros of this tool are alleviation of inter-observer variability and helps to automate AST in low resource settings even in absence of trained microbiologists.

Future scope of the study

- The study utilized only 50 antibigrams. Hence, evaluating the performance of the Ab.ai tool with much larger number of antibigrams would make the tool more robust. This could be done considering large samples of various species of GPC and GNB and a wide range of antibiotics including both first- and second-line drugs. Furthermore, this exercise could be expanded to multicentric setup wherein antibiotic resistance patterns could even be analyzed globally.
- The images used in this study were captured using a single smartphone camera. Analyzing the antibigrams captured using different cameras would be critical in eliciting any bias and if found, suitable corrective measures could be taken.

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Information System for Integration of Genetic Information and Clinical Knowledge

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Abstract. This paper deals with a developed information system called a Personal Genetic Card (PGC). The system aims to integrate the known clinical knowledge (interpretations and recommendations) linked to genetic information with the analysis results of a patient. Genetic information has an increasing influence on the clinical decision of physicians as well as other medical and health services. All these services need to connect the genetic profile with the phenotypes such as drug metabolism, drug toxicity, drug dosing, or intolerance of some substances. It still applies that the best way to represent data of medical records is a structured form of record. Many approaches can be used to define the structure (syntax) of the record and the content (semantics) of the record and to exchange data in forms of various standards and terminologies. Moreover, the genetic analysis field has its terminology databases for representing genetic information (e.g. HGNC, NCBI). The next step is to connect the genetic analysis results with c clinical knowledge (interpretation, recommendation). This step is crucial because the genetic analysis results have clinical benefits if we can assign them to some valid clinical knowledge. And the best final result is when we can make a better recommendation based on the genetic results and clinical knowledge. Genetic knowledge databases (e.g. PharmGKB, SNPedia, ClinVar) contain many interpretations and even recommendations for genetic analysis results based on different purposes. This situation is appropriate for developing the PGC system that takes inspiration from case-based reasoning in purpose to allow integration of the assumptions and knowledge about phenotypes and the real genetic analysis results in the structured form.

Keywords. Information system, genetic analysis, eHealth, terminology, standards

Introduction

The importance of genetic information grows in link with an increasing volume of known connections of genetic information with clinical information. Genetic information can influence the decision in standard health care as well as in nutrition consultancy or sports medicine. Regarding genetic analysis, the important clinical areas are medication metabolismization, substance intolerance (e.g. higher toxicity), and possible predisposition for diseases.

The important parts of a genetic analysis results storage system are part of the genetic analysis results representation and interpretations and their binding with the analysis results. Of course, there is a request for the issue of security and privacy, such as pseudo anonymization and full encrypted data (according to the best practice).

The genetics area has several specifications that must be considered in the analysis and design of the application for genetic results representation and their connection with the clinical knowledge (interpretation, recommendation). There are recommendations and guidelines for genetics analysis result representation. Therefore, these issues should be based on best practices in the field (e.g. based on CPIC [1]). The important conditions for using genetic information are a substantial benefit for healthcare and/or life quality and structured and powerfully secured storage and manipulation with the genetic information. In the first step, we developed a strategy for our system, called Personal Genetic Card (PGC) [2]. The PGC system was developed within the project Genomkit, where the primary intention was to design and create microarray chips for three fields – pharmacogenetics, nutrigenetics and sports genetics. Although the project's main goal was to design and create microarray chips, it was clear that the clinical usefulness of the results must be declared from the beginning. Since pharmacogenetics was the lead topic, the PGC was primarily developed for pharmacogenetics but can also be used for all fields. Therefore, the created strategy determines the use of existing terminologies and standards of the genetic analysis representation and interpretation for our project. The request was to create a system for integrating individual genetic analysis results and relevant clinical knowledge but with the potential to extend this information pool to other (clinical) parameters. In this paper, we would like to describe and discuss the clinical knowledge assignments to the given analysis results.

1. Material and Methods

First, we should mention the issue of transforming the genetic analysis results from a sequencer into a usable format (for the PGC). This issue is not a part of the PGC because the situation with sequencing can be complicated, and there is no reason to incorporate it into the system for storage and interpretation linking. The important is a clearly defined format that we request at the system's input. The PGC system is built on integrating genetic analysis results and their interpretations for particular patients. From this perspective, we can create the system as a partial variation of the Case Based Reasoning (CBR) [3] methodology. In the CBR approach, the knowledge base is created by cases, where each case contains the problem description part and solution part. In our case, the problem part of a case is determined by the purpose of the analysis and obtained genetic analysis results. The solution of the case is represented by the known connections to the clinical knowledge.

In [2], we stated systems LOINC [4, 5], and SNOMED [6] as the possible resource for a definition of the structure items of the created systems. Further, we determined LOINC as the system we want to use to define our components. The LOINC was chosen because its primary aim is the representation of laboratory and clinical results and a more direct description of particular components. However, it is necessary to say that the LOINC is used only as vocabulary for our system components, and it is not a template for the system's structure.

Further, we define the necessary resources for genetic analysis results representation, and the LOINC helps us to determine these terminologies. The first database is the HUGO Gene Nomenclature Committee (HGNC) [7] for defining codes and names for particular genes. The second database is the NCBI Single Nucleotide Polymorphism Database (NCBI dbSNP) [8] that represents the polymorphism by a code with the "rs" prefix and a various numbers of digits. Finally, we use the standard expression for alleles (A,C,G,T) or expression for haplotypes (e.g *1/*1). Thus, The import of the results into the PCG is in a simple form to test our concepts. There are to possibilities of this import form (as well as test definition): HGNC gene, rs code from NCBI dbSNP, allele name triplet and HGNC gene and haplotype definition pair.

Finally, we need to define clinical interpretations of the genetic analysis results. Our purpose is to allow to use of existing interpretations as well as the possibility of creating internal interpretation by a provider of the system. However, the first step was to create the interpretation model based on the existing knowledge database. Several databases can be used. In the [2], we describe three basically known of them: PharmGKB [9], SNPedia [10], and ClinVar [11]. There are differences between these databases, but the mutual elements of each of them are the use of terminology and referencing to the articles that create the validation of declare interpretations. In our perspective, the most advanced database is the PharmGKB, which is also associated with CPIC [1] initiatives. The second reason for this step was that our primary focus in the interpretations is on drug administration optimization.

2. Results

As we mentioned in the previous chapter, both knowledge base and reasoning structure are based on case-based reasoning (CBR). These assumptions allow us to create the structure depicted in Figure 1. From our perspective, there are several following specifics to create a case:

- The first one is the atomicity of the problem description. The problem description part of the case is theoretically compounded not only by a given gene, polymorphism, and alleles (genotype, haplotype) but also by some factor (in our case by drug), and analysis purpose. The purpose can be, for example, disease (effect) and dosing (effect type) or toxicity (effect type). If we know how the interpretation/recommendation is bonded with this combination, we can transfer the factor and purpose as part of a problem description.
- The second one is the "solutions" part. In our cases, this solution is given by empiric research that is verified by a study and published as an article. Therefore, it is crucial to link these articles with knowledge. However, as we mentioned, this is already standard for the existing knowledge databases, so it is also natural for our system. The described difference is more important because we have a limited number of solutions to the problem. We have a final number of genes

and polymorphisms that we define for genetic analysis and a finite combination of this genetic setup with the factors and purposes of the analysis. Moreover, the number of appropriate clinical knowledge (interpretation, recommendation), which we can link with the problem description, is the next limiting factor for the case number. Therefore, we can create a basic pool of a final number of cases in the system knowledge base in advance. Of course, this knowledge base can be extended based on the new knowledge from knowledge databases or by other knowledge defined based on the system (more in the next item). We should mention the difference between interpretation and recommendation. In our perspective, the interpretation (you can also find it as clinical annotation) is assigned to each result of the genetic analysis. However, the patient probably takes just a few drugs, and the relevant interpretations pool is most likely significantly smaller (but still quite extensive). A recommendation is based on guidelines from an expert group (e.g. CPIC). The recommendation is usually based on information about drug metabolization speed, which is linked to the dosage adjustment. It is a more aggregated form of knowledge that is more practical for clinical intentions.

- In standard CBR, cases in the case base and the new input case are compared based on some defined similarity. It means that the selected case, from the case base, can be only partially matched with the new case. However, we are in a different situation because we cannot rely on the similarity of genetic information. Therefore, we need to find an absolute matching of genetic information and ideally even of the factor and analysis purpose. So, we use the simple 0 or 1 similarity for each part of the problem description. However, we can set up the system so that if there are known interpretations or recommendations for a given factor or purpose, the system can provide the knowledge based on the genetic information for another factor or purpose. Moreover, if we have some structure (e.g. ontology) that can determine the similarity of categorical terms, we can use it for the comparison between the cases (e.g. dosing of the drug is close to metabolization of the drug - depending on our knowledge to revise the solution). The solution revision step is open in our case because many issues must be solved. The next important point is the request to extend the approach for other parameters. The problem description can be extended by several other parameters such as gender, age, anamnesis, laboratory result, etc. For this case arrangement, we can define various similarities for continuous and categorical variables. Of course, it is necessary to update also the solution part in relevance to the problem extension.

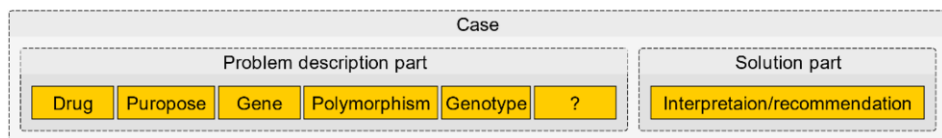


Figure 1. The PGC case arrangement.

Several basic parts of the PGC's record representation are depicted in Figure 2. First, there is necessary to define the scope of the genetic analysis and thus the considered purposes of the analysis. Then, the defined analysis purpose should be linked with the interpretations that there are available. This combination creates the case base. After that,

the new case is imported into the PGC, the proper test definition in the case problem part is found, and the appropriate case is distributed to the user. It is necessary to mention the security issue. The idea is that the records in the system are connected only with the anonymous patient identificatory. The identificatory is same as the identificatory of patient in the clinical system of physician who request the analysis. Moreover, the patient record (representation of the analysis result and linking to the knowledge base) is encrypted with symmetric encryption.

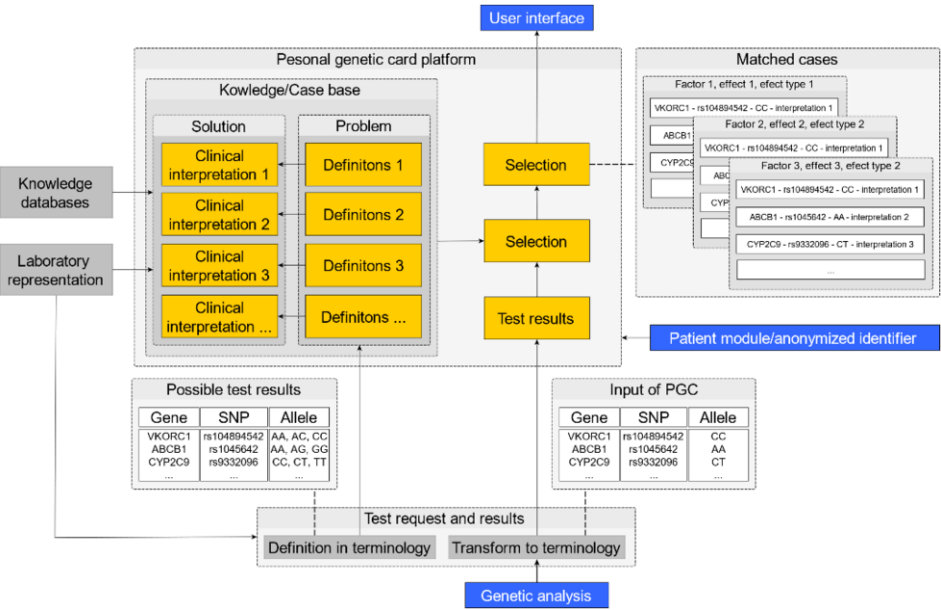


Figure 2. The Personal Genetics Card (PGC) modules organization

Thus, the workflow for the creation of a new record in the PGC from the genetic analysis is following:

1. Based on known information, the knowledge base of the PGC is built up/updated for given purposes.
2. The structure of cases in the knowledge base and the transformed analysis result are given by laboratory (item) representation (it is also a terminology service).
3. There is a request for analysis from a physician during a medical examination (e.g. drug administration).
4. The genetic analysis is performed by the laboratory worker, and the results of the analysis (in requested form) are uploaded to the PGC system for the specified patient and type of test (defines polymorphisms for interpretations assignment).
5. The predefined interpretations are automatically assigned to the results. The predefined interpretations were created by an expert or taken from the knowledge databases and imported into the PGC system (see 1).
6. The user can browse interpretations and filter them by a factor (e.g. substances) and highlighted polymorphisms.

3. Conclusion

We described our integration approach of representation and interpretation of the genetic analysis in the personal genetic card system. The aim is to link genetic analysis and clinical issues. The system allows physicians to use the interpretations and even the recommendations and does not sort the raw data of the analysis. We described choosing terminology systems appropriate for representing genetic analysis in the structured form. The structured representation of the analysis is completed by a structured format of the interpretation and recommendation. We describe our system based on CBR for selecting appropriate clinical knowledge for the given analysis purpose and results. In the described simple case, the selection is a simple task where we just want to find a matched solution to the analysis result. However, it will be very interesting when we can add the new observation from the real measurement and find the confirmation or irregularity in the case base. So, the PGC system approach can bring a new perspective to the personal genetic analysis results and applications of their clinical knowledge.

4. Acknowledgement

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Data and Knowledge Management, Modeling, Simulation, Automated Design

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Analysis of the Representation of Frequent Clinical Attributes in the Unified Medical Language System

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Abstract. Mapping clinical attributes from hospital information systems to standardized terminologies may allow their scientific reuse for multicenter studies. The Unified Medical Language System (UMLS) defines synonyms in different terminologies, which could be valuable for achieving semantic interoperability between different sites. Here we aim to explore the potential relevance of UMLS concepts and associated semantic relations for widely used clinical terminologies in a German university hospital. To semi-automatically examine a sample of the 200 most frequent codes from Erlangen University Hospital for three relevant terminologies, we implemented a script that queries their UMLS representation and associated mappings via a programming interface. We found that 94% of frequent diagnostic codes were available in UMLS, and that most of these codes could be mapped to other terminologies such as SNOMED CT. We observed that all examined laboratory codes were represented in UMLS, and that various translations to other languages were available for these concepts. The classification that is most widely used in German hospital for documenting clinical procedures was not originally represented in UMLS, but external mappings to SNOMED CT allowed identifying UMLS entries for 90.5% of frequent codes. Future research could extend this investigation to other code sets and terminologies, or study the potential utility of available mappings for specific applications.

Keywords. Unified Medical Language System, Semantic Interoperability, Application Programming Interface.

Introduction

The introduction of electronic health records intent to improve the health care of individuals, and for researchers increases the possibilities to gain more knowledge about diseases and treatments. It has been proposed that realizing this potential requires that a critical mass of health care providers adopt the collection of patient data in a digital format, as well as interoperability between the involved systems [1].

Semantic interoperability between different systems can be achieved through the use of standard terminologies. If an international study attempted to accumulate clinical

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records from participating sites for an aggregate analysis, the uniform use of a standardized terminology would allow a consistent scientific reuse by simply pooling contributed datasets. If no homogenous semantic reference is available, on the other hand, a mapping between the attributes of the participating sites would have to be set up manually, which can be laborious.

The four consortia of the German Medical Informatics Initiative are currently in the process of establishing data integration centers at university hospitals, which aim to support medical research by collecting and harmonizing patient records from routine care information systems [2]. These organizations manage data reutilization with specific provisions that consider the privacy rights of the involved patients, and ideally reuse clinical data for multiple studies, so expanding the semantic integration of frequent attributes would be particularly valuable.

The Unified Medical Language System (UMLS), developed by the U.S. National Library of Medicine, was chosen for this work because of its more than 3.25 million concepts (as of 2016) from over 220 source vocabularies (as of 2021), making it one of the richest thesauri in biomedicine [3,4]. UMLS is regularly updated and extended. It allows users to access terminology data via an application programming interface (API), which enables automated fields of application [5,6].

The goal of this study is to explore the potential relevance of UMLS concepts and associated semantic relations for frequently used clinical attributes in a German university hospital by semi-automatically analyzing their representation in UMLS.

1. Method

To analyze the availability of relevant clinical attributes in the UMLS metathesaurus, we automatically queried the provided API with lists of the most frequently documented codes for three commonly used clinical terminologies.

We focused on “The International Statistical Classification Of Diseases And Related Health Problems, 10th revision, German Modification” (ICD-10-GM), “Logical Observation Identifiers Names and Codes” (LOINC) and “German procedure classification” (*Operationen- und Prozedurenschlüssel* - OPS), based on their relevance for routine clinical documentation and on their usage at Erlangen University Hospital [7]. ICD-10-GM is the statutory classification for coding diagnoses in inpatient medical care in Germany [8], LOINC codes are used for identifying clinical observations and measurements such as laboratory tests [9], while OPS codes denote diagnostic and therapeutic medical procedures [10].

As a subsample, we focused on the 200 most frequent codes from Erlangen University Hospital for each of the three terminologies. To automatically examine the UMLS representation and potential semantic mappings, we implemented a Python script that iterates through input codes and communicates with the UMLS API. Information from the API responses is first stored and then visualized according to the following recipe:

1. The top 200 ICD-10-GM codes are provided as input.
2. For each code, the concept ID in UMLS is identified.
3. All atoms associated with this concept ID are queried and stored in a separate list.
4. This output is used to count for each terminology how many of the 200 codes have a mapping to that specific terminology.

- For visualization, the output list from step 4 is imported into Excel and displayed in a diagram.

The same procedure is used for LOINC codes. The mapping of OPS codes required another step since we observed that UMLS did not originally contain any OPS codes. A previous research project with TrinetX, a global health research network [11,12], had produced and published a list of OPS to SNOMED CT mappings, which we used for an intermediate mapping step.

The developed script that accesses the UMLS API is available at <https://github.com/brsgngr/UMLSMappingsReader>.

2. Results

The procedure described above leads to the results shown in figures 1 to 3. Figure 1 illustrates the frequency distribution of available UMLS mappings for the 200 most common ICD-10-GM codes, Figure 2 shows the corresponding frequencies for the 200 most frequent LOINC codes, and Figure 3 displays the same data for the 200 most frequent OPS codes.

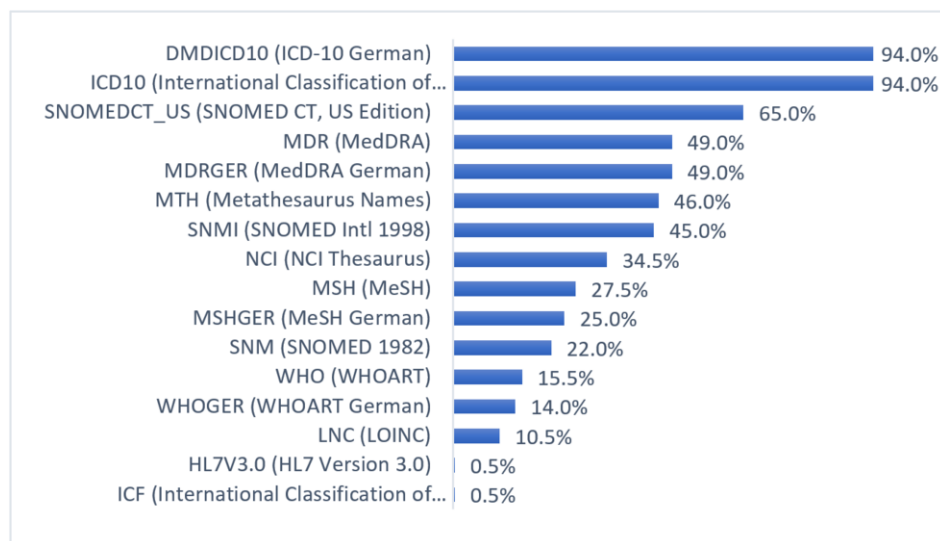


Figure 1. Frequency distribution of a subset of available UMLS mappings for the 200 most frequent ICD-10-GM codes. Out of the 200 studied ICD-10-GM codes, 94.0% were found in UMLS and 65.0% had a SNOMED CT mapping. The terminology labels are used as defined by UMLS.

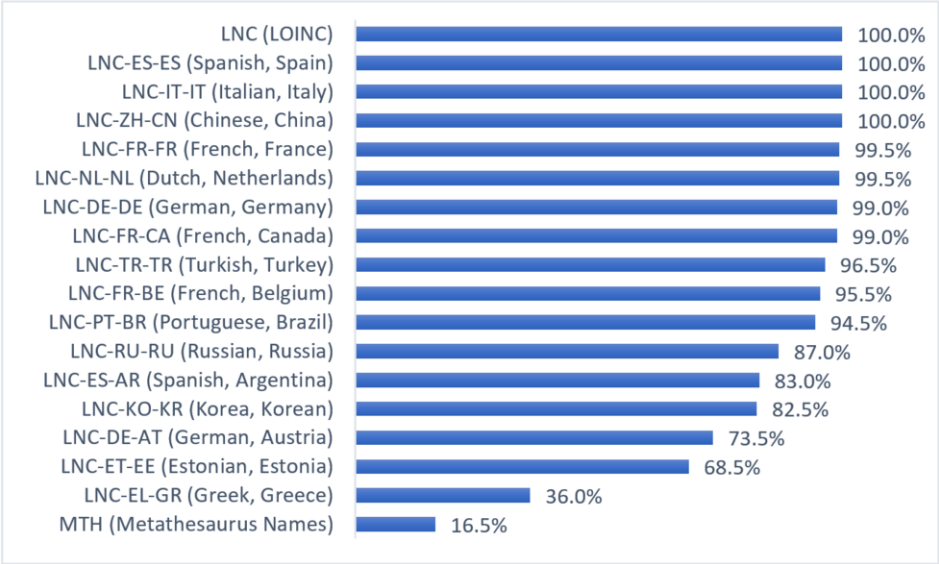


Figure 2. Frequency distribution of available UMLS mappings for the 200 most frequent LOINC codes. The terminology labels are used as defined by UMLS.

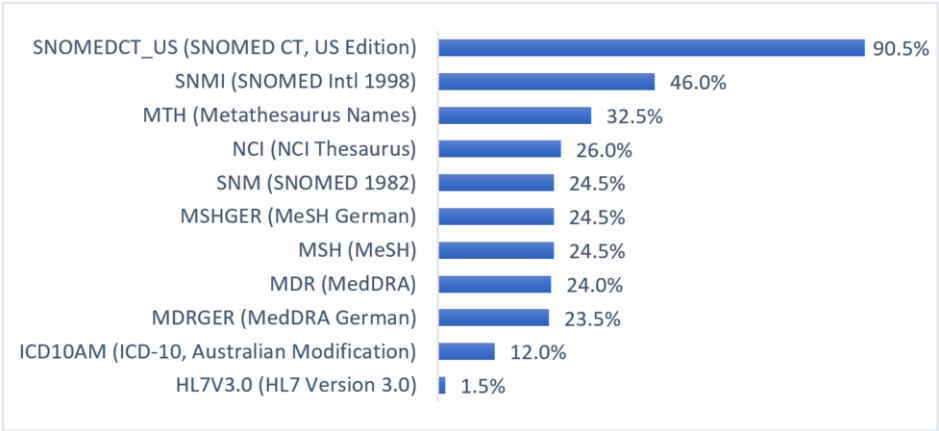


Figure 3. Frequency distribution of a subset of available UMLS mappings for the 200 most frequent OPS codes after mapping the OPS codes to SNOMED CT codes. The terminology labels are used as defined by UMLS.

The Figures can be read as follows: 65.0% of the 200 most frequent ICD-10-GM codes had a SNOMED CT mapping in UMLS.

Also, it can be stated that 94% of the most frequently used 200 ICD-10-GM codes were found in UMLS, whereas 6.0% were not found. All LOINC codes were present in UMLS. For the OPS codes, 90.5% of the codes were found in UMLS after mapping the OPS code to SNOMED CT. The remaining OPS codes could not be identified either because the OPS code could not be mapped to any SNOMED CT code or UMLS does not contain the corresponding SNOMED CT code.

Note that Figures 1 and 3 display only a subset of mappings, because only terminologies with frequent mappings have been included in order to improve readability. Figure 2 does not include any filtering.

3. Discussion

We observed that for all three terminologies at least 91%, and for LOINC even 100% of the 200 most frequent codes could be identified in UMLS. For ICD-10-GM as well as for OPS, many mappings were found, also to terminologies that are relevant in Germany, whereas LOINC codes were mostly mapped to LOINC codes in other languages (i.e. translations).

Three aspects were observed when examining the most frequent ICD-10-GM codes. First, in UMLS, an ICD-10-GM code only exists if the corresponding ICD-10 code is present. This is the reason for the imperfect overlap of the ICD-10-GM codes with the ICD-10 codes in Figure 1. Second, it is important to note that the initial list of the 200 most frequent ICD-10-GM codes actually included 33 5-digit codes. Since ICD-10 only allows 4-digit codes, the 5-digit ICD-10-GM codes could not be found in UMLS. If the higher-level category, i.e. the 4-digit code, is used for these 33 codes, it generates the result shown in Figure 1. Third, eight codes from the second run could not be found in UMLS, because these codes were added to ICD-10 after the last update of ICD-10 in UMLS. Overall, it can be stated that treating ICD-10-GM more as an independent terminology in UMLS could enable the integration of 5-digit codes and would thus also allow a more precise mapping analysis. A feasible extension of our script would thus automatically revert to the higher-level category of a code if it is not found.

Examination of the 200 most frequent LOINC codes revealed that even though all LOINC codes were found in UMLS, a large fraction of codes was only associated with translated versions of these LOINC codes itself. This makes it difficult to draw conclusions about other terminologies. Perhaps LOINC codes could be mapped to a different terminology using other data sources and examined in UMLS using this other terminology.

Although OPS codes were not directly represented in UMLS, some semantic relations to other terminologies could be found in UMLS with the help of the TriNetX mapping. In this way, results similar in quality to ICD-10-GM were achieved. One difference, however, is that in the ICD-10-GM yielded more mappings to other relevant terminologies.

Through the mappings across terminologies and different concepts, the scientific use can be increased, further fields of knowledge can be identified, and additional conclusions can be made. An exemplary use could be to suggest publications or clinical studies appropriate to specific clinical situations based on linked codes, such as through Medical Subject Headings (MeSH Terms). A high rate of mappings between terminologies increases the potential for the different application fields.

In the future, the Python script could be run with additional codes in order to gain insight into the available UMLS mappings for a different set of codes. It could be extended to also support other terminologies, or underpin prototypical applications that leverage such dynamic semantic mapping, such as the use case of suggesting relevant publications based on mapping clinical codes to synonymous MeSH codes.

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A Visualization and Benchmarking Simulator for Clinical Data

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Abstract. The availability of Big Data has increased significantly in many areas in recent years. Insights from these data sets lead to optimized processes in many industries, which is why understanding as well as gaining knowledge through analyses of these data sets is becoming increasingly relevant. In the medical field, especially in intensive care units, fast and appropriate treatment is crucial due to the usually critical condition of patients. The patient data recorded here is often very heterogeneous and the resulting database models are very complex, so that accessing and thus using this data requires technical background knowledge. We have focused on the development of a web application that is primarily aimed at clinical staff and researchers. It is an easily accessible visualization and benchmarking tool that provides a graphical interface for the MIMIC-III database. The anonymized datasets contained in MIMIC-III include general information about patients as well as characteristics such as vital signs and laboratory measurements. These datasets are of great interest because they can be used to improve digital decision support systems and clinical processes. Therefore, in addition to visualization, the application can be used by researchers to validate anomaly detection algorithms and by clinical staff to assess disease progression. For this purpose, patient data can be individualized through modifications such as increasing and decreasing vital signs and laboratory parameters so that disease progression can be simulated and subsequently analyzed according to the user's specific needs.

Keywords. Big Data, Health Care, Simulation, Time Series, Anomaly Detection

Introduction

The SARS-Cov-2 pandemic has shown that hospitals can become overloaded very quickly. In the future, digital decision support systems will be able to relieve hospital staff. A major challenge is that research team members tend to be highly specialized. Clinical staff provide the medical expertise, while programmers and database specialists are technically proficient and mathematicians perform the calculations.

This article is dedicated to this topic. The open-source software presented here is a visualization and benchmarking simulator for clinical data (ViBeSiC)². It enables time-based simulation, manipulation, and analysis of patient vital signs and laboratory data.

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² The project is available at: <https://gitlab.rlp.net/m.morgen/vibesic>

The data come from the Medical Information Mart for Intensive Care (MIMIC)-III database, a well-known research database in the field of critical care [1]. Such datasets are elementary for research, especially for training artificial intelligence algorithms. Such algorithms can help, for example, to support ventilation strategies [2] or to make predictions about possible courses of disease [3][4].

1. State of the Art

Most of the applications for visualizing data in health care focus on the visual presentation of disease progression or the identification of specific patient cohorts [5][6]. Some tools require experience in programming or query languages, while others require knowledge of the structure and content of the MIMIC-III database e.g. PhysioBank's Automated Teller Machine (ATM) [7] or LightWAVE [8]. Qualified use of both applications requires knowledge about the databases and the data sets. In 2019 a tool that visualizes and extracts patient-specific time series from the MIMIC-III database was presented [9]. The MIMIC database also contains non-public records that users can access if they have been given access by the PhysioNet curators. Unlike the previously mentioned tools, in this application it is possible to include these records as well. There are no filtering options for patient selection, but the visual display is more appealing and simultaneous display of multiple patients is possible. The functionalities the previously mentioned applications are limited to visualization and extraction and do not include real-time simulation, modification or analysis of patient data.

There are tools which, like our software, aim to make it easier for inexperienced users to use MIMIC-III database. One web-based application [10] extracts and visualizes data regarding to a specific patient's stay within one timeline. The selection and preparation of the data is clear and intuitive. The application has a risk prediction function for the in-hospital mortality of patients where various features such as respiratory rate, oxygen saturation and recorded events are analyzed. For previous versions of the MIMIC database, there are other tools that, in addition to visualizing patient data, include predictive models for patient mortality [11].

2. Implementation of the Simulator

The MIMIC-III database was used for the visualization tool. This is a freely accessible database that contains information such as demographic data, vital signs and laboratory values for more than 40,000 patients treated in the ICU [1]. We added the MIMIC-III Waveform Database Matched Subset (Waveform) with records of physiological signals and vital signs [12]. We extracted a cohort of patients with matching records in MIMIC-III and Waveform. This task was complex due to issues such as missing values, non-matching timestamps and incorrect linkages. The database was enriched, for example, by the indicator of whether patients developed sepsis during their stay. For this purpose, we integrated research findings identified by Johnson et al. [13]. Furthermore, we added relevant attributes to avoid time-consuming calculations and SQL join clauses.

A major challenge in the research sector is that the skills of team members are often highly specialized. Clinical staff provide the medical expertise, while programmers are technical specialists and mathematicians perform the background calculations. Since visualizations can improve the comprehensibility of Big Data and thus support the

evaluation of algorithms, the developed patient simulator serves as a user interface for the application and validation of algorithms. For demonstration, we used the patients demo database [12].

The MIMIC-III database was created as a local PostgreSQL database and extended with Python scripts that generate and execute SQL commands to achieve the database state described above. The front end of the application is a dashboard, for which programming languages were combined due to the various components that need to communicate with each other. This approach is used to provide the functionality and to integrate different analyses (R, SQL, Python, Matlab), as well as to customize the layout (HTML, CSS) whose approaches are more extensive to configure or faster to execute in another language.

The web-based, interactive patient simulator allows time-based simulation of vital and laboratory data. It is a two-screen application, where the user can select, show and modify patient data. Within the first screen, a user chooses a cohort of patients based on criteria like age and diseases. This input is converted into an SQL query and applied to the database to extract suitable ICU stays (Figure 1).

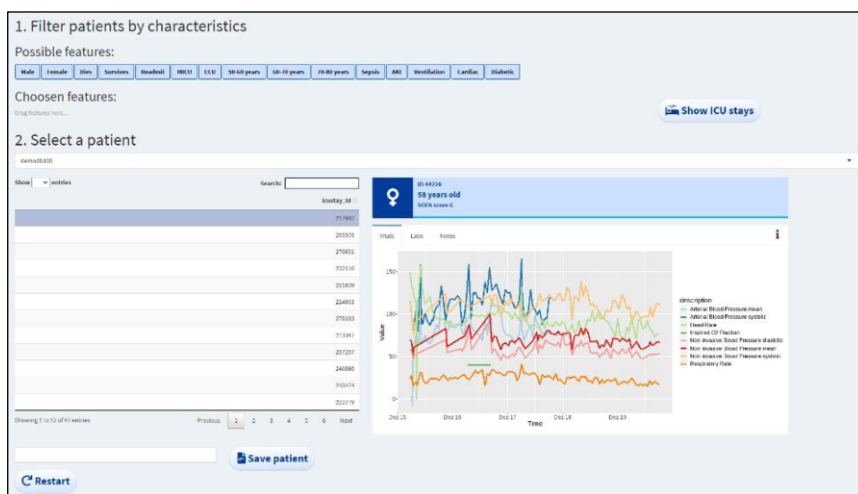


Figure 1. Screen 1 – Patient overview with tab showing graph with vital values.

By selecting an ID, a summary of the patient's stay appears. Key data about the patient and a graphical representation of the vital signs appear. The user can switch tabs to get an overview of the laboratory parameters as well as notes recorded during the stay. In the second window, the selected ICU stay is animated as a time series simulation (Figure 2). It shows values of the heart rate, respiratory rate and arterial blood pressure (y-axis) depending on the selected point in time (x-axis). Tables underneath show all vital signs and lab values in relation to time. Furthermore, patient parameters can be manipulated through predefined modifiers. The manipulation starts from the selected point in time and continues until the end of the time series. Modifications affect and visualize a copy of the MIMIC-III database to preserve the original data, but they can be saved as new patients. To avoid mixtures of the original with the manipulated entries, a prefix is added to the original IDs and the data is stored in a second database. The storage

function allows to recall, further edit and analyze previously configured patient cases at a later time.

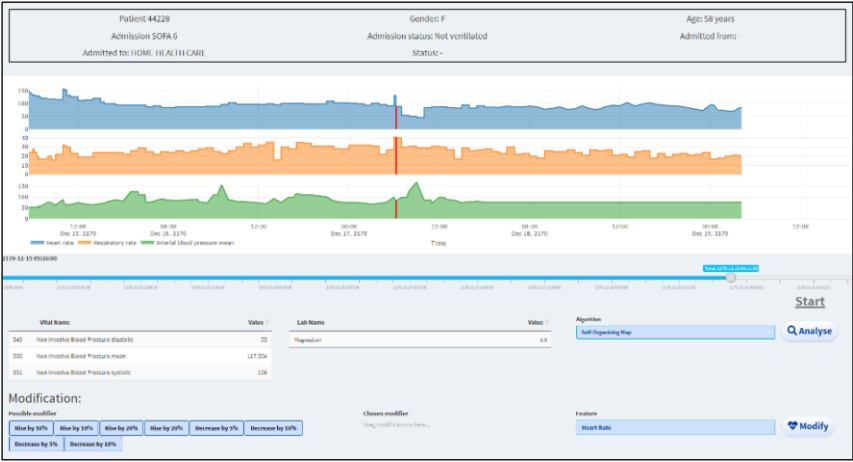


Figure 2. Screen 2 - Visualization of anomaly analysis of a modified patient data set.

3. Benchmarking

The simulation includes an anomaly detection module in addition to the visualization of the recorded patient values to indicate irregularities in the values in order to make the user aware of them. Some of the algorithms are based on statistical probabilities of low complexity to visualize outliers within a specific vital feature while others consider multiple features and work with trained networks to locate anomalies.

Statistical concepts include uni- and multivariate analyses. The first method uses the interquartile range (IQR) to identify outliers. This measure of dispersion is used to establish the upper and lower thresholds by which we determine when a value is either too high or too low compared to the other values [14]. When either condition is met, the corresponding value is comparatively exceptionally high or low (red line in Figure 2). This functionality can be used in combination with the modification of datasets described below, allowing the creation of disease trajectories for individual test scenarios.

Vital signs are not inherently subject to trends or seasonal variation. However, internal and external influences can cause regular fluctuations. External influences include, for example, the administration of medications that cause vital signs to respond. Internally, for example, the daily rhythm can have an influence. The resting pulse during sleep is generally lower than during waking hours. Therefore, the Moving Median Decomposition (GMD) approach was implemented [15]. A time series is decomposed into seasonal, trend, and random residual time series. The last two mentioned can be used to identify abnormal values. Moving average is often used to extract trends. Combining these analyses, which consider only one parameter at a time, allows for the inclusion of multiple characteristics. However, the disadvantage of statistical approaches is that single observations are made [16]. Each feature is analyzed separately and the anomaly can then either be an outlier of one feature or described by combining abnormal values of several features. The latter has the disadvantage that anomalies are not detected if only

one value deviates, regardless of how strong the deviation is. The Mahalanobis distance (MD) measures the relative distance of a data point to a centroid [17]. This is the point where all means from all features intersect and therefore it is considered the overall mean for the data. A data point is flagged as anomalous if it exceeds a certain quantile of the chi-squared distribution or, if it is identified by an adaptive process that looks for anomalous values in the tails of the distribution above a certain chi-squared quantile [18].

Machine learning approaches are also based on statistical concepts but can reconfigure themselves without manual effort. This means that the trained model is constantly being automatically adjusted. The hybrid algorithm was developed for sepsis prediction in MIMIC-III, but has also been applied to environmental sensors for testing purposes [19]. This model integrates several scientific fields by combining statistical methods, self-organizing maps (SOMs) [20], and linear discriminant analysis (LDAs) [21][22]. Dynamic Time Warping (DTW) finds the optimal alignment between two temporal sequences even if their speed varies using Levenshtein distance. Because DTW does not include averaging techniques, Dynamic Time Warping Barycenter Averaging (DBA) was designed. The algorithm integrated here uses these two approaches [23]. The procedure involves the four steps Data Preparation, Statistical Transformation, DBA Algorithm, Classification and Validation. In addition, the probability of risk for positively classified patients is calculated using the conditional probability. The algorithm calculates the risk probability of a patient developing sepsis within a predefined period of time per time unit. There is no standard threshold value from which the risk is classified as too high, i.e., from which point a warning is necessary or useful. Due to this fact, in our case the user chooses this threshold value.

4. Discussion and Outlook

There are several applications for visualizing data from the MIMIC database, but their functionality is very limited. Our approach is a novel visualization tool that can easily extract patient time series and simulate it in real time for analysis within the simulator or for an external artificial intelligence (AI). It allows modification of the given data to artificially create anomalies and generate alerts for the user or an external AI. The current version of the simulator is based on the MIMIC-III database and all queries of the database are adapted to the structure of the MIMIC database. However, generalization is easily possible by adapting the queries and tables to another medical base according to their functionality. This application could also be used for real-time operation in hospitals. The use of the simulator is applicable to data sets other than medical. The algorithms used could detect inconsistencies ranging from simple measurement errors to the occurrence of complex events in sensory records. The functionality of anomaly detection in the time series is also extendable. Risk prediction and detection algorithms have been integrated into the simulator. These were validated not only on a group of patients but also by selecting individual patients according to the parameters of interest. This allowed young researchers (clinicians and computer science students) to work together to create different patient scenarios, analyze the data, validate the algorithm, and compare the results. Next step is to investigate and integrate further learning algorithms for anomaly detection, which can then also be executed directly in the simulator. Thus, the results of the different algorithms can be evaluated by the qualified user.

5. Acknowledgement

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Structuring Research Directions in Medical Domain with Topic Modeling: Application for PhD Theses Synopses in Dentistry

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Abstract. The study analyzed scientific texts based on a manually created database of synopses of theses in dentistry. The main goal was to structure medical texts into various topics by means of natural language processing techniques (topic modeling). Furthermore, a dynamic topic modeling showed the most popular in the field of dentistry over almost the last thirty years.

Keywords. Machine Learning, Natural Language Processing, Topic Modeling, ARTM, Unstructured Data, Dentistry

Introduction

Lately many scientific spheres have started to use artificial intelligence and machine learning extensively including health care and dentistry. When machine learning practitioners work with texts, it is mostly about unstructured data.

As part of a larger ongoing study of structuring textual data, this research paper presents an idea of systemizing knowledge from unstructured medical texts by finding specialized topics in a carefully created corpus of dentistry synopses of theses.

1. Dataset Description

The dataset is a collection of 5779 Russian synopses of theses in the scientific specialty of dentistry from 1993 to 2020. Each one comprises the objectives and the conclusion for an actual thesis and the average text length is 209 words. It worth mentioning that each text has the corresponding dentistry specialty code either 14.01.14 (14.00.21) according to Higher Attestation Commission.

The distribution of the total number of theses synopses over the years is presented in Figure 1. We may conclude there was a rapid decline between 2014 and 2015 in terms a total number of theses defences due to the changes in Higher Attestation Commission.

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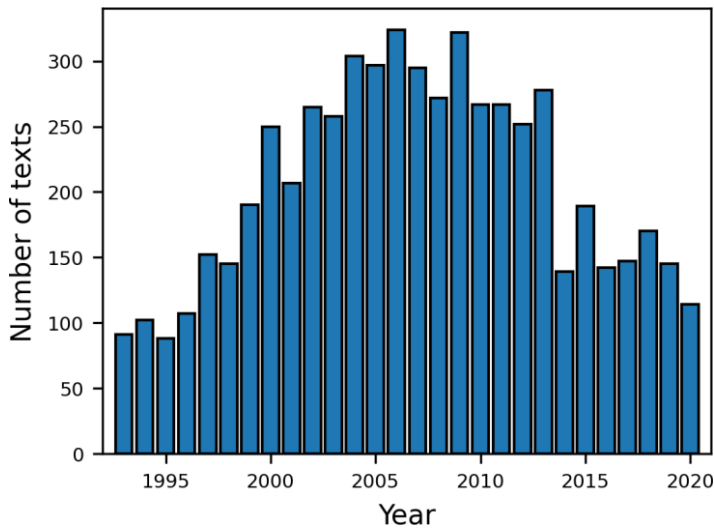


Figure 1. Distribution of documents across the years.

2. Understanding Dentistry Texts with Topic Modeling

2.1. Common Topic Modeling Techniques Application

The main task was to structure dentistry texts, especially distinguish different nosological forms and matching them with the mentioned Higher Attestation Commission “Dentistry” research area items. In the study, we tried various topic modeling options:

- Top2Vec [1]
- LDA [2]
- BERTopic [3]
- ARTM [4]

We tested each model against 6, 10 and 13 topics. These numbers were set via trial-and-error method. The number 6 was selected, since there are six available items in the “Dentistry” research area. We also opted for 10 and 13, since we had a hypothesis that there could be more meaning separation for nosological forms within the dataset. From the expert point of view, the most interpretable model was ARTM with six topics, which the results are provided in Table 1. The keywords in each topic in the table are highlighted in bold. Second paragraph.

Topic 1 describes the issues of prevention of major dental diseases, high prevalence and intensity rate of tooth caries among children in particular as well as quality healthcare delivery to them.

Topic 2 addresses the general problems of maxillofacial surgery and dental implantation in various medical cases in particular.

Topic 3 illustrates the issues of dental orthopedics, dental prosthetic rehabilitation with arch deficiency.

The terms selection in topic 4 matches the problems of preventive therapeutic dental care dedicated to etiology, pathogenesis, epidemiology, preventive methods, diagnostics and treatment of periodontium diseases.

Topic 5 relates to the general problems of maxillofacial surgery and specifically jaw fractures in different cases.

Topic 6 as well as topic 4 also targets the issues of preventive therapeutic dental care. However, topic 6 particularly focuses on the chronic generalized periodontitis, its features, the development and course of the disease and its complications among distinct categories of population.

Table 1 The topics produced by ARTM

№	Topic Terms	Topic Name
1	Стоматологический (dental), ребенок (child), кариес (tooth caries), помощь (help), распространенность (prevalence), зуб(tooth), пациент (patient), уровень (level), лечение (treatment), заболевание (disease), группа (group), рот (mouth), высокий (high),показатель (index), качество (quality), население (population), интенсивность (intensity)	Стоматологическая помощь детям (Child disease prevention)
2	Костный (skeletal), имплант (implant), дефект (deficiency), челюсть (jaw), материал (material), метод (method), лечение (treatment), разработать (develop), пациент (patient), дефект (deficiency), исследование (research), результат (outcome)	Имплантация зубов (Dental implantation)
3	Протез (denture), жевательный (masticatory), конструкция (structure), зубной (dental), дефект (deficiency), пациент (patient),лечение (treatment), группа (group), мышца (muscle), нижний (lower), ткань (tissue), показатель (index), функциональный (functional), материал (material)	Зубопротезирование (Dentofacial orthopedics)
4	Пародонт (periodontium),ткань (tissue), воспалительный (inflammatory), хронический (chronic), лечение (treatment), зуб(tooth), применение (application), терапия (therapy), группа (group), слизистый (mucosal), оболочка (capping), хронический (chronic), пациент (patient)	Лечение заболеваний пародонта (Periodontiumdiseases treatment)
5	Челюсть (jaw), нижний (lower), перелом (fracture), угол (corner), положение (location), верхний (upper), костный (skeletal), группа (group), метод (method), лицо (face), канал (channel), ряд (arch), случай (occasion), окклюзия (occlusion)	Переломы челюстей(Jaw fractures)
6	Хронический (chronic), пародонтит (periodontitis), степень (extent), воспалительный (inflammatory), пациент (patient), заболевание (disease), ткань (tissue), уровень (level), активность (activity), изменение (change), тяжесть (severity), группа (group), процесс (process)	Лечение хронического генерализованного пародонтита (Chronic generalized periodontitis)

As with any topic modeling technique, there are general words within each topic, such as “treatment”, “patient”, “index” or “disease”, which cannot help provide a determined topic description.

The experiments with 10 and 13 topics gave similar results, though this higher number of topics could be generalized into six topics presented in Table 1.

Top2Vec and BERTopic are one of the state-of-the-art topic models, though they showed virtually similar results. We believe that the modern approaches such as

Top2Vec or BERTopic do not work with this scarce amount of data. Furthermore, these models take considerably longer time to train.

LDA did not perform well either producing uninformative topics.

2.2. Topic Visualization

In order to visually understand how research directions interconnect or differ we applied a dimensionality reduction technique with the UMAP [5] algorithm.

We considered the probability topics of ARTM as our features for each text document and reduced the dimensionality from the initial number of topics down to two. Figure 2 represents the UMAP 2D projection of the best ARTM instance with six topics (refer to Table 1 for the topic numbers).

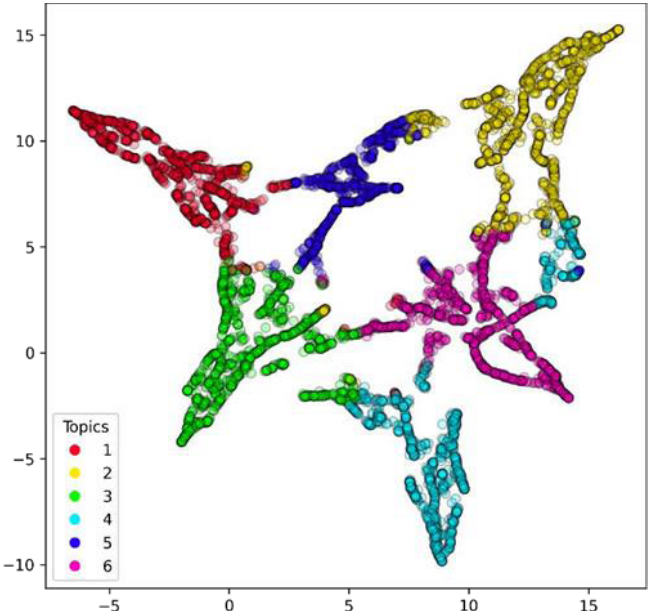


Figure 2. UMAP projection of the ARTM topics.

Considering Figure 2, there are several points that we could highlight. Firstly, in our dataset of dental theses synopses the topic of child dental health does not intersect with the works about periodontium diseases. Secondly, the theses which focused on maxillo-facial area injuries only partially or implicitly were linked to the topics of teeth implantation or dentofacial orthopedics. As a general fact, the topic “Chronic generalized periodontitis” (Table 1) is a sub-topic of treatments of various periodontium diseases. This is also shown in Figure 2.

2.3. Dynamic Topic Modeling

During the research, we also analyzed the chronological dynamic of the most popular topics within the dataset (Figure 3). For visualization purposes, Figure 4 shows the maximal topics for each year (refer to Table 1 for the topic numbers). We could see that

before 2010 the dominant topics for the dentistry theses were “Dental implantation”, “Periodontium diseases treatment” and “Chronic generalized periodontitis”.

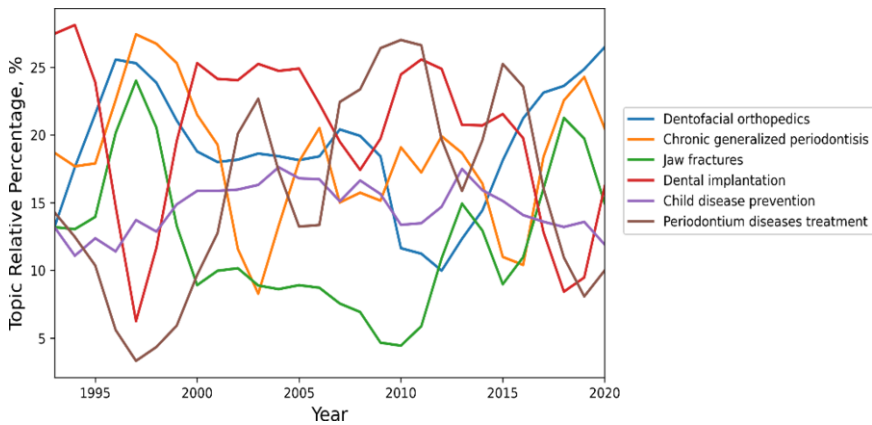


Figure 3. Chronological Dynamic of the most popular ARTM topics.

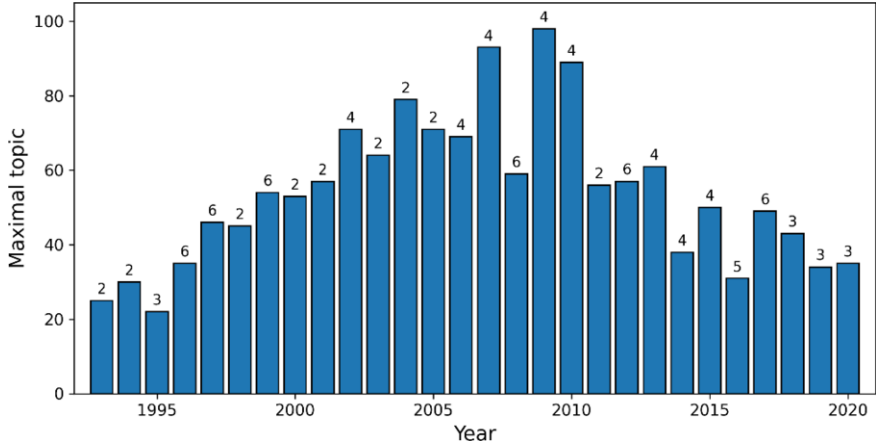


Figure 4. Maximal topics in the theses across the years.

Another important observation could be that before 2010 the research area “Jaw fractures” was underrepresented but since 2014 it has been receiving more popularity in scientific community. These results could propose that the changes in Higher Attestation Commission scientific specialties classification in 2020 had this area moved into a new specialty 3.1.2 “Maxillofacial Surgery” in 2022.

3. Discussion and Future Works

The results of the study infer a number of discussion items regarding data science and machine learning, scientometrics as well as dentistry research topics structuring.

In spite of the fact that the study focused only on a narrow medical domain, dentistry in particular, the machine learning techniques for textual data analysis used showed promising results. We managed to produce appropriate topics, which the subject matter

expert could interpret and match them with the corresponding dental scientific specialties classification. There are not many machine learning production-ready solutions for this and other medical domains. One can consider the accomplished analysis as a perspective future data science tool for processing different existing medical domain text corpora; including such common natural language processing tasks as topic modeling and evaluating interconnections of produced topics or assessing topic popularity throughout a given period. We believe that the methodology and practical applications of the techniques used in the study are not limited to the dentistry domain and can be applied to obtaining a dynamic structure of knowledge from textual data in various areas. As a result, our pipeline provides research and educational personnel with a tool for searching scientific knowledge in selected medical areas and correctly categorize between similar scientific research directions.

In the view of scientometrics, it is important to determine main research areas in a certain scientific domain. It is also significant to predict which research area is going to be dominant in the upcoming decades. Within this paper, we managed to discover certain structure and features of the dynamic in the scientific studies of the dentistry domain by means of the machine learning techniques.

A significant validation fact of our study is reflecting the upcoming changes in the dentistry specialty code from 14.01.14 to 14.00.21 by embedding a new specialty “Maxillofacial Surgery” and expanding knowledge domain according to the new specialties classification introduced by Higher Attestation Commission responsible for thesis defense in Russian Federation.

4. Conclusion

In the study, we carried out the analysis of Russian dentistry synopses of theses with topic modeling. One of the models, ARTM, gave us the most interpretable topics that we could treat as various nosological units. In addition, we performed a dynamic topic modeling to observe which topics were the most popular throughout the last thirty years in the scientific area of dentistry and predict which areas will likely be prevalent in the years to come.

As part of further research, we aim to perform a more detailed analysis of various models’ outputs (resulting topics and their probabilities for documents) as well as topic interpretation. Furthermore, as of machine learning, we plan to build a pipeline that could automatically classify scientific knowledge of a given subject.

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Forecasting Trends in the Tuberculosis Epidemic Situation in the Region of the Russian Federation by Dynamic Simulation Model

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Abstract. The spread of a new coronavirus infection in the last two years together with HIV infection preserves and even increases the potential for the spread of tuberculosis in the world. Sverdlovsk oblast (SO) of Russian Federation is the region with high levels of HIV and tuberculosis (TB). The search for new methods of forecasting of the future epidemic situation for tuberculosis has become particularly relevant. The aim was to develop an effective method for predicting the epidemic situation of tuberculosis using an artificial intelligence (AI) method in the format of a dynamic simulation model based on AI technologies. Statistical data was loaded from the state statistical reporting on TB patients for the period 2007-2017. The parameters were controlled through a system of inequalities. The proposed SDM made it possible to identify and reliably calculate trends of TB epidemiological indicators. Comparison of the predicted values made in 2017 with the actual values of 2018-2021 revealed a reliable coincidence of the trend of movement of TB epidemiological indicators in the region, the maximum deviation was no more than 14.82%. The forecast results obtained with SDM are quite suitable for practical use. Especially, in operational resource planning of measures to counteract the spread of tuberculosis at the regional level.

Keywords. Machine learning, epidemiology of tuberculosis, dynamic simulation model

Introduction

Over the past few years, there has been a tendency in the world to reduce the incidence of tuberculosis by about 2% per year. The fastest decline at the regional level was observed in the WHO European Region (5% per year), as well as in the Russian Federation (5% per year) [1]. For a long time, the Russian Federation was on the list of 22 two countries with the greatest burden of tuberculosis, but thanks to systematic efforts to counteract the spread of the infection [1,2,3,4,5,7], it was possible to achieve a significant reduction in the morbidity and mortality of the country's population from tuberculosis and to be excluded from this list. However, Russia remains among the

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countries with the highest prevalence of MDR and XDR *Mycobacterium tuberculosis*, as well as tuberculosis in combination with HIV [8].

According to WHO, the spread of a new coronavirus infection and HIV infection preserves and even increases the potential for the spread of tuberculosis in the world [4]. The Sverdlovsk Region is a region with high levels of HIV and tuberculosis (TB), one of the leaders in the number of patients with HIV+TB co-infection, and the general epidemiological trends indicated above are also evident in this region [9,10]. The need to combat the new coronavirus infection has caused the redistribution of already limited health resources. Therefore, in the new epidemiological conditions, there are required detailed planning and calculation of resource requirements for countering the spread of tuberculosis [11,12]. In this connection, a search for new methods of analyzing the current and predicting the characteristics of the future epidemic situation for tuberculosis becomes particularly relevant.

The aim of this study is to develop an effective method to predict the tuberculosis epidemic situation by using of the AI method on the example of the Sverdlovsk region.

1. Material and Methods

The mathematical models of the spread of tuberculosis have more than half a century of history. In the early 60s of the twentieth century, Hans Waaler [13] and his collaborators proposed using of a mathematical model based on difference equations to analyze the epidemiological situation. In the subsequent years, mathematical modeling was actively used in the works of S. Brogger, K. Stiblo, E. Vinniki and P. Fine and a number of other authors [14,15,16]. A detailed review of these models and a proposal of their own are contained in the work of K. K. Avilov and A. A. Romaniukha [17].

In 2017, the authors of this article began to work on modeling of the tuberculosis epidemiological situation in the Sverdlovsk region. A comprehensive assessment of the epidemiological situation for the period 2012-2017 was carried out in the real socio-economic conditions of a large industrial region in appliance with the recommended methods [18, 19]. According to the results of the assessment, it was found that there are multidirectional trends in the main epidemiological indicators of tuberculosis in the subject. As the in-depth analysis of variance has shown, despite the high level of variation of indicators in the context of the municipalities, a unified epidemic process formed in the Sverdlovsk region, which makes it possible to identify typical situations and their corresponding organizational, managerial and planning measures.

The task was to give a forecast of the development of the tuberculosis epidemic situation in the near future and until 2030 in the whole region and for each of the districts, provided that the prevailing trends continue. It was decided to use a single mathematical model to assess the situation in the context of each municipality and the region as a whole, in total. This approach is due to the fact that the socio-economic and climatic conditions of the individual areas differ significantly, so the development of the epidemic situation can be described by the different features.

At the initial stages of the study, K. Stiblo's epidemiological model modified by the authors, including a system of the difference equations by G. Vaaler, was used, taking into account the limitations and recommendations of Avilov K.K., Romaniukha A.A. [15, 17]. The study was conducted on the material of the Sverdlovsk region, a region with a population of more than 4.5 ml with a high prevalence of tuberculosis and HIV. Information from more than 45,000 medical records of patients was used.

The model is based on statistical data obtained from the official forms of state statistical reporting: Form # 8 "Information on active tuberculosis diseases" and Form # 33 "Information on tuberculosis patients", forms 089-u/tub, data from the Federal Register of Tuberculosis Patients, registers of tuberculosis patients of health care facilities of the Sverdlovsk region, received for the period 2007-2017. [20,21,22,23]. Based on the information obtained using Excel, complex analytical tables of absolute values and epidemiological coefficients for variables were compiled in the context of 63 municipalities of the Sverdlovsk region and the region as a whole. Additional controllable parameters are provided to improve the accuracy of the model. When working with the model, the parameters were controlled by setting the absolute rates of their growth, from the previous year to the next. This approach is legitimate, since the formation of the rate of change of parameters is of a long-term nature and is formed by a set of measures carried out over many years. The use of the Greek-Latin alphabet was minimized, mnemonically understandable abbreviations based on Cyrillic alphabet were used to designate variables. The main and additional controlled parameters of the model are listed in Table 1. They are conditionally constant values for each municipal district and have a weak influence on trends in general. In the mathematical record, they are combined as a single variable other changes (at).

Table 1. Model parameters

Main and additional controlled model parameters	Additional managed model parameters
The main controlled parameters of the model	Relapses
The percentage of cure (transferred to clinical cured)	got sick in contacted with MBT+ TB cases
The percentage of MBT + in active TB	got sick in contacted with MBT- TB cases
The coefficient of contact with MBT +	Mortality from other causes
Percentage of newly identified (new cases) MBT+ in contact	
Percentage of in/in MBT- in contact	
Percentage of mortality	

Description of designations of quantitative and qualitative variables of the model are presented in Table 2.

Table 2. Designations of quantitative and qualitative variables of the model

Quantitative variables		Qualitative variables	
Sign	Description	Sign	Description
T	an index of a time period	pv(t)	percentage of cured in period t
T	a number of periods under consideration	pbcp(t)	percentage of MBT+ in period t
A(t)	a number of active TB cases in a period t	kbbkp(t)	a coefficient of contact with MBT+ in period t
B(t)	a number of cured TB cases in a period t	pvbvkp(t)	percentage of newly identified MBT+ in period t
BCP(t)	a number of MBT+TB cases in a period t		percentage of newly identified MBT- in period t
BCM(t)	a number of MBT-TB cases TB in a period t	pu(t)	percentage of deaths from tuberculosis in period t
KBKP(t)	a number of contacts with MBT+TB in a period t	pvvbkm(t)	percentage of other changes in a period t
VVBKP(t)	a number of newly Identified MBT+ in a period t		
VVBCM(t)	a number of newly Identified MBT- in a period t		
UT(t)	a number of deaths from tuberculosis in a period t		
At(t)	other Changes in a period t		

The epidemiological process is described by the following system of equations, determining the number of the active TB cases:

$$A(t+1) = A(t) - B(t) - UT(t) + BBBCP(t) + VVBKM(t) + PI(t) \quad t=0,...,T \quad (1)$$

Calculation of quantitative variables of the current period:

$$B(t) = pv(t) * A(t) / 100 \quad t=0, \dots, T \quad (2)$$

$$BCP(t) = pbc(t) * A(t) / 100 \quad t=0, \dots, T \quad (3)$$

$$BCM(t) = A(t) - BCP(t) \quad t=0, \dots, T \quad (4)$$

$$BCP(t) = BCP(t) * BCP(t) \quad t=0, \dots, T \quad (5)$$

$$VVBKP(t) = pvvbkp(t) * KBKP(t) / 100 \quad t=0, \dots, T \quad (6)$$

$$VVBKM(t) = pvvbkm(t) * KBKP(t) / 100 \quad t=0, \dots, T \quad (7)$$

$$UT(t) = pu(t) * A(t) / 100 \quad t=0, \dots, T \quad (8)$$

$$PI(t) = ppi(t) * A(t) / 100 \quad t=0, \dots, T \quad (9)$$

Thus, 7 qualitative indicators were used in the model and the increase or not in the number of patients with active tuberculosis in the next period in comparison with the previous one depends on their values. To assess the situation as a whole, it is advisable to have a single indicator that evaluates the qualitative characteristics in the aggregate, which we call the Coefficient of General Dynamics or abbreviated COD. This indicator should have the following properties, if it is strictly less than 1, then the number of active decreases, if strictly more, then increases. The value of this indicator is calculated within our model by the equation:

$$COD = 1 - pv / 100 + pbkp * kbbkp (pvvbkp + pvvbkm) / 10000 - pu / 100 + ppi / 100 \quad (10)$$

From this Ex. (10) it follows how each of the qualitative parameters affects the development of the epidemiological situation. In addition, it is possible to calculate what the value of each of them should be when fixing the others so that the COD is less than one. For example, the Minimum Percentage of Cure (MPV) in this case will be calculated as follows:

$$MPV = pbkp * kbbkp * (pvvbkp + pvvbkm) / 100 - pu + ppi \quad (11)$$

The code and the MPV in this form rather simplistically describe the development of the situation, but are meaningfully interpreted and are quite suitable for approximate calculations. Based on the available data, 16 parameters of the development of the epidemic situation for tuberculosis until 2030, including the COD and the MPV, were calculated for all districts of the region and the region as a whole. In 2022, the authors had the opportunity to compare the calculated values of the model (forecast) with the actual ones for 2018-2021, registered by means of state statistical observation [20,21,22,23], which was done to verify the relevance of the model. The model was verified by comparing the calculated values with the actual values obtained in the period 2018-2021. To determine the statistical reliability of the differences, the Student's coefficient t was calculated [24]. The accuracy of the forecast can influence the quality of the decisions made [25]. The level of reliability of the model for each forecast period is verified by calculating the indicator of the clarity of the ratio of actual values with predicted values, the indicators of forecast accuracy are calculated. The average absolute percentage error ("Mean Absolute Percentage Error"- MAPE) is calculated using the equation (12) [26].

$$MAPE = \frac{1}{h} * \sum_{j=1}^h \frac{|e_{T+j}|}{y_{T+j}} \quad (12)$$

The reliability of the forecast is estimated through the coefficient of symmetric mean absolute percentage error ("Symmetric MAPE" – SMAPE) according to the Ex. (13) proposed by Makridakis, S. and Hibon, M. 1979 [27] taking into account the possibilities and limitations of the method [28]:

$$SMAPE = \frac{1}{h} * \sum_{j=1}^h \frac{2 * |e_{T+j}|}{y_{T+j} + \hat{y}_{T+j}} \quad (13)$$

The estimation of the root mean square deviation (RMSD) is applied according to the Ex. (14) [29]:

$$RMSD = \sqrt{\frac{1}{N} * \sum_{t=1}^N (y(t) - ME)^2} \quad (14)$$

2. Results

The results of the model analysis are shown in Table 3. The method of graphical analysis is applied to compare the predicted trend with the actually registered values in the period 2018-2021.

Table 3 Comparison of the calculated values (forecast) of the model with the actual (fact)

Name	2019 Forecast	Fact/Fore- cast, %	2020 Forecast	Fact/Fore- cast, %	2021 Forecast	Fact/Fore- cast, %
Number of Active TB cases	77146	4,84	6931	-11,51	6770	-20,92
Percentage of cured, %	227,54	-5,56	27,21	45,87	26,93	29,56
Transferred to clinical cured group	11968	-0,97	1886	29,06	1823	2,47
Percentage of MBT + in active TB, %	336,82	14,34	36,81	17,63	36,74	18,40
Number of Contacted with MBT+ TB	22631	19,99	2551	4,12	2487	-6,31
Number of Contacted with MBT- TB	22,91	-25,09	2,92	1,03	2,93	16,38
Contacted with MBT+, abs	7668	-10,05	7450	5,10	7280	9,29
Share of MBT - TB cases, %	63,18	-8,36	63,19	-10,27	63,26	-10,69
Total Number of MBT - TB cases	4515	-3,99	4380	-20,62	4283	-29,40
Number of New MBT+TB cases	925	28,97	900	0,44	878	-3,30
Number of New MBT- TB cases	1418	-28,63	1390	-39,78	1371	-34,94
Mortality in TB patients, %	5,95	-17,65	5,89	-6,62	5,88	-0,85
Number of dead from TB	425	-13,41	408	-17,16	398	-21,61

Most of the deviations are due to the fact that the actual values of characteristics such as the Absolute number of deaths from tuberculosis, the total number of active contingents, the MBT+ Contingents first identified by MBT were lower than predicted, which indicates both a positive trend in the epidemic situation and the effectiveness of anti-tuberculosis work in the region. The results of assessing the quality of the forecast using the method are shown in Table 4, from which it follows.

Table 4. Results of the forecast quality assessment by model parameters

Name	Forecast for 2019	Forecast for 2020	Forecast for 2021	Overall forecast 2019-2021
MAPE, %	13,14	15,14	14,87	14,38
SMAPE, %	13,54	15,24	15,68	14,82
SD, %	16,08	17,76	20,52	18,12

3. Conclusion

The proposed mathematical simulation dynamic model, based on the use of AI, made it possible to identify, reliably calculate and graphically display trends in the movement of values of the studied characteristics of the epidemic process of tuberculosis in each of the 63 municipalities and in the Sverdlovsk region as a whole.

Comparison of the calculated values (forecast) of the model made in 2018 with the actual values of 2019-2021 revealed a reliable coincidence of the trend of movement of the studied parameters in the region. If we assume that the quality indicators will remain at the level of 2018, then in the next 20 years the epidemiological situation on tuberculosis in the region will develop as follows.

The forecast results obtained with the help of a simulation model are quite suitable for practical use in operational resource planning for measures to counteract the spread of tuberculosis at the regional level.

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Evaluation and Assessment

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What Can We Learn from Quality Requirements in ISO/TS 82304-2 for Evaluating Conversational Agents in Healthcare?

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Abstract. Evaluating conversational agents (CA) that are supposed to be applied in healthcare and ensuring their quality is essential to avoid patient harm. However, most researchers only study usability and use the CA in clinical trials before conducting such careful evaluation. In previous work, consensus on metrics for evaluating healthcare CA have been found. However, the metrics are still too generic to form an evaluation framework. In this work, we try to link the ISO technical specification ISO/TS 82304-2 Quality Requirements for Health and Wellness Apps to the set of metrics to come a step closer towards an evaluation framework. We identify three links between ISO requirements and the set of metrics, namely accessibility, usability, and security. Although the technical specification rather lists aspects to be considered during development instead of concrete metrics for studying the quality, we can link to some aspects that are also of interest for health CA evaluation. For example, measuring the readability for ensuring accessibility or implementing the Web Content Accessibility Guidelines are two aspects of relevance for health CA.

Keywords. Conversational agent, chatbot, evaluation, ISO, quality

1. Introduction

Conversational agents (CA) become more popular outside medicine for dealing with customer requests, but also for delivering digital health interventions. They are for example applied in mental health for treating patients with posttraumatic stress disorder [1] or for patient education [2]. CA in healthcare differ from customer service or general domain CA. Similar to the physician-doctor conversation, the content of a conversation with a health CA has to be tailored based on the application area, use case, user's context and has to address privacy [3]. CA often process personal identifiable information that are in healthcare settings protected. They are supposed to be used in a care setting; thus, patient harm has to be avoided. To become accepted as treatments, CA are studied in

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clinical trials regarding efficacy, safety, or cost effectiveness. However, to avoid patient harm, frustration or negative outcomes due to low quality implementations, it is essential that prior to massive investment in clinical trials, a health CA is evaluated to demonstrate that it has an acceptable quality which includes freedom from any of a myriad of possible deficiencies.

Several tools have been suggested for evaluating mobile health apps (e.g. Mobile App Rating Scale [4], Health-ITUES). Hensher et al. developed a mobile app evaluation framework comprising among other things interoperability, technical features and support or developer credibility [5]. However, health CA require additional criteria for evaluation given their focus on communication-based interaction. Evaluation approaches for general domain CA focused on assessing effectiveness, efficiency and usability [6]. To overcome the limitation of a missing evaluation framework for health CA, we identified in previous work metrics for evaluating healthcare CA [7]. To advance this set of metrics to a health CA evaluation framework, the pool of metrics has to be linked to the potential data sources and collection methods, to support formulation of the methodology for evaluation of any specific health CA.

The objective of this work is to come one step closer to an evaluation framework for evaluating conversational agents in healthcare. To achieve this objective, we will study the 2021 released technical specification *ISO/TS 82304-2 Quality requirements for health and wellness apps* towards its applicability to healthcare CA. The concrete focus is on CA that are rule-based, based on written input and output, have a simple personality without any kind of embodiment. They are running on a mobile device, are implemented as stand-alone software and the interaction time is rather short.

2. Material and Methods

We go through the quality requirements that are specified in the ISO technical specification ISO/TS 82304-2 and check, whether there are overlaps with the set of global metrics that has been identified in previous work (see Table 1). We are focusing on global metrics, since the ISO specification is considering quality of apps for health and well-being. It is not addressing specific technological implementation features, but the apps as a whole. Therefore, we are convinced, that we will not find any overlaps with metrics for response generation or understanding which are elements of the set of CA evaluation metrics [7]. For all overlaps found, we will discuss the applicability to apps with conversational user interface. In the following, we briefly describe the global evaluation metrics and the ISO/TS 82304-2.

2.1. Global Health CA Evaluation Metrics

A panel of experts working in the field of healthcare CA found consensus regarding metrics deemed relevant for health CA evaluation [7]. This work resulted in 24 metrics comprising 13 global metrics, 8 metrics related to response generation, 3 metrics related to response understanding and 3 metrics related to aesthetics. Definitions for the global metrics are shown in Table 1. We can see that some of the metrics are rather technical (e.g. speed, flexibility in dialogue handling) while others rather focus on the interaction with the user (e.g. ease of use, accessibility).

Table 1: Global metrics with definitions (from [7])

Metric	Definition
Accessibility	Whether all users are able to access an equivalent user experience of the CA
Ease of use	Extent to which a person believes that using a particular CA would be effortless
Engagement	Whether a user finds value in using a CA and therefore continues using it
Classifier performance	How well the algorithm performs in classifying data
Speed	How quickly a session / task can be completed using a CA
Technical issues	Number of errors or glitches that occur while using a CA
Task completion rate	Proportion of tasks successfully completed by the CA
Dialogue efficiency	Number of dialogue steps used to complete a task
Flexibility in dialogue handling	CA's ability to maintain a conversation and deal with users' generic questions or responses that are more, less, or different than expected
Content accuracy	Proportion of responses that are consistent with clinical evidence, also includes correctness of triage and escalation strategies.
Context awareness	CA's ability to utilize contextual knowledge to appropriately respond to users
Error tolerance	CA's ability to detect and understand misspelled words in users' replies
Security	How protected the system is against hack attacks

2.2. Technical specification ISO/TS 82304-2

The technical specification *ISO/TS 82304-2 Health software — Part 2: Health and wellness apps—Quality and reliability* was first published in August 2020 (<https://www.iso.org/standard/78182.html>). It builds on guidelines and requirements for apps by many local and national health organizations around the world. Its purpose is to ensure that health and wellness apps are safe, reliable and effective. The guidance provides an internationally-agreed set of specifications to assess the apps. CEN ISO/TS 82304-2 was developed under CEN lead by ISO/TC 215 'Health informatics', in collaboration with IEC/TC 62 'Electrical equipment in medical practice', and adopted by CEN/TC 251 'Health informatics', whose secretariat is held by NEN, the Dutch national standardization committee. The technical specification is intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. It groups quality aspects along 5 categories: product information, healthy and safe, easy to use, secure data and robust build. These five categories bundle a set of subcategories. For example, *healthy and safe* is split up into 5 subcategories: “health requirements”, “health risks”, “ethics”, “health benefit” and “societal benefit”. *Easy to use* comprises “accessibility” and “usability”, while *secure data* relates to “privacy” and “security”. The guideline covers the entire life cycle of an app. We will extract the aspects that are of interest in the phase our evaluation framework is expected to be used, which is before conducting a clinical trial.

3. Linking ISO/TS 82304-2 to CA Evaluation Metrics

Our metrics “dialogue efficiency”, “task completion rate”, “flexibility in dialogue handling”, “context awareness” and “classifier performance” are very specific metrics for CA. In contrast, “ease of use”, “engagement”, “technical issues”, “error tolerance”, “speed”, “security”, “accessibility” and “content accuracy” might be of relevance also for health apps without conversational user interface. Out of the latter set, we identified 3 quality requirements in the ISO specification that match with metrics in our set of global metrics: “easy to use” with its subcategories “usability” and “accessibility” as well

as “security”. These quality requirements are represented by our metrics “ease of use”, “security” and “accessibility”. In the following, we will discuss what the ISO guideline suggests and what we can conclude from it for health CA.

3.1. Accessibility

Related to accessibility, the specification suggests to develop health apps that are age appropriate and compliant with the Web Content Accessibility Guideline 2.1 (WCAG, <https://www.w3.org/TR/WCAG21/>). More specifically, compliance measures for perception of user interfaces and navigation, for operation and navigation, and for understanding of user interfaces and navigation should be implemented and a mobile health app should be AA or AAA compliant (medium or highest level of conformance). For example, contrast should be considered and zoom functions be available. Considering the WCAG within a CA is clearly of relevance. All elements of a dialogue with a CA must be available to a user according to their available senses (i.e. to address hearing and vision deficits) [8]. This makes it necessary to provide different input and output modalities. The ISO specification also asks for a readability assessment. This would be of particular interest for a health CA since the interaction is basically realized as conversation (written or spoken). The sentences should not be too long and have to be easy understandable. A number of scales and innovative machine learning approaches could also be used for assessing readability level of the CA in order to match the reading level to the level of expected users [9]. The WCAG provides additional aspects of relevance, for example the success criteria 1.3.2 “meaningful sequence” is particularly interesting. In case of a CA this concerns the ordering of a conversation. Beyond, its history should be accessible to the user [8]. There are a number of health literacy and e-health literacy surveys and questionnaires that can be used to assess the literacy level of the CA (and their users) and adjust the wording based on the results of applying those instruments [10,11].

3.2. Usability

The eight usability requirements listed in the ISO specification provide guidelines how to ensure usability of health apps. Development should start with a requirement analysis involving future users and should continue involving users throughout the entire development. A user-centered evaluation should be conducted to refine the app design. Measures should be in place to avoid use error. Furthermore, information should be provided to the user on the health app (e.g. functionality, intended use), together with instructions for use. Delivering resources for helping users who experience problems with the app are recommended. Finally, usability should be systematically gathered throughout the entire lifetime of the app. Providing information on the purpose or functionality of a health CA and instructions to use are something, a CA could do at the very beginning of the conversation when introducing itself, its purpose and what the user can expect from it. From our experiences, this could be very helpful for users since otherwise, they don’t know what they can ask or write. Providing help in using the agent would require that the user can ask for help at any stage of the conversation and the CA goes back to the initial context after providing help. If such help function is realized this would be one of the benefits of a CA (compared to a normal user interface and even human-human conversation): the CA has no time pressure, can reply to all questions, but

should be able at some point to return to the original topic. These aspects clearly have to be considered already in the design phase of a CA and can be checked as part of the usability testing. No concrete metrics or measurement tools are suggested in the ISO specification for studying usability. Related to usability, a study found out that a broad range of tools is used for studying usability in health CA (e.g. System Usability Scale, User Experience Questionnaire), but also individual questionnaires are exploited [12]. Due to the differences in the study designs and assessment tools that have been conducted so far, it is impossible to compare usability among health CA. It was recommended to develop a standardized procedure that can be always applied and which can be enriched by assessments needed for evaluating usability of specific features of a particular health CA. This would make usability test results better understandable and comparable. Nielsen's heuristic evaluation could be applied to the CA interface [13] as well as the cognitive walkthrough [14]. There are now usability testing standards that could be applied to guide analyses of user interactions with CA [15].

3.3. Security

The security requirements of the ISO specification consist of 11 components. They ask for proof of implementation of ISO/IEC 27001 or another recognized standard related to information security management. Information security risks and potential consequences should be assessed. Beyond, a secure by design process is encouraged (e.g. ensuring correct usage of biometric sensors, secure data integration). Measures should be in place to ensure that all third-party software libraries are reliable and maintained. Unauthorized access and modification to the source code should be prevented. An information security policy has to be available; security of the app has to be regularly tested; a process of dealing with security vulnerabilities should be in place, as well as data encryption, user authentication, authorization and session management; finally, standard operating procedures have to be in place for processing personal identifiable information according to the privacy statement.

In principle, these 11 items can be used as checklist when developing health CA. It was already found that data security and privacy are under-researched and remain most often unconsidered in current health CA [16]. Checking whether these 11 items from the ISO specification are fulfilled by a concrete health CA would clearly provide a guidance and ensure information security within a health CA. Consideration must be given to privacy and security so that data would be accessible in emergency situations by health professionals and family members (e.g. during a health crisis) to be able to address the situation appropriately.

4. Conclusions

In this work, we linked requirements specified in the ISO/TS 82304-2 to metrics for evaluating health CA. Three links could be identified for the metrics ease of use, accessibility and security. The limited overlap is not surprising given the technical peculiarities of health CA that are reflected in our set of metrics (the interaction aspect). Beyond, the ISO specification targets already software products which we did not had in mind. Our focus was on health CA to be evaluated before conducting a clinical trial. While a few concrete metrics (e.g. readability score) could be derived from the ISO guideline, it rather provides recommendations that might be of relevance during the

development of a health app. Some of them are clearly also useful to be considered in health CA development for developing high quality apps (e.g. considering WCAG or user involvement in the development). We will integrate the 11 items on security as a checklist to the health CA evaluation framework. As a next step, we link the other metrics to corresponding data sources and collection methods. In addition, we are exploring development of metrics related to assessing the level of integration of CA with other information systems as well as the patient's overall healthcare system (e.g. stand-alone applications versus CA applications integrated with their healthcare professionals). Further work in developing metrics for assessing the impact of CA on health outcomes is also needed.

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Usability of Iranian Primary Vitiligo Patient Registry (IPVPR): A Pilot Study

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Abstract. Background: Usability is essential for the acceptance and success of vitiligo patient registry system. Poor usability could decrease system efficiency and effectiveness, and have a negative impact on using the system and providing services. This study aims to evaluate the usability of vitiligo patient registry system. Methods: This pilot study was conducted in 2021. In total, 17 users who were working in the vitiligo ward participated in the study. System usability scale (SUS) was used to evaluate the usability of vitiligo patient registry system. Results: In the usability evaluation stage, the mean score of the system usability scale was obtained as 77.79. Conclusion: Developing vitiligo patient registry system with high usability and making decisions based on the registered data could provide better understanding of this disease and facilitate research in this field. Application of this system and its acceptance by users could decrease costs and increase effectiveness and quality of services.

Keywords. Registry system, Vitiligo, Usability, System Usability Scale (SUS)

Introduction

Vitiligo patient registry system could be used to study the natural history of disease in the population, identify risk factors, pathogenesis and optimal treatments and provide better understanding of disease progression and its impact on patients' quality of life (1). Ensuring the usability of this system by its users is among the basic requirements for providing high quality services and meeting individuals' needs (2). Usability is defined as the extent, to which a product could be used by specific users in a specific context, in order to achieve the specified goals effectively, efficiently and satisfactorily (3). Having this feature, the system could help users perform things quickly and easily. Moreover, usability is directly associated with clinical productivity, user fatigue, error rate as well

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as user satisfaction (4). Poor usability of clinical information systems could affect users' performance and lead to fatigue, low productivity, medical errors and threats to patient safety (5). Therefore, organizations that are aware of the importance of usability seek to design systems with high usability. SUS is the most widely used and standard scale for evaluating the usability of various products and services, and has advantages such as easy to use, low cost, providing quick feedbacks and being non-exclusive and applicable for all types of user interfaces in the situations where time and resources are limited (6-8). To the best of our knowledge, no study has ever been conducted on the usability of vitiligo patient registry system from the perspective of its users at Razi Skin Hospital, as the only center that uses this system. Therefore, this study examined the usability of this system. The obtained results could help identify and solve usability problems of the mentioned system.

1. Method

This pilot study examined the usability of vitiligo patient registry system in the vitiligo ward of Razi Skin Hospital in June, 2021. A 10-item questionnaire designed by John Brooke was applied to measure the system usability (9). The research population included all users of the vitiligo patient registry system, including 7 dermatologists, 9 nurses and 1 health information manager working in the vitiligo ward of Razi Skin Hospital. The usability questionnaire was provided to these users and they were asked to work with the system for at least 10 days under the supervision of the research team and fill out the questionnaire. Each item was scored from 1 (strongly disagree) to 5 (strongly agree). To obtain a score for odd items, one unit was deducted from the score given to each item. For even items, the score given to each item was deducted from the number of 5. The sum of these scores was multiplied by 2.5 and the final score was obtained, which ranged between 0 and 100. Scores higher and lower than 68 were considered as higher and lower than the average level, respectively (10-12). After collecting the users' opinions, the mean and standard deviation of the points given to each item were calculated. The results were analyzed using SPSS 23.0.

Ethical approval was received from the Shiraz University of Medical Sciences, (Approval number: IR.SUMS.REC.1399.1219).

2. Results

The participants included 7 dermatologists (41.1%), 9 nurses (52.9%) and 1 health information management specialist (5.8%). In total, 14 participants (82.3%) were female and 3 (17.6%) were male. The majority of the participants ($n=9$, 52.9%) aged 30-40 years old and 10 participants (58.8%) had 10-20 years of work experience. The vitiligo patient registry system obtained the score of 77.79 by the users, indicating its acceptable level in terms of ease of use. Most of the users ($\text{mean}=4.41$) believed that the system functions had integrity and using the system increased their confidence. The majority of the users ($\text{mean}=4.24$) tended to use the system frequently. Although the users believed that the system was not complicated ($\text{mean}=1.59$) and it was easy to use ($\text{mean}=1.35$), they required to receive training by a technical technician to work with the system ($\text{mean}=2.18$). Table 1 presents the results of usability of vitiligo patient registry system.

Table 1. Descriptive statistics of each item of system usability scale (SUS) for Iranian primary vitiligo patient registry (IPVPR)

System Usability Scale (SUS)		I think I would like to use the vitiligo registry system frequently	I found the vitiligo registry system unnecessarily complex	I thought the vitiligo registry system was easy to use	I think that I would need the support of a technical person to be able to use the vitiligo registry system	I found the various functions in the vitiligo registry system were well integrated	I thought there was too much inconsistency in the vitiligo registry system	I would imagine that most people would learn to use the vitiligo registry system very quickly	I found the vitiligo registry system very cumbersome to use	I felt very confident using the vitiligo registry system	I needed to learn a lot of things before I could get going with the vitiligo registry system	Total score
Mean		4.24	1.59	3.29	2.18	4.41	1.53	3.59	1.35	4.41	2.18	
S.D		0.75	0.71	0.47	0.88	0.61	0.51	0.71	0.49	0.61	0.88	
User	1	3	1	3	2	4	2	3	1	4	1	75
	2	4	1	3	1	5	1	3	1	5	1	87.5
	3	3	2	3	2	5	1	3	1	4	2	75
	4	4	2	3	2	5	1	3	1	5	2	80
	5	3	1	3	3	4	1	3	2	4	3	67.5
	6	4	1	4	1	5	2	4	1	4	3	82.5
	7	5	2	3	2	5	1	3	1	5	1	85
	8	5	2	3	3	4	2	5	1	5	3	77.5
	9	4	2	3	2	4	2	4	2	4	2	72.5
	10	5	2	4	1	4	2	4	2	4	2	80
	11	5	1	4	1	4	2	4	1	5	2	87.5
	12	5	3	3	2	5	1	5	1	5	3	82.5
	13	4	1	4	2	5	1	4	1	3	2	82.5
	14	4	1	3	3	5	2	3	2	4	2	72.5
	15	4	1	4	4	4	2	4	2	4	3	70
	16	5	1	3	3	4	1	3	1	5	4	75
	17	5	3	3	3	3	2	3	2	5	1	70
Total questionnaire scores												1322.5
Mean												77.79
S.D												6.05
Acceptable domain				0-64 : Unacceptable			65-85: Acceptable			85-100: Excellent		

NOTE: SUS Score above 68 is considered excellent usability based on the general guideline on interpretation SUS score.

3. Discussion

The results indicated the designed software had an acceptable level in terms of ease of use by obtaining the score of 77.79 from the users. High system usability from users' perspective shows the system success and strong correlation between the system and users. A usable system should be learnable, efficient and memorable (13). Poor usability of the system and lack of intention to its use continuously could cause a poor return on investment and decrease productivity (14). Results of evaluating the vitiligo patient

registry system from the target user's viewpoint showed the components of the designed software were integrated properly and there was the minimum amount of inconsistency between its components (mean=1.53), so that most of the users tended to use it frequently. The results revealed although the system design was not complicated, some users required basic training by a technical technician in order to use it. It should be noted that training is not only specific to the registry system, but it should be considered for all systems in order to improve usability and reduce error rate (15). Several studies have reported that usability problems of the information system could increase user error and decrease effectiveness and trust in the system and, ultimately, have a negative impact on the quality of healthcare services provided (16, 17). Lack of attention to these problems could affect the quality of users' interaction with the system and healthcare services (18) and lead to fatigue and abandonment of the system by users in the long term. The strength of this study was that the system was evaluated by real users in the vitiligo ward. These users participated in the software design phase and were familiar with all functions of the system, which validated findings of the study. The main limitation of the study was that the system usability results could not be generalized. Considering that the system was implemented in only one center, it was evaluated by the users of the same center. Although attempts were made to compensate for this limitation by increasing the sample size and including all the users, it is suggested to quantitatively and qualitatively evaluate the system usability on a larger scale considering a larger sample size in future studies. To adapt the system to users' needs, an information needs assessment should be performed before designing the system. Before conducting the evaluation process, users should be fully familiar with the system features and the necessary training should be given to them for using the system properly. Moreover, it is better to use the specific methods designed for evaluating registries in order to evaluate the usability of registry systems.

4. Conclusions

The results indicated that the vitiligo patient registry system could greatly satisfy the users, so that they tended to use the system frequently and believed that using it increased their confidence. Some of the users stated that training should be given by a technical expert and planning is required for the continued use of the system.

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A Bibliometric Analysis of the Trends in the Research on Wearable Technologies for Cardiovascular Diseases

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Abstract. In this paper, a bibliometric analysis of research on wearable technologies for cardiovascular diseases was conducted with Bibliometrix and based on 1675 papers collected in Scopus from 2000 to 2022, and interesting results were presented. The US and China stood out for their sustained productivity in the field of cardiovascular diseases. The examination of the authors' keywords revealed that between 2000-01 and 2009-12, "Respiration" and "personalized applications" were the most popular research topics, however from 2010-01 to 2019-12, attention was given to "ECG," "Wearable devices," "Wearable sensors," and "heart rate". This study suggests that in the present decade, researchers should focus on topics related to artificial intelligence, hypertension, ECG, wearable sensors, and African countries must address their technological gap in the coming years.

Keywords. Wearable, Cardiovascular, Bibliometric, Bibliometrix

Introduction

Cardiovascular diseases constitute a great interest among practitioners and scientists in the last years because of the high number of deaths they cause worldwide [1]. In cardiology, traditional wearable devices are limited because they cannot continuously collect physiological parameters during periods of activity but also for monitoring the patient in real-life conditions. These days, advances in nanotechnology, material science, and information technologies allow us to remove these limitations with smart wearable technologies [2]-[6].

This bibliometric study carried out with the Bibliometrix software [7] deals with 1675 documents collected on Scopus. It focuses on wearable technologies for cardiovascular diseases with a particular focus on the thematic orientation of scientific publications in the field from 2000 to 2022. Our development is based on the following research questions:

RQ1: From 2000 to 2022, what are the characteristics of the thematic evolution of research on wearable technologies for cardiovascular diseases?

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RQ2: What are the motor, basic, declining, and emerging topics in wearable technologies for cardiovascular diseases as we enter this new decade (2020-2030)?

RQ3: Who are the leading authors and countries in wearable technologies for cardiovascular diseases research?

RQ4: What are the future directions of research on this topic?

Our work will guide researchers, especially younger ones, in defining their research objectives and critical aspects to explore in the field of wearable technologies for cardiovascular diseases.

1. Methods

As the main objective of this study is to present the thematic dynamics, and research productivity in wearable technologies for cardiovascular diseases, we opted for a bibliometric analysis using the Bibliometrix software, which is very flexible and which allows for an in-depth analysis of scientific mapping on a given topic [7, 8]. Biblioshiny, a graphical interface offered by Bibliometrix, allows performing bibliometric analysis from several databases (Scopus, web of science, Pubmed, etc.). For this work, we leveraged Scopus, a transdisciplinary reference database offering a greater coverage of health sciences than the Web of Science database. Compared to Pubmed, Scopus provides the possibility to perform an analysis of the number of citations [9].

On March 12, 2022, a search on Scopus with the string “wearable” AND “cardiovascular” allowed us to gather a set of 1675 documents from various sources. We used this bibliographic database to conduct performance analysis and scientific mapping to address our research questions.

2. Results

2.1. Performance Analysis

2.1.1. Global Information about Data

From 2000 to the time of writing, 6869 authors have written 1675 papers from 876 different sources with an average of 14.93 citations per paper. The annual production of publications is growing at a rate of 14.04%, with a maximum value of 331 publications for the year 2021.

2.1.2. Leading Authors and Countries

This section presents the most influential authors and countries based on the published literature on wearable technologies for cardiovascular diseases. Tables 1 and 2 show the 5 authors and sources respectively that have had the most significant impact on the scientific world in the last 2 decades on the topic. We considered three bibliometric indicators for a better overview: productivity, local influence, and citation. Inan OT is the most productive author (29 publications) with the highest local impact (H-index:11), while Wang Z is the most locally cited author with a total of 69 citations.

Table 1. Top 5 Leading Authors. AN: Articles Number. H-I: H-Index. LCN: Local Citations Number.

Most Relevant (AN)	Local Impact (H-I)	Most Local Cited (LCN)
Inan Ot (29)	Inan Ot (11)	Wang Z (69)
Na (23)	Wang J (10)	Turakhia Mp (59)
Zhang Y (22)	Martin Ss (8)	Halperin JI (53)
Poon Ccy (16)	Yang J (8)	Krittanawong C (53)
Wang J (16)	Zhang Y-T (8)	Zhang Y (53)

Statistics from the *Journal of the American College of Cardiology* have shown that in the world in 2019, 17.9 million deaths are recorded each year due to cardiovascular diseaseand 81% of these deaths, of which more than a third are early, occur in low-income African countries [1]. We, therefore, considered it important to present in this section a geographical overview of the scientific production of wearable technologies for cardiovascular disease. Table 2 shows the top 5 most productive countries, with the USA and China leading with 2632 and 1114 publications, respectively. African countries combined have 57 papers, with South Africa, Tunisia, and Nigeria at the top of the list with 11 and 9 articles, respectively. South Africa is the African country with the highest number of citations, with a total of 12.

Table 2. Top 5 Leading countries in the world and in Africa. AN: Articles. LCN: Local Citations Number.

In the world		In Africa	
Most Relevant (AN)	Most Local Cited (LCN)	Most Relevant (AN)	Local Impact (H-I)
USA (2632)	USA (9504)	South Africa (11)	South Africa (11)
China (1114)	China (2279)	Tunisia (9)	Tunisia (9)
Italy (522)	Italy (1334)	Nigeria (9)	Nigeria (9)
Germany (442)	Hong Kong (1134)	Algeria (8)	Algeria (8)
Japan (383)	Korea (1062)	Cameroon (6)	Cameroon (6)

2.2. Science Mapping

2.2.1. Trend Topics

An interesting method for gaining a general overview of the topics of interest in the scientific output in a given field is to observe the occurrence of “authors” keywords. Thus, the trend of topics summarized in Table 3 shows that during the decade 2000- 2009, the topics of interest according to their frequency are: “respiration” and “Personalized applications”. On the other hand, during the decade 2010-2019, we identify: “ECG”, “wearable devices”, “wearables sensors”, and “heart rate” with an occurrence higher than 50%. It is interesting to note that the first 3 topics that have been emerging in research since 2000 at the time of this study are Cardiovascular diseases, Wearables, and Machine learning.

Table 3. Trend Topics from 2000 to 2022.

2000-01 to 2009-12 Topic (frequency)	2010-01 to 2019-12 Topic (frequency)	2020-01 to 2022-03 Topic (frequency)
Respiration (5)	ECG (71)	Cardiovascular diseases (68)
Personalized applications (4)	Wearable sensors (67)	Wearables (67)
Embedded systems (3)	Heart rate (64)	Machine learning (59)
Decision support system (3)	Wearable devices (63)	Deep learning (30)
Integration (3)	Heart rate variability (46)	Artificial intelligence (25)
Inductive plethysmography (3)	Wearable sensor (27)	Sensors (21)
	Sudden cardiac death (24)	Biomedical monitoring(6)

2.2.2. Thematic Evolution

To better understand the conceptual structure of the scientific production in a given field, it is interesting to analyze the thematic map of the “authors” keywords.

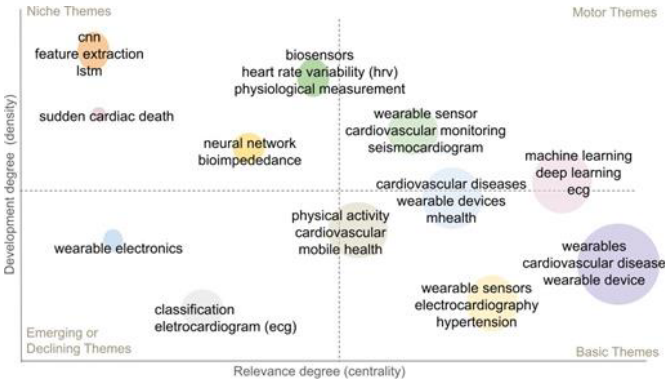


Figure 1. Thematic map of the ’’ author’s keywords (Time slice 2020-2022).

We can note in **Figure 1** that the different keywords used by researchers between January 2020 and March 2022 are grouped under 12 different clusters, and each cluster belongs to a specific quadrant allowing us to categorize it. In the bottom left quadrant named emerging and declining themes, we find two clusters that include “electrocardiogram” & “classification” on the one hand and the other hand “wearable electronics”. Their position denotes their low density and slightly below average centrality for wearable technologies related to cardiovascular diseases. The top left quadrant contains four clusters: “neural network” & “bioimpedance”, “cnn” & “feature extraction” & “lstm”, “sudden cardiac death” and finally “biosensors” & “heart rate variability” & “physiological measurement”. This quadrant presents the themes with a high density despite their non-vital importance to the subject. The themes that are vital to the field but have low development are presented in the lower right quadrant. These are: “physical activity” & “cardiovascular” & “mobile health”, “wearable sensors” & “electrocardiography” & “hypertension” and “wearable” & “cardiovascular disease” & “wearable device”. The two clusters “wearable devices” & “cardiovascular diseases” & “mhealth” and “ECG” & “deep learning” & “machine learning” have a slightly above-average degree of development despite their vital importance for the use of wearable

technologies to detect or monitor cardiovascular diseases. They are intermediate between the basic themes and the motor themes, which are the central themes for the field with a high degree of development. The cluster “wearable sensors”&“cardiovascular monitoring”&“seismocardiogram” is the only one that belongs to the quadrant of motor themes.

3. Discussion

We have identified in the literature some similar studies [10], [11] but this one improves the understanding of the conceptual structure of research on wearable technologies for cardiovascular diseases.

The first research question RQ1 concerns the main topics that mark research on wearable technologies for cardiovascular care. Through the analysis of the ” authors’ keywords, the results show “Respiration” and “Personalized applications” as the main topics of interest for researchers between 2000-01 and 2009-12 while in the past decade (2010-2019), researchers focused on: “ECG”, “Wearable sensors”, “Wearables devices” and “Heart rate”. This observation suggests a change in the focus and interest of researchers over the last two decades. Indeed, we can also note notable changes in the field of research over the last three years (2020-2022) with the appearance of evocative themes such as artificial intelligence, machine learning, and deep learning. These themes are undoubtedly linked to challenges such as the management of Big data, their security, and personal data protection. The results of the thematic evolution analysis that we performed between 2020 and 2022 give us important characteristics of the current thematic dynamics of research on the use of wearable technologies for cardiovascular diseases and the topics that deserve particular interest from researchers in the future. These elements allow us to answer research questions RQ2 concerning motor, basic, dying, and emerging topics in wearable technologies for cardiovascular diseases. Thus, among the basic topics, it is appropriate to put a particular emphasis on these: "physical activity" & "cardiovascular" & "mobile health", "wearable sensors" & "electrocardiography" & "hypertension" and "wearable" & "cardiovascular disease" & "wearable device". Indeed, it will be necessary to orient research to obtain significant results regarding the use of wearable technologies as a tool for early detection or diagnosis (ECG) and prevention (physical activity) of cardiovascular diseases. Because hypertension is one of the most dangerous risk factors for cardiovascular diseases, it is essential to increase the research effort in this area. In addition, some irrelevant terms have been developed over time, such as “sudden cardiac death” and “feature extraction”, while other relevant topics, such as those mentioned above requiring special attention from researchers, are at a very low-density level.

The performance analysis allowed us to solve research question RQ3 and provided future research guidelines for research question RQ4. Indeed, here we summarized the 5 researchers and countries that influenced the world of research on the use of wearable technologies for cardiovascular disease between 2000 and 2022. Despite the growing burden of cardiovascular disease in Africa, we noted the continent’s poverty regarding scientific production on the subject. Considering the data analysis conducted from the Scopus database, which is not exhaustive, the conclusions of this study could have some limitations.

4. Conclusion

In this paper, a bibliometric analysis of research on wearable technologies for cardiovascular diseases was performed, and interesting results were presented. Through performance analysis, this article identifies the five leading authors and countries. While African countries remain at the bottom of the statistics overall, the US and China stood out for their sustained productivity. Analysis of the thematic evolution of the subject has allowed us to identify the main topics that have marked the past two decades. Between 2000-01 and 2009-12, researchers focused on respiration and personalized applications. From 2010-01 to 2019-12, new topics of interest such as ECG, wearable sensors, wearable devices, and heart rate were explored.

To inform the scientific community and incite implications for policy, practice, and research, we have identified highly developed but non-capital topics: feature extraction, physiological measurement, and sudden cardiac death. Our study finds that researchers might focus in the next decade on issues related to prediction and prevention supported by wearables. However, this study has some limitations related to the sample size considered. It will have to be expanded for a complete analysis.

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Change Management in Hospitals: A Framework Analysis

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Abstract. Background: Hospitals are complex organizations that frequently need changes especially in service delivery processes, organizing, human resource management, monitoring and evaluation and technologies. Maintaining and improving productivity is a key requirement in hospital change management. Therefore, we need to develop and expand an appropriate model for management of changes in hospitals; which is the main purpose of this study. **Method:** A qualitative approach was used to conduct semi-structured interviews in 2019-2020 with 12 expert managers at Mashhad University of Medical Sciences, Mashhad, Iran. A pre-structured framework was applied for the data analysis. **Results:** Four main themes and nine sub-themes were identified as the main phases or stages of the framework that can be used to manage changes that aim to improve efficiency in hospitals. The main themes were problem identification and initial support; studying, designing and planning; participation in implementation; considering executive requirements; and implementation, assessment, feedback and stabilization. **Conclusion:** Management of changes that aim to improve hospital efficiency requires a practical model that was specifically developed by this study. This model should consider all the key elements that were identified; and should consider the expectations of the key stakeholders and their contribution in implementing the change.

Keywords. Change management, Productivity, Hospital Administration, Improvement

Introduction

The improvement healthcare system will not be possible without some improvements in hospital's performance[1].Improving hospital productivity requires constant changes [2]. In recent years change management has evolved to change management models, processes and plans in order to facilitate the impact of change in organizations [3]. ADKAR change model includes 5 words: awareness, declination, knowledge, ability and reinforcement. As a manager, this tool can be used to identify gaps in the change management process and provide an effective leadership role for its employees [4,5].

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The use of change management models as a guiding framework and not as a prescriptive management process is in accordance with the prevailing thinking in the present era about healthcare as complex systems [6]. Research in the United States, studied changing strategies in hospitals which considered the scope of implementation as an important element in making changes. Communication, empowerment and delegation of implementation decisions to the leaders of departments and units are among the success factors in applying change models [7]. The majority of change models used in health and treatment centers are considered to create a framework in order to establish a wide and diverse range of activities and rarely address the resistance issues of the change stakeholders [6-8]. In a recent example of opening a new hospital building in Australia, employee attitudes shifted from appreciation in the early stages of change to frustrations as the development progressed [9]. Nowadays, we have witnessed a paradigm change in the performance of hospitals, that its main concepts express the multilateral management of hospitals and consider them as a social phenomenon that requires a dynamic view and to achieve that there must be change [10]. Hence, the purpose of this study was to develop a suitable model for managing changes in hospitals in order to improve productivity.

1. Methods

The present study with a qualitative approach was conducted in 2019 and 2020 at Mashhad University of Medical Sciences, Mashhad, Iran. This study had 12 participants who had been chosen through purposive sampling. There were some conditions to enter this study which included participating voluntarily in the study, having experience in making at least one change in the modification of the hospital process and acting as a change manager or significant stakeholder who is aware of all the steps in the change process. Face to face interviews have been conducted in the format of semi-structured interviews. According to the type of the study (framework analysis), the interview guide was extracted from the ADKAR model. The primary questions to interview participants included the following: **1.** How was the need for change felt or discovered? **2.** How was support for change and stakeholder participation done? **3.** How is the implementation path of change defined? **4.** How has the process of implementation and consolidation of change been? Sampling and data collecting hadn't stopped until obtaining new data from interviews [11]. In this study, the framework analysis method was used to analyze which includes 5 steps: "introduction", "identifying a thematic framework", "Indexing", "Tabulation" and "combine and interpret data or map". This method has been developed particularly to analyze the qualitative data in study policies. At the introduction stage, the researcher absorbs the data by listening to audio files or reading manuscripts. During this process, researchers learn about the key ideas of the frequent contents and start the note taking process. Determining a thematic framework is not an automated process but requires logical thinking and intuition. In order to make change, the ADKAR model was used to design the initial study framework to analyze. The ADKAR model is a five-step framework which helps dealing with change management. This method had been provided by best-selling author and founder of Prosci, Jeffrey Heath [12] (Figure 1).



Figure 1. ADKAR model [12]

Basic thematic framework was discussed by researchers in a number of repetitive sessions. At first, the researcher indexed the transcribed interviews using the ATLAS/ti. V8 software. Then the other authors have discussed the index and the essential arrangements were made. This process has been repeated several times for all interviews. After that, they were compared to the point of view of every different interviewee about each topic by using an analysis chart. The relation between main and alternative contents were also examined. They have used transcribed interviews and in case of need charts were added. Contents were interpreted by using the same process which was explained for indexing. The thematic framework was updated in the analysis process.

2. Results

In this study, 12 participants were interviewed. Table 1 shows the demographic information of the participants.

Table 1: Characteristics of participants

Characteristics	Average ± deviation / number (per)	
Age (years)	45.2 ± 6.1	
Years of work experience	17 ± 8.7	
Education	Non-medical PhD	3(25)
	Specialist (medical)	2(17)
	General Practitioner	3(25)
	Master of nursing	4(33)
Gender	female	4(34)
	male	8(66)
Marital status	single	0(0)
	married	12(100)

In total, in the process of framework analysis of the present study, 4 main themes and 9 sub themes were identified (Table 2).

Table 2: Themes related to hospital change management

Themes	Sub-themes
Problem identification and the initial request for support	- Identify the issue - Identifying key stakeholders and the initial request for support
Studying, designing and planning	- Examine the previous related experiences and knowledge - Clarification of modus operandi and study plan

Participation seeking for implementation and executive requirements	• Information and obtaining the consent of stakeholders • Confirming the executive requirements
Implementation, assessment, feedback and stabilization	• Managing executive challenges • Assessment and feedback • Stabilization after implementing changes

2.1. Theme 1 – Problem Identification and the Initial Support

2.1.1. Sub-Theme 1- Identify the Issue

“...The first question that comes to mind when talking about change is what is about to change and why. In fact, the determining point of the change process is to identify the problem which our change revolves around.” (P10)

2.1.2. Sub-Theme 2- Identifying Key Stakeholders and the Initial Support

“...Look, when you decide to make a change on a topic or improve a process, there are always individuals at hospitals or universities who legally have the authority, power or inclination to not give you the permission to make a change or improve a process. It might be the opposite. It means that the above-mentioned individuals actually support your change and accelerate the process. Those are the people who must be completely legitimized before everything starts.” (P08)

2.2. Theme 2 – Studying, Designing and Planning

2.2.1. Sub-Theme 1- Examine the Previous Related Experiences and Knowledge

“...Sometimes we think we know it all and basically, we refuse to examine the previous experiences about a topic. We mostly think that we are the first person in the universe who wants to improve a process. But in fact, we are not. We need to believe that nothing in the world is with no theoretical background and research experiences.” (P04)

Heading

2.2.2. Sub-Theme 2-Clarification of Modus Operandi and Study Plan

“...Make things clear about what exactly you want to do. Consider everything in detail, not in general. When senior managers of a hospital or university come up with an idea, we need to think about it and write down the things we are about to do in detail. We need to know what the starting points are and what will be during the process, another participant said.” (P10)

2.3. Theme 3 – Participation Seeking for Implementation and Executive Requirements

2.3.1. Sub-theme 1- Information and Obtaining the Consent of Stakeholders

“... The success of implemented changes highly depends on the stakeholders of that change. Before implementing, there are people we need to inform, satisfy and clarify.

Sometimes a matron needs to be informed of a change and sometimes this needs to be done through a face-to-face conversation. That's the skill of a change manager." (P11)

2.3.2. Sub-theme 2- Confirming the Executive Requirements

"...It doesn't matter how much a change manager focuses on the design process of work and the performing methods, there will still be challenges on its way. Most of these challenges are related to neglecting some of these executive requirements. Therefore, we ought to keep the stakeholders in the loop before everything starts and they need to inform you if there are any obstacles in the implementation process." (P03)

2.4. Theme 4 – Implementation, Assessment, Feedback and Stabilization

2.4.1. Sub-Theme 1- Managing Executive Challenges

"...If the change manager informed the stakeholders in the previous stages, there wouldn't be any challenges on his/her way in the implementation stage. Indeed, there will always be issues in the name of executive challenges of work which the change manager must make the necessary arrangements for." (P01)

2.4.2. Sub-Theme 2- Assessment and Feedback

"...There is always a cycle in the implementation process when talking about change management. By assessing and giving feedback to this cycle, we allow the stakeholders and the study itself to review the process." (P04)

2.4.3. Sub-Theme 3- Stabilization after Implementing Changes

"...If changing the stakeholders of a change, particularly the important ones, doesn't affect the process, then we can say that changes are sustainable and they have been implemented perfectly and presented as a positive experience. In other words, stabilization of a change is crucial and it is closely related to persistence of evaluation, feedback and improvement of implementation methods and it is considered as a kind of accommodation." (P05)

3. Discussion

According to this study, change management at hospital has 4 main themes which includes: problem identification and the initial request for support, studying, designing and planning, participation seeking for implementation and executive requirements, implementation, assessment, feedback and stabilization. In this study, the ADKAR model was used for framework analysis to change management in hospitals. Problem identification and the initial request for support were one of the main themes identified in this study. This theme is similar to step one of Kelin's reengineering method which includes preparation [14]. In Iranian hospitals, due to the large number of project stakeholders, it is necessary to analyze key stakeholders and prepare those [15]. Another main theme was participation seeking for implementation and executive requirements. These results are similar with a report of hospitals in Australia [16], which shows the importance of stakeholder engagement in the implementation process [17]. Regarding the

last theme “Implementation, assessment, feedback and stabilization” it is in line with the refreezing step in Kurt Lewin's change theory [18]. The results of the Rechel et al. study showed that collecting complete information, stakeholder participation, and getting feedback from them about the decisions made had the greatest impact on the managers' decision-making performance [19]. Making changes in Iran's public hospitals and not fully implementing these changes shows the weak performance of managers in this field [20]. In Iran's health system, implementation, assessment and feedback are done to some extent, but due to many changes in the management systems, the stabilization stage rarely happens, and most of the projects remain unfinished despite spending a lot of time and cost. Thus, particular attention should be paid to the change management and sustainability of the change in hospitals to improve productivity. Although the main approach of the participants in this study was change management in government hospitals, apparently the extracted themes of the present study can be used in other non-governmental hospitals and even other organizations. In order to use the findings of this study for other organizations, the cultural condition and climate of the concerned organization must be taken into account. One of the most important limitations of this study was deficiency of documentation and written organizational memory of individuals or processes that have been reviewed and modified over the years. This limitation caused challenges in identifying the individuals who were process owners and activists as change managers or a key stakeholder.

4. Conclusion

Managing change is certainly a challenge but it is not impossible. Linking the potential solutions can lead to improved methods for managing changes, offer new approaches that have not yet been discovered, and provide broader insights on how to use them against an organization that is always changing. An important advantage of the identified themes in the present study is that it's a combination of models related to change management, re-engineering and action research methods. Our finding indicates that the organizational culture of state hospitals in the field of change management requires methods that should have the features of change models, re-engineering models and action research methods.

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Posters

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Identification of Medicinal Products: Providing an Educational Framework

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Abstract. The ISO standards for the Identification of Medicinal Products (IDMP) prove to be difficult to implement. Guidance needs to be provided to those using and further developing IDMP-related standards and terminologies. Providing fitting and structured education would be a step forward. This article describes research of current education and certification on IDMP and the creation of an educational framework for targeted IDMP knowledge transfer. This framework indicates the required level of knowledge for the various identified roles within the organizations working with IDMP. Based on a combination of desk research, a questionnaire, and individual interviews, relevant roles were identified covering the various organizations (Users, Educators, Medicine Authorities, Standard Developing Organizations, and IT-suppliers) and five levels of required knowledge were determined, including applicable roles and educational components. Furthermore, this article lists several recommendations that should be taken into consideration whilst developing content and implementing educational modules for IDMP.

Keywords. IDMP, standards, education, medication, patient safety, interoperability

Introduction

Increased usage of structured terminologies and standards in the domain of Identification of Medicinal Products (IDMP) and the exchange of its data is expected to improve patient safety and increase efficiency of development, use and monitoring of medicinal products. While relevant ISO standards have been available since 2012¹, the impact of these norms can be considered as sub-optimal. Organizations make use of local/national standards or have developed their own system to classify and identify medicinal products. To prevent issues due to mistakes in translation and to facilitate interoperability and cooperation, such complexity should be prevented. This article aims to provide a concrete educational framework by answering the following questions what level of knowledge is expected of people and how do they acquire that knowledge, now and in the future? An educational framework would create common understanding among users, provide flexibility for distinct roles and could function as a first step for the further adoption and development of the set standards on IDMP. The end goal is providing users with an education framework to adopt IDMP related standards and terminologies. The expected growth in the number of new medicinal products seeking market authorization should also function as a motivator to use of the set of IDMP standards.

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1. Methodology and Findings

Information was gathered from both existing documentation as well as experts and industry users. The *e-Competence Framework*² describes 41 competences and roles relevant in an ICT environment. From this list, the relevant roles on the topic of IDMP were drafted which also provided input for a set of questions to be used in a questionnaire. The questionnaire was sent to industry professionals and experts, who were contacted over a period of two months and based on their UNICOM³ involvement.

In two months, 82 individuals have replied to the questionnaire. The distribution across the various types of organizations was the following Users (41.5%), Educators (17.1%), Medicine Authorities (15.9%), Standard Developing Organizations 13.4%), and IT-suppliers (12.2%). Nearly all respondents indicated that the current situation was not ideal (93.9%); the lack of uniformity, unclear guidance and the lack of governance has led to variation. Note that none of the respondents that considered the current situation as ideal originated from the group of educators and the Standard Developing Organizations. Furthermore, 24.4% of the respondents required certification on IDMP from their staff but a majority referred to publicly available information or internal knowledge transfer even though 78.8% indicated that specific groups in their organization focus on IDMP. The variation in answers indicated that there are many different specializations and professionals working with IDMP. They also indicated that required knowledge was dependent on their role and engagement. Dividing those into groups of technical, business, clinical and regulatory was a first step.

Individual interviews with a number of industry users and experts on the topic of IDMP, were conducted to validate the outcomes of the questionnaire and provide more details on the current issues. The interviewees indicated that the lack of coherent education together with the great variation in used terminologies and standards, as the main thresholds for efficient exchange of data and increased patient safety.

1.1. Definition and Scope

In context of this study, an educational framework⁴ is defined as the following: “An instructional framework provides a cohesive structure made up of proven components, but it is adaptable so as to work with varying teaching styles, content areas, and student needs (while maintaining the core structure of the framework)”⁵. Furthermore, an educational framework should adhere to the following objectives⁶:

- Promote a consistent view of body of knowledge worldwide;
- Specify its scope;
- Be publicly accessible;
- Enable the identification of role specific competencies;
- Provide a foundation for (health informatics) course and curriculum design; Development and accreditation.

2. The Educational Framework

Based on the input, relevant roles and applicable levels could be identified. Below, five levels of understanding and specialization have been identified to create a curriculum with a clearly defined purpose in mind. The levels start with basic information and build

up to specialized understanding. Using these levels, fitting educational goals or topics could be defined, enabling educators.

2.1. Informative Level

The first level of education should be considered informative and is aimed at spreading awareness and a basic understanding of the standards and terminologies of IDMP. It is recommended that use cases and guidance on the ISO documents should be available to the public as a basic means of education to achieve a broad basic understanding.

2.2. Foundation Level:

Users are familiar with the basics of IDMP and are familiar with publicly available information. They understand the status quo and the main drivers for IDMP. Operational users should be able to integrate IDMP-libraries in their environment and import data. Strategic users are expected to have a high-level understanding of IDMP, its benefits and an overview of relevant stakeholders.

Relevant roles: IT Account manager, CIO/CTO, Database Administrator.

2.3. Intermediate Level

Users should be able to understand the logic of IDMP and its implementation. Furthermore, the relevant terminology should be clear to them in such a way that they grasp the relevance of terms in discussions. Business users should be able to propose new uses of IDMP in their organization while overseeing the impact on the processes in combination with stakeholders.

Relevant roles: Analyst, Product Owner, Information Manager, Medical Coder.

2.4. Advanced Level – Clinical and Regulatory

Users should be able to understand the terminology of IDMP fully. Furthermore, they should be able to scrutinize the standards and make suggestions for improvement that will be beneficial for the general population of users. Users should be proficient in understanding terms and concepts and *their* applicability. They should proactively assist in the implementation of IDMP.

Relevant roles: Medication Compliance Officer, Pharmacovigilance Professional, Authors of medication related information (e.g., CDS or MPD), Medication Information Analyst, Regulatory Information Analyst.

2.5. Advanced Level – Technical

Users possess detailed knowledge on the structure of IDMP and its relevance in a technical sense. They should keep up to date with ongoing changes on a technical level and be aware of the impact of adjustments. Implementations and changes can be carried out with little preparation time including the connection to external reference databases/services.

Relevant roles: Innovation Manager, Data modeler and Interface Specialist, Standard Specialists (participating in standard development).

3. Discussion and Conclusions

The construction of an educational framework would be a means to promote the adoption and usage of IDMP and its corresponding terminology. During the construction of the framework, its objectives were taken into consideration but it needs to be discussed further in order to refine the levels and content of the modules. Subsequently, pilot educational modules could be developed and expanded upon. Below a number of recommendations are listed.

Currently, the curricula are determined by a diverse group of professionals across various types of organizations. Centralized guidance on such a curriculum at a higher level would be preferred. Input for the curriculum should come from all users, while education could be provided by (non-)commercial organizations. Coordination and supervision could be done by independent organizations, such as medicine authorities.

It is noted that the various ISO documents, including several implementation guides, do not provide a generic overview regarding the usage and the step-by-step approach required for familiarizing or implementing IDMP. Therefore it is advisable to provide a roadmap that provides guidance getting familiar with the standards. This will clarify the necessary steps and logic to new and existing users. It will also lower the threshold for individuals and organizations that are new to IDMP. By keeping the threshold low, the awareness and basic understanding of this topic will grow resulting in effective implementation of IDMP.

Standards tend to grow organically to vast systems. By actively limiting new additions, the size of IDMP can be kept at a manageable level without the loss of important nuances. This keeps the threshold low for new users.

This article has focused on the creation of an educational framework leading to the education and certification of individuals. However, a certification could also be used to mark organizations as IDMP compliant. A similar approach as being used for other ISO norms such as ISO 9001 could be attained.

4. Acknowledgement

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Migration from HL7 CDA to FHIR in Infectious Disease System of Estonia

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Abstract. On the basis of the Estonian National Health System, we propose a universal and reusable methodology for migrating HL7 CDA documents or their components.

Keywords. HL7 FHIR, HL7 CDA, Interoperability, Estonian NHS

Introduction, Objectives and Methodology

Many countries have successfully implemented HL7 V3 and CDA standards to ensure document-based interoperability between EHRs, registries and healthcare institutions [4, 5, 7]. HL7 CDA is a document markup standard that specifies the structure and semantics of clinical documents [2]. The biggest drawback of the HL7 CDA document-based approach is the timing of sharing the information. The document is generally shared once all the agreed data elements have been precisely filled in and the necessary confirmations received.

The Estonian Health Information System (TIS²) is a set of healthcare services that covers many aspects of health care – discharge summaries, referrals, e-prescriptions, the national appointment system, etc. [5]. TIS development began in 2005 and is based on HL7 V3 and CDA standards. Today, Estonian TIS is transitioning from a document-based approach to an event-based approach by utilizing the HL7 FHIR standard. During this transition, one of the tasks is to describe the patient's socioeconomic status according to the FHIR profile.

One of the data exchange services offered by TIS is NAKIS [8], which serves the purpose of sharing information about dangerous diseases, infections and suspected infections through the Infectious Diseases Information System to the register of infectious diseases, including AIDS, hepatitis and COVID-19. Regarding the COVID-19 pandemic, the NAKIS notice was one of the most frequently used notices from 2020 to 2021. In order to thoroughly analyse the reasons for infection, NAKIS requires the collection of social characteristics: occupation, employment organisation, and educational or preschool institution.

Socioeconomic status (SES) is defined as a measure of a person's combined economic and social status and tends to be positively associated with better health [1]. This entry focuses on three common measures of socioeconomic status: education,

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² Letter 'T' comes from the Estonian word 'Tervis', meaning Health.

income, and occupation. Listing 1 contains a fragment of the NAKIS report message with socioeconomic elements. In the NAKIS report, a message from the employee organisation or educational or preschool institution is presented as free text. Occupation is defined as *ValueSet* 1.3.6.1.4.1.28284.6.2.3.1 [9]. Officially, the register of occupations is managed by the Department of Statistics. The attribute socioeconomic status is defined as *ValueSet* 1.3.6.1.4.1.28284.6.2.3.9 [10] with specified values. In NAKIS, however, the message uses the occupation name as free text instead of a code.

Listing 1. Fragment of NAKIS message with extended patient section

```
<patient classCode="PSN" determinerCode="INSTANCE">
  <name>
    <given>First name</given>
    <family>Last name</family>
  </name>
  ...
  <!-- Estonian extension of COCT_MT030200UV04. Person -->
  <ext:patientPerson ext:HL7-ClassName="PSN" ext:HL7-
    Domain="PRPA_RM000000" ext:realmCode="EE">
    <ext:asEmployment>
      <ext:jobCode codeSystem
        ="1.3.6.1.4.1.28284.6.2.3.1.1"
        codeSystemName="Occupation" displayName="
        Developer"/>
      <ext:employerOrganization>
        <ext:id nullFlavor="NI"/>
        <ext:name>Kodality </ns2:name>
      </ext:employerOrganization>
    </ext:asEmployment>
    <!-- Socioeconomic status -->
    <ext:asMember classCode="MBR">
      <ext:groupEntity classCode="ORG"
        determinerCode="INSTANCE">
        <ext:id extension="1" root
          ="1.3.6.1.4.1.28284.6.2.3.9.2"
          assigningAuthorityName="employed"/>
      </ext:groupEntity>
    </ext:asMember>
  </ext:patientPerson>
</patient>
```

According to the plan, NAKIS was migrated from HL7 V3 and CDA to FHIR. During the migration, the following questions had to be answered:

- What resources are suitable for submitting SES?
- What similar FHIR profiles and terminologies exist in the world?

The aim was to create FHIR profiles and terminology that are suitable for the transmission of SES in Estonia and potentially comprehensible in other countries [3].

1. Results and Conclusion

As a result of our project, collecting information in the form of granular observations, the owner of the NAKIS register always receives up-to-date and correct information that can be analysed from the necessary angle. The owner of the NAKIS register can now produce the necessary statistical values by creating a decision table, as provided in Table 1, or using a rule engine for the calculation of values. We have created profiles for

EducationLevel and *EducationRecord* and provided suggestions for reusing OHD profiles. The decision table shows other observations, such as parental leave and imprisonment period, which we have not touched on in this article but which are important for calculating socioeconomic status and can be reported analogously to the described indicators. The given information often remains unreported upon patient registration at the registry office.

Table 1. Decision table for socioeconomic status calculation for NAKIS

Code	Name	Education Level	Education Record	ODH Employment Status	Parental Leave	Retired	Combat Period	Imprisonment Period	Disability
1	working employee, contractor, freelancer			employed					
2	unemployed or actively looking for work			unemployed					
3	conscript						active		
4	detainee							active	
5	student		active						
6	incapacity pensioner								active
7	old-age pensioner			denial of "employed"		active			
8	other pensioner					active			active
9	parental leave				active				
10	housewife or not looking for work			not in labor force					
13	preschool child attending kindergarten	no schooling	active						
14	preschool home	no schooling							
99	unknown	unknown or not exists	not active	does not exist	not active	not active	not active	not active	not active

In an ideal world, information on employment and occupation is delivered automatically to the Estonian Health Services from the Estonian Employment Register, information on education from the Ministry of Education and Research, information on combat periods from the Ministry of Defence, imprisonment information from the Ministry of the Interior and parental leave information from the Ministry of Social Affairs, whereas healthcare facilities should be free from the obligation to send this kind of data. As a result of our work, a reusable migration methodology for CDA documents or their components was developed. The methodology comprises the following steps:

- Analyse each element and each list critically and decompose them, where necessary
- Create a list of all possible search keywords and their synonyms
- Check the FHIR site for profiles matching your search keywords
- Check the FHIR register for profiles matching your search keywords
- Reuse profiles, where possible
- Search openEHR for suitable archetypes; validate their suitability and reuse, if possible
- Search SNOMED and LOINC for matching terminology based on all search keywords
- Develop/adapt/adopt appropriate profiles and terminology

It is a common opinion that characteristics reflecting the patient's status, such as SES, must be part of the Patient resource. According to the modelling principle, it is reasonable to add an attribute to a resource if it reflects an event [6] that is complete, i.e. it changes very rarely, e.g. one or two times during the life of the resource. Since SES may change frequently e.g. several times a year, and multiple indicators may be valid simultaneously, and since a historical overview of changes in SES may generally be clinically useful, socioeconomic status cannot be an attribute or an extension of the Patient resource but a separate FHIR Observation resource with its own profile or profiles.

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Human Resource Planning in Health Care: Outlining a Basic Model and Related Complexities

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Abstract. The effectiveness of the health care system is largely dependent on the knowledge, skills, and motivation of health care workers, which was particularly evident during the COVID-19 pandemic. The systemic planning of human resources is therefore an important condition for ensuring the sustainability and efficiency of the health care system. This article focuses on outlining a basic model of human resource planning in health care and the investigation of related complexities. An in-depth analysis framework based on various materials and evidence is proposed in order to outline the factors that influence human resource planning in health care. In order to achieve greater credibility of the research results, the in-depth analytical process employs an extensive review of the literature and carries out an investigation of numerous sources and materials, in both the national and international contexts. The purpose of the human resource planning initiatives in health care is to calculate the needed number of health care workers in the future, on the basis of past and current data, and based on assumptions about future trends in supply and demand. The research findings reveal that this is a very challenging task, as there are typically many unknowns in future planning, and, in addition, planners often face a lack of reliable data and systemic deficiencies. Moreover, the study indicates that unplanned and delayed solutions concerning the human resource needs in health care can only alleviate problems, but in no way can they replace effective strategic measures and timely structural changes within the health care ecosystem.

Keywords. Human resource planning, health care, basic model, complexities.

Introduction

The health care sector constitutes one of the most significant branches in the EU economy with important employment potential due to the ageing population and increasing demand for health care services [1]. The current global health crisis and the problems of health care systems around the world due to the COVID-19 pandemic only confirm the important socio-economic role of health care systems [2, 3]. In Slovenia, health care generated 7.9% of GDP in 2020 and employed 6.8% of the active population [4]. According to the National Institute of Public Health, the health care sector employed 60,862 people in 2020 [5]. The provision of health care requires the combination and

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coordination of numerous resources, whereas human resources make the largest contribution to the delivery of health care services in the first place [6].

Due to the ageing population, the population of the EU aged 65 and over is projected to increase by 66.9 million by 2060 [7]. The introduction of new technologies requires additional health care workers and proper training. On the other hand, new health risks are emerging due to lifestyle changes, pollution, and epidemiological threats [8]. All of this is leading to continually increasing the number of health care workers and spending on health care, and poses serious concerns for the sustainability of health care systems in many countries. Policymakers and health care system managers face numerous difficulties in the course of human resource planning in health care. To this end, the main purpose of human resource planning models is to calculate the future number of health care workers needed based on past and current data and on the basis of the assumptions regarding the future trends in workforce supply and demand. Accordingly, this article focuses on outlining a basic model of human resource planning in health care and the investigation of related complexities.

1. Methods

In order to achieve the research objectives, this article employs an in-depth analysis methodological framework. Outlining a basic model of human resource planning in health care requires multilateral and detailed insight that delves beyond the superficial layers to investigate the related complexities. Since this study is largely exploratory in nature, quantitative research methods could not yield dependable results. The selection of the methodological approach was adapted to the particularities of the research matter and the availability of evidence [9].

The in-depth analysis was conducted from November 2021 to May 2022. During that time, we carried out extensive document analysis through the exhaustive investigation of primary and secondary sources, policy papers, EU and national strategies, project reports, interviews, and other materials containing subjects related to human resource planning in health care. The in-depth analytical process used content from both national and international contexts to attain greater credibility of the research results [10]. In this sense, the evidence from the field, statistical data, and records from the national health care databases were particularly important. An all-encompassing methodological approach should ensure the greater consistency of the research results and provide a more applicable platform for drawing sensible conclusions [11].

2. Results

The in-depth analysis revealed that the following factors have the most significant impact on health care workforce planning [2, 6, 7, 12]: the demographic trends, numerous diseases and chronic conditions, the ageing and gender structure of the health care workforce, the capacity of the educational institutions, the required new knowledge and technologies. The basic model of human resource planning in health care presented in Figure 1 incorporates seven factors in two categories [13]: “Supply” and “Demand”.

On the supply side, “*Training*” denotes the highly significant factor concerning the number of new health care professionals produced each year by the education system [6]. “*Current health care workforce*” refers to the health care workers working in the public

health care system and external health care professionals. The relevance of “*Migration*” varies depending on the weight of this social phenomenon in each country. In any case, as the EU Member States become more integrated and the importation of health care workforce from the third countries continues to rise, the effect of migration is likely to expand [7]. “*Retirement*” is determined by individual choices and regulations governing the right to retire. Other groups within this category, i.e. death, inability, other departures, have a large impact on the number of health care workers and reflect the movements of workers in the field [12]. “*Job retention*” addresses the parameters and occupations (e.g. nurses) in the health care system that may be more closely tied to job retention than others [5]. Factors on the supply side and related complexities are largely the result of the national strategic orientations, development goals, and underlying policy decisions.

Regarding the demand side, there are various research studies that consider a variety of factors influencing the demand for health care services [14]. “*Population need*” refers to the demand based on the population’s underlying needs, where the number and competences of health care workers meet the health-related objectives, such as ensuring better health, reducing inequalities, and the accessibility of the health care system. “*Health care production*”, expresses the ratio between the total current health care spending and the number of health care workers [12]. The demand side can be influenced by the prioritization of health care issues, prevention campaigns, etc. Unlike the supply side, the demand side factors and related dimensions are relatively more difficult to measure and, consequently, to predict.

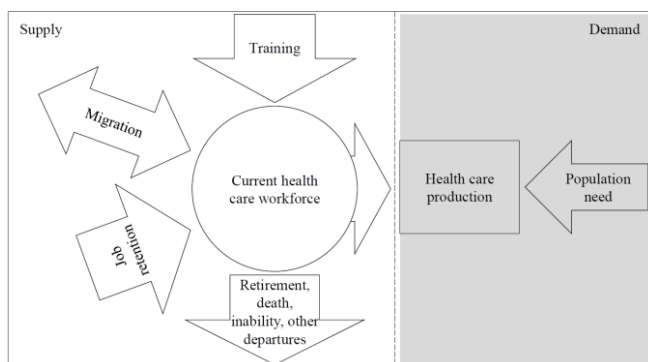


Figure 1. The basic model of human resource planning in health care.

3. Discussion

The challenges related to human resource planning in health care stem from complex national and global social factors, multifaceted professional interactions, and specific health care sector dynamics [7]. Our basic model of human resource planning in health care comprises critical factors, a suitable set of data, various assumptions and scenarios, and algorithms for calculating results. Such models typically combine quantitative and qualitative prediction methods and advanced digital solutions. The information used to define the baseline state and the data used to calculate future health care workforce supply and demand trends serves as the basis for measures regarding the training, education, employment, and migration of health care workers, ensuring favorable working conditions for young and older workers and preventing them from moving into

other professions early or retiring. Generally, the models of human resource planning in health care and the derived indicators should enable recognition of the main imbalances within the health care workforce, the analysis of these imbalances concerning all relevant factors, and the identification of potential solutions. Preferably, the results of the modeling should facilitate the assessment of future health care workforce supply and demand, expressed in the indicators defined during the planning process. However, due to various limitations and long prediction periods, such models do not represent a magic solution, and should not be unreasonably imposed on all health care systems without regard for their innate circumstances [15]. The identification of the most important facilitators of the effective human resource planning initiatives in health care and the exploration of their implications should be addressed in future research in this area.

4. Conclusions

The compelling experience from the Covid-19 pandemic has further fueled the heated debates about human resource planning in health care. All such initiatives require well-coordinated action of the stakeholders, efficient digital infrastructure, a sufficient number of competent experts, and, certainly, a suitable normative framework and sufficient funding. Without a wide-ranging approach, such failed projects can lead to long-lasting setbacks, which could seriously threaten patients' access to health care services and undermine all efforts to achieve public health goals in the country.

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Patients and Organizations eHealth Services Model

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Abstract. The current Finnish public hospitals' eHealth services are organization-oriented rather than patient-oriented. Patients remain passive and use eHealth services that are designed by private or governmental organizations. Patients had little or no involvement in that process. This paper introduces a novel eHealth Services Model that can be used as a tool to capture the needs of both organizations and patients. Two eHealth services were used to verify and support the validity of the presented model. The first eHealth service features came from an existing Finnish eHealth service that was designed by a Finnish organization. The second eHealth service features have been derived from the collected patients' feedback. A survey was carried out to compare the selected two eHealth services features. The finding of this paper suggests that an eHealth service with features that capture patients' needs is favorable against the eHealth service features that came from a Finnish organization. The presented model is a long-term solution that can be utilized in designing and providing the right technologies and services that will continuously satisfy the needs of patients and organizations.

Keywords. eHealth, Services, Patients, Organizations, Model.

Introduction

Finnish public health care has undergone several positive developments, which have impacted the eHealth services offered through Finnish public hospitals. Current issues with Finnish eHealth services are rooted in the problems faced by patients using websites and patient portals. These websites and patient portals are established based on what organization can provide rather than what patients want to have [1]. Several studies [2, 3, 4] assessed and suggested solutions for Finnish eHealth services from the perspective of the organizations. This paper assessed and suggested solutions to Finnish eHealth services from the perspective of the patients. The merit of this paper is to introduce and verify the validity of a model that will bring both patients and organizations to work as a team to build eHealth services. The introduced model is called the Patients and Organizations eHealth Services Model (Figure 1). The objectives of this paper are first to introduce an eHealth service model that will continuously capture the needs of both patients and organizations, and second to verify the validity of the Patients and Organizations eHealth Services Model (Figure 1).

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1. Methods

Two eHealth services features were used to verify the validity of the introduced novel Patients and Organizations eHealth Services Model (Figure 1). The first eHealth service features came from an existing Finnish eHealth service called Maisa, which was designed by a Finnish organization called Apotti. The Maisa eHealth service was selected because Maisa is used in the Finnish region Uusimaa that represents the largest population in Finland. Maisa provides the following eHealth service features: book appointments; communicate by sending messages or asking a question; perform other activities such as requesting test results, health summary, care plan, social services, coronavirus information, upcoming tests & procedures, a prescription renewal or referrals; manage access to data; realize other services such as links to other eHealth services from different providers and account setting. Maisa and other eHealth services are not necessarily known to all Finnish people. The features of the second eHealth service resulted from the collected feedback from 351 patients between the years 2014 and 2015 [1]. The features of the second eHealth service comprise: allowing patients to book, cancel or postpone appointments; send messages, videos, pictures; interact with their health care professionals; check their own health records; renew their prescriptions, remote consultations; request to choose their own doctors, find their hospitals, emergency services, send feedback; check who has access or uses their data, when and why; ability to see their health trends, news about current diseases, how to act, where to ask for help; record their activities & diet and see, pay or postpone their bills due date payment. The two eHealth services were presented as (A) and (B). The participants did not know that the features of eHealth service (A) came from an existing eHealth service nor that the features of eHealth service (B) originated from the collected patients' feedback. The participants were asked to assess features of both eHealth services (A) and (B) using the rating scales of 1, 2, 3, 4 and 5. Scale 1 represents poor service, scale 2 satisfactory service, scale 3 medium service, scale 4 good service, and scale 5 excellent service. A Microsoft online survey form was used to collect the participants' ratings. A text was added at the beginning of the Microsoft form to explain the participants the aim of the survey and that their data will be used anonymously for this paper only. The Microsoft form was communicated to the participants through several Finnish groups on Facebook and through the Tampere University Intranet news. The collected data comprised the participants' age, gender, regions of Finland they come from, employment status, new feedback, and ratings of both eHealth services (A) and (B). The use of an online survey fitted the purpose of this paper, as the considered eHealth service are provided through online platforms that require participants to have devices with an Internet connection. Accessibility of the survey was an important aspect, and the survey content was designed in compliance with AA-level criteria laid down in the Harmonized European Standard EN 301549: 2019 Accessibility requirements for ICT products and services, Clause 9.

2. Results

The survey was running from 19th of April 2022, when the first participants were active, until 10th of June 2022, when the last participation was received. Thereafter, no input from new participants was recorded. The survey was formally terminated on the 22nd of June 2022. Answers from in total 177 participants' were collected. Only one participant

among the 177 participants declined to participate in the survey as this participant expressed his/her concerns about safety such as hacking or spam through Facebook. From the resulting 176 participants, 34 feedbacks were collected. The eHealth service (B) was favorable and scored on average 4.54 out of 5, whereas the eHealth service (A) scored on average 1.96 out of 5. The participants' age distribution showed that 92% of participants were between 18 and 61 years, and 8% over 62 years. The participants' gender distribution showed that 49% represented women, 47% represented men, other and undisclosed genders were 2% each. The participants' employment status results were 50% employed, 31% were students, 15% were retired, 15% were unemployed and 1% represented the other employment status. The overall results among participants showed that the eHealth service (A) features scored on average 1.96 out of 5 and the eHealth service (B) features scored on average 4.54.

3. Discussion

This paper introduces the following Patients and Organizations eHealth Services Model Figure 1:

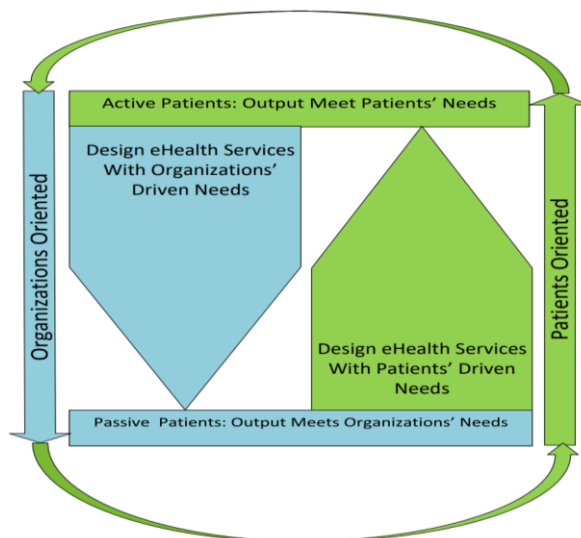


Figure 1. Patients and Organizations eHealth Services Model.

The introduction of the Patients and Organizations eHealth Services Model is an attempt to enhance the way the Finnish hospitals eHealth services are offered. The current Finnish hospital eHealth services are organizations oriented rather than patients oriented. Organizations-oriented eHealth services follow a top-down approach (blue color) and their design is driven by organizations' needs. In a top-down approach where the patients are passive, patients have almost no say in how the eHealth services are designed, offered or organized. In the bottom-up, patients-oriented approach (green color), the design of eHealth services is based on patients' needs and the patients are active participants and drivers of the eHealth services. Organizations and patients need each other in delivering the appropriate eHealth services that meet the needs of both organizations and patients.

The results used to verify and support the validity of the introduced model in this paper are reliable and unbiased as the participants did not know that the features of eHealth service (A) originated from an existing eHealth service offered by a Finnish organization. Also, the participants did not know that the feature of eHealth service (B) originated from patients' feedback. Uusimaa and Pirkanmaa represent almost half of the participants. Pirkanmaa has the highest participants' records as the survey was published in Tampere University Intranet. Most of the participants from Tampere University do not originally live in Tampere.

The regions, age, gender, employment status distributions, and new feedback in this paper are considered enough to verify the validity of the model presented in the Figure 1. The results showed that the eHealth service (B) was favorable and scored on average 4.54 out of 5, whereas the eHealth service (A) scored on average 1.96 out of 5. Furthermore, 34 participants provided feedback on the eHealth services through the survey demonstrating that Finns are highly interested in being an important active player in eHealth services. The provided feedback interestingly suggested combining both features from eHealth service (A) and eHealth service (B). Additionally, due to the COVID-19 pandemic, the feedback touched on the vaccine alternatives related to COVID-19, flu, and ticks. This is a sign that Finns are highly interested in finding information and guidance about health issues in the well-established eHealth service where they will be engaged and empowered to present their needs.

4. Conclusion

eHealth services are inadequate if they are not known to patients and do not fully meet their needs. Organizations that will design eHealth services, although they will use state-of-the-art information technology, they are required to collaborate with patients and continuously capture evolving needs of the patients. The Patients and Organizations eHealth Services Model (Figure 1) is the framework that can be utilized to capture the needs of both patients and health organizations. Furthermore, hospitals will be able to gain the trust of people and equipped with powerful tool to manage the health of their patients, overcome the abundance of misinformation in social media [5] and fight against current or future pandemic.

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