

JAIR

October 2024
Special Issue

Journal of Applied
Interdisciplinary Research



Special Issue: Digital Health
Proceedings of the DigiHealthDay 2023

a joint publication with the Ukrainian journal

Reprint

**Medical Informatics
and Engineering**

JAIRS

Journal of Applied
Interdisciplinary Research



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DESIGN

Sandra Maier, Diana Karl
ISSN: 2940-8199

The Journal of Applied Interdisciplinary Research (JAIR) is published as a series of the Bavarian Journal of Applied Sciences.

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Foreword

Dear readers,

We are proud to present the second special issue of the JAIR, dedicated to the primary field of digital health. As in the last issue, the contributions are the result of the discussions at the virtual conference DigiHealthDay which took place on November 9th and 10th, 2023. The hosting institution of the DigiHealthDay at the Deggendorf Institute of Technology was the European Campus Rottal-Inn (ECRI). After the successful issue in the last year, the DIT and the Shupyk National Healthcare University of Ukraine (Shupyk NHU of Ukraine) decided again to realize a joint publication. The guest editors for this issue are Prof. Dipak Kalra (Shupyk NHU), Prof. Dr. Georgi Chaltikyan (DIT), Prof. Dr. biol. hum. Horst Kunhardt (DIT), Prof. Ozar Mintser (Shupyk NHU) and Fara Fernandes (DIT). For special issues, the guest editors take the sole responsibility of selecting the articles and ensuring the quality process.

The Journal of Applied Interdisciplinary Research, short JAIR, is an academic journal that aims to provide a current and international overview of interdisciplinary research which is also undertaken in an applied manner. The combination of these two types of research is a niche that has so far found little attention in academic journals and we are happy to close a previously existing gap by combining these two types of research in its own new journal. As this type of research is a growing field, it warrants a journal of its own type. Various areas of academia are overlapping more and more, so we want to provide an opportunity for researchers to publish their interdisciplinary research in a journal dedicated to advancing this particular field, and committed to the exchange of ideas across academic disciplines.

The JAIR is generally published annually as an online only issue. The present print version constitutes a reprint of the online issue. Please cite the articles published online by indicating their respective DOI.

Your JAIR editors,

Michelle J. Cummings-Koether

Kristin Seffer

Guest Editorial

The realm of digital health continues to transform healthcare systems on a global scale. With its expanding possibilities and diverse applications, digital health is revolutionizing how care is accessed, delivered, and managed, bringing benefits to patients and citizens worldwide.

This symposium proceedings compiles the scientific oral and poster presentations, student projects, and theses showcased at DigiHealthDay-2023. DigiHealthDay, an international educational and networking series, is hosted annually by the European Campus Rottal-Inn, Deggendorf Institute of Technology, Germany. Now in its fourth edition, DigiHealthDay-2023 took place on November 9th and 10th, 2023, featuring an array of keynote presentations by leading experts, as well as panel discussions. This hybrid event revolved around the theme “Global Digital Health – Today, Tomorrow and Beyond” and attracted more than 1400 participants from 104 countries who engaged both in-person and virtually. This yearly symposium primarily aims to inspire emerging researchers to explore innovative solutions through digital health to address global healthcare challenges. This year’s edition provided a platform for researchers to present their work in areas focusing on digital health.

The first article in the field of telemedicine and remote healthcare presents a study that conceptualizes telemedicine as the intersection of two vectors, namely patient condition and technological readiness, addressing the potential and challenges in telemedicine for healthcare workers and patients. As part of our theme on EHR and Health Information Systems, we present three insightful articles that tackle critical issues in medical data management and decision-making. The article on problems of medical data compatibility in the integration of information systems explores the challenges of medical data compatibility, focusing on the complexities of integrating health information systems to create unified patient portfolios for healthcare providers. The next article is a scoping review of the role of clinical decision support systems in ICUs during the COVID-19 pandemic. Finally, the article on innovative databases in ecomonitoring information systems introduces a novel approach to biomedical information storage by proposing the use of genetic code images as relational database keys, aiming to enhance data reliability and integrity.

Within the theme of health data management and analytics, we present the article ‘Unlocking the power of Health Data - by ensuring the public can trust the EHDS.’ The article discusses public trust as a cornerstone for scaling the European Health Data Space (EHDS), proposing a societal compact to ensure ethical and transparent health data reuse. Another key piece in this issue is titled 'Global Digital Health Diplomacy,' which explores delivery models and bottlenecks in global health data systems. This paper advocates for global digital health diplomacy as a crucial strategy for establishing interoperable health data systems, fostering cross-border healthcare through coordinated international efforts. It offers insights into the path forward for overcoming existing challenges in digital health diplomacy.

We present a special focus article, 'AI Research Advancing Healthcare: AI Integration, Interoperability, and Sustainability Challenges,' which delves into the critical role of artificial intelligence in healthcare. This article explores the transformative role of AI in healthcare, addressing challenges in integration, interoperability, and sustainability, with a focus on patient-centric and blockchain-based systems. Our second special focus on digital health education highlights the outcomes of the first Blended Intensive Program (BIP) on AI for Health that was organized in collaboration with partners from five European nations and support from the EU's ERASMUS+ program. Reflecting on the outcomes of the DigiHealth-AI Blended Intensive Program, this study highlights participants' evolving views on AI's role in healthcare and their concerns about benefits of AI in the healthcare sector, employment, bias and privacy of AI systems.

Once again, we are delighted to partner with the Journal of Applied Interdisciplinary Research and the Ukrainian Journal of Medical Informatics and Engineering to present this collection of articles from DigiHealthDay-2023. These articles are organized by the key themes discussed during the symposium. We sincerely thank all the contributors for their valuable research and contributions to this edition of the Journal of Applied Interdisciplinary Research. We hope that this edition provides inspiration as you explore the ever-evolving landscape of 'Global Digital Health'!

Prof. Dr. Dipak Kalra, International Chair of DigiHealthDay
Prof. Dr. Horst Kunhardt, Scientific Chair of DigiHealthDay
Prof. Dr. Georgi Chaltikyan, Organizing Committee Chair of DigiHealthDay
Prof. Dr. Ozar Mintser, Editor-in-Chief of Ukrainian Journal of Medical Informatics and Engineering
Fara Aninha Fernandes, Associate Guest Editor



Vector Diagnosis of Patient Conditions in Telemedicine. Conceptualization.

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DOI: 10.25929/v1aerr18

ABSTRACT

Telemedicine is a rapidly growing field in healthcare, offering wide-ranging opportunities to address various challenges faced by healthcare workers and patients. Despite its many benefits for both patients and healthcare providers, there are still a number of unresolved issues. This study aims to explore the potential of telemedicine by conceptualizing it as the interplay of two vectors: the patient's condition and technological readiness for consultation.

Research Objectives. The patient's condition vector includes physiological, biochemical, and clinical indicators. The technological readiness vector is defined by the treating physician's competence, the consultant's expertise, modern information processing capabilities, and the availability of necessary time, among other factors. **Conclusions.** 1. Telemedicine consultations require a robust real-time medical data management system that allows consultants and attending physicians to efficiently process data, retain validated data for patient-specific recommendations, and enhance the global telemedicine framework with decision-making expertise. 2. Integrating big data analytics can improve the prediction and identification of disease diagnoses and prognoses, aiding in the development of effective strategies for complication prevention and disease treatment. Real-time communication with each patient and complex data processing can only be achieved through artificial intelligence. Manual intervention is insufficient for serving thousands of users simultaneously. 3. It's crucial during telemedicine consultations to consider not only the static indicators of the patient's condition but also their baseline data, stable condition indicators from previous studies, and personalized correlation galaxies. Recommendations based solely on the analysis of the patient's status during the telemedicine session risk incorrect conclusions. 4. Biosemiotics, which focuses on the language and rules of signals and codes in biological systems, combines ideas from systems theory, information theory, and linguistics. This integration may offer a new perspective on the classification and interpretation of biological and medical signaling. A coherent theory of biosemiotics needs to be developed.

KEYWORDS

Telemedicine, transdisciplinary approach, vector diagnosis of patient conditions, data discrimination, information asymmetry, big data, error by omission, data envelopment analysis (DEA)

1. Introduction

The rapid advancement of diagnostic technologies presents a new challenge: the emergence of decision-making difficulties caused by inaccuracies in patient treatment procedures. These procedures become more complex with the introduction of telemedicine technologies. Common issues include data discrimination, information asymmetry, and missed opportunities for early diagnosis, which are widespread and resource-draining, but often receive little attention.

It is important to note that organizational culture transforms with the implementation of telemedicine. Motivating involved parties is a crucial component of the procedure. Patients often interact with various service providers within a healthcare organization, so telemedicine should promote a team-centric approach to coordinated care. Coordination is a key healthcare advantage as it eliminates geographical barriers that hinder communication between providers and patients.

2. Research Objectives

This study explores the potential of telemedicine as the interplay of two vectors: the patient's condition and technological readiness for consultation.

An additional objective is to identify the role of anamnestic data, the persistence of stable conditions amidst the dynamics of the pathological process in a specific patient, and the enduring symptom correlations manifesting as correlation galaxies.

The final objective is to establish a strategy for a secure and effective medical data management system within telemedicine technologies to ensure accurate diagnosis and prognosis.

3. Results Obtained

Telemedicine is defined as the provision of healthcare services by any healthcare specialist in situations where distance is a critical factor, using information and communication technologies (ICT).¹ It is used for the exchange of reliable information for diagnosis, treatment, prevention of diseases, research, assessment, and continuous education of healthcare professionals to strengthen individual and societal health.

The concept of information asymmetry (INAS) refers to an unequal distribution of information among participants in the treatment-diagnostic continuum. One entity may have more knowledge or understanding regarding diagnostic and treatment processes than the other. The concept was first defined within the healthcare domain by K. Arrow in 1963.²

Attention should be paid to six technologies where data discrimination threats are particularly significant.³ These technologies, which will impact medicine over the next decade, include molecular diagnostics, image analysis, robotics, information management, and artificial intelligence.

The use of telemedicine has seen rapid growth and expansion. Although the feasibility of many applied programs has been tested for almost 50 years, discussions about regulatory support, clinical effectiveness, and cost optimality in telemedicine are still lively.⁴ This is partly due to a long list of technological challenges, including interactive patient involvement (e.g., mental health-related requests), information asymmetry, examination data discrimination, missed diagnostic opportunities, and the safety and effectiveness of new telemedicine technologies (e.g., robotics, virtual reality). Unresolved issues also include the use of anamnestic information (due to semantic difficulties), the logic of operational image processing, and more.

The difficulties in telemedicine have led to the development of a new concept for remote patient consultation. This concept is based not on patient symptoms, but on identifying stable (or unstable) states (clusters) of the organism. The patient's trajectory is considered in three distinct phases:

1. Pre-transition, demonstrating high stability;
2. Critical, characterized by a certain instability and signaling impending adverse consequences (e.g., complications, exacerbation of a painful condition);
3. Post-transition, with increased stability after the transition.

Strategically, the telemedicine consultation procedure is viewed as the interaction of two vectors: the patient's condition vector and the technological readiness vector. The patient's condition vector covers physiological, biochemical, and clinical indicators, while the technological readiness vector is determined by organizational factors such as the attending physician and consultant's competence, modern information processing capabilities, and the availability of necessary time.

Note that the patient's state vector reflects the above steady state. Otherwise, a correction factor is introduced for the patient's state vector equal to the average Mahalanobis distance for all coordinates. The Mahalanobis distance is calculated as the distance of the real indicator (or a group of independent symptom complexes if a high correlation coefficient is determined between the symptoms included in the symptom complex) of the patient's condition from the mathematical expectation of its value in a multidimensional space determined by correlated (non-orthogonal) independent variables.

If the concern is the vector of technological readiness, its coordinates are determined by regulatory tables based on expert assessments. The extent to which various innovative technologies are used to enable evidence-based diagnostics to improve patient care is also determined. Expert assessments reflect the readiness of these technologies in terms of their effective integration and focus on patient care.

The experience of using telemedicine consultations clearly demonstrates significant problems associated with data processing. The integration of patient data (especially big data—indicators of instrumental studies), processing of various types of data (from batch to streaming), and their transformation for further use lack clear rules. The concepts of relevance, credibility, reliability, and persistence of information do not apply. This leads to many diagnostic errors, missed opportunities, and data discrimination.

Thus, it becomes obvious that the challenge of data management during telemedicine consultations goes beyond simply organizing medical data. Directed personalized integration and analysis of the information received about the patient's condition are required.

4. Factors Complicating Telemedicine Consultations

First, let us focus on data discrimination (DD) in diagnostic procedures. The underlying factors for this issue include a lack of widespread problem awareness, numerous complex elements contributing to diagnostic errors, and the absence of well-defined, generalized measurement strategies for evaluating the diagnostic process and its outcomes, primarily data discrimination. Additionally, the diagnostic process is a core physician responsibility, making diagnostic errors a delicate discussion topic. This necessitates a conducive, non-hostile culture promoting patient safety.⁵

A contributing factor to data discrimination is information processing, which requires scientists to convert survey data into formal computer code. However, the choice of target variable and class labels is inherently subjective. Moreover, there is a tendency for data to be distorted within the model.

Bias in data collection can arise from the under- or over-representation of certain groups and/or protected

classes in a data set, potentially resulting in unfair or unequal treatment of the data. Often, certain groups of data receive undue attention. This increased attention can sometimes trigger intentional misconduct.

If the training data includes biased or discriminatory cases, the system will perceive them as valid and reproduce the bias in its output. In this scenario, the phenomenon of "overfitting" can occur, where models become over-specialized based on the training data. Therefore, a constant search for the optimal decision rule is necessary, which can only be done by monitoring patient observations. We emphasize that it is impossible to implement simple decision-making during telemedicine consultation.

A few words need to be said about the features of DD in big data technologies. From this perspective, the notion of norm and adherence to this norm are pivotal, necessitating a clear differentiation between prevalent and legitimate issues, and more abstract concerns like the alteration of the concept of personal identity through "profiling or analysis," "datafication," "information society," and so forth.

5. Information Asymmetry

Information asymmetry should be distinguished from incomplete information. While parties may lack all necessary information, they may still operate on equal (or unequal) terms. Potential patients, and sometimes potential expert groups, often hide the true goals of their behavior and use almost any method to obtain certain (own) results. In outpatient care, patients often do not provide the physician with all the information relevant to a specific diagnosis or treatment.

In general, doctors have an advantage over patients because of the preponderance of information about the latter's state of health and knowledge of the most beneficial treatments. In addition, the degree of information and knowledge asymmetry, along with the cost of obtaining relevant information, is likely to increase as the patient's health deteriorates.

Solving the problem of asymmetry of information and knowledge is one of the significant advantages of the introduction of information technologies in the field of healthcare. Currently, in many developed national health services, large eHealth infrastructures and systems are seen as central to the future provision of safe, effective, high-quality, and citizen-oriented health care. ⁶

Asymmetric information between different parties at successive levels of the healthcare system makes it reasonable and even necessary to incentivize entities holding private information in the form of information rents. However, the most important finding of this analysis is that if there is a two-way information asymmetry between the parties to a transaction at different levels (i.e., low levels of trust between the parties to the transaction), then the incentive system between service providers and buyers (i.e., hospital or government institution) turns out to be perverted. In this case, ⁷ it is called a perverse incentive system because it punishes an effective doctor or medical institution and rewards an ineffective one.

Data processing and reasoning techniques frequently exhibit a bias towards "middle" or dominant groups. This is particularly noticeable during surveys. The entire testing concept reinforces this, as average results (like the frequency of a certain effect) are extrapolated to the broader audience. Even with meticulous segmentation during testing, the ultimate "success" metric is derived from data decisions based on averages. However, relying on averages emphasizes a generalized "ideal" customer, which, at best, mirrors only a segment of the user's preferences.

The swift advancement of diagnostic technologies engenders a new issue – the onset of errors in decision-making due to inaccuracies in patient examination procedures. Among the global problems in organizing telemedicine consultations are diagnostic errors (DE) associated with the initial examination of patients, that is, before the actual telemedicine session. They are alarmingly common and harmful, but unfortunately receive insufficient attention in the field of patient safety. Diagnostic errors, including

inaccuracies, delays, or omissions in communication with patients, can lead to an escalation of morbidity, especially in children.

Even often, diagnostic errors are associated with the lost capabilities of different diagnostic methods, so named missed opportunity for diagnosis (MOD). "Error by omission" epitomizes a form of informational processing function misspecification, arising when discriminatory terms are overlooked or unaccounted for in the model. In essence, this implies the model neglects to consider the variances in algorithmic classification between protected and unprotected classes. These processes are recognized to be insufficiently studied in pediatrics, which gave rise to the European RedDE project. ⁸ National studies showed that DE or MOD rates in pediatric primary care became 54% for patients with advanced arterial pressure (n = 389), 11% for patients with pathological laboratory indicators (n = 381), and 62% for subjects building assessments presence of depression (n = 400).

According to a recent study published in the Journal of the American Academy of Pediatrics, pediatricians frequently report misdiagnoses and mistreatment of children that lead to chronic illness. Diagnostic errors are widespread in pediatric practice, and the error rate in these areas reaches 62%. More than 54% of licensed pediatricians know that diagnostic tests are performed once or twice a month. ⁸ The most common errors in pediatric patients were missed or inaccurate diagnoses for the following conditions: viral and bacterial diseases; appendicitis; mental disorders; increased blood pressure; side effects from drugs; and false or inaccurate results of laboratory tests. ⁹

In particular, refusal of screening (68%) is the most common reason for missed adolescent depression. For missed hypertension, it was the inability to recognize (36%) and act on abnormal blood pressure values (28%). For "missing laboratory data," common scenarios included failure to notify families (23%) and document action (19%) regarding abnormal results. ¹⁰

6. Routine Telemedicine Challenges

1. **Image Quality and Resolution:** Telemedicine consultations require substantial bandwidth to ensure the video image's resolution and quality, as a low-resolution video is inadequate for medical purposes.
2. **Data Security and Interoperability:** The second challenge arises from the need to secure and enable interoperable patient examination data, particularly when multiple healthcare organizations are simultaneously engaged in telemedicine consultations.

Recently, assessing the effectiveness of telemedicine consultations has become an urgent problem. Various methods are used. A popular approach is based on the construction of the so-called efficiency frontier. ¹¹ Associated with this concept are concepts such as the technological possibility frontier and the production function. The DEA method has a number of properties that are important for the practical application of telemedicine technologies: ^{12,13}

- allows you to calculate one aggregate indicator for each object in terms of the use of input factors (independent variables) to produce the desired output characteristics (dependent variables);
- can simultaneously process many inputs and many outputs, and each of them can be measured in different units of measurement;
- allows you to take into account variables external to the system under consideration – environmental factors. In other words, it is ideal for the two-factor approach proposed in this study;
- does not require a priori indication of weighting coefficients for variables corresponding to input and output parameters when solving the optimization problem;

- does not impose any restrictions on the functional form of the relationship between inputs and outputs;
- allows, if necessary, to take into account managers' preferences regarding the importance of certain input or output variables;
- forms a Pareto-optimal set of points corresponding to efficient objects. Note that the DEA method allows us to take into account the presence of environmental variables, i.e., variables that influence model calculations, but which cannot be influenced within the framework of the task being solved. Such variables cannot be classified as ordinary input variables since they cannot be controlled by the decision-maker (DM). Examples include climatic conditions in a given territory, the level of health of an individual (in the short term), concomitant diseases, etc.

7. Data Management in Digitalization Processes in Medicine

Modern data management methods are based on transdisciplinary foundations. A transdisciplinary approach in telemedicine underscores evolutions in data processing, grounded on novel elements of information theory. These elements spawn subsets of medical language, forming the foundation of telecommunications, biomedical data processing, and biomedical signaling. They further propose a metric for gauging the efficacy of health monitoring endeavors.

Biological and medical semiotics delve into the language and rules governing signals and codes within biological and medical systems. This field amalgamates insights from various domains including systems theory, information theory, and linguistics. Consequently, biomedical semiotics furnishes a fresh perspective on both the categorization and interpretation of biological and medical signaling, along with the errors tied to data discrimination.

8. Conclusions

1. Telemedicine consultations require a robust real-time medical data management system that allows consultants and attending physicians to efficiently process data, retain validated data for patient-specific recommendations, and enhance the global telemedicine framework with decision-making expertise.
2. Integrating big data analytics can improve the prediction and identification of disease diagnoses and prognoses, aiding in the development of effective strategies for complication prevention and disease treatment. Real-time communication with each patient and complex data processing can only be achieved through artificial intelligence. Manual intervention is insufficient for serving thousands of users simultaneously.
3. It is crucial during telemedicine consultations to consider not only the static indicators of the patient's condition but also their baseline data, stable condition indicators from previous studies, and personalized correlation galaxies. Recommendations based solely on the analysis of the patient's status during the telemedicine session risk incorrect conclusions.
4. Biosemiotics, which focuses on the language and rules of signals and codes in biological systems, combines ideas from systems theory, information theory, and linguistics. This integration may offer a new perspective on the classification and interpretation of biological and medical signaling. A coherent theory of biosemiotics needs to be developed.

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Medical Data Compatibility Problems in the Tasks of Information Systems Integration. Conceptualization.

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DOI: 10.25929/695sar10

ABSTRACT

Integration of medical data is a critical component of the functioning of modern healthcare systems and a primary task of personalized medicine. Aggregating data from disparate sources, such as electronic medical records and medical devices, allows service providers to obtain a complete picture of patients' health status and optimize workflows.

It is noted that the strategy of integration is closely linked with the logic of medical data compatibility. The problems of integration also reflect in the tasks of creating Portfolios for physicians and pharmacists. Research objective. Summary of biomedical data compatibility issues. It is emphasized that data compatibility depends on the consistency of standards applied in programs. The quality of data also requires special attention. This directly affects the quality of the decisions made. Although data interoperability is one of the primary requirements of information and communication systems (ICS), it is often overlooked. As a result, data exchange is not performed, significantly limiting the flow of information. The problem of large dimensionality is also serious. It is evident that such multidimensional and labor-intensive computational processes are a primary task for modern algorithms and models of artificial intelligence (AI) and machine learning (ML).

It is highlighted that one of the ways to solve the problems of standardization and integration of large-scale medical data are metadata, which are also useful for improving statistical analysis, probabilistic models, and ML models. Conclusions.

1. Precision Medicine (4P Medicine) was introduced as a new paradigm approach to healthcare with a more predictable, preventive, personalized, and participatory manner. Precision medicine is closely related to data-intensive approaches, as well as to ML and AI. 2. Integration of data for placement in structures useful for precision medicine is only possible after several previous stages of their processing, namely: data (metadata) collection, processing, obtaining 'clean' data, data compression. 3. To realize the prospects of precision medicine, approaches to computational learning must evolve with the help of well-chosen and well-integrated digital data ecosystems.

KEYWORDS

Integration of medical data, interoperability of medical data, Portfolio of doctors and pharmacists, information and communication systems, 4P Medicine, interoperable data standards, metadata

1. Introduction

The primary goal of precision medicine is the aggregation and integration of extensive arrays of diverse data into analytical structures that enable the development of individualized, context-dependent diagnostic and therapeutic approaches. In this regard, artificial intelligence (AI) and machine learning (ML) approaches can be used to construct analytical models for complex diseases and be utilized in predicting personalized health outcomes.¹

Computational approaches in medicine are characterized by large datasets that combine both structured and unstructured formats. Clinical and biomedical data offer a wide selection of shapes and formats, sizes, complexity levels, and are often poorly annotated and unstructured, creating heterogeneity in many situations. For instance, various types of variables (different encoding), different datasets (electronic health records [EHRs] from different hospitals), inconsistent distributions or scaling, diverse modalities of data (continuous signals, intervals, categories, etc.), and different formats (various standards of medical reporting). Each of these issues poses a challenge for effective modeling using AI and ML.

A range of problems also arises in analyzing medical data in modern personalized medicine settings, depending on time, available computational power, and bioethical constraints. One of the primary challenges in deriving knowledge from electronic medical records is that they represent extremely heterogeneous data sources with complex arrays of quantitative, qualitative, and transactional data. Different types of data include ICD (International Classification of Diseases) codes, biochemical and laboratory analyses, clinical (textual) notes, historical archives of medical interventions, treatment methods. These data sources are often collected by dozens of people, separately for each case, making the data from Electronic Health Records (EHR) quite challenging to analyze. EHRs were not designed as a resource for automated learning; hence the data structures representing information for preservation were not considered during their usage. As EHRs are primarily adapted for clinical and hospital logistics, modeling such data and training AI algorithms based on them often encounter problems related to structural heterogeneity or issues of adaptation through existing strategies or by redesigning these medical records.^{2,3} The problem of dimensionality is also significant. The dimensionality problem is particularly evident in the case of genomic and transcriptomic analysis, where the number of genes or transcripts is about tens of thousands, while the number of samples seldom exceeds a few hundred or a few thousand.

2. Research objective

Summarize the problems of compatibility of biomedical data. Our work is aimed at presenting general options for approaches to overcoming these problems by applying machine learning and artificial intelligence to analyze biomedical and health-related data in the context of precision medicine. The methodological basis of the study is the conceptualization of contemporary problems of ensuring the compatibility of biomedical data.

3. Discussion

Since the late 20th century, the field of medicine and healthcare has employed an approach to the proper verification of existing clinical and biomedical research, known as evidence-based medicine (EBM). It aims at the comprehensive utilization of confirmed accumulated scientific and clinical data for the development of health-related measures and policies. With the emergence of large, qualitatively selected data arrays obtained from large-scale clinical trials (large-scale data analytics, LSDA) and powerful methods of such data analysis as well as the development of mechanisms for converting them into useful information, the ideals of EBM have been incorporated into Precision Medicine.⁵ Later, biological databases were added to such data, which include individual EHR data as well as social information (social determinants of health).^{6,7}

Advancements in artificial intelligence play a central role in the development of such integrated structures. Data integration indeed is a highly complex task. The ability to perform complex queries, construct heterogeneous models, and develop hierarchically nested data search operations in multiple databases is the primary goal of data integration strategies, useful for artificial intelligence and machine learning models in precision medicine.

The necessity of exchanging clinical research data to ensure the reproducibility of results, plan subsequent research stages, perform quantitative comparisons of diagnostic or treatment methods' effectiveness, accelerate the reporting of results, and ensure continuous medical education becomes evident. Optimal utilization of shared data is associated with the need for their standardization, which becomes a central task in both medical research and personalized clinical practice.

In resolving issues of standardization and integration of large-scale medical data (LSDA), metadata have become a central element in modern solutions, which can help to ensure efficient exchange, analysis, and usage of information in healthcare. For this reason, the aspiration to create high-quality, well-formatted, and standardized metadata has become highly relevant.⁸

Metadata also prove useful in enhancing statistical analysis, probabilistic models, and ML models. The use of metadata can improve query optimization through resampling and initial loading, standardization of data sets, and as an auxiliary source for multi-dimensional Bayesian analysis, and analysis of datasets with different dynamic ranges.⁹⁻¹²

Integration of multiple data sources and metadata further requires the design, development, and implementation of analysis algorithms capable of processing heterogeneous data in conditions of noise accumulation, false correlations, and random endogeneity, while maintaining a balance between statistical accuracy, computational efficiency, and interpretability. Addressing such issues may require new models for the implementation of metadata reporting standards.

Standardization of the method of presentation and acquisition of metadata in biomedical and clinical settings is critically important for the development of comprehensive machine learning approaches that fully utilize these unified data structures.¹³

The current development of complex and quite effective AI algorithms and the accompanying proliferation of large-scale data sources in biomedical conditions have heightened expectations regarding the many potential benefits that can be derived from the combination of "good" methods and "good" data ("clean" data). However, to make these large volumes of data useful for creating high-quality artificial intelligence models, it is necessary to address not only the dimensionality challenge. There's a need to create a system of "clean" data that can amalgamate diverse sources, technologies, infrastructures, and processes for the collection, storage, processing, analysis, and utilization of medical data in a specific organization or in the industry as a whole. Such systems are called digital data ecosystems.



Figure 1. Digital data ecosystems.

A data ecosystem creates a conducive environment for data management and utilization in making informed decisions, refining processes, and achieving strategic goals. It consists of various elements such as software, hardware, data, and people, fostering communication and collaboration at different stages.

In the context of healthcare, a digital data ecosystem can also denote a set of digital platforms and technologies used for interaction with doctors, patients, and other stakeholders based on prepared data of any nature and origin. The digital ecosystem should eliminate barriers in the diagnosis and treatment of patients and enable each participant to utilize the most advanced technologies and systems to meet their needs.

Conclusions.

1. Precision Medicine (4P Medicine) is introduced as a new paradigm approach to healthcare, characterized by more predictive, preventive, personalized, and participatory methods. Precision Medicine is closely linked with data-intensive approaches, as well as with ML (machine learning) and AI (artificial intelligence).
2. The integration of data for placement in structures beneficial for precision medicine is only possible after several preceding stages of data processing, namely: data (metadata) collection, processing, obtaining "clean" data, and data compression.
3. To realize the prospects of precision medicine, approaches to computational learning must evolve with the help of well-selected and well-integrated digital data ecosystems.

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A Scoping Review of the Role of Clinical Decision Support Systems in Intensive Care Units during the COVID-19 Pandemic

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DOI: 10.25929/ezsh8p05

ABSTRACT

During the COVID-19 pandemic, clinical decision support systems (CDSS) have been increasingly instrumental in reshaping the intensive care unit (ICU) landscape. This paper highlights the importance of CDSS in improving healthcare professionals' decision-making processes by examining their numerous contributions to the management of critically ill patients.

This scoping review comprised information concerning the role of CDSS in ICUs during the COVID-19 pandemic and lessons for the future of public health care (PHC). The identified literature was published during the COVID-19 peak years (2019–2023), retrieved from the Cochrane Library, Embase, Medline, PubMed, CINAHL, Google Scholar and Scopus. A set of predefined inclusion criteria were used, then thematic analysis was applied. The reporting followed the PRISMA guidelines for scoping reviews.

A total of 9 studies were included in the final synthesis (all articles). These studies examined various aspects of the role of CDSS in ICUs during the COVID-19 pandemic. The scoping review was comprehensive and focused on the emerging topic of discussion but lacked risk of bias assessment.

In the midst of the COVID-19 pandemic's unparalleled obstacles, CDSS in ICUs became a vital resource for medical professionals. These technologies help physicians diagnose, treat, and manage COVID-19 patients by using innovative algorithms and real-time data analytics. Early identification, monitoring, timely alarms, and insights into patients' changing clinical status are some of the most crucial functions of CDSS. This capacity was vital in quickly recognising conditions that were getting worse, facilitating quick action, and enhancing patient outcomes.

Additionally, CDSS in ICUs proved effective in therapy guiding, providing evidence-based suggestions for therapeutic approaches. Through the integration of patient information, test findings, and established procedures, these systems enabled tailored and efficient treatment, guaranteeing that medical interventions corresponded with the dynamic course of the illness. Moreover, CDSS helped with risk classification, which enabled medical practitioners to carefully manage resource allocation and customise interventions based on the unique profiles of each patient.

Through the reduction of errors and improvement of patient safety, CDSS was significant in the field of drug management. These technologies met the vital requirement for accuracy in COVID-19 patient care by providing notifications for drug interactions, dosage modifications, and medication administration. The extensive capabilities that were required in the ICU highlight the revolutionary influence on healthcare delivery that CDSS have. CDSS was invaluable in navigating the challenges of caring critically sick patients in the demanding setting of the global health crisis by integrating evidence-based practices, optimising resource utilisation, and offering real-time decision support.

KEYWORDS

Clinical decision support systems, clinical decision support, patient outcomes, COVID-19, intensive care unit

1. Introduction

In order to optimise the delivery of healthcare, CDSS became essential, especially in intensive care units (ICUs) during the COVID-19 pandemic. Healthcare practitioners can make well-informed decisions about diagnosis, treatment, and management with the help of these technologies that combine medical knowledge with patient data. ¹⁻³ Personalised treatment, risk assessment, and early detection of COVID-19 patients were made possible by CDSS in ICUs through the use of algorithms and data analytics. ³ These solutions improved clinical outcomes, expedited workflows, and supported more effective resource use in critical care settings by offering real-time assistance. This paper will explore the role of CDSS in the ICUs during COVID-19.

2. Background

Decision support systems are used to support business operations and management while CDSS are a variation of a decision supports system using computerised clinical knowledge management to make decision for quality care and patient safety. ⁴ An overview of some further applications of decision support systems is listed in Table 1.

Table 1: Overview of some applications using decision support systems.

<i>Field</i>	<i>Example</i>
Healthcare	Assist healthcare professionals in diagnosis, treatment, and patient management, ensuring evidence-based care delivery
Business and finance	Business support strategic planning, financial analysis, market forecasting, and risk management, aiding in informed decision-making
Supply chain management	Optimise inventory control, logistics, and supply chain operations by analysing data and predicting demand, ensuring efficiency

Agriculture	Aid farmers in crop management, irrigation scheduling, pest control, and predicting crop yields based on weather and soil data
Environmental management	Help in environmental monitoring, resource allocation, and policy planning by analysing ecological data and simulating scenarios
Education	Assist in curriculum planning, student performance analysis, and adaptive learning, enhancing teaching strategies and student outcomes
Transportation and logistics	Optimise route planning, fleet management, and transportation scheduling, reducing costs and improving efficiency
Military and defence	Aid in tactical planning, intelligence analysis, mission planning, and supporting military operations
Marketing and customer relationship management (CRM)	Assist in market segmentation, customer profiling, and personalised marketing strategies based on data analysis
Energy management	Optimise energy distribution, resource allocation, and demand forecasting in the energy sector, promoting sustainability

CDSS are utilised in clinical settings to help physicians, nurses and allied health professional make evidence-based decisions at the right time that improve clinical performance and patient care. ^{5,6} CDSS find widespread application across various healthcare domains and are commonly administered through electronic patient records. ⁷ Table 2 lists some of the clinical uses of CDSS in healthcare.

Table 2: Clinical uses of CDSS in healthcare.

- Clinical uses of diagnostic support: Assisting in differential diagnosis by analysing symptoms, patient history, and test results
- Drug interaction and prescription assistance: Alerting healthcare providers to potential drug interactions, allergies, and suggesting appropriate medications
- Therapeutic decision support: Providing guidance on treatment options and protocols based on patient data and evidence-based guidelines
- Chronic disease management: Supporting long-term care plans and monitoring for chronic conditions such as diabetes, hypertension, etc.
- Imaging interpretation: Assisting radiologists in interpreting medical images (e.g., X-rays, MRIs) for accurate diagnosis
- Clinical documentation and reporting: Aiding in accurate and timely documentation of patient information and generating reports
- Alerts and reminders: Notifying healthcare professionals about critical events, overdue tasks, or necessary interventions
- Surgical decision support: Offering guidance in surgical planning, risk assessment, and post operative care

3. Methodology

The scoping review is a literature review conducted to create an overview of the existing published works on the role of CDSS in ICUs during the COVID-19 pandemic. A scoping study was more appropriate than a systematic review, with focused research questions and a strict quality filter, because it is a recent topic and there was a need to evaluate what literature was available. This scoping review followed the methodology developed by Arksey and O'Malley⁸ with the adoption of some of the recommendations of Peter et al.⁹

A scoping review of existing literature on the use of CDSS in the ICU was conducted to answer the following three research questions:

1. What types of CDSS were used in ICUs to monitor the COVID-19 pandemic?
2. What were the impacts of the use of CDSS in the ICUs during the COVID-19 pandemic?
3. What are the effects of integrating CDSS with Electronic Patient Records EPR in ICUs during the COVID-19 pandemic?

Review technique

A comprehensive scoping review was implemented to gather information from various sources, including electronic databases, reference lists, and non-traditional or grey literature. The databases of the Cochrane Library, Embase, Medline, PubMed, CINAHL, Google Scholar and Scopus were searched using combinations of the following keywords: (*CDSS or clinical decision support systems*) and (*ICU or intensive care unit or critical care facility or medical crisis unit or critical care units or intensive therapy units or high dependency care or high dependency unit or ITU or HDU*). The search was conducted from December 2019 up to February 2024. The selection of the articles followed the PRISMA 2020 flow.

To standardise the research thoroughly, this process involved the six essential stages suggested by the Arksey and O'Malley Framework:

A. Identification of the research question

The Levac et al.¹⁰ and Peter et al.⁹ school of thought that advocated the inclusion of consultations in scoping reviews was implemented for this review. These consultations are to enable the comprehensiveness and relevance of the review process, thereby validating findings, improving the interpretation of results, and enhancing the applicability of the review findings in real-world settings. Two sets of stakeholders consultations involving staff from three National Health Service (NHS) trusts (provider organisations) in the United Kingdom were conducted to elicit information on the use of technology by the NHS during the COVID-19 pandemic. The first consultation included stakeholders involved in the use of technology in the NHS. A snowball sampling technique was used to include participants for the study. A total of six members of medical personnel participated in the consultation. The second consultation involved stakeholders from three local NHS trusts (provider organisations).

B. Discovery of relevant literature

The articles were first selected based on title and abstract, then the full texts of those that were tentatively relevant were retrieved.

C. Choosing relevant studies

The full texts were then screened using the inclusion criteria for the study in EndNote. Inclusion criteria

for this review included all publication types including articles, books, and reviews clearly defining “any technology used in monitoring all aspects of healthcare during COVID-19 outbreak in hospitals”; published and accepted but not yet published review articles, original research articles, meta-analyses, reports and guidelines published in English language; studies on healthcare information technology and healthcare delivery during the COVID-19 pandemic, adoption of technology in the health sector, impact of technology in decision-making process in the health sector during the COVID-19 pandemic, the adoption, use and efficiency of technology during the COVID-19 pandemic that cited technologies used to combat COVID-19. Only literature published since 2019 until February 2024 was included in the study because the pandemic started in December 2019.

D. Mapping out the data

Details of selected papers such as author, year of publication, country of publication, type of publication, the main aim and objective of the study and key findings that are related to the scoping review questions were all recorded. The recorded data was charted and classified using main themes to organise the major findings. A formal quality appraisal was conducted using the JBI appraisal checklist for systematic reviews and research syntheses. The reporting of the findings of this review followed the PRISMA-ScR formulated by Tricco et al.^{10, 11}

Realist Evaluation

The goal of realist evaluation is to comprehend the intricate interrelationships between these mechanisms and how context affects their operationalisation and result. The formula for this is context + mechanism = outcome. After that, this is shown as a context–mechanism–outcome (CMO) configuration. Realist analysis uses the CMO configuration as its primary structural model. The selected articles were analysed using realist evaluation theory to find the underlying causal mechanisms that explain how the intervention in the use of CDSS in the ICU during the COVID-19 pandemic works, who it benefits, and under what circumstances the focus of realist evaluation is.

4. Results

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

The EndNote software was used to manage the search results, and duplicates were manually eliminated and double-checked. Two steps were taken in the selection of studies: abstract screening and full text evaluation based on the predetermined exclusion and inclusion criteria.

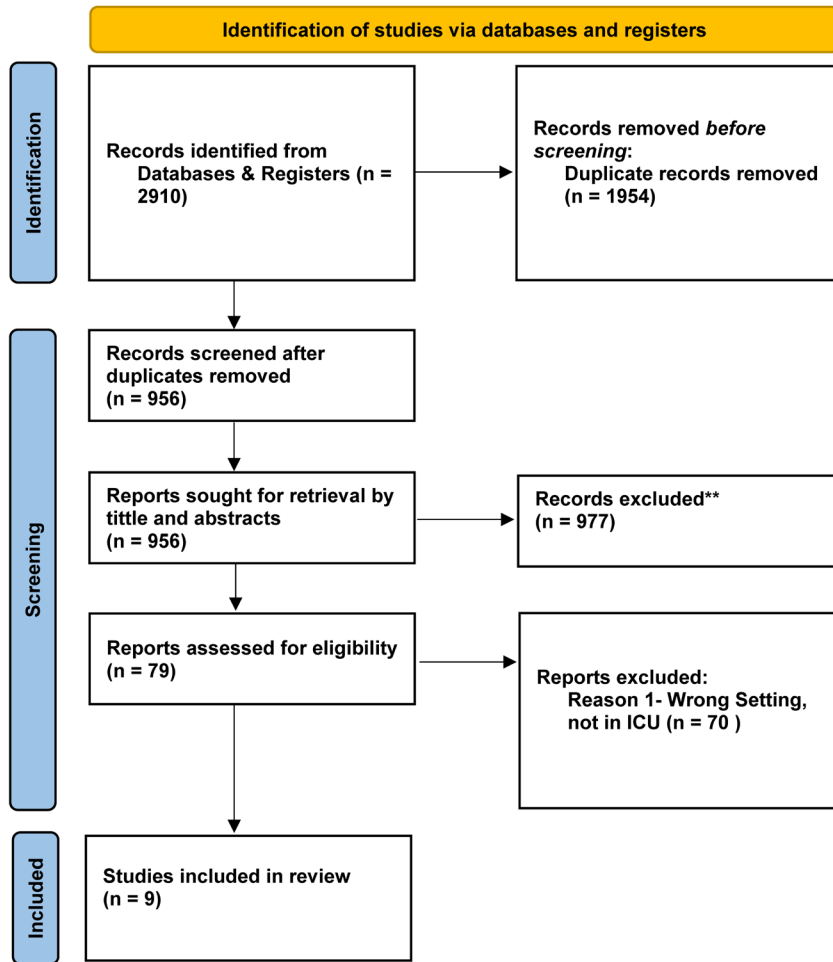


Figure 1. PRISMA Flow diagram of literature search.

At the end of the searches 2,910 articles were retrieved, including 1,954 duplicate articles and 956 unique articles. 977 articles were not eligible based on the inclusion criteria. After further screening, 70 articles out of the remaining 79 were excluded. Reasons for exclusion include: the non-availability of the full text, some articles did not discuss the use of CDSS in monitoring COVID-19 and some records discussed non-ICU use of CDSS during the COVID-19 pandemic. Data were extracted from 9 articles that meet the inclusion criteria (Figure 1).

Study characteristics

Overall, 9 studies were included from the scoping review papers to develop the programme theory and CMOs for the rapid realist review. The main characteristics includes the authors, year, country of origin, and topic of each document. This are listed in table 3 below.

Table 3: Scoping review documents used in the rapid realist review.

Author and Year	Country	Topic of paper	Study design
1. Martín-Lázaro et al. ¹²	United Kingdom	Clinical decision support systems in critical care during the COVID-19 pandemic	Case study
2. Sutton et al. ⁷	Canada	An overview of clinical decision support systems: benefits, risks, and strategies for success	Literature review
3. Deif et al. ¹³	Thailand	Automated triage system for intensive care admissions during the COVID-19 pandemic using hybrid XGBoost-AHP approach	Quantitative model developed with data from Kaggle online resource to Sirio Libanês, an elite hospital in Brazil
4. Jansson et al. ¹⁴	Finland	Artificial intelligence for clinical decision support in critical care, required and accelerated by COVID-19	Editorial
5. Murri et al. ¹⁵	Italy	A real-time integrated framework to support clinical decision making for COVID-19 patients	Quantitative model developed in SAS Software
6. Karthikeyan et al. ⁶	India	Machine learning-based clinical decision support system for early COVID-19 mortality prediction	Quantitative – time series
7. Shah et al. ¹⁶	USA	Implementation of an anticoagulation practice guideline for COVID-19 via a clinical decision support system in a large academic health system and its evaluation: observational study	Observational study
8. Moulaei et al. ¹⁷	Iran	Diagnosing, managing, and controlling COVID-19 using clinical decision support systems: A study to introduce CDSS applications	Literature review and questionnaire
9. Ameri et al. ¹⁸	Iran	Clinical decision support systems (CDSS) in assistance to COVID-19 diagnosis: A scoping review on types and evaluation methods	Scoping review

A. Types of CDSS in the ICU

CDSS applications are categorised in 4 classes: “diagnosis”, “medication”, “monitoring”, and “health services”.¹⁷ CDSS can then be further categorised based on five distinct characteristics including mode of advice provided, style of communication, core decision-making process system function, human computer interaction and underlying model for giving advice.^{7,19}

In a scoping review of the usefulness and efficacy of CDSS in identifying and diagnosing COVID-19, the results showed that the CDSS based on machine learning (ML) was the most often used approach for this purpose, ahead of those based on expert systems (ES). It was discovered that knowledge-based CDSS (ES) and non-knowledge-based CDSS (ML) both contributed significantly to the accurate diagnosis of COVID-19.¹⁸

B. Benefits of CDSS during the COVID-19 pandemic

CDSS have always been useful in hospitals for supporting clinical decisions, yet healthcare professionals have never used it in such proportions as demanded during the COVID-19 pandemic. This led to some innovative CDSS applications that were flexible, saved time, enabled collaboration, and were target-driven while allowing clinicians to make better decisions.^{2,17}

CDSS were used as evidence-based tools^{20,21} for early mortality prediction,⁶ severity risk prediction and triage on admission,²² elective operations resource utilisation,²³ deployed to direct hospital frontlines and healthcare administrators in making informed decisions about patient care and hospital volume plan.²⁴ The COVID-19 pandemic prompted activities to collect and consolidate patient data, yet the substantial volume of newly acquired data necessitated ongoing quality assurance measures to guarantee the attainment of desired outcomes.²⁴

CDSS have also been used in emergency departments where it has been very impactful in bringing about significant improvement in care delivery.²⁵ CDSS are known to permit non-clinical staff along with clinical staff, to conduct thorough clinical assessments of phone callers to emergency and urgent care services.^{26,27}

In a study that addressed the challenge of exceeding ICU and ventilator capacity during the COVID-19 pandemic despite healthcare systems prioritizing admissions, CDSS was used to create a classifier model predicting ICU necessity based on 38 commonly used clinical variables such as blood test, liver function, kidney function, vital signs, blood gas analysis, etc. and also to allocate importance to these variables using the Shapley value and weighting them through the analytic hierarchy process (AHP), facilitating the prioritisation of patients for ICU admission based on risk levels.¹³ AHP is a time-constrained decision-making model, while the Shapley value aids interpretability in predictive models²⁸ and constitutes the average marginal contribution of a feature value across all possible coalitions.²⁹

Programme theory development

Before the onset of the COVID-19 pandemic, a considerable number of up to 20 million individuals annually necessitated ICU admission and mechanical ventilation (MV). In response to the pandemic, the demand for critical care services has undergone an exponential increase. Faced with this "new reality", ICUs and emergency departments (EDs) underwent a redesign.¹⁴

Table 4 shows the context, mechanisms, outcomes CMOs constructed for this study taken from the 9 documents that best illustrate CMO relationships.³⁰⁻³²

The use of CDSS in ICUs

Intervention	Context	Mechanism/Resource	Outcome
CDSS was used in admitting to the ICU	The input of triage committees are timely but traditional tools such as Sequential Organ Failure Assessment SOFA are obsolete	There was an urgent need for a COVID-19 disease severity assessment that can assist in critical care in resource allocation for patients at risk for severe diseases	CDSS reduced the burden of decision-making placed on clinicians
The referral of a patient for ICU care triggered complex triage (prioritisation) decision-making when ICU beds are limited	CDSS was expected to increase objectivity and transparency in triage decision-making, and helps to enhance consistency between doctors both within and across ICUs	The complexity of the decision-making process and the multiple factors that require careful consideration requires the final decisions to be made by an experienced ICU doctor.	Junior doctors be trained to read CDSS for assistance to guide and enhance consistent and justifiable decision-making in uncontrollable circumstances when experienced doctors are not available
The sudden increase in patients with severe COVID-19 has obliged doctors to make admissions to ICUs in healthcare practices where capacity is exceeded by the demand.	The CDSS is proposed to aid healthcare professionals in prioritising patients infected with COVID-19 based on the results of biological laboratory examinations, provide the desired intensive care facilities, and to manage patients' health conditions by indoor healthcare providers	CDSS classified patients in a dataset into patients with COVID-19 who need ICU admission and those who do not	The CDSS criteria weights determined which patients will use the ICU first during emergency or limited-resource situation
Over 20 million people annually require ICU admission and mechanical ventilation	Geolocated critical care demands prediction, optimal hospital resource planning, and intelligent patient flow management with decision support algorithms, which can be achieved by integrating real-time clinical data with population statistics and health interventions	Safe, effective, efficient, and ethical clinical management of COVID-19 patients in ICUs urgently requires integrating AI capabilities into CDSS at the patient bedside	Advances in the CDSS direction of predicting the entire temporal evolution of a patient used for developing personalised patient management and treatment plans

<p>The applications of a CDSS in the diagnosis, management, and control of COVID-19</p>	<p>Identify general, basic knowledge of the design and implementation of clinical decision support systems in the real world to prevent irreversible complications and even many persons' deaths</p>	<p>Classification of patients based on the severity of complications, signs and symptoms, global COVID-19 protocol, and CT images taken from damaged lung tissue (for hospitalization in the wards, ICUs, or home quarantine)</p>	<p>CDSS applications were categorised in 4 classes: "diagnosis", "medication", "monitoring", and "health services"</p>
<p>The high number of people with COVID-19 admitted to emergency rooms, general wards and ICUs critically stressed hospitals</p>	<p>Extensive amounts of data were quickly available for data monitoring, data analysis and clustering</p>	<p>Predictive models identified clinical criteria and laboratory values to safely allocate a person to common wards or to be discharged at home or to be de-isolated when probability of a COVID-19 diagnosis is poor</p>	<p>CDSS provided the opportunity to realise a real-world, readily available, interactive dashboard and to build sophisticated and advanced predictive models</p>
<p>The sudden spike in the number of COVID-19 infections and high mortality rates have put immense pressure on the public healthcare systems</p>	<p>It is crucial to identify the key factors for mortality prediction to optimize patient treatment strategy</p>	<p>Various ML models (neural networks, logistic regression, XGBoost, random forests, SVM, and decision trees) have been trained and their performance compared to determine the model that achieves consistently high accuracy across the days that span the disease</p>	<p>The best performing method using XGBoost feature importance and neural network classification predicts with an accuracy of 90%</p>
<p>Study evaluated strategies for the rapid development, implementation, and evaluation of clinical decision support (CDS) systems supporting guidelines for diseases with a poor knowledge base, such as COVID-19</p>	<p>Developed an anticoagulation clinical practice guideline (CPG) for COVID-19</p>	<p>Institutional experience demonstrated that adherence to the institutional clinical practice guideline (CPG) delivered via the clinical decision support (CDS) system resulted in improved clinical outcomes for patients with COVID-19</p>	<p>CDSS systems proved to be an effective means to rapidly scale a CPG across a heterogeneous healthcare system</p>
<p>Identifying and introducing CDSS applications to manage, control, and monitor the patients infected with COVID-19</p>	<p>CDSS with alert capabilities or recommendations for clinicians permitted decisions based on the known side effects of medications, their interactions, and potential contraindications</p>	<p>CDSS implementation has been associated with decreased unnecessary treatments and diagnostic costs, streamlined diagnostic processes, enhanced clinical performance, and improved patient-related outcomes.</p>	<p>The proactive identification, diagnosis, and treatment facilitated by CDSS contribute significantly to preventing the further spread of COVID-19</p>

C. Evaluation of the integration of CDSS with EPR

Studies on clinical decision support systems (CDSS) based on the integration with electronic patient records (EPR) in the ICU revealed high accuracy in decision making,^{17,18} however, questions about replacing these systems as clinician assistants in decision-making were raised due to concerns about the novelty and biases in the dataset.

Clinicians profited from an electronic patient record (EPR) that was properly deployed because it increased their productivity, streamlined their workflows, and gave them more visibility into their patients.

5. Discussion

Clinical decision support systems (CDSS) have been instrumental in alleviating the decision-making burden on clinicians, particularly in situations where experienced doctors are unavailable, thus facilitating consistent and justifiable decisions. It is imperative that junior doctors receive adequate training to effectively use CDSS, especially in navigating uncontrollable circumstances. Moreover, the determination of patient prioritisation during emergencies or limited-resource situations relies heavily on the criteria weights established within the CDSS framework.

Advancements in CDSS technology have enabled the prediction of patient outcomes, which in turn facilitates the development of personalised management and treatment plans. The applications of CDSS are typically categorised into distinct classes such as diagnosis, medication, monitoring, and health services, underscoring their multifaceted utility within healthcare settings. Furthermore, the potential of CDSS extends to the creation of interactive dashboards and the construction of sophisticated predictive models, thereby enhancing the efficacy of real-world clinical decision-making processes.

It is accepted that although EPR are seen to have valuable advantages, there remains significant capacity to improve clinicians' interaction and satisfaction with these systems. Some of the inadequacies identified by clinicians include human computer interaction – usability, systems navigation and information visualisation.³³ CDSS play a positive impact in medication safety and cost savings, but engagement of relevant stakeholders was deemed critical for the initial and sustained use of the technology.³⁴ The level of engagement with a mobile clinical decision support system by junior physicians was discovered to be reduced due to a number of cultural, institutional and individual barriers.³⁵

CDSS developers must collaborate with end users for a clear understanding of the clinic workflow pathway and provide users training to reduce the immense occurrence of false alerts which causes critical decision alerts to be ignored. There must be collaboration and synergy between hospitals and vendors/producers of CDSS solutions.³⁶

In conformity with other studies where CDSS are known to have been integrated with EPR despite interoperability issues to increase the acceptance by physicians there must adequate training and users input during development.³⁷ The need for CDSS systems development, procurement, and implementation to be tailored to the needs of users is regarded as user 'pull'.³⁶

6. Conclusion

Clinical decision support systems (CDSS) exert a significant impact within intensive care units (ICUs), notably in furnishing precise recommendations for patient management. The integration of CDSS with electronic patient records (EPR) amplifies its benefits in the ICU setting, thereby augmenting patient care and healthcare management. Ensuring seamless integration into EPR is imperative for CDSS, given the pivotal role of EPR as the principal data repository within the ICU.

The collective findings underscore the importance of leveraging the combined strengths of CDSS and EPR for improved decision-making, enhancing patient outcomes and healthcare efficiency in the ICU setting. Future research and implementation efforts should continue to explore and optimize this synergistic relationship for maximum benefit.

To enhance usability, ICUs should prioritise the implementation of explainable systems, adhering to the principles of explainable AI, and ensure adequate training and education for junior clinicians. This approach not only promotes transparency in decision-making processes but also empowers clinicians with the necessary knowledge and skills to effectively use and interpret CDSS within critical care settings.

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Innovative Databases in Ecomonitoring Information Systems: Images of Genetic Codes as Keys

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DOI: 10.25929/re84ry96

ABSTRACT

Introduction: Images of biological objects are used very often now for the creation of novel information systems for biology and medicine. But the sphere of their use, tasks which are possible to solve with them, can be successfully expanded.

Problem statement: Contemporary biomedical relational databases (DBs) very often include images. But additionally, images themselves can play important functional roles in DBs.

Purpose: To use images of fishes' genetic codes fragments as keys for the construction of relational DB; this has to ensure the reliability of biomedical information storage better than in prototypes, and to provide better data integrity.

Methods: DB Design, object-oriented system analysis for DBs design in an optimal way, ER diagrams design.

Results: An algorithm for the construction of relational DBs with images, other biomedical information, analytical approaches and recommendations for doing this in an optimal way were presented. The main attention was paid to the creation and application of the most functionally high-quality codes for keys in DB (including primary keys). To perform this function, usages of codes based on images of fishes' genetic codes fragments were proposed. The example for such a task solution, described in this article, was the creation of DBs with information about fishes (or other aquatic organisms) and chemical inorganic environmental pollutants which affected them.

Conclusions: The results of the use of images of genetic codes fragments as keys for the construction of DBs with ecological data in an information system for environmental monitoring were presented. Through the high level of individualization of the data in a system with such keys the maintenance of species-specific information is substantiated. The work has theoretical and practical values. It may also be applied in an academician process for teaching students.

KEYWORDS

Information and computer technology, information system, image, database, coding

1. Introduction – Biomedical information systems with databases of images and algorithms of ecological monitoring

The first versions of information systems with databases were constructed for the purposes of technique. The idea of developing databases (DBs) and information systems (ISs) for biology and medicine was formulated comprehensively in its complicity and was formalized, probably for the first time, at the International Conference on Very Large Data Bases (VLDB) in 2000. 1 Biomedical objects specifics stimulate new inventions, the development of new methods and approaches in the design of such DBs and ISs. ¹⁻⁴ In the present article we will demonstrate the results of our work in this direction.

Reliable information on the various schemes of distribution of biological species is necessary for the work in medicine, ecology, biogeography, for preserving these species, etc. Numerous projects have been initiated and realized to unite great volumes of data on the taxonomy of organisms and their distribution. ²⁻³⁰ Novel mathematical methods were invented and perfected in the process of these works. ³¹⁻³² Electronic atlases, data from museums and DBs should provide relevant information to the developers of electronic maps which could predict changes in the future number of species (also under the influence of chemical substances – environmental pollutants). ²⁵⁻²⁸ Some of such DBs can be used as determinants in the future, provided they meet the required high quality standards. ^{1,21,23} The construction of future electronic DBs with information on living organisms which may be accessed via the Internet is an extremely important task; it will simplify the problem of identifying organisms for thousands of users and facilitate a wide range of applications, such as the use of expert systems in medicine, agriculture, etc. At the time of its construction, each of such biomedical systems was a perfect functional structure. Today they contain huge amounts of data and continue to be updated on a daily basis; they are utilized by thousands of users around the world. However, today there are new requirements that these ISs can no longer meet. For example, the question of the possibility of using such ISs as determinants is open. This requires the significant improving of the quality of the material in these DBs, including the quality of images. Thus, the quality of images of organisms should be improved by using specially designed digital photography, the definition of species/subspecies should be improved through the use of cluster analysis methods and so on. ^{3,4} Such projects have already been implemented in natural history museums in the USA, Great Britain, Germany and other countries. ^{1,2,13,16,17,21,24} Such contemporary requirements should be taken into account in the process of creating domestic analogues. There were also attempts to solve the linked problems of species conservation, environmental protection, etc. by using electronic academic DBs and by means of modeling based on these data.

Interdisciplinary approaches like the creation of electronic DBs with a spatial distribution of information on the Internet and modern mathematical modeling based on the data from such DBs allow exploring the following problems at a contemporary level: how regular and daily factors (geographical, environmental and ecological), as well as the same factors which have been influences throughout history, have affected the spread of organisms and biodiversity. ^{3,4,17,21,23,26} In addition, such approaches allow us to determine better how to preserve biodiversity in the face of a rapid increase of anthropogenic impact.

2. Methodology

Design of DB, object-oriented system analysis for design of DBs in an optimal way, ER diagrams design, ecological monitoring with ordering results in DBs.

3. Purpose

The purpose of our work was to use images of fishes' genetic codes fragments as keys for the construction of relational DBs; this has to ensure the reliability of biomedical information storage better than in prototypes, and to provide better data integrity.

4. Results

Processing of environmental monitoring data based on the use of information systems with databases. Necessity to create databases with specific keys.

Nowadays, the ecological monitoring of biological organisms in order to prevent the reduction of their numbers due to various factors of damage – urbanization, anthropogenic influences, etc. is an important task. The sequence of steps for solving such problems, which could be regarded as standard today, can be described in two stages by the algorithm in Figure 1.^{3,4}

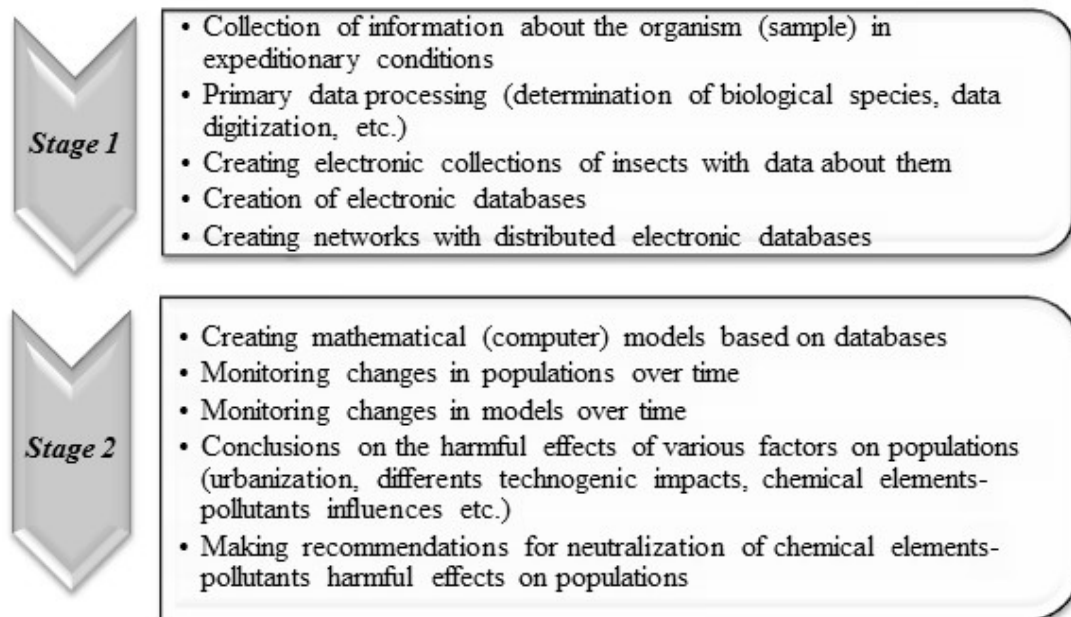


Figure 1: Two stages of processing environmental monitoring data based on the use of information systems with databases:

1. ****Stage 1**** – Creation of a collection of biological organisms and electronic databases.
2. ****Stage 2**** – Monitoring of populations and areas of species inhabitation using DB-based models (see details in text).^{3,4}

Biomedical data constitute a substantial portion of input information for contemporary information systems (ISs) with databases (DBs). As a consequence, numerous ISs with DBs have been globally constructed to record, store, and process such data. Numerous publications have described this extensive experience in detail.^{1–29} Our research endeavors over the past sixteen years were also dedicated to this domain.^{2–4,27,28} Previous works by our team were documented in the context of constructing biomedical ISs and DBs, specifically focusing on information related to fishes³ and insects (*Noctuidae*, *Lepidoptera*)^{4,27,28}. The construction of DBs in information systems necessitates high-quality input data. Our sources for biomedical data include our own research findings^{2,3,27,28,33,34} and contributions from our colleagues.^{30–32} Standard algorithms were employed for the development of relative DBs.^{35,36} Taxonomic data for biological organisms' DBs were extracted from previous works^{37–40} and based on our research. We secured patents for some of our ISs with DBs dedicated to ecological monitoring.^{27,28}

The abundance of publications worldwide on DBs with information about fishes attests to the evolving nature of this knowledge domain.^{3,21–26,29,37–40} Our team actively contributes to advancing this field. In this article, we introduce an original method utilizing images as keys in relational DBs, representing a potential avenue for innovation. As an illustrative example, we elaborate on the construction of a database containing information about fishes and the inorganic chemical pollutants affecting them.

The methodologies employed encompass DBs design, object-oriented system analysis for optimal DB design, and ER diagram design.^{3,4}

The method presented in this article is distinctive, introducing innovative approaches that hold relevance. The heightened information protection characteristics sought in DBs, such as individualization of data for each biological species (or individual person), data integrity, and overall data protection necessitate the development of novel methodologies. Addressing these challenges, Dr. Klyuchko proposes a potent innovative method for key coding in DBs with biomedical information based on codes derived from fragments of genetic sequences represented as images. Previous publications from our team delved into and described the simplest case, where a single genetic sequence fragment code corresponded to one fish species.^{41–43} In this article, we explore scenarios where several different fragments of the genetic code of a species may correspond to one fish species, presented in the form of images (as detailed below). To accommodate this, we introduce an additional object, namely, the "image of a genetic code fragment" (Figures 2 and 3).

The article follows a logical sequence, encompassing a description of object selection for relational DB construction through logical analysis, the subsequent design of an ER diagram tailored to the defined task, an elucidation of the analysis and procedure for key formation in relation to the database using "traditional" keys, and a proposal of a newly invented method for key formation using images of genetic code fragments from organisms, demonstrated by using fishes as an example. Object-oriented analysis initiates the database construction algorithm.

To illustrate the proposed problem-solving approach, we selected four objects for analysis: 1) "Fishes' species" as the biological object (in the DB construction process, various fish species were chosen); 2) "images of fragments of genetic codes", material sourced from contemporary genetics laboratories where such fragments have been examined with results accessible on the Internet—this object was selected to realize our idea of using images of genetic code fragments for key coding in relation to DBs; 3) "inorganic chemical elements" found in wastewaters, either dissolved or present as pollutants in industrial regions of Ukraine, negatively impacting fish fauna;⁴⁴ and 4) "taxonomic category," a suggested fourth object for the ER diagram. The designed ER diagram is depicted in Figure 2.

The initial steps in the algorithm for constructing such DBs are briefly described to facilitate an understanding of the invented coding technique. In the center of Figure 2, the primary selected object, "fishes' species," is represented as a rectangular symbol. This object is characterized by attributes denoted as ellipsoid symbols, which signify the main blocks of information intended for insertion into the database related to the "fishes' species" object. Attributes include, among others, the fish's name in Ukrainian and Latin, its area of inhabitation, and the "code of genetic sequence," a specific attribute elaborated upon later.

Figure 2 illustrates that the selected and designed object, "fishes' species", possesses identified characteristics represented as attributes within the DB context. The same principle applies to the other objects: "images of fragments of genetic codes", "chemical element", and "taxonomic category". In the context of this task, we selected and listed specific characteristics (attributes) for these objects, as presented in Figure 3. The second and third objects, namely "images of fragments of genetic codes" and "chemical element" (inorganic elements were exclusively selected for this model), adhere to the same attribute principles. Further details regarding selected characteristics (attributes) for all three objects are outlined in Figure 3.

The ER diagram employs main geometric symbols, as described previously.^{3,4} The designation "ellipsoid" with alternating dots signifies that additional characteristics, not explicitly detailed in the figures, can be chosen for such schemes. The "rhombus" symbol denotes the type of relations between objects, characterized by verbs explaining the sense of relations (e.g., "fish species are influenced by specific chemical elements"). For these relations, our newly invented codes for the keys—images of genetic fragments—will be employed.

In summary, the objects represent nouns, denoting main entities for which all data and characteristics must be included in the DB (in rectangles): fishes’ species, chemical elements, and images. Attributes represent object characteristics essential for object description (in ovals), while relations (rhombus) signify logical links uniting objects where logical connections exist (e.g., "fishes’ species" is affected by "chemical elements"). The same principles apply to the fourth object, "taxonomic category." The geometric symbols used in the ER diagram have been extensively elucidated in numerous manuals and articles.^{3,4,35,36} Symbols such as "many dots" are employed in subsequent figures within this article.

The characteristics (attributes) outlined in Figures 2 and 3 were derived from determinants of fishes species.³⁷⁻³⁹ The selection of inorganic elements (environmental pollutants) was based on information derived from monographs detailing inorganic substances and their derivatives, recognized as pollutants in wastewaters in industrial regions of Ukraine.⁴⁴ Information about images of genetic code fragments was sourced from.^{42,43,45,46}

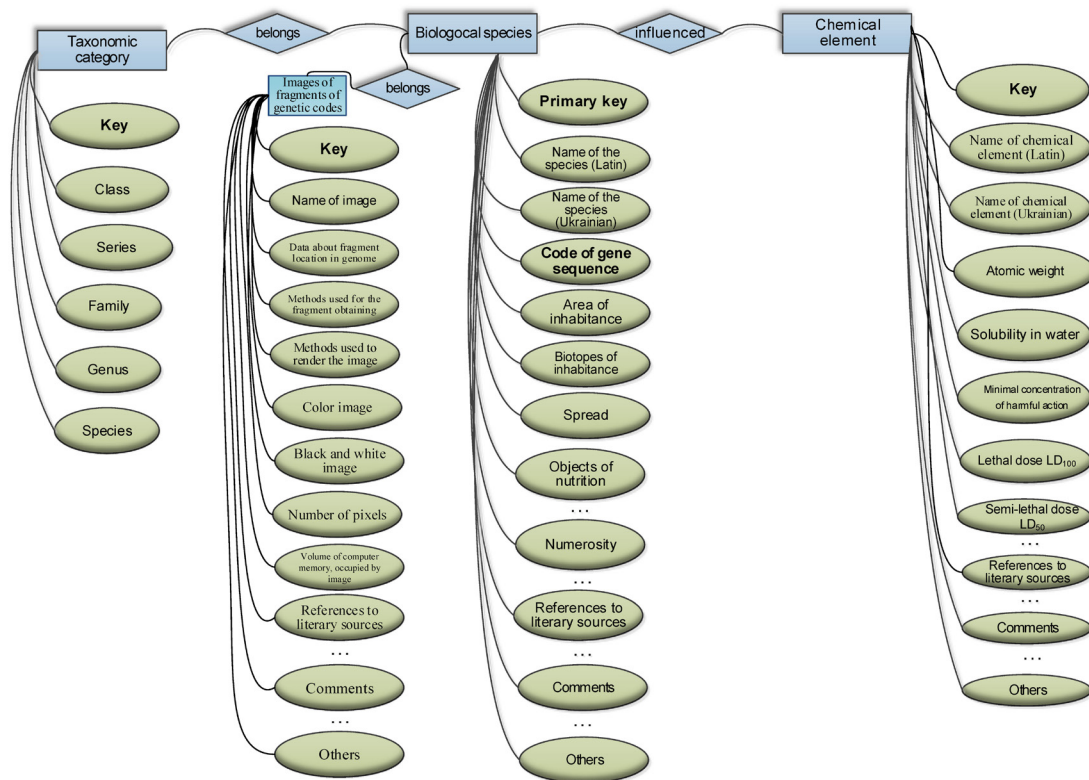


Figure 2. Fragment of ER diagram “fishes’ species and inorganic chemical elements influencing them» for various fishes’ species. The diagram was designed for 4 objects: “fishes’ species”, “images of fragments of genetic codes”, “chemical elements”, and “taxonomic category” (see explanations in text).

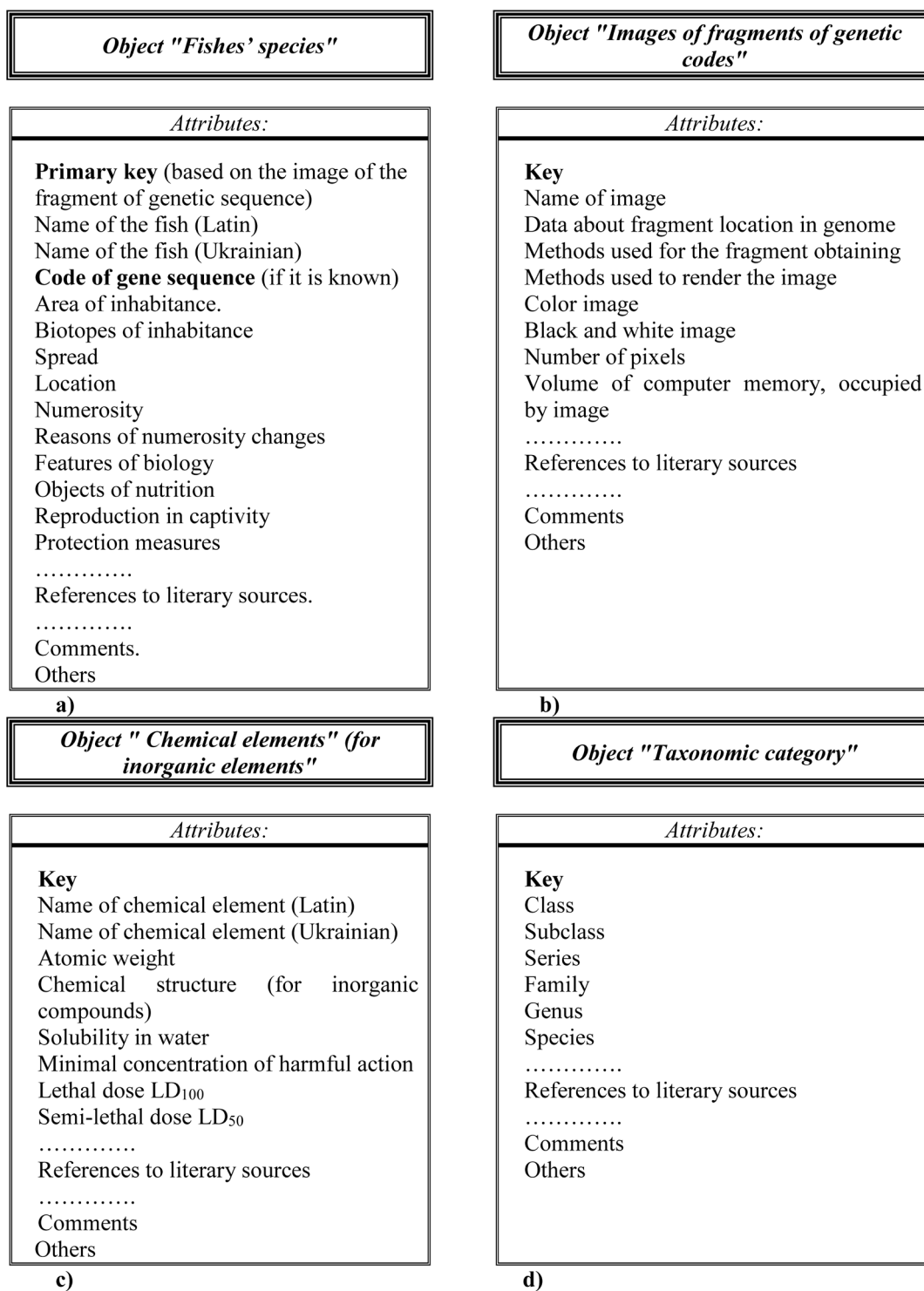


Figure 3: Attributes of objects “fishes’ species”, “images of fragments of genetic codes”, “chemical elements”(environmental pollutants), and “taxonomic category”.

For the continued development of the database, a more detailed specification is required regarding the selection of fishes' species and inorganic chemical elements-pollutants from industrial regions in Ukraine. For this illustrative example, we have chosen the following objects:

a) Fishes' species:

- *Oncorhynchus mykiss* Walbaum (rainbow trout)
- *Cyprinus carpio* L. (common carp)
- *Hypophthalmichthys molitrix* (silver carp)

b) Inorganic elements-pollutants:

- Lead (Pb)
- Fluorine (F)
- Aluminum (Al)
- Copper (Cu)
- Beryllium (Be)
- Chrome (Cr)
- Arsenic (As)
- Cadmium (Cd)
- Zinc (Zn)
- Mercury (Hg)
- And others

To further illustrate, Figure 4 demonstrates how the abstract forms described in Figures 2 and 3 can be populated with specific content, i. e. the names of fishes and the identification of specific chemical elements considered as pollutants. The alignment of these elements is visually presented in Figure 4.

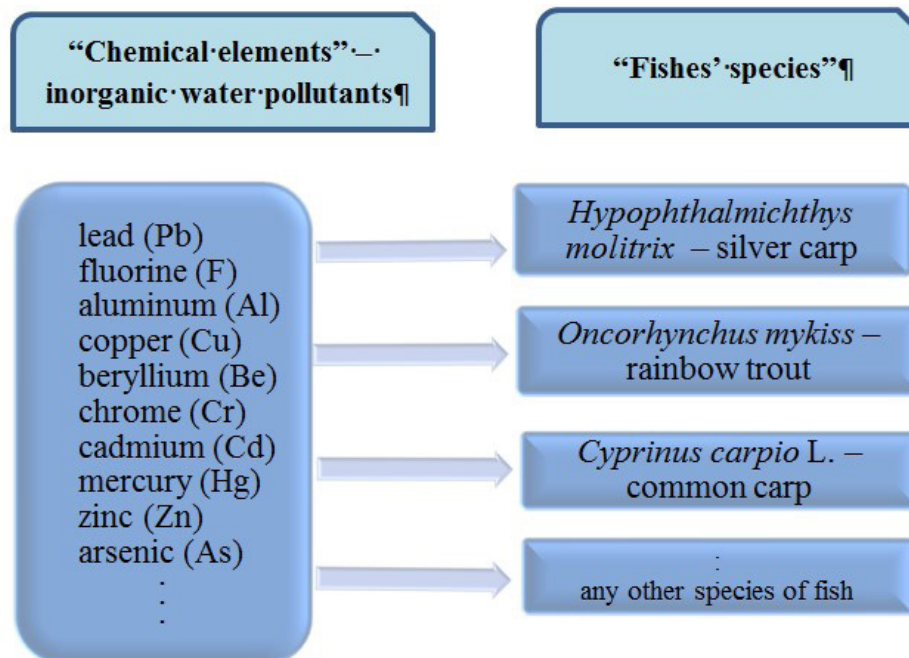


Figure 4: Construction of the database with data on fishes' species and inorganic chemical elements affecting them. Fragment of the ER diagram 'fishes' species and inorganic chemical elements that influence them,' illustrated with selected fishes' species from water basins in Ukraine. ⁴⁴

In the subsequent phases of the database (DB) construction process, certain transformations are necessary. The objects 'fishes' species' and 'inorganic chemical elements' (Figure 2) are transformed into tables, as depicted in Figures 4 and 5. The columns in these tables represent the transformed attributes of these objects (refer to Figure 5).

Example of the Fragment of the Table “Fishes’ species”

<u>Primary key</u>	<u>Species</u>	<u>Images of fragments of genetic sequence</u>	<u>Area of inhabitation</u>	<u>Biotores of inhabitation</u>	<u>Spread</u>	<u>Objects of nutrition</u>	<u>Numerosity</u>	...	<u>References to literary sources</u>	...	<u>Comments</u>	<u>Others</u>
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Example of the Fragment of the Table “Chemical elements” - with information about inorganic pollutants of environment

<u>Key</u>	<u>Name of chemical compound (Latin)</u>	<u>Name of chemical compound (Ukrainian)</u>	<u>Molecular weight</u>	<u>Solubility in water</u>	<u>Minimal concentration of harmful action</u>	<u>Lethal dose LD₁₀₀</u>	<u>Semi-lethal dose LD₅₀</u>	...	<u>References to literary</u>	...	<u>Comments</u>	<u>Others</u>
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Figure 5: Two objects and their corresponding tables in a constructed relative database. Description of the invented method of the links formation through the images as “keys”.

The transformations required during the DB construction process are as follows: ^{3,4}

1. Objects ('entities') of the ER diagram must be transformed into linked tables.
2. Attributes must be transformed into the columns or 'fields' of these tables.
3. The relations ('rhombus') between the objects must be transformed into relations between the tables, facilitated through the mechanism of 'keys.'

The ER diagram provides a comprehensive overview, evaluation, and analysis of all entities (objects) that need to be integrated into the DB. It serves as an abstraction that facilitates a comprehensive demonstration of all DB objects, their relationships, and attributes as characteristics of these objects. This holistic representation and analysis are crucial for high-quality DB construction. For the biomedical DB under analysis, additional data, such as nucleotide sequences in gene fragments, taxonomic characteristics (family, genus, etc.), gain significance as attributes.

By accumulating monitoring data in databases, users can assess whether changes in ecosystems have

occurred under various influences, such as technogenic pressure and chemical pollution of the environment. This approach enables the identification of changes in fish organisms, entire ecosystems, and more. Consequently, it becomes possible to develop methods for nature protection against such adverse influences. These DBs facilitate operations such as sorting and filtering of biomedical data, searching for specific records, data output realization, data processing, and more. Such capabilities are valuable for both professionals and enthusiasts in their respective endeavors."

The mechanism of 'keys' serves as a critical tool for establishing connections ('relations') between objects in relational databases (DBs). These 'keys' ensure the accessibility of information in databases by establishing links between tables with diverse data. Leveraging 'keys' allows for the retrieval of data not only from one table but also from other tables linked to it. The connections between keys, represented as codes from the tables (derived from previously defined 'objects'), can be easily implemented using contemporary software.^{3,4,35,36} The application of the 'keys' method enables accessibility to data in the DB and ensures data integrity, preventing data loss. Integrating genetic information into DBs enhances the level of information individualization within the database. Consequently, information about each species, and in some cases, individual-specific information, can be defined.^{3,4,35,36, 41-43} Inaccessible data cannot be outputted, underscoring the crucial importance of keys.

The construction of keys commences with the design of the ER diagram and its subsequent analysis, ensuring that all entities (objects) are interconnected. A profound analysis of the ER diagram allows for a comprehensive understanding of the organization of keys; no element can be overlooked.

In our model, depicting the influences of inorganic chemical elements on different fishes' species (see Figure 2), we linked the objects 'fishes' species' and 'inorganic chemical elements' (pollutants) through keys in the DB. Subsequently, we can retrieve information on which inorganic substance influences any fishes' species and in what manner. For instance, one might seek to understand how the chemical element beryllium (Be) affects carps (or a carp population). Researchers are aware that beryllium in water indeed influences carps. Therefore, in the programme, the key 'ImageGenCodeCarp*' from the table 'fishes' species' must be linked with another key associated with 'beryllium' in the table 'chemical elements' (pollutants). Similar connections are established for other elements. Keys for chemical elements in Figures 4 and 5 can be coded in the traditional widely used way, employing a group of symbols (randomly generated numbers or letters) as exemplified by the key for 'beryllium.'

Another aspect of the coding challenge involves determining which elements, groups of elements, or symbols should be selected as keys, meeting the aforementioned requirements. In relational DBs, codes, primarily sequences of numbers, letters, or other symbols, serve as 'keys.' In some of our previous publications addressing innovative key types for relational DBs, keys based on genetic codes were suggested—these involved fragments of genetic code sequences expressed as combinations of letters and numbers (alphanumeric codes).⁴¹ Keys created in this manner were termed 'natural keys', wherein real natural objects (genetic code fragments, in our case) formed the basis for such codes, and these codes were organized in a single field within the completed DB.

In the following sections, we present one of our inventions where 'natural keys' take the form of IMAGES of fragments of genetic code sequences. These images are the foundation for this novel key type. Examples of such images of genetic code fragments for various fishes' species are illustrated in Figure 6. The object 'images...' depicted in Figure 1 is essential because an increasing number of deciphered fragments of the genetic codes of various fishes' species emerge daily, necessitating their organization within the constructed database. However, only selected images are proposed to serve as keys within the same database.

Such images of genetic code fragments in DBs containing information on living organisms have already been integrated as a separate field in some contemporary databases. This integration stems from advancements in genetics research, particularly in genome studies, where such information holds significant importance. However, prior to our work, these images played no functional role in the DB; they

merely constituted a volume of images organized in a separate field (never as keys).

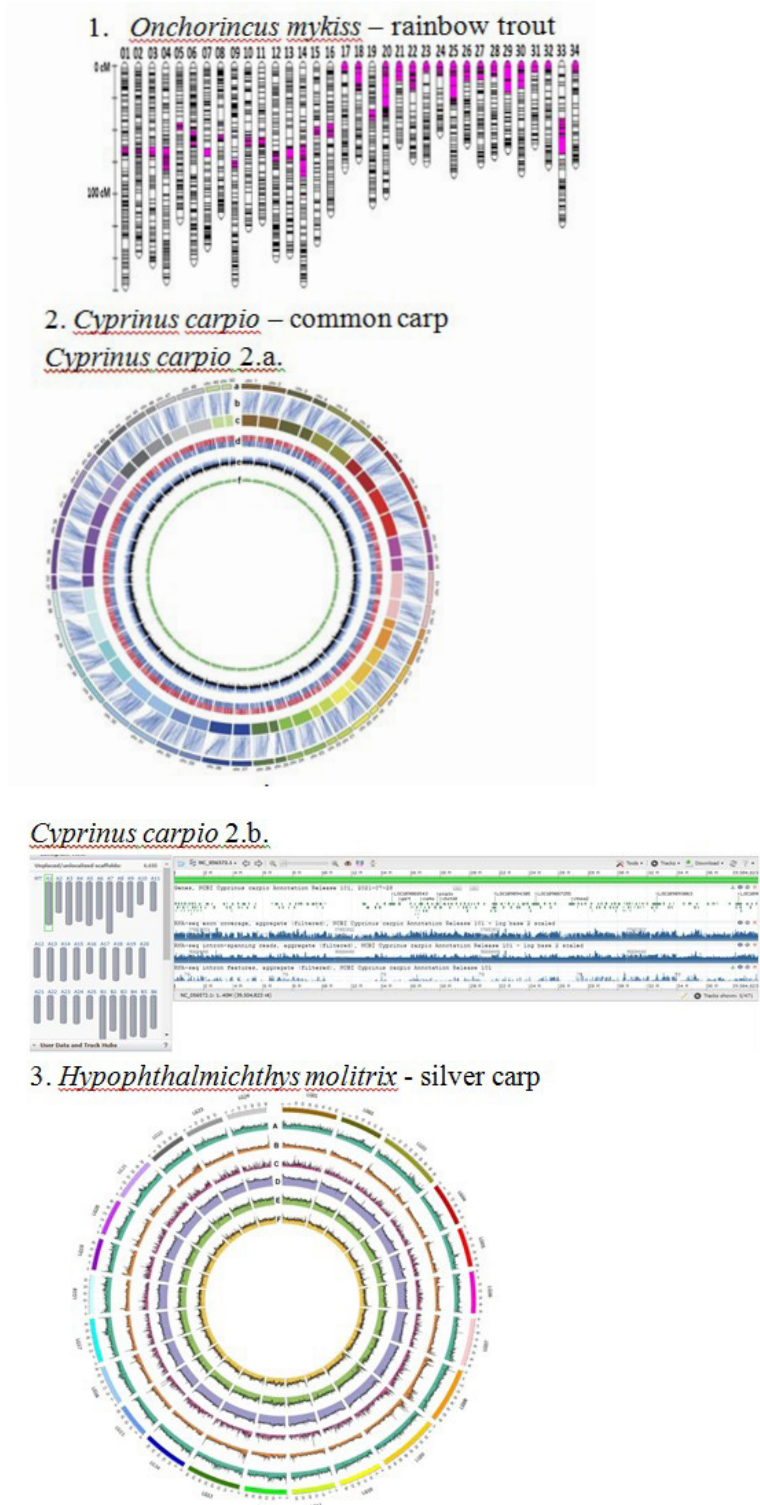


Figure 6: Images of the fragments of genetic codes of some fishes that can be used as keys in the databases (as well as primary keys). 42,43,45,46

Consider a scenario where the role of keys is assigned to specific images—referred to as 'natural keys' (Figure 6). In this case, the 'images of fragments of genetic codes' field in Figure 5 transforms into a field containing these image keys. Additionally, as depicted in Figure 2, the images on the ER diagram are represented by the 'Image...' object, characterized by its own attributes. Consequently, a situation of intriguing complexity arises. The subsequent analysis of this scenario and proposed solutions are elucidated in the following chapter.

An analysis of the inventive method of utilizing images of genetic code fragments as 'keys' for database construction unfolds new avenues for creative ideas in coding for DBs construction. Dr. Klyuchko has conducted research in this domain, yielding innovative methods, one of which is expounded here. In the context of the model task, biological organisms and species possess unique genetic codes. Previously, we published results regarding the use of genetic code fragments as keys, expressed in sequences of alphanumeric symbols.⁴¹ These symbol sequences exhibit high individuality, specific to each species and, in some cases, each individual organism. Hence, leveraging such symbol groups as keys, including primary keys, is considered a promising idea.

Real nucleotide sequences correspond to these codes in symbolic form, and images of these sequences, obtained by geneticists, are illustrated in Figure 6. For example, the upper image of a genetic code fragment is characteristic of the fish rainbow trout (*O. mykiss*). This code serves as a key (including a primary key) in relational databases of fishes and other aquatic organisms. Each code entry is species-specific, and the images vary for different species. This naturally suggests the idea of using such images as keys in DBs with biological material. While a vast number of images may require significant computer memory, given contemporary technology, including 4G and 5G, this is not a hindrance.

Numerous examples of fragments of genetic sequences have been investigated to date.^{45,46} Moreover, the number of decoded DNA and RNA fragments continues to grow daily, with new information being added to such DBs in subsequent years. From a contemporary standpoint, the necessity of using such detailed images of genetic codes as keys may be questioned. However, considering the capabilities of modern computers with substantial memory, the advantages of this method may outweigh the disadvantages. On the other hand, the challenge lies in determining what fragment of the genetic sequence to select as a suitable image for use as a key, which is contingent upon the specific task at hand.

Examining the modeling task at hand, which serves as a good example of utilizing a 'natural key' or 'primary key,' offers an opportunity to enhance data integrity in the DB. Other keys in Figures 3 were suggested for use as 'alternate keys,' and in our case, such keys can also be formed as 'surrogate keys.'

The traditional method of key formation^{35,36} has a drawback in that constructed DBs may not always operate reliably. The use of prototype methods may lead to data integrity violations, interruptions in information flows, and other adverse effects. In a biomedical information system, such integrity violations can hamper system performance, impacting the quality of monitoring the environmental effects of chemicals on living organisms in nature. To address these challenges, we propose using IMAGES of fragments of genetic codes AS KEYS in the process of DBs construction, especially as primary keys, based on primary unique information.

Considering the practical realization of this idea, two possible approaches are suggested:

1. The first approach involves using the image from the 'images of fragments of genetic sequence' field as the key itself. This application is depicted in Figure 5 with a dotted arrow, indicating that the image of the genetic code fragment is included in the 'key' field. In this case, there is no need for two separate fields—one for keys and one for images—since the images themselves serve as keys. This can result in saving computer memory, which is particularly crucial for large DBs with extensive biological material.

2. The second approach is for cases where keys for the DB were formed solely based on images of genetic code fragments, but not equivalent to them. In this scenario, a group of random characters (a mixture of numbers and letters) can be coupled with the image of the genetic code fragment to create 'intelligent keys'. Unlike the previous approach, in this case, two fields in the table are necessary, and there is no significant memory savings. However, this method also has its advantages, which will be discussed in future publications.

In conclusion, this article presents an algorithm for constructing novel relational DBs with images, other biomedical information, analytical approaches, and recommendations for optimal execution. Emphasis is placed on creating and applying the most functionally high-quality codes for keys in the database, including primary keys. The use of codes based on images of genetic code fragments of fishes, illustrated in the example of a DB on fishes and chemical inorganic environmental pollutants affecting aquatic organisms, is proposed and demonstrated. The examination and analysis of this task considered cases where one species of fish corresponds to multiple fragments of its genetic sequence, introducing the concept of an additional object, 'image of genetic code fragment'. The proposed method has theoretical and practical significance, expanding the capabilities of electronic systems. Several examples of the method's application were explored, each presenting its own set of advantages and disadvantages.

For instance, the described inventions can find application in constructing information systems for environmental monitoring and other biomedical information systems.^{3,4,27,28} The method can also be applied to devices for reading information in barcodes. Barcodes, representing information in a format convenient for technical reading, such as linear-shaped readers or round-shaped fingerprint sensors, can benefit from these methods. Other practical prospects include applications in medicine, such as studying hereditary genetic diseases or DNA mutations under the influence of chemical pollutants (Figures 2–5), criminology, police and military databases, etc.

The method contributes significantly to the development of data protection methods, offering a balanced approach to ensuring the integrity and availability of data in DBs. By applying this method, information integrity is enhanced, leading to better continuity of information flows. The results described herein hold both theoretical and practical importance for improving methods of database construction and enhancing certain data protection methods. This material can be incorporated into courses for educating students.

3. Acknowledgments

The authors sincerely thank their scientific supervisor, Prof., Dr. A. Beletsky (National Aviation University, Kyiv, Ukraine), who guided the investigations, participated in results discussions, and supported this work. Gratitude is also extended to Prof. Dr. P. Kostyuk and Prof. Dr. O. Kristhal for providing the opportunity for years of work in the laboratories of the O.O. Bogomoletz Institute of Physiology of the National Academy of Sciences of Ukraine, which significantly contributed to the authors' professionalism in science. The author(s) declare(s) no conflict of interests regarding the publication of this paper."

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Unlocking the Power of Health Data by Ensuring the Public Can Trust the EHDS

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DOI: 10.25929/wgxbmf28

ABSTRACT

It is vitally important to assure public trust during the European scaling up of health data reuse for research, public health and health systems strategy. The European Health Data Space (EHDS) proposals are catalysing the multi-stakeholder debate on this, and include some provisions that are aimed at giving that assurance, such as strict purposes for which data may be reused, and which may not be used. However, the public needs a way of trusting that the organisations that reuse their data are bound to by ethical and transparency principles. Furthermore, these organisations are to be held accountable for how they use data. This paper summarises the Big Data rationale for needing a European scale for the secondary use of health data, and the provisions in the proposal for a Regulation for the EHDS to enable and safeguard this secondary use. It proposes a complementary measure, a Societal Compact, that could strengthen public trust in the EHDS.

KEYWORDS

Health data, electronic health records, big data, information governance, transparency

1. The need for European scale real-world data

Health systems right across the developed world are challenged to meet current healthcare demands and public expectations of quality and timeliness. They are working within funding constraints following the depletion of public budgets due to the COVID-19 pandemic, in the face of an aging society and increasing multi-morbidity which increases treatment complexity and costs. ¹ In parallel, there is a growing recognition of the importance of equity of access to health services and equity of outcomes. ² Health systems need to make structural reforms and deliver better value, for which digital and data transformation is needed. ³

Healthcare providers need to make better use of their patient-level data for monitoring the health outcomes they achieve, streamlining care pathways and interconnecting multi-professional care teams, delivering remote telehealth and more monitoring, and implementing more personalised care. Health systems need to transform on the basis of evidence, and public health systems need greater access to patient-level and population-level data for bio-surveillance and rapid outbreak management. Research increasingly needs large-scale data for the development of targeted therapies, medical devices and AI algorithms. ^{4,5}

2. The growth of European health data infrastructures

Over the past several years Europe has seen substantial investment in Big Data infrastructures, for example at national levels in Germany ⁶ and France, ⁷ and in particular health sub-sectors such as for medicines regulators, ⁸ life sciences research ⁹ and for rare diseases. ¹⁰ Some of these utilise a federated analysis architecture, in which a research computable query is cascaded across multiple repositories and only the analysis results are returned, which avoids centralising large volumes of fine-grained patient data. This provides a more safeguarded way of undertaking large-scale analysis, whilst conforming to the European General Data Protection Regulation (GDPR). ¹¹

The conduct of Big Health Data research is challenged when it comes to interpreting the GDPR, because different jurisdictions and sometimes even different data protection officers will arrive at different interpretations of the acceptability and/or required safeguards when conducting Big Data research. This includes the requirement for patient consent, which is nearly impossible to collect in a fully informed way when constructing a Big Data resource such as a research infrastructure, because the multitude of future research purposes cannot be explained accurately enough to comply with GDPR informed consent. Anonymisation of data is one method for conducting Big Data research, but is challenging to apply in a robust manner when it comes to rare disease groups where patient numbers are small, to genetic information, images, etc. Pseudonymised data, which are often necessary for longitudinally linked datasets, are still considered personal data under the GDPR and require a legal basis as well as stringent safeguards.

3. Proposals for a European Health Data Space (EHDS)

All eyes in Europe are now on an ambitious programme announced by the European Commission, with an allocated budget of many billions of Euro: the European Health Data Space (EHDS) ¹² It is expected that the regulation to enact this pan-European channel for data sharing will be passed during 2024, and be implemented over the next several years across all 27 member states. The European Parliament and Council has debated this proposal over several months, and reached a final text that has strengthened many of its provisions, ¹³ which will now be finalised, passed and enacted.

For many people this is an exciting proposal. Firstly it will establish a patient-level communications ecosystem for identified patient data (containing a patient summary, recent prescriptions, test results and hospital discharge reports) to be accessible wherever a patient needs urgent healthcare across Europe. This will make their care safer and enable their original clinical team to know what treatments were issued whilst they were cared for abroad. Patients will also be able to access their health summary and recent correspondence, and it is likely that innovative apps will enable patients to understand and use their data for better self-care, for example for chronic diseases and prevention. A summary of the main provisions for patient-level data (primary use of data) is shown in Figure 1, reflecting the text agreed in March 2024, although it may still be subject to final changes.

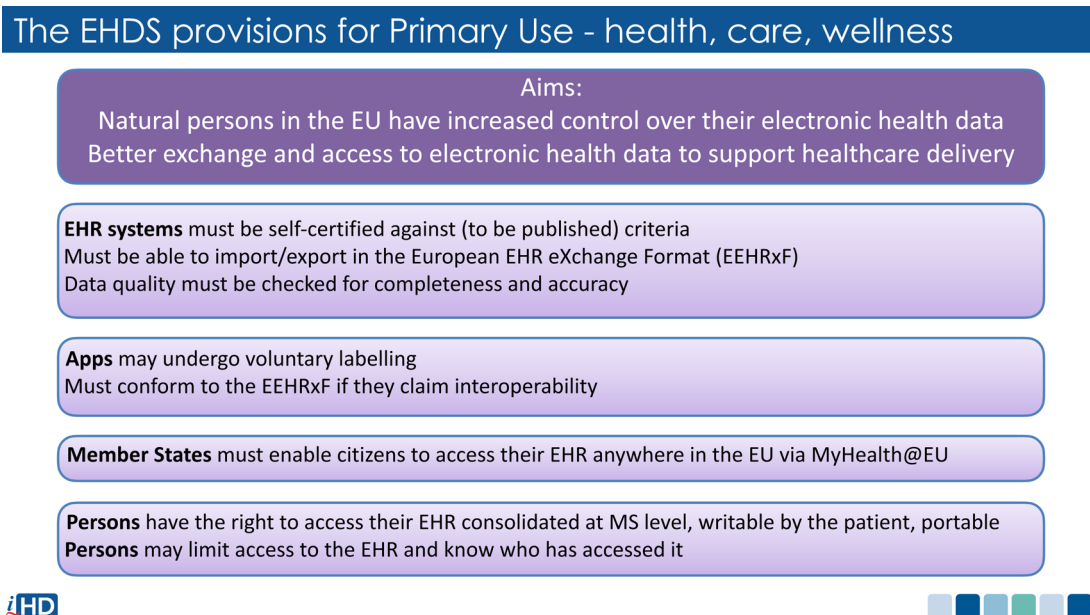


Figure 1: Summary of the provisions in the provisional political agreement on a European Health Data Space (March 2024) relating to the primary use of health data.

The provisions relating to the secondary use of data are quite distinct from those relating to primary use. It is generally considered that the prioritisation given to the health data space ahead of other sectoral data spaces is at least in part driven by a wish to strengthen Europe’s capability to determine appropriate public policy and real-time evidence-based public health strategy in the case of another pandemic or a similar large-scale threat to the health of European citizens. The secondary use provisions cover the analysis of data sets for the purposes of public health, research, education, innovation, policy, regulation and the development of personalised medicine, but with a strong emphasis on enabling the access to data by public authorities. This is enabled through a governance mechanism to access data sets that will be curated and provided through national Health Data Access Bodies (HDABs) in all 27 member states. This part of the regulation places an obligation on health data holders (almost all kinds of public and private institutions) that have any of a wide range of categories of health data to document the datasets they hold in a transparent way, with standardised FAIR¹⁴ metadata and optionally a data quality assessment (to be developed) through a centralised catalogue to be maintained by each HDAB. This catalogue will enable these data sets to be discovered, and to request from their HDAB a permit to access these data. The EHDS Regulation will include a list of permitted purposes and prohibited purposes that the data user must agree to adhere to.

HDABs will be the ultimate arbiters of whether to grant a data access permit or not. They will then require provision of the requested data from the data holders, and will seemingly be the arbiters of any safeguards or restrictions that are needed to protect intellectual property or other commercial sensitivities regarding the released data. HDABs will establish secure processing environments for using the data and require that the results of data use are openly published within 18 months.

A summary of these provisions is given in Figure 2.

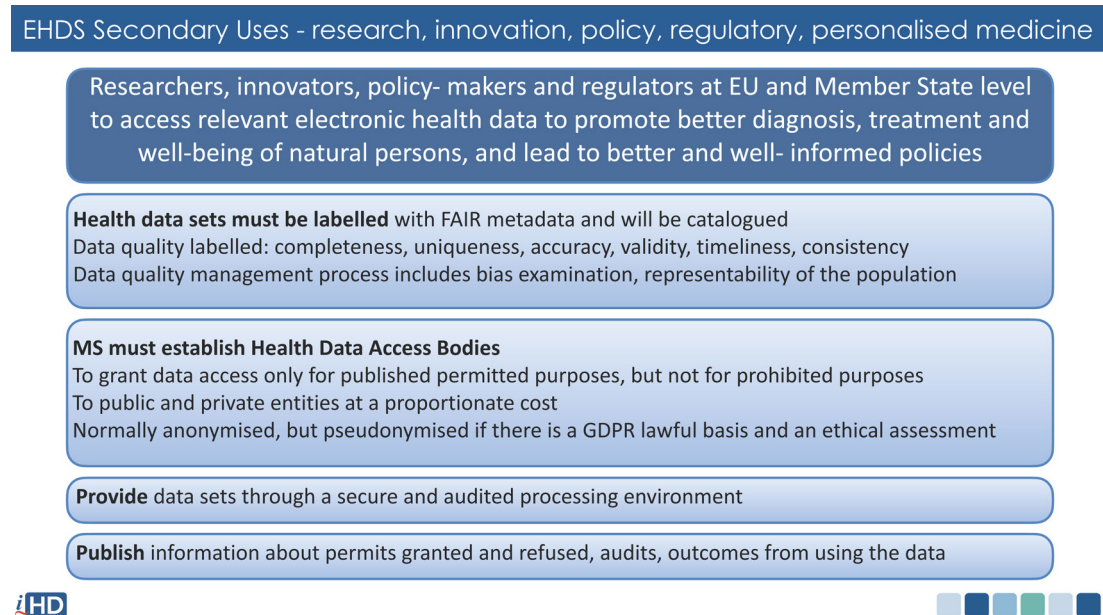


Figure 2: Summary of the provisions in the provisional political agreement on a European Health Data Space (March 2024) relating to the secondary use of health data.

There is debate amongst research organisations about the powers that will be bestowed on HDABs, and whether the requirements and mechanisms for data sharing will actually help or hinder innovation within Europe.

The regulation proposes that every member state puts in place a process for its citizens to opt out of secondary uses of data (other than by public authorities when responding to a public health crisis, which cannot be opted out of). It is not clear, and it may vary between countries, whether citizens might be enabled to opt out of the secondary use of certain categories of their data (such as genetic data), to opt out of certain purposes of secondary use (such as research) or to opt out of secondary used by certain types of organisation.

4. The challenge of winning public trust

Whilst there are many supporters of this right to citizen control and self-determination with regard to the use of personal information, there are concerns that public confidence in the secondary use of data may be vulnerable to misinformation campaigns and lead to an opt-out by particular sectors of society. This introduces a risk of important bias in the data which are used for research, such as for the development of AI, and may lead to solutions that are less accurate in those populations, placing that at a future health or safety risk.

What will encourage individuals to not opt out? The author proposes that one important factor will be a way for the public and data access decision-makers to determine who to trust to use their health data, and why. Reciprocally, bona fide research organisations need a way of demonstrating they are trustworthy data users.

5. Proposal for a societal compact

In late 2022 and early 2023, two not-for-profit organisations, which included the author's institute, convened multi-stakeholder round tables and further consultations to consider this issue, and to formulate a "proposal for a societal compact for the secondary use of health data".¹⁵ It is offered as a voluntary agreement between a range of stakeholders who cooperate to achieve social benefits by granting access to and reusing health data. The compact aims to provide an assurance to all stakeholders in the health data ecosystem, especially to the public, that the organisations and individuals who sign it will reuse health data in legal, ethical and secure ways and that they will use the data in society's interests.

This proposal comprises a set of ethical and data usage undertakings that any data user should a priori commit to before being granted data access, and against which they should be held accountable and audited, and be sanctioned, if necessary. The ethical principles are summarised in Figure 3 below. The compact requires data users to only use data for a list of permitted purposes, and never for the listed prohibited purposes; these lists are aligned with the draft EHDS Regulation and will be updated when the Regulation is finalised. In addition to these principles, data users are required to adopt a number of stipulated measures to safeguard the data they are processing, including legal compliance and adopting data protection and information security practices, many of which align with the EU GDPR. It emphasises transparency, requiring data use of organisations to have a public location (such as a website) where they list and briefly summarise the accesses to data they have been granted and the purposes for which they are using it, later to be updated with a summary of the learning acquired or the product or service implemented. The compact proposal includes an operational and governance workflow, including the basis for applying sanctions. Some of these measures echo those in the recent Council draft of the EHDS Regulation, suggesting that this compact could fit well as a complementary measure.

Wider consultation is now taking place with stakeholders, globally, about this compact, and some bodies are considering if it might form the basis of self-regulation within their sector.

1. Reuse data to contribute and bring benefits to society in terms of improved opportunities for better health and care.
2. Never reuse data unethically, or by violating human rights, discriminating against individuals or groups of individuals, or to further individual or organisational interests exclusively without bringing benefits to society.
3. Reuse by always safeguarding the privacy of individuals whose data are being reused and apply the principle of data minimisation.
4. Reuse data respectfully toward data holders and adhere to data use terms agreed with the data holders.
5. Results should be published or shared in some way unless publishing such results violates Principle 2.
6. Organisations reusing data must make every effort to be transparent to the public about their use of health data and the outcomes of each data use, complying with the H2O data use commitments.

Figure 2: Summary of the ethical principles in the societal compact proposal.

6. Conflict of interest statement

The author declares that there is no conflict of interests regarding the publication of this paper.

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Global Digital Health Diplomacy: The Global-EHR and First Steps for a Global Treaty on Digital Health

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DOI: 10.25929/tnev8s71

ABSTRACT

Successful globalisation in health is dependent on Global Digital Health. As of today, however, we do not enjoy the interoperability needed to enable a global health care delivery system that is equitable, safe, effective, patient-centered, timely and efficient. People are afraid to travel to a remote location where access to their device or health data is not possible. They are aware that healthcare services in another country may not be of the same quality and these factors leave them feeling unsafe to travel and ‘chained’ to their locality.

A real worldwide cross-border digital health service includes a Global Electronic Health Record (G-EHR). This could be realized with co-ordinated efforts across countries. Some progress is possible through international agreements for mutual health data transmission, recognition of information systems and common approaches to the use of an international standard. To achieve full interoperability, however, political consensus is needed: Digital Health Diplomacy (DHD) efforts can deliver such alignment. DHD refers to concentrated international efforts towards supranational interoperability in Digital Health leading to cross-jurisdictional digital health services and data access and/or exchange.

KEYWORDS

Global digital health, electronic health record, digital health dipolomacy

1. Introduction

Global Digital Health should not just be limited to the “global” adoption of Digital Health. A global approach to disease management and health promotion is dependent on a co-ordinated effort to address the interoperability of people, processes and information systems crucial for this purpose; this requires Global Digital Health. This, however, cannot be limited to just the “global” adoption of Digital Health

by each country and territory but to the adoption of Digital Health across the whole world in all its interconnected complexity.

Orchestrated strategies emerge only where there are common perspectives on regional and world health and disease. The World Health Organization (WHO) strategy on Digital Health ¹ aims to improve health for everyone and everywhere by accelerating the development and adoption of appropriate, accessible, affordable, scalable and sustainable person-centric digital health solutions. These solutions would prevent, detect, and respond to epidemics and pandemics, developing infrastructures and applications that enable countries to use health data. This strategy requires contributors to:

1. Acknowledge that institutionalization of digital health in the national health system requires a decision and commitment by countries;
2. Recognize that successful digital health initiatives require an integrated strategy;
3. Promote the appropriate use of digital technologies for health;
4. Recognize the urgent need to address the major impediments faced by least-developed countries implementing digital health technologies.

However, it is not easy to serve every citizen worldwide through digital health. The challenges for digital health in the present and particularly into the future include:

- **Digital inclusion** – The capacity to ensure advanced tech is equitably accessible to both organizations and to all individuals.
- **Minimally disruptive telehealth/metahealth services** – The introduction of telehealth and “metahealth” services that offer high quality of care without significant disruption of health systems and paradigms.
- **Trustworthy digital clinical services** – Ensuring that people will trust the mHealth Apps they are offered, especially when these embed AI-based decision support systems or provide digital therapeutics (DTx)
- **Health data economy & health innovation** – Health data spaces for data exploration and care integration and innovation
- **Digital sovereignty & sustainability** – **Creation of digitally advanced infrastructures and processes that reflect cybersecurity, governmental sovereignty and cost-effective architectures.**

2. Global Electronic Health Record

Key to global digital health is the availability of a global Electronic Health Record (G-EHR), a set of interconnected digital systems and services that enable the sharing of personal health data across the globe. G-EHR supports the primary use of health data regardless of geographical, jurisdictional and language barriers. It is person-centric and citizen-driven, based on standards and de-facto enables the promotion of data harmonization, leading to a potential “Global Health Data Space” of anonymized health data for potential secondary and tertiary use. ²

A G-EHR is not a utopian idea. It does, however, require focus, concrete steps, value creation and determination to explore the following elements:

1. Creating worldwide voluntary patient and health professionals’ registries

2. Setting up a global regime/governance forum for the advancement of agreements and common creations
3. Enacting legally binding agreements grounded in international treaties of voluntary participation, in three areas:
 - i. global rules for telehealth
 - ii. global rules for the detailed reporting and information exchange in cross-border health threats
 - iii. decisions on the implementation and governance of concrete digital health services.

3. Interoperability

A vital feature of G-EHR is interoperability, defined as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged”.³ The European “LOST” framework for interoperability is based around legal, organisational, semantic and technical aspects.⁴

Efforts such as the collaboration with ISO, HL7 and SNOMED International on the International Patient Summary address the semantic and technical levels and could help lead to the open sharing of digital health standards. There are issues about languages, but the use of standardized terminology and codes would allow for local translations to be made available.

This is a start, but it is not sufficient. To take an example, medical devices (e.g. insulin infusion pumps or non-invasive home ventilators) are increasingly globally produced and standardised, yet the information that they require and generate is constrained to local, regional or national health systems. This in turn restricts citizens to their institutions, or even their homes. People fear to travel to a remote location where access to their device or health data is not possible. They know healthcare may not be equally safe, which makes them feel ‘chained’ and unable to travel. What is needed is full interoperability.

In 2022, the European Commission issued the Proposal for a Regulation on the European Health Data Space (EHDS).⁵ The EHDS Proposal has two main aims: 1) to grant citizens increased access to and control of their (electronic) health data across the European Union (EU), and 2) to facilitate health data re-use for research, innovation, and policymaking. The EHDS proposal for “natural persons” or citizens to have the right to a copy of their health data means that a traveller could take their record with them on a smart device, according to an agreed format, and show and/or share their data with anyone treating them.

The sharing of data is based around the European Electronic Health Record Exchange Format (EEHRxF). This is promoted by projects such as X-eHealth, XpanDH, xShare, Xt-EHR that, starting in the European Union, can be progressively road-tested and used across the globe with benefit for all as it also is being built on a set of international standards and SDOs contributions. Each country could have the specification and hence would be able to consume such data and make sense of the health record produced in both ways.

An approach could be to start with the essential information and progress to more complex data. The following worldwide cross-border eHealth services might be logical initial steps:

1. Global ePrescription system
2. Global sharing of minimum sets of data (for example, the ISO International Patient Summary) and, progressively, bigger components, such as vaccination passports/summary/e-cards

3. Exploring the global use of the EU EHRxFormat
4. Internationally approved minimum information sets for advanced data-rich medical devices
5. Internationally approved and maintained digital information leaflets for prescribed drugs
6. International sharing of large datasets for research/public health based on commonly agreed specifications

The availability of (free) open standards and the ubiquitous availability of smart devices would allow for early substantive progress in the area of primary use of data.

This is an ambitious mission, but with two principal barriers:

- First, it is not clear how health professionals take responsibility for data when data is transferred across borders and or when patients are given the right to upload data to their electronic health record, health professionals cannot control the data they receive, its language, or format.
- Second, different national healthcare systems with different disease classification systems in place, and differing levels of specialization and medical specialties could make it difficult to consolidate or compare data.

More work, therefore, is needed on joint approaches to legal and organisational issues. Two examples: health information cybersecurity, which presents particular challenges requiring global positioning and response, and artificial intelligence where the challenge is to exploit the opportunities it provides.

4. Cybersecurity for Digital Health is a Global Task

The high value of the sensitive patient data that healthcare organizations hold makes them prime targets for cyberattacks. ⁶ With the COVID-19 pandemic, remote work, virtual care, and electronic consultations became new targets for cybercriminals. ⁷

Current efforts in international cooperation in cybersecurity for healthcare, as those happening under the Global Digital Health Partnership (GDHP), should continue. They can be expanded, and this is likely to be of benefit to healthcare systems and societies in multiple countries. Such expansion can happen by:

1. Making existing cooperation in health cybersecurity more sustainable and structured
2. Expanding stakeholders' engagement to involve, in particular:
 - i. patient associations and professional scientific societies
 - ii. industry, from medical device and equipment manufacturers to software development companies
 - iii) research and higher education institutions
 - iv) standards setting organisations
3. Enlarging the number of involved countries and working under the auspices of larger, well-established international bodies like the Organisation for Economic Cooperation and Development (OECD) or the WHO.

At the global level, following this direction means ensuring such collaboration with regard to cybersecurity in general could eventually be hosted in a sustainable manner under the UN umbrella, or at the WHO. As we see the global discourse on the increased speed in the digitalization of healthcare and the increased need for international collaboration, we need to make sure that digital health comes with solid defence. Otherwise, whilst digital is good for health, it may bring more risks than benefits. Countries should implement national digital health strategies and be willing to support and contribute to international efforts and agencies where the sharing of that implementation can help them and boost these much-needed efforts.

Inspired by the WHO definition of health, we should see information security and health cybersecurity as a total state of integrity, availability and privacy, and not just the absence of cyber incidents. Cybersecurity in healthcare includes network security, application security, information security, operational security, disaster recovery, operational continuity, and end-user training.⁸ In this environment, cybersecurity concerns are critical as the essence of the health system functioning depends on the 'health' of the information systems that support it.

5. “First, Do No (Digital) Harm”

There is much discussion on the application of artificial intelligence (AI) to health. The availability and application of medical knowledge can deliver huge benefits but can overwhelm those trying to keep up with the latest data.

Most doctors will follow the “first, do no harm” rule as they have committed to in the Hippocratic Oath. Whilst the absence of digital solutions has been associated with lower patient safety, it is also true that digital threats to human health and dignity can come from misuse or abuse of digital health technologies. Such trade-offs are often the case with any impactful human invention. An increasing number of scientific reports point out to the potential risks of digital technology and its damaging effects on health. Literacy, digital and health literacy are powerful digital vaccines to fight this menace. These digital vaccines and some digital therapeutic interventions face distribution problems, their scope is often limited, the incentives and political visibility are often surpassed by more glamorous and eye-catching technologies. This is the case with blockchain EHRs or robotic physiotherapist care in highly matured digital health settings. A focus on literacy is essential, but it is possible to promote both. This has been shown in examples of mHealth use in low-resource rural areas to help healthcare provision and foster literacy, while capturing valuable data for further sophisticated secondary data uses.

Human dignity is at risk in privacy matters, in cybersecurity breaches, in robotized clinical decisions. It is also at risk when a two-year wait time for a visit to a dermatologist could be cut down to two months with the use of simple teledermatology screening. Reflection, pondering and, sometimes waiting and awaiting – these are old remedies to some of these challenges, although not the panacea.

6. Working together

The two examples of cybersecurity and AI illustrate the need for a co-ordinated international approach.

The GDHP and some regional efforts by WHO Regional Offices are trying to create bridges at the organisational level, but there are no common legal grounds on which to build.

Facing up to these challenges is a task not only for the WHO or any other one global organisation. High-level responsible health agents, such as ministries or public health authorities, need to understand that multinationals and other private or third-sector agents are all key to global development.

An approach to digital health is needed at each nation's level, but also in the EU, or other regions, and globally for all citizens alike. A combination of policymakers, country digital health leads, suppliers and citizens can work together to make this happen.

globally for all citizens alike. A combination of policymakers, country digital health leads, suppliers and citizens can work together to make this happen.

In Europe, it could mean using the Eastern Partnership (EaP) and/or Central European Initiative (CEI) to enlarge the debate and capacity building outside immediate EU influence. Likewise, other regional organisations like the Asia-Pacific Economic Cooperation (APEC), the Association of Southeast Asian Nations (ASEAN), or the African Union (AU) should be more engaged with international health policies, and at the intersection of economic and well-being concerns ensure the security of their increasingly digital national health systems.

There are already relevant global actors co-ordinating efforts across different countries:

- i) Standards Developing Organizations (SDOs) such as the International Organization for Standardization (ISO), Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE),
- ii) clinical terminology-focussed organizations like SNOMED International or the Regenstrief Institute, responsible for the (LOINC, Logical Observation Identifiers Names and Codes) terminology,
- iii) promoters of digitalization efforts such as the Health Information and Management Systems Society (HIMSS) or the International Data Corporation (IDC) and, the International Medical Informatics Association (IMIA), with regional groups in America, Europe and Asia

Through a holistic, global and sustained approach to digital health worldwide, digital health can be seen as the only way forward for universal health coverage, for fair and balanced healthcare transformation, and for fighting the emergence and prevalence of many diseases and health-threatening conditions. This would lead into a new Digital-First Healthcare System, as Cassese⁹ notes, “in the global space, several global regulatory regimes act without subjection to one hierarchically superior regulatory system”.

7. Digital Health Diplomacy

An international treaty on digital health is urgently needed for two reasons: 1) to address threats from pandemics, present and future, recognizing the increasingly important role of digital health in their deterrence; 2) recognizing telehealth as a globalized phenomenon, where medical liability and privacy issues need to be regulated, however, in such a way that still enables the great benefits that can be achieved in preventative healthcare, health promotion and the provision of health services.

This is the empire of the ‘adhocracy’», because there is no uniformity and no common pattern. Therefore, building this global digital healthcare system will require new set of skills and forums to face a constrained globalized world. Patient access rights, AI, digital ethics and privacy-as-a-platform are moving targets. These topics will be critical in the future.

To create this global digital health network and explore the value of this international ecosystem, we need Digital Health Diplomacy, which could be defined as follows: Digital Health Diplomacy refers to the concentrated international efforts towards supranational interoperability in eHealth/Digital Health.¹⁰ These may include international agreements for mutual health data transmission, recognition of information systems or common approaches to the use of international standards. It is the basis for real cross-border health data exchange projects, pilots and infrastructure creation, connecting all healthcare actors worldwide through data. It is key to global health cybersecurity risk alert and response, and to the use of digital health to contribute decisively to global health threats.

Digital Health Diplomacy is not just a matter of commercial interest or the facilitation of interoperability

amongst Electronic Health Records (EHRs). It is equally a matter of healthcare provision, increased and improved cross-border care, and, so important these days, fighting cross-border health threats. World strategies, memorandums and declarations about telehealth, eHealth and now digital health are not in short supply from many international and global organisations. ¹¹ Real working sandboxes and green fields await. Policy collaboration, technical collaboration and concrete common projects realization are key to establishing a worldwide interoperable health ecosystem, which is urgently needed. Digital health policy is an issue of growing interest in the world health policy. Like many other international efforts, this one equally requires targets and a common mission. Those of global Digital Health Diplomacy should be threefold:

1. To reach full digital health interoperability
1. To uphold health information cybersecurity
1. To guard from digital threats to human health and dignity.

Targets include the enactment of legally binding agreements grounded in international treaties of voluntary participation, in four areas:

- Global rules for telehealth
- Global rules on medicines/devices coding/identification and its usage for global digital health services (e.g. use of IDMP – PhPID)
- Global rules for the detailed reporting and information exchange in cross-border health threats
- Decisions on the implementation and governance of concrete digital health services.

8. Conclusion

Establishing a worldwide interoperable health ecosystem requires policy and technical collaboration as well as common projects' realization.

A global approach to healthcare is only possible through creating interoperability between people, processes and technologies towards a global electronic health record (G-EHR). Necessarily this means refining and stabilizing the vision and concept, linking it to global discourses and assets (e.g. International Patient Summary, Vaccination Passport or EEHRxF) and exploring what could be the first and subsequent steps to aggregate efforts around that common target departing from a set of commonly agreed human rights and digital health interoperability common grounds.

At the level of political and societal understandings, a Global Treaty on Digital Health is needed as cross-jurisdictional and cross-countries and continents digital health services are becoming a widespread reality. Dependencies and fears on data sovereignty are starting to block major cloud investments or rendering clouds to be “on premises”. Cross-country/continent prescription, global medical device production chains, or the need for EHRs and other digital tools certification and the mutual recognition processes all are trends that will need written-down principles, rules and commitments to boost trust and promote investment.

Building a global digital healthcare system is possible through Digital Health Diplomacy efforts. Digital Health Diplomacy is the basis for real cross-border health data exchange between all healthcare actors and is key to the use of digital health for universal health coverage and integrated care systems.

9. Conflicts of interest statement

The authors declare no conflict of interests regarding this publication.

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Advancing Healthcare: AI Integration, Interoperability and Sustainability Challenges

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DOI: 10.25929/j3xxy63

ABSTRACT

This article explores the evolving landscape of healthcare transformation through intelligent integration, focusing on artificial intelligence (AI), interoperability, and sustainability in the digital era. This analysis thoroughly investigates various aspects, including patient-centric immunization systems, blockchain-based e-health management, resource optimization, and adaptable clinical solutions. The investigation is framed around evolving healthcare considerations, emphasizing a thorough exploration of advancements, comparisons, and challenges encountered in the implementation of intelligent and integrated healthcare systems. The conclusion provides valuable insights for healthcare professionals and policymakers, guiding the development of a more connected and intelligent healthcare ecosystem.

KEYWORDS

Intelligent integration, artificial intelligence (AI), interoperable systems, healthcare, sustainability

1. Introduction

The healthcare sector is undergoing a profound conversion due to the integration of innovative technologies, particularly the convergence of artificial intelligence (AI), interoperable systems,¹ and sustainable practices. In recent years, the healthcare industry has experienced a shift in basic assumptions towards intelligent integration, highlighting a development recognition of the capability assistance and encounter by these advanced technologies.

The need for a patient-centric, interoperable immunization information system is growing, with the rise of healthcare and public health associations recognizing the potential of the internet of things (IoT) in facilitating efficient healthcare services.² The emergence of decentralized e-health systems built on blockchain technology presents challenges and opportunities, requiring careful attention to interoperability and synchronization management. Security³ concerns in smart IoT applications require a comprehensive analysis to identify and address potential vulnerabilities.

The integration of AI in healthcare is promising for optimizing resources and promoting sustainability. It can transform diagnostics, treatment, and resource allocation. However, challenges include ensuring

environmental sustainability in data-driven health analysis. This analysis investigates the intersection of AI and blockchain technology in electronic health records, identifying interoperability^{4,5} requirements and challenges. Surveys provide insights into current trends and potential developments in IoT and AI implementation⁶ in remote healthcare systems.⁷ The analysis explores Medical 4.0 knowledge, focusing on advancements and applications in healthcare. It highlights the importance of consistent, flexible AI and IoT-based personalized healthcare assistance, emphasizing the need for a robust and adaptable healthcare infrastructure.

The integration of AI in smart cities⁸ and healthcare techniques is transforming urban and healthcare environments. The scalability and interoperability of care medicine platforms and cloud-based hospital intelligence systems are crucial for advanced healthcare solutions. However, concerns about environmental sustainability have led to a scoping evaluation to assess current issues and identify potential improvements. This exploration extends to future computing paradigms for medical and emergency applications, emphasizing the need for alignment with sustainability goals.

The rapid digitization of the healthcare sector is driven by AI, interoperable⁹ systems, and sustainable practices. However, challenges such as interoperability, security, and regulatory restrictions hinder their optimal integration. This analysis aims to explore ways to integrate these technologies to improve healthcare delivery, minimize challenges, and ensure long-term viability. Stakeholders recognize the benefits of AI, interoperable systems, and sustainable practices, and regulatory adaptation is crucial. Collaboration and knowledge sharing among stakeholders are essential for addressing challenges and driving innovation in healthcare.

This analysis aims to guide healthcare policy, technology development, and implementation by analyzing the intricate interactions between AI, interoperable systems, and sustainable practices. It seeks to provide a patient-centric approach, empower stakeholders to navigate digital transformation challenges, capitalize on opportunities, and foster global innovation in healthcare systems.

The dynamic interplay between AI, interoperable systems, and sustainable practices in the digital¹⁰ era forms the bottom of this analysis. By addressing these issues, the analysis intends to provide valuable insights that can guide the ongoing transformation of healthcare towards a more efficient, patient-centric, and sustainable future. The article is formed into six sections: section 2 with analysis framework, section 3 with evolving healthcare considerations, section 4 with comprehensive explorations, section 5 with comparisons and challenges, and section 6 with a conclusion.

2. Analysis Framework

Intelligent Integration in Healthcare: The imperative for intelligent integration in healthcare envisions a patient-centric, interoperable immunization information system.¹¹ This approach aligns with the broader call for a comprehensive and connected healthcare ecosystem, facilitating the seamless flow of information for improved patient outcomes.

AI and Healthcare Transformation: The transformative potential of AI in healthcare has been extensively explored. Lim & Rahmani have published a survey on semantic IoT load inference attention management, emphasizing AI's role in facilitating collaboration in healthcare and public health.¹² The integration of AI promises to revolutionize diagnostics, treatment plans, and resource optimization.^{13,14}

Interoperable Systems and Blockchain in Healthcare: The decentralized e-health systems are crucial factors in interoperability and administration^{4,15} Blockchain-based decentralized e-health systems emphasize the need for effective interoperability and synchronization.⁴ The systematic examination of interoperability calls for blockchain-aided automated health records.¹⁵

Security Challenges in Smart IoT Applications: Security confronts in smart IoT applications within

healthcare have been a focal point. ¹⁶ A comprehensive analysis based on security questions and conditions for smart IoT applications, highlights the need for robust solutions to safeguard healthcare data. ¹⁶

Sustainability in AI-Driven Healthcare: The incorporation of AI in healthcare advances sustainability concerns, particularly in data-driven health exploration. ^{17,18} Samuel & Lucassen, and Richie conducted feasibility investigations on the environmental impact of data-driven health analysis, highlighting the need for environmentally conscious approaches in AI-driven healthcare analysis. ^{17,18}

Advancements in Medical 4.0 Technologies: Medical 4.0 technologies, characterized by the fusion of AI, interoperable systems, and sustainable practices, are a pivotal focus, ¹⁴ which explores the capabilities and applications of Medical 4.0 technologies, shedding light on their potential to reshape healthcare delivery. ¹⁴

Future of Healthcare Computing Paradigms: The future of healthcare computing paradigms emphasizes the need for computing solutions that cater to medical and emergency applications. ^{19,20} These paradigms are crucial for ensuring the alignment of technological advancements with sustainability goals in healthcare.

Surveying AI Sustainability and Edge AI: Surveys on AI sustainability and edge AI contribute insights into emerging trends and challenges. ^{20,21} A survey on edge AI provides a comprehensive overview of scalable and interoperable platforms. ²¹ An analysis on AI sustainability outlines developing tendencies and analysis encounters. ²⁰

Wireless Standard-Compliant E-Health Solution: Martínez & González contribute to the literature by presenting a wireless standard-yielding e-health results catering to the specific needs of elderly populations. ²² This wireless solution aligns with the broader goal of creating interoperable systems that accommodate diverse healthcare requirements.

Blockchain-Based Models for Continuous Health Monitoring: Uppal et al. developed a blockchain-based model for endless health observation using the interplanetary file system. ²³ This model addresses interoperability challenges and ensures secure, continuous health data monitoring in a decentralized framework.

Dynamic Bayesian Network Model for Resilience Assessment: Shah et al. present a dynamic Bayesian network model for flexibility evaluation in blockchain-based IoMT. ²⁴ This model addresses encounters related to security, resilience, and adaptability in healthcare systems, emphasizing the importance of a dynamic approach to healthcare infrastructure.

Digital Care in Next-Generation Networks: Digital care explores next-generation networks, highlighting conditions and future directions. ²⁵ This perspective is essential for understanding the evolving landscape of healthcare delivery and ensuring the adaptability of healthcare systems in the digital era.

Incremental Federated Learning for Infectious Diseases Monitoring: Incremental amalgamated learning contributes insights into infectious disease monitoring, highlighting the potential of collaborative, privacy-preserving approaches in healthcare data analysis. ²⁶ This aligns with the broader goal of creating intelligent and interoperable systems for healthcare surveillance.

AI in Physical Rehabilitation: Sumner et al. conducted an organized evaluation on the application of AI in physical rehabilitation, highlighting the promise of AI in developing rehabilitation outcomes. ²⁷ This analysis aids the intelligence of AI's role in improving patient care and aligns with the broader theme of intelligent integration in healthcare.

Insights into the Internet of Medical Things (IoMT): It focuses on data mixture, security problems, and results. ^{28,29} This analysis addresses the challenges of interoperability and security in IoMT, contributing valuable insights to the broader discourse on intelligent healthcare systems.

Understanding Medical 4.0 Implementation: Akhtar et al. offer a unified multi-criteria decision-making method for understanding Medical 4.0 implementation. ³⁰ This analysis provides a comprehensive perspective on the enablers shaping the implementation of intelligent, interoperable, and sustainable healthcare systems.

The related works reveal a rich needlepoint of analysis contributions focused on the integration of AI, interoperable systems, and sustainable practices in healthcare. From envisioning patient-centric immunization systems to addressing security challenges in Smart IoT applications, these studies collectively contribute to the ongoing discourse on reshaping healthcare delivery in the digital era.

3. Evolving Healthcare Considerations

This comprehensive analysis leads the way to the integration of AI, interoperable systems, and sustainable practices in healthcare. It will follow established guidelines, including inclusion and exclusion criteria, data extraction, thematic synthesis, comparative analysis, and conceptual framework development. As shown in Figure 1, the analysis will acknowledge potential limitations and ethical considerations, undergo validation through an iterative process, and synthesize insights to provide a holistic understanding of AI-driven, interoperable, and sustainable healthcare systems.



Figure 1: Evolving Healthcare Considerations.

Systematic Literature Review: An organized literature review was conducted to examine the existing body of knowledge on the integration of AI, interoperable systems, and sustainable practices in healthcare. The analysis will adhere to established guidelines, ensuring a rigorous and structured approach to identifying, screening, and evaluating relevant studies. ^{15,17,19}

Inclusion and Exclusion Criteria: It is determined to include studies available in peer-reviewed journals, conference proceedings, and reputable sources from the time period between 2020 and 2024. Studies focusing on AI applications in healthcare, interoperable systems, sustainability, and the interplay of these elements will be prioritized. The exclusion criteria will involve studies lacking relevance to the analysis focus or not meeting predefined quality standards.

Data Extraction: Data extraction will engage systematically gathering appropriate data from chosen findings, entering the authors, publication year, analysis design, methodologies, key findings, and implications. ^{4,11-14,16-18,20-28} This process will be conducted meticulously to ensure a comprehensive overview of the contributions made by each finding.

Thematic Synthesis: The extracted data will be thematically synthesized to determine recurrent themes, patterns, and gaps in the literature. This synthesis will be guided by the key elements of intelligent integration, challenges in AI adoption, interoperability, sustainability, and the broader implications for healthcare transformation. ^{4,11-14,16-18,20-28}

Comparative Analysis: A comparative analysis will be conducted to assess similarities, differences, and advancements across studies. This approach will aid in identifying evolving trends, emerging technologies, and areas where consensus or divergence exists within the literature. ^{15,19,20}

Framework Development: A conceptual framework developed based on the synthesized findings, providing a visual representation of the relationships between AI, interoperable systems, and sustainable practices in healthcare. ^{4,11-14,16-18,20-28} This framework ³¹ will be an instrument for understanding the complex interplay of these elements and guiding future analysis endeavours.

Limitations and Ethical Considerations: The analysis will acknowledge potential limitations such as publication bias and variations in analysis methodologies across studies. Ethical considerations will be paramount, ensuring that the data extraction process respects the intellectual property rights of authors and adheres to ethical standards. ^{4,11-14,16-18,20-28}

Validation and Iterative Process: This methodology will undergo validation through an iterative process involving feedback from peer reviewers and subject matter experts. This iterative approach will enhance the reliability and robustness of the analysis, ensuring that it captures the nuanced dynamics of intelligent integration in healthcare. ^{15,19}

Synthesis of Insights: The final stage will involve synthesizing insights derived from thematic analysis, comparative assessment, and conceptual framework development. This synthesis will contribute to a holistic understanding of the state-of-the-art in AI-driven, interoperable, and sustainable healthcare systems. ^{15,19}

This methodology aims to provide a comprehensive and structured analysis of the literature, offering valuable insights into the current landscape, challenges, and opportunities in the integration of AI, interoperable systems, and sustainable practices in healthcare.

4. Comprehensive Investigations

A transformational revolution is underway in the healthcare industry, facilitated by the seamless incorporation of technologies such as AI, interoperable systems, and sustainable practices. The

convergence of these elements plays a pivotal role in reshaping healthcare delivery, optimizing resource utilization, and fostering a patient-centric approach, as illustrated in Figure 2.

Intelligent Integration in Healthcare: The concept of intelligent integration in healthcare heralds a new era where disparate systems collaboratively contribute to a more efficient and holistic patient care ecosystem. ¹¹ This change in basic assumptions envisions the creation of patient-centric, interoperable immunization information systems that transcend traditional boundaries, ensuring the seamless exchange of vital health data. ¹¹

AI and Healthcare Transformation: The incorporation of AI into healthcare practices represents a monumental leap towards precision medicine and optimized resource utilization. ¹³ Leveraging AI, healthcare providers can streamline diagnostics, personalize treatment plans, and enhance overall patient outcomes. ¹⁴



Figure 2: Comprehensive Exploration.

Interoperable Systems and Blockchain in Healthcare: The need for interoperability extends beyond AI integration, with blockchain-based decentralized e-health systems presenting novel opportunities and challenges. ⁴ Interoperability and synchronization management of these systems become critical components in realizing the full potential of blockchain in healthcare. ^{4,15}

Security Challenges in Smart IoT Applications: As healthcare systems embrace the IoT, security concerns become paramount. ¹⁶ The survey on security challenges in Smart IoT applications underscores the necessity for a comprehensive analysis to fortify the resilience of these interconnected healthcare ecosystems. ¹⁶

Sustainability in AI-Driven Healthcare: The rise of AI in healthcare must be tempered with a commitment to sustainability.¹⁸ As we explore the capabilities of AI in healthcare and social services, it becomes imperative to address environmental sustainability concerns associated with data-driven health analysis.^{17,18}

Advancements in Medical 4.0 Technologies: The transition towards Medical 4.0 technologies represents a milestone in healthcare evolution.¹⁴ By understanding the features, capabilities, and applications of these technologies, healthcare systems can adapt to the changing landscape and harness the benefits of innovation.¹⁴

Future of Healthcare Computing Paradigms: The evolution of computing models for medical situation applications underscores the importance of aligning technological advancements with the unique demands of healthcare delivery.¹⁹ This forward-looking perspective aims to chart a course for the integration of emerging technologies in a sustainable manner.¹⁹

Surveying AI Sustainability and Edge AI: A comprehensive survey on AI sustainability and edge AI provides insights into emerging trends and challenges.^{20,21} These insights are critical for shaping the discourse on sustainable AI implementation in healthcare and beyond.^{20,21}

This embarks on a complete analysis interplay between AI, interoperable systems, and sustainable practices in the digital era is evident. By synthesizing findings from a myriad of studies and surveys, we aim to contribute valuable insights that can inform and guide the ongoing transformation of healthcare towards a more efficient, patient-centric, and sustainable future.

5. Comparisons and Challenges

The comparison of findings is shown in Figure 3. with the previous investigation reveals a nuanced understanding of the practical implications of integrating AI, interoperable systems, and sustainable practices in healthcare. The synthesis of insights from the related work offers a basis for evaluating the progress made in the field and identifying key practical implications for healthcare practitioners, policymakers, and technology developers.

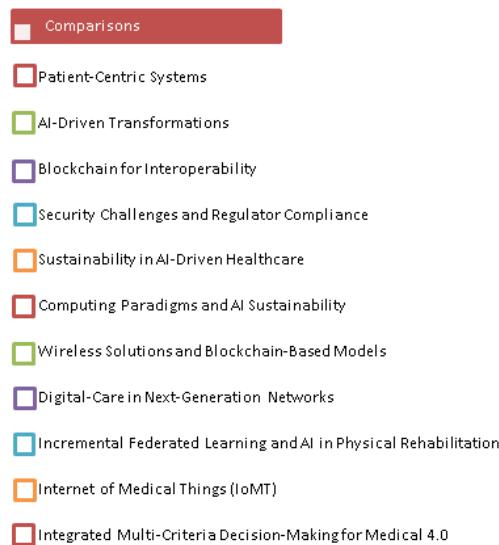


Figure 3: Comparison of Findings.

Patient-Centric Systems: Previous analysis, as highlighted, ¹¹ emphasizes the importance of envisioning patient-centric, interoperable immunization information systems. The practical implication is the need to prioritize the development of systems that empower patients, facilitate seamless information exchange, and enhance the overall healthcare experience.

AI-Driven Transformations: The transformative potential of AI in healthcare, as explored by Lim & Rahmani, ¹² is reaffirmed. Practical implications revolve around the implementation of AI-driven solutions to improve diagnostics, treatment plans, and resource optimization, aligning with the broader goal of enhancing patient outcomes. ^{13,14}

Blockchain for Interoperability: Analysis on blockchain-based decentralized e-health systems ⁴ and interoperability challenges ¹⁵ underscores the practical significance of addressing data exchange issues. The implication is the imperative for healthcare systems to invest in interoperable solutions, leveraging blockchain to enhance transparency, security, and synchronization. ^{4,15}

Security Challenges and Regulatory Compliance: Security challenges in Smart IoT applications ¹⁶ and the need for regulatory compliance are critical considerations. The practical implications highlight the obligation for healthy security procedures and adherence to regulatory frameworks to encourage AI-driven healthcare solutions. ¹⁶

Sustainability in AI-Driven Healthcare: Insights into the environmental sustainability of data-driven health investigations ^{17,18} underscore the upright and realistic implications of sustainable AI implementation. The findings emphasize the importance of aligning technological advancements with sustainability goals, acknowledging the environmental impact of AI in healthcare. ^{17,18}

Medical 4.0 Technologies: Advancements in Medical 4.0 technologies ⁸ offer practical insights into features, capabilities, and applications. The practical implication is the strategic adoption of these technologies in order to reshape healthcare delivery, optimizing resource utilization and improving patient care. ⁸

Computing Paradigms and AI Sustainability: The future of healthcare computing paradigms ^{19,20} and surveys on AI sustainability ²⁰ provide practical guidance for the integration of emerging technologies. The practical implications involve aligning computing paradigms with sustainability goals, ensuring scalability, and addressing emerging challenges in AI sustainability. ^{19,20}

Wireless Solutions and Blockchain-Based Models: The exploration of wireless standard-compliant e-health solutions ²², blockchain-based models for continuous health monitoring, ²⁵ and dynamic Bayesian network models ²⁶ offers practical solutions for specific healthcare needs. The implications involve the adoption of wireless solutions, decentralized monitoring, and dynamic approaches for resilience assessment in healthcare systems. ²²⁻²⁴

Digital-Care in Next-Generation Networks: It provides practical insights into the evolving environment of healthcare delivery. Practical implications involve understanding the requirements and future directions for implementing digital care solutions within advanced network infrastructures. ²⁵

Incremental Federated Learning and AI in Physical Rehabilitation: Studies on incremental federated learning ²⁶ and AI in physical rehabilitation ²⁷ offer practical approaches for collaborative data analysis and improving rehabilitation outcomes. The implications include adopting privacy-preserving approaches and leveraging AI for personalized rehabilitation programs. ^{26,27}

Internet of Medical Things (IoMT): Insights into the IoMT ²⁹ highlight practical aspects regarding data fusion, security, and results. The practical implication involves addressing interoperability and security challenges in IoMT, ensuring continuous, secure health data monitoring. ²⁹

Integrated Multi-Criteria Decision-Making for Medical 4.0: The implementation of Medical 4.0 via a combined multi-standards decision-making method ³⁰ offers practical enablers for stakeholders. The implications involve utilizing a structured decision-making framework for effective implementation of intelligent, interoperable, and sustainable healthcare systems. ³⁰

The comparison of findings with previous analysis reveals a cohesive narrative on the practical implications of intelligent integration in healthcare. Stakeholders can draw from these insights to make informed decisions, implement interoperable systems, address security challenges, and foster sustainability in the era of AI-driven healthcare. The practical implications underscore the need for a collaborative, patient-centric approach that embraces technological advancements while ensuring ethical, secure, and sustainable healthcare practices. There are more challenges confronting the integration of AI, interoperable systems, and sustainable practices in healthcare. These include:

- **Interoperability:** It ensures seamless data exchange and interoperability between disparate healthcare systems and remains a formidable challenge.
- **Security and Privacy:** It safeguards patient data from cybersecurity threats. Maintaining privacy standards poses significant hurdles.
- **Regulatory Compliance:** It navigates complex regulatory frameworks. Ensuring compliance with healthcare regulations adds layers of complexity to technology implementation.
- **Resource Allocation:** It optimizes resource allocation while maintaining sustainability goals. It requires careful planning and coordination.
- **Ethical Considerations:** It addresses ethical implications related to AI decision-making, data usage, and patient consent. It presents ongoing challenges.
- **Technological Complexity:** It manages the complexity of integrating AI algorithms, blockchain technology, and IoT devices. It demands expertise across multiple domains.

6. Conclusions

The article explores the intersection of AI, interoperable systems, and sustainability in healthcare analysis by providing a comprehensive understanding for practitioners, policy-makers, and technology developers. It highlights the transformative potential of intelligent integration in patient-centric, technologically advanced, and sustainable healthcare solutions. The article highlights patient-centric approaches, AI-driven transformations, blockchain interoperability, security challenges, sustainability considerations, and the integration of Medical 4.0 technologies. It serves as a roadmap for advancing healthcare through intelligent integration, advocating for patient-centric systems, robust security, sustainability, and strategic implementation of evolving knowledge. This analysis contributes to shaping a future where AI, interoperable systems, and sustainability converge, redefining healthcare delivery for a healthier, more connected world.

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DigiHealth-AI: Outcomes of the First Blended Intensive Programme (BIP) on AI for Health – a Cross-Disciplinary Multi-Institutional Short Teaching Course

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DOI: 10.25929/dcmwch54

ABSTRACT

We reflect on the experiences in organizing and implementing a high-quality Blended Intensive Programme (BIP) as a joint international event. A BIP is a short programme that combines physical mobility with a virtual part. The 6-day event, titled “DigiHealth-AI: Practice, Research, Ethics, and Regulation”, was organized in collaboration with partners from five European nations and support from the EU’s ERASMUS+ programme in November 2023. We introduced a new learning method called ProCoT, involving large language models (LLMs), for preventing cheating by students in writing. We designed an online survey of key questions, which was conducted at the beginning and the end of the BIP. The highlights of the survey are as follows: By the end of the BIP, 84% of the respondents agreed that the intended learning outcomes (ILOs) were fulfilled, 100% strongly agreed that artificial intelligence (AI) benefits the healthcare sector, 62% disagree that they are concerned about AI potentially eliminating jobs in the healthcare sector (compared to 57% initially), 60% were concerned about their privacy when using AI, and 56% could identify, at least, two known sources of bias in AI systems (compared to only 43% prior to the BIP). A total of 541 votes were cast by 40 students, who were the respondents. The minimum and maximum numbers of students who answered any particular survey question at a given period are 25 and 40, respectively.

KEYWORDS

Machine learning, healthcare, pedagogy

1. Introduction

The use of artificial intelligence (AI) in healthcare, or AI for Health (AI4H), has become an indispensable part of the wider domain of digital health. Acquisition of knowledge, skills, and competencies (KSCs) in AI4H is deemed important for building the capacity necessary to support the digital transformation of healthcare. Students of technical disciplines (such as Computer Science, Information Technology,

Informatics, or Information Science) planning to work in the health sector, as well as students of health-related disciplines interested in technology applications, and students in interdisciplinary degree programs such as Digital Health may benefit from add-on or built-in training courses in AI4H.

This motivated the partners in this Blended Intensive Programme (BIP) to create the short cross-disciplinary certificate course in AI4H to be available at no cost to students of health and technology degree programs. The funding instrument within the European Union (EU) programme Erasmus+ was selected to support the endeavor. A consortium of higher education institutions (HEIs) from five countries in the EU/EEA (European Economic Area) was formed with the inclusion of teaching and administrative staff of the institutions: the Deggendorf Institute of Technology (DIT) in Germany (the originating and hosting partner), the University of Agder (UiA) in Norway, Luleå University of Technology (LTU) in Sweden, the Czech Technical University (CTU) in the Czech Republic, and the Technical University of Catalonia (UPC) in Spain.

The work on the development of the course began in late 2022 and continued in 2023. The programme was delivered in 2023 on November 2 (online via Zoom) and 6–10 (physical) within the framework of a larger event series organized and hosted by DIT's European Campus Rottal-Inn (ECRI) – the DigiHealthDay-2023. The course was designed to be inclusive and included students from all cycles – senior undergraduate students (Bachelor's), Master's students, and PhD students, with the distribution as shown in Figure 1. We report our experience with the implementation of the BIP on AI4H and the main outcomes of the activity, including the survey by students with the online tool Smart Delphi.ⁱ

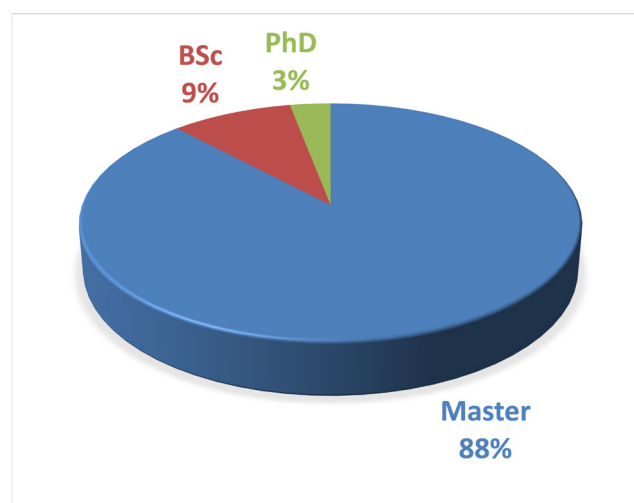


Figure 2: Figure 1: Distribution of students' study levels.

2. Literature Review

A BIP is a relatively short, innovative programme combining physical mobility with a virtual part.ⁱⁱ The intensive nature of the programme makes it important to plan well ahead of time. Some higher education institutions (HEIs) plan one year in advance¹ because of the potential challenges involved. Implementing a BIP can be fraught with multiple challenges.² These include (i) finding teachers who would be interested and willing to invest time in planning the programme, (ii) conflicting syllabuses from partner institutions, (iii) defining the language of instruction (a challenge called Englishization³), (iv) funding for mobility, (v) quality assurance procedures, and (vi) disparities in digital skills, among others.

ⁱ app.smartdelphi.com

ⁱⁱ op.europa.eu/en/publication-detail/-/publication/8a4bbab0-540d-11ed-92ed-01aa75ed71a1

ⁱⁱⁱ total respondents of 40

Despite the challenges of organising a BIP, some HEIs have identified several benefits that make it worthwhile. These include (i) improved quality of education through collaboration, (ii) increasing internationalization of partner institutions, (iii) access to Erasmus+ funding, (iv) more research opportunities, (v) cultural exchange, (vi) student networking, (vii) professional development for teachers, and (viii) technology exchange, among others.^{1,4,5}

The teaching methodologies applied to BIPs are designed to incorporate the traditional physical approach and online components in a blended approach.^{6,7} We implemented an active blended learning method in this BIP.⁸ Indeed, some recognize that the health sciences are the most common field with empirical studies on this and focus on student-centred learning.⁸ Technological tools are very instrumental to the success of learning in such environments. These tools may have contributed to blended learning being as effective or better than traditional modes or online-only mode although they come with their own challenges.^{9,10} The active learning approach ensures more students are successful learners so that less student failures are recorded.¹¹⁻¹³

3. Intended Learning Outcomes

The ILOs of the BIP were:

1. Understand the basics, use, potential, benefits, limitations of AI in healthcare and its impact on the healthcare industry;
2. Gain knowledge of the theory and practice of machine learning (ML) and how it can be used in healthcare;
3. Analyze the role of deep learning in medicine with a focus on medical imaging;
4. Describe the sources of bias and the use of explainability in AI;
5. Understand key ethical issues of using AI in healthcare and the requirements of regulation.

4. Methodology

The learning methodology is a combination of the Interactive Constructive Active and Passive (ICAP) framework¹⁴ and constructive alignment (CA).¹⁵ The ICAP framework is a taxonomy differentiating four categories of overt behaviour of engagement (interactive, constructive, active, and passive) by students and generates the hypothesis that predicts varied levels of learning outcomes. Constructive alignment, as a pedagogical tool, ensures that courses and programmes make a coherent set of teaching activities and assessments that ultimately guide students toward achieving clearly defined ILOs.

4.1. Demographics

In order to cater for students with diverse backgrounds in the programme, as expected from any BIP, it was important to collect some useful information about the students before the start of the BIP. Using the online tool identified in the introduction (Smart Delphi), we established that about 52% of the students were male and 48% female.ⁱⁱⁱ In Figure 2, it is shown that about 66%, 24% and 10% of the students are of the age brackets 20–29 years, 30–39 years, and 40–49 years, respectively. When asked about any previous BIP experience, 97% said they had no experience while only 3% had previous experience. The distribution of the study levels of the students who participated is shown in Figure 3.

ⁱ app.smartdelphi.com

ⁱⁱ op.europa.eu/en/publication-detail/-/publication/8a4bbab0-540d-11ed-92ed-01aa75ed71a1

ⁱⁱⁱ total respondents of 40

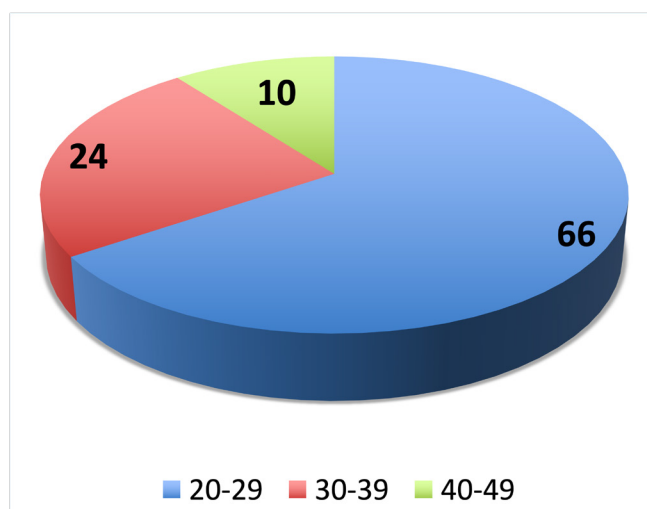


Figure 2: Age of students – 66% 20–29, 24% 30–39 & 10% 40–49.

Furthermore, about 34% of the students had minimal or no experience with AI or ML at the start of the BIP, where half of these had no experience at all. Meanwhile about 55% had some experience and 11% had extensive experience. Of these students, about 52% had beginner or no knowledge of the Python programming language, where 14% of these had no knowledge at all. About 38% had intermediate knowledge and 10% had advanced knowledge.

4.2. Implementation of the BIP

The recent advancements in AI ^{16,17} and the potential benefits to the healthcare sector motivated the title of the BIP “DigiHealth-AI: Practice, Research, Ethics, and Regulation”. The BIP was designed to award 3 ECTS credits to each student on successful completion, according to the requirement ¹⁸ and as an extrinsic motivation for students.

The partner institutions were selected from the pool of networks of the host institution, the DIT, based on their expertise and experience. The relatively short time for organizing the programme made it challenging but the enthusiasm of the students, to whom the BIP was advertised, and the hard work of the partner institutions ensured it was successful. It was beneficial to secure more than the minimum number of total participating students (15), in case of last-minute cancellations by any students, which actually occurred for different reasons.

The partner institutions held periodic online meetings via the conferencing tool Zoom ^{iv} to plan the BIP. Planning included the learning activities, the schedule, teaching assignments, onsite accommodation and transportation for participants, funding, and technological tools for learning, among other things. These are factors we considered essential for the successful implementation of the BIP. The administrative team of the host institution also planned recreational activities and a dinner for participants.

The **online component** addressed “Foundations of AI and AI in Healthcare”. The **physical component** ran and culminated in the prestigious Digital Health Day (DHD) symposium with over 1,000 participants. Topics covered during both components are given below. ^v

1. *Foundations of Artificial Intelligence (AI) and Machine Learning (ML) in healthcare*
2. *Fundamentals of Machine Learning*

^{iv} zoom.us

^v docs.google.com/document/d/1bHbGvXIordcaBtBXRky8_8OeA44NM1v3IYm8ZQPU3d0edit

3. *AI Use Cases in Healthcare*
4. *Data Quality and Trust in Health AI*
5. *Ethics and Regulation of AI*
6. *UX Design in Healthcare AI*

The topics were agreed on and assigned to teachers from partner institutions before the start of the BIP. The learning periods were put in blocks of 90 minutes and each day had two or more blocks with breaks of a few minutes between blocks or intra-block. Overall, the teaching method was structured so that lecture and training constituted 25%, case studies and discussions 25%, and group work plus hands-on sessions constituted 50%.

Students participated in different activities geared towards the ILOs. These include flipped classroom, group discussions, pop quizzes, writing exercise, hands-on sessions, and shared tasks, among others. The pedagogical tools that were used include Jupyter Notebooks and Google Doc, among others.

4.3. Survey

The student survey included the 10 key questions given below and a Likert scale from 1.0 (strongly disagree) to 6.0 (strongly agree). The questions were designed through an iterative process before the final version was agreed upon, based on the ILOs. Respondents were asked to fill the survey at the start and the end of the BIP.

1. I feel comfortable using Python programming language at this moment.
2. I feel comfortable using Generative AI (e.g. DALL-E) or Large Language Models (e.g. ChatGPT) generally.
3. I feel comfortable using Large Language Models (e.g. ChatGPT) for writing (e.g. emails).
4. I can identify at least two known sources of bias in AI.
5. I have interacted with an AI system that provided explanations for its decisions.
6. I have fears associated with the utilization and potential implications of AI.
7. I am concerned about my privacy when utilizing AI systems.
8. I am concerned about AI potentially eliminating jobs in the healthcare sector.
9. I think AI brings benefits to the healthcare field.
10. 10. The intended learning objectives (ILOs) of this BIP were successfully achieved

4.4 Probing Chain-of-Thought (ProCoT)

Probing Chain-of-Thought (ProCoT) was introduced for the first time during this BIP. It is a method whereby users, the students in this case, scrutinize the output of a large language model (LLM) by using a reference-based tool to provide up-to-date, fact-checked feedback on the model's output. This

knowledge-enhancing feedback leads to faster independence and self-awareness of the students. It is entrenched in the “self-regulation” method, which is the self-directive process by which learners transform their mental abilities into task-related skills.²⁰

The method involves comparing three outputs: 1) LLM-only outputs, 2) students’ ProCoT outputs, and 3) LLM ProCoT outputs. LLM-only output is the direct answer of the LLM after asking any of the original questions listed below. A student’s ProCoT output is the written feedback, containing peer-reviewed references, to the initial LLM-only output while an LLM ProCoT output is the LLM answer feedback to their initial LLM-only output. The students were required to pick one question from the following list, pose it to ChatGPT vi or any LLM and write one page to affirm or refute assertions made by the LLM by using references from peer-reviewed articles. The set of questions are:

1. Did cancer exist before man-made chemicals were around to create it?
2. Who will benefit from AI in healthcare?
3. How long do you have to exercise for it to count?
4. How will we avoid machine bias?

These questions were randomly picked from two blogs.^{vii} The ProCoT instruction to the students was “Write 1 page to affirm or refute assertions/statements made by ChatGPT/LLM in the response by using references from peer-reviewed articles”. They were under 30-min supervision while providing answers.

Large Language Model (LLM)

A large language model (LLM) is a deep probabilistic or neural network model which is trained on large amounts of data, such that it generates probabilities over a set of words (or tokens) in order to predict the next token in a sequence. There are many types with different sizes that have been released over the years.^{21,22} ChatGPT is, apparently, the most popular example of this type of technology.

5. Results and Discussion

At the end of the BIP, a total of 541 votes had been cast by 40 students. The minimum and maximum numbers of students who answered any particular survey question at a given period are 25 and 40, respectively. The survey revealed that 84% of the respondents (Figure 3) agree the intended learning outcomes (ILOs) were fulfilled, 100% strongly agree AI benefits the healthcare sector, 62% (Figure 4) disagree they are concerned about AI potentially eliminating jobs in the healthcare sector (compared to 57% initially), 60% (Figure 5) were concerned about their privacy when using AI, and 56% (Figure 6a) could identify, at least, two known sources of bias in AI systems (compared to only 43% [Figure 6b] prior to the BIP).

Furthermore, 88% (Figure 7a) agree they feel comfortable using LLMs (e.g. ChatGPT) for writing (e.g. emails) (compared to 83% [Figure 7b] before the BIP), where those who strongly agree virtually doubled. This follows in the same vein as 75% (Figure 8a) who agree they feel comfortable using generative AI (e.g. DALL-E), generally, compared to 62% (Figure 8b) prior to the BIP. 58% of the respondents agree they feel comfortable using the Python programming language BIP.

^{vi} chat.openai.com

^{vii} wtamu.edu/cbaird/sq/category/health; magazine.utoronto.ca/research-ideas

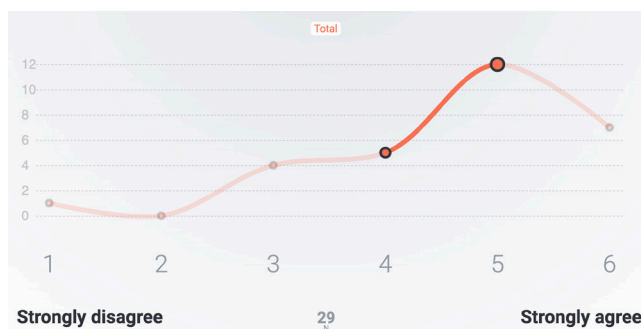


Figure 3: 84% agree the BIP's ILOs were achieved.



Figure 4: 62% disagree about concerns AI eliminating jobs in healthcare.

5.1. Qualitative Results

In addition to the quantitative evaluation provided, students had the opportunity to give qualitative, formative feedback about the BIP if they so desired, either through the online survey tool or social media. ^{viii} Some of the positive comments include:

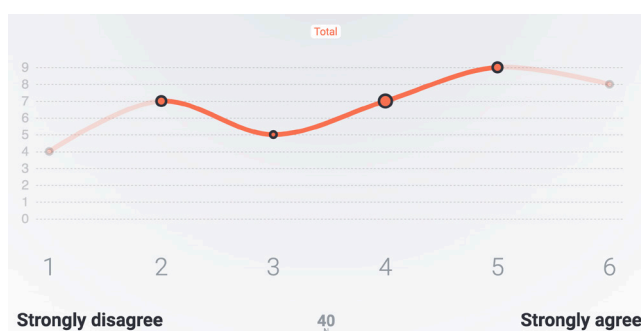


Figure 5: 60% are concerned about privacy when using AI.

1. I can finally announce that I have had my first Erasmus+ Scholarship experience! Last week, I was blessed to attend the Blended Intensive Programme (BIP)... and intensive doesn't begin to describe this massively impactful week.

^{viii} particularly on LinkedIn

2. Quite intuitive. There's a lot to take away from this course but it is even more so to say the scope of AI in healthcare is a broad one that cannot be encompassed in one seminar but so far an amazing job has been done.
3. GREAT EXPERIENCE
4. I have had the pleasure of attending the Blended Intensive Programme (BIP)... in which I had the opportunity to broaden my knowledge about AI in healthcare thanks to the many crucial topics that were raised by all the amazing speakers during the event. As an AI master's student, I see a clear need for pushing the advancements of technology in favor of humanity.

A comment for improvement was:

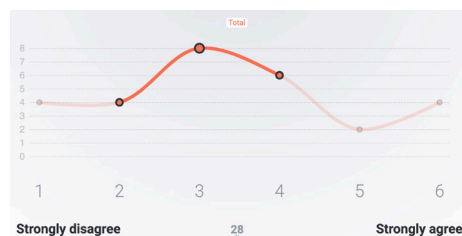
[The] deep learning session needed to be more practical and application[- based].

5.2. ProCoT

Valid results from the students' ProCoT answers (24 out of 26) show cheating can be prevented while stimulating critical thinking in students through

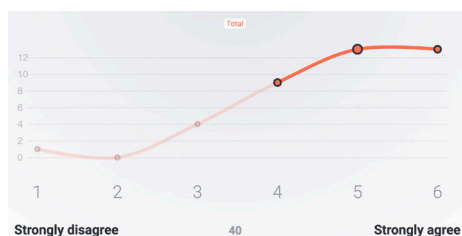


(a) 56% could identify two sources of AI bias post BIP

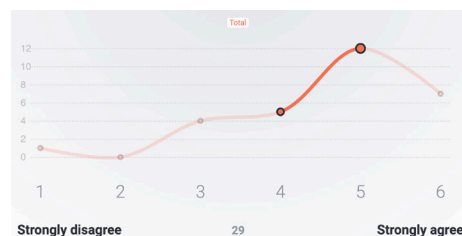


(b) 43% could identify two sources of AI bias pre-BIP

Figure 6: AI Bias

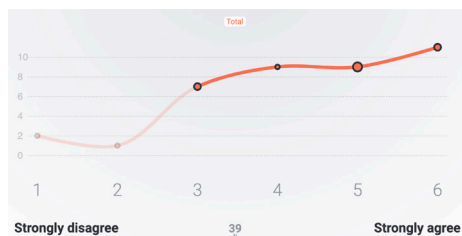


(a) 88% agree they feel comfortable using LLMs

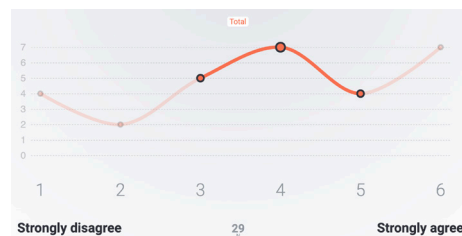


(b) 83% agree they feel comfortable using LLMs

Figure 7: LLM Usage



(a) 75% agree they feel comfortable using GenAI post BIP



(b) 62% agree they feel comfortable using GenAI pre-BIP

Figure 8: GenAI

LLMs. The average word counts used by students (208) is smaller than the usually verbose LLMs (391 and 383 for ChatGPT and Phind, respectively). The quality of students' ProCoT answers is better than those by ChatGPT, based on grounding by references. We further compared the LLM ProCoT feedback on its own answers to the original questions and found ChatGPT (v3.5) expressly had difficulty giving references and Phind (v8) typically lifted words from the input it was given, in what may be considered plagiarism, though it did a better job at providing references.

6. Conclusion

BIPs appear to provide beneficial modes of learning for participating students. Our experience reveals that the BIP added value to both students and teachers in many ways, including the following: increasing internationalization, sharing of best practices through collaboration, and providing cultural exchange. We also observed high turnout of interested students, motivated teachers from partner institutions, and high achievement of the ILOs. The success of the BIP is attributable to the determination of the many stakeholders. However, one of the challenges of evaluating an educational programme is that its achievement is usually based on the final experience of the students. The long-term impact, on the work, careers etc., for the students takes time to materialize. In the future, a long-term follow-up survey of the students may help to understand the impact. Also, a teacher survey (in a future BIP) will be worthwhile to consider, in addition to the student survey. This will provide teachers' perspectives on the programme and opportunities for evaluating the programme from a different perspective.

7. Acknowledgment

The authors wish to thank the reviewers for their valuable feedback and recommendations for improving the paper. Teachers from Luleå University of Technology (LTU) acknowledge the Wallenberg AI, Autonomous Systems and Software Program (WASP), funded by the Knut and Alice Wallenberg Foundations and the LTU counterpart fund.

8. Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Acronyms

AI artificial intelligence.

AI4H AI for Health.

BIP Blended Intensive Programme.

CA constructive alignment.

CTU Czech Technical University.

DHD Digital Health Day.

DIT Deggendorf Institute of Technology.

ECRI European Campus Rottal-Inn.

EU European Union.

HEI higher education institution.

ICAP Interactive Constructive Active and Passive.

ILOs intended learning outcomes.

KSCs knowledge, skills, and competencies.

LLM large language model.

LTU Luleå University of Technology.

ML machine learning.

ProCoT Probing Chain-of-Thought.

UiA University of Agder.

UPC Technical University of Catalonia.

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The logo for JAIR features a large, bold, black 'JAIR' text. To the right of the 'R' is a blue graphic element consisting of a vertical bar at the top, a horizontal bar extending to the right, and a curved line that loops back down and to the left, resembling a stylized 'J' or a bracket.

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