















DIGITALIZATION IN HEALTHCARE

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Project title: "Increasing of digital knowledge in health care to enhance personalized medicine in the future"

Project number: 2023-1-SK01-KA210-VET-000165411

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1 Introduction

Healthcare is undergoing a major transformation due to the rise of digital technologies. Digitalization in healthcare means using modern technologies like electronic health records (EHRs), telemedicine, wearable devices, big data analytics, and artificial intelligence (AI) to improve patient care and healthcare operations. These tools are changing how we deliver healthcare services, making them more efficient, accurate, and accessible [1, 2, 4].

One of the biggest benefits of digitalization is improved communication between healthcare providers and patients. Telemedicine allows doctors to consult with patients online, making healthcare more accessible for people living in remote areas or those unable to visit a doctor in person [4]. Wearable devices and the Internet of Medical Things (IoMT) let doctors monitor patients' health remotely, track vital signs, and even predict potential health issues before they become serious [2, 3].

Digitalization also helps improve operational efficiency in healthcare settings. Tasks like scheduling appointments, managing resources, and processing bills are automated, reducing human error and saving time. With better data sharing across hospitals and research centers, healthcare professionals can make more informed decisions, and research can progress faster [1, 3, 4].

Digital transformation goes beyond simply upgrading old systems—it changes how healthcare functions, benefiting patients and healthcare providers. For patients, tools like AI-driven diagnostics and wearable health monitors help doctors catch diseases early and provide more personalized care. AI can rapidly analyze medical images, making diagnoses faster and more accurate, which is crucial for improving patient outcomes [3, 4].

From an operational perspective, digital tools significantly reduce inefficiencies. Automated systems free up healthcare professionals from routine administrative tasks, allowing them to focus more on patient care. Predictive analytics help hospitals and clinics manage patient demand more effectively, such as forecasting high patient volumes during flu season or predicting emergency room traffic [2, 4]. Patients also benefit from digitalization. Online platforms and mobile apps give them more control over their health by allowing them to schedule appointments, access medical records, and communicate with their doctors directly. This transparency improves patient satisfaction and builds trust in healthcare providers [1, 4].

As the demand for better and more affordable healthcare grows, digital transformation has become a vital part of modernizing healthcare systems. It addresses challenges like rising healthcare costs and aging populations, while also ensuring that healthcare facilities are equipped to meet future needs [2] [3] [4].

2 Trends in Digital Healthcare

2.1 Internet of Medical Things (IoMT)

The Internet of Medical Things (IoMT) is revolutionizing healthcare by connecting medical devices, software, and systems through the Internet. This network enables real-time health monitoring, personalized treatment, and efficient healthcare delivery, making medical services more accessible and patient-centered. IoMT combines wearable devices, hospital equipment, and advanced software to create a seamless flow of health data between patients and providers [5, 6]. IoMT includes wearable devices like smartwatches, glucose monitors, and fitness trackers, which collect data such as heart rate, blood pressure, and blood sugar levels. These devices communicate with healthcare systems to continuously update a patient's health. For example, a









wearable ECG monitor can alert doctors to irregular heart rhythms, enabling early intervention [7, 8].



Picture 1.: Internet of Medical Things structure by ChatGPT.

In hospitals, IoMT is being extended to connected devices such as ventilators and infusion pumps, ensuring optimal operation and integration into the hospital's electronic health record (EHR) system [9, 10]. One of the greatest benefits of IoMT is its ability to improve patient outcomes through real-time data collection and analysis. For example, IoMT devices can detect early signs of complications of chronic diseases, allowing physicians to adjust treatment proactively [6, 11]. Patients benefit from the convenience of remote monitoring, as they can manage their health from home and connect with their healthcare providers. This is especially valuable for individuals living in rural areas or those with mobility issues [12, 13]. IoMT also plays a critical role in hospital efficiency. Smart inventory systems track medical supplies and equipment, reducing waste and ensuring resources are available when needed. Connected devices help streamline workflows, allowing healthcare professionals to focus on patient care instead of manual data entry [10, 14]. In addition, IoMT supports predictive maintenance of hospital equipment, preventing failures and reducing downtime [5, 8].

Despite its many benefits, IoMT presents challenges such as security and interoperability. The large amounts of sensitive data generated by IoMT devices must be protected from cyber threats. Healthcare providers must implement robust encryption methods and comply with data protection regulations such as GDPR and HIPAA to secure patient data [9, 11]. Another challenge is ensuring that different IoMT devices and systems can communicate effectively. Standardization efforts are underway to address these issues and enable seamless integration across healthcare networks [13, 14]. The economic impact of IoMT is also significant, as it reduces healthcare costs by reducing hospital admissions, optimizing resource allocation, and minimizing unnecessary procedures. For example, remote monitoring can identify health problems early, reducing the need for costly emergency care [7, 10]. However, deploying an IoMT infrastructure requires significant upfront investments in equipment, software, and training, which can be challenging for smaller healthcare providers [8, 12].









2.2 Telemedicine and remote patient monitoring

Telemedicine and remote patient monitoring (RPM) are tools of the modern healthcare system due to their ability to broaden service reach, increase efficiency, and render patient-oriented services. With the use of digital applications and communication networks, physicians and patients can be geographically separated, yet still achieve improved access and enhanced patient results. Continually multiplying challenges and needs of healthcare systems have made telemedicine and RPM indispensable in the delivery of modern medical services [14][15].

Some of the advanced technologies within telemedicine and RPM are real-time communication, the use of wearables, and networked systems. Telemedicine makes it possible for patients and doctors to consult with each other via video calls while specialists can later retrieve the medical data and video recordings for analysis at their convenience [15]. RPM is a step beyond telemedicine, using wearables and smartphone applications to extract and monitor patients' vital signs, including heart rate, blood pressure, and oxygen saturation. These data-gathering devices generate large amounts of data that are filtered and analyzed by artificial intelligence (AI) algorithms trained to identify and flag the most common medical problems for quick diagnosis and treatment [16][17]. These devices are linked to medical IoT (IoMT) networks that ensure remote monitoring and data transfer between the devices and the healthcare system [18].



Picture 2.: A digital illustration of a futuristic telemedicine setup, featuring a patient sitting comfortably at home using a tablet device to connect with a doctor. The doctor appears on the screen in a virtual consultation.

Telemedicine and remote patient monitoring (RPM) come with numerous advantages, such as the ability for patients to consult specialists without the need for long-distance travel [16]. Chronic conditions like diabetes and heart failure can be more effectively managed with real-time health monitoring, enabling patients to take charge of their own health [17][19]. Additionally, telemedicine helps to cut down on wait times and ensures that patients receive continuous care by allowing access to doctors from the comfort of their homes [15][20]. However, challenges such as limited digital literacy and poor internet access must be tackled to guarantee equitable utilization of these technologies [14][18].









Healthcare providers also gain significantly from telemedicine and RPM, as they enhance operational efficiency by lightening the load on hospitals through remote consultations and timely interventions [15][18]. These tools became especially crucial during the COVID-19 pandemic when in-person visits were limited [16][17]. RPM provides ongoing patient data, which enables healthcare professionals to tailor treatments effectively. For instance, artificial intelligence can analyze RPM data to catch early signs of deterioration in patients with chronic conditions, allowing for proactive adjustments to care plans [19][20]. Nonetheless, successfully integrating telemedicine requires training to adapt to new workflows and harness the full potential of the technology [14][19].

From an economic perspective, telemedicine and RPM present significant cost-saving opportunities by reducing hospital admissions, emergency room visits, and transportation expenses for patients [16][18][20]. These technologies also help optimize resource allocation, directing healthcare efforts where they are most needed. Despite these benefits, the initial investment in telemedicine infrastructure—including devices, software, and training—can be quite hefty, particularly for smaller healthcare providers. However, the long-term financial perks often outweigh these initial costs [17][19].

Data management represents a crucial facet of telemedicine and RPM. These systems produce large volumes of sensitive patient data, highlighting the need for robust data security and governance practices. Platforms utilize encryption to safeguard this information, and adherence to regulations such as GDPR ensures ethical handling of data. Transparent data practices help to build trust between patients and providers, encouraging broader acceptance and use of these technologies [18][20].

In summary, telemedicine and RPM are transforming healthcare delivery by improving access, enhancing patient outcomes, and lowering costs. Still, challenges like digital literacy, infrastructure shortages, and data privacy concerns must be addressed to fully unlock their potential. As healthcare continues to evolve, these technologies are set to play a pivotal role in fostering more efficient, patient-centered care systems [15][17][19][20].









2.3 Artificial Intelligence (AI) in diagnostics and treatment

Artificial Intelligence (AI) is changing healthcare by introducing advanced tools that improve accuracy in diagnosis, offer personalized treatment options, and make medical systems more efficient. Technologies like machine learning (ML) and deep learning (DL) help analyze large amounts of data, finding patterns that assist in detecting diseases early and making better decisions about patient care [20][21]. Al is used in many areas of medicine, including medical imaging, pathology, genomics, and even telemedicine, making it a vital part of modern healthcare.



Picture 3.: A digital illustration of data usage in Al.

Al in Detecting Cancer

Al is an important tool in the fight against cancer. In medical imaging, Al helps analyze Xrays, CT scans, and MRIs to find tumors and classify them accurately. This is especially helpful for detecting colorectal cancer because Al can spot small precancerous changes. This allows doctors to take action early and potentially save lives [22]. In pathology, Al looks at tissue samples under a microscope to identify cancer types and predict how they might respond to treatment. This information is critical for tailoring treatments to individual patients [23]. However, using Al in cancer care needs high-quality data and clear systems so both doctors and patients can trust the results [21][24].

Al in Heart Disease

Cardiovascular diseases (CVDs) are a major cause of death around the world. However, artificial intelligence (AI) is helping doctors diagnose and manage these diseases more effectively. Al systems can analyze electrocardiograms (ECGs) and echocardiograms to identify issues like irregular heartbeats and heart failure more accurately than traditional methods [25].

Wearable devices, such as smartwatches, can monitor vital signs like heart rate and blood pressure in real time, alerting doctors to potential risks. This technology enables early detection and prevention of serious heart conditions [26][27].

However, there are challenges to consider, especially regarding patient privacy, since heart health data is very sensitive [25][28].

Al in Brain and Nerve Disorders

Al is making it easier to diagnose neurological conditions like Alzheimer's, Parkinson's, and epilepsy. It can look at brain scans to spot early signs of Alzheimer's or predict when someone









might have a seizure by analyzing EEG data. For Parkinson's disease, AI helps keep track of changes in speech and movement, so doctors can better monitor how the disease is progressing and fine-tune treatments. But there are still some hurdles to overcome, like needing large amounts of data to train AI and dealing with the different symptoms that patients experience [26][28].

Al in Infectious Diseases

Al has changed how we manage infectious diseases, especially during the COVID-19 pandemic [25][29]. For example, Al analyzed chest CT scans to check how severe COVID-19 cases were. It also helps fight antimicrobial resistance (AMR) by examining bacteria and predicting which antibiotics will work, which reduces treatment failures [23][28]. Additionally, Al models can predict disease outbreaks by looking at patterns in health data, helping governments and healthcare systems prepare for pandemics [29][30].

Al in Genomics and Rare Diseases

Al has completely changed how we study genetics, especially when it comes to diagnosing rare diseases. By looking at DNA data, Al can spot mutations tied to conditions like cystic fibrosis or Marfan syndrome, which helps doctors make early and accurate diagnoses [27][30]. This means they can create personalized treatment plans that really improve patient outcomes [24][29]. But since genomic data is super sensitive, it's crucial to protect patient privacy through encryption and sticking to strict regulations. Al is reshaping healthcare diagnostics, allowing for early disease detection, better treatments, and improved outcomes for patients. Whether it's identifying cancer, managing heart and brain issues, or tackling infectious diseases, Al provides some amazing tools that help both patients and doctors. To make the most of this potential, teamwork among healthcare pros, researchers, and policymakers is essential [27][30].

2.4 Digital twins in healthcare

Digital twins are basically digital copies of real-world things or systems that help us understand how they work and what they might do in different situations. In healthcare, they're a game-changer. These tech models can mimic a patient's body or even an entire hospital, allowing doctors and healthcare teams to run different scenarios and make smarter choices without having to dive into real-life procedures right away. [30][31].



Picture 4.: A digital illustration of a digital twin of a patient in clinical office.









Digital twins in healthcare are driven by cool tech like artificial intelligence (AI), machine learning (ML), and the Internet of Things (IoT). These tools pull in real-time info from sensors, medical devices, and patient records to create living models that change over time. For instance, a digital twin of a patient can show how a disease might progress or how a treatment could work, which helps doctors tailor care to each individual.[32][33]. This approach has already shown promise in cardiology, where digital twins model heart conditions to guide surgeries and other interventions [34].

One important use of digital twins is in healthcare. By updating the digital model with realtime patient information, doctors can foresee health risks or disease development before any symptoms show up. For example, digital twins can help predict the start of chronic conditions like diabetes or high blood pressure, which allows for early treatment. [35][36]. Similarly, in oncology, digital twins simulate tumor growth and test different treatment strategies, improving the precision of cancer care [37][38].

Digital twins are changing the game when it comes to surgical planning. These virtual models of organs or systems give surgeons a closer look at a patient's anatomy, letting them practice and perfect tricky procedures before actually doing them. This helps lower risks and leads to better results in surgery. [39]. In orthopedics, doctors are using digital twins of joints and bones to create custom implants and rehab plans. This helps patients recover quicker and get back on their feet faster [40][41].

3 Legal and Regulatory Framework

Digitalization in healthcare has revolutionized patient care, research, and operational efficiency, bringing new opportunities to improve outcomes and reduce costs. However, this technological shift comes with significant legal and regulatory responsibilities to ensure patient safety, privacy, and ethical practices. Understanding the regulatory framework is crucial for healthcare providers, vendors, and policymakers to harness the benefits of digitalization while addressing compliance challenges.



Picture 5.: ChatGPT illustration of a legal framework in healthcare.

Healthcare systems worldwide operate under various legal frameworks designed to protect patient data and regulate digital technologies.

Key laws include:











General Data Protection Regulation (GDPR): GDPR is a cornerstone of data protection in the European Union, mandating explicit patient consent for data collection and processing. It gives individuals the right to access, rectify, and erase their data. Healthcare providers must ensure secure storage, use encryption, and report data breaches within 72 hours [42][43].



Health Insurance Portability and Accountability Act (HIPAA): HIPAA governs electronic health records (EHRs) in the United States, requiring safeguards for protected health information (PHI). It outlines standards for data sharing, encryption, and de-identification, allowing the use of anonymized data for research [44][45].

EU-MDR

Medical Device Regulation (MDR): MDR applies to digital devices and software in the EU, including mobile health apps and diagnostic tools. It enforces stringent requirements for clinical evaluation, risk assessment, and post-market surveillance to ensure patient safety [46][47].

Global Guidelines: Organizations like the World Health Organization (WHO) provide recommendations on digital health strategies, focusing on interoperability, equitable access, and ethical use of digital technologies [48][49].

While GDPR and HIPAA are leading frameworks, healthcare digitalization laws vary significantly across regions. These differences reflect varying technological advancements, healthcare priorities, and cultural attitudes toward privacy:

- **Europe:** GDPR's patient-centric approach places strict limitations on data processing and cross-border data sharing. MDR complements these regulations by addressing the safety and performance of medical devices [44].
- United States: HIPAA is less restrictive on data sharing for research but places significant emphasis on safeguarding PHI in clinical environments [43].
- Asia: Countries like South Korea and Japan are adopting privacy laws inspired by GDPR, but enforcement and implementation vary. China focuses on leveraging healthcare data for public health while balancing privacy concerns [41].
- **Developing Countries:** Many regions face challenges in implementing comprehensive digital health laws due to resource constraints, although global partnerships are aiding progress [43].

The rules around digital healthcare are always changing, especially with updates to laws like GDPR and HIPAA. It's super important to keep up with these changes and adjust to new requirements to avoid fines and keep patient trust. This means constantly monitoring things and often reworking existing compliance processes. Smaller healthcare organizations, however, really struggle with this due to their limited money and tech resources. Setting up secure systems, training staff, and keeping up with complicated regulations can be way more than they can handle. This leads to differences in how well they can meet these requirements, which might affect the quality of care they offer. Plus, global healthcare partnerships often run into issues because of different regional rules about sharing data. For instance, sending patient data from the EU, where GDPR rules are strict, to places with looser privacy laws is heavily regulated. These legal challenges complicate the situation even more. [48]. FFor smaller healthcare organizations, having limited money and tech resources can be a big headache. Setting up secure systems,









training staff, and keeping up with complicated regulations can be too much for these providers to handle. This can lead to gaps in meeting the rules, which might affect the quality of care they can provide. [49]. Global healthcare partnerships often run into issues because of the differences in data-sharing laws around the world. For instance, when it comes to sharing patient info from the EU, where GDPR rules are strict, things get tricky compared to countries with looser privacy rules. These legal hurdles make working together internationally more complicated, so we really need solid legal agreements to make it work. [45][47].

4 Privacy and Security in Healthcare

Keeping patient information safe is super important in today's healthcare world. With more people using electronic health records (EHRs), fitness trackers, and cloud storage, it's crucial to protect patient data. This helps build trust, stay on the right side of the law, and provide ethical care. [50].

Healthcare data is super sensitive because it has all kinds of personal and medical info, like diagnoses, treatments, and even genetic details. If someone gets unauthorized access to this data or it gets leaked, it can result in identity theft, financial scams, and a lot of emotional stress for patients. [53]. When patient data gets leaked, it can really hurt healthcare providers' reputations and lead to legal trouble. So, keeping things private and secure isn't just about following rules—it's also the right thing to do. [51].



Picture 6.: A digital illustration of a privacy imagined by ChatGPT.

4.1 Common Threats to Healthcare Data

Data Breaches: Data breaches happen when unauthorized people manage to access sensitive healthcare info, like electronic health records (EHRs), lab results, or billing details. This can occur for several reasons:

- Phishing Attacks: Cybercriminals can trick healthcare workers into giving away their login info or other important details.
- Weak Passwords: If passwords are easy to guess or there's no two-factor authentication, it becomes a lot easier for hackers to break in.
- System Vulnerabilities: Using outdated software or failing to fix security holes can leave systems exposed and easy for attackers to access. [53].









Ransomware Attacks: Ransomware is malicious software that encrypts healthcare data, rendering it inaccessible to the organization until a ransom is paid. These attacks can:

- Disrupt Operations: Hospitals may have to shut down IT systems, delaying patient care.
- Compromise Safety: Emergency treatments may be hindered if vital patient information is locked.
- Impose Financial Costs: Ransom payments and the costs of recovery from such attacks can be significant.

Insider Threats: Insider threats arise from employees or contractors who misuse their access privileges, either intentionally or accidentally.

- Malicious Insiders: Some employees may intentionally access or leak sensitive data for personal gain or revenge.
- Unintentional Actions: Mistakes such as sending patient data to the wrong recipient or failing to log out of shared workstations can also lead to data exposure.

These threats are particularly concerning because insiders are often trusted individuals, making their actions harder to detect and prevent.

4.2 Strategies for Ensuring Data Privacy

Encryption: Encryption is all about turning sensitive information into a jumbled mess that only the right people can read with a special key. There are two main types: symmetric encryption, where you use the same key for both locking and unlocking, and asymmetric encryption, which involves a pair of keys—one public and one private. People use encryption for different things, like securing data when it's being sent (think of patient info being sent to the cloud) and when it's stored away (like electronic health records). This helps keep everything safe from prying eyes and unauthorized access.[54].

Access Control: Access control helps keep sensitive data safe by deciding who can see or edit it, which reduces the chances of unauthorized access. For example, Role-Based Access Control (RBAC) gives permissions based on a person's job in the organization, like only allowing doctors to access certain patient records. Another method is Multi-Factor Authentication (MFA), which adds an extra layer of security by needing more than one form of verification, like a password and a fingerprint. [55][56].

Anonymization: Anonymization is all about taking out any details that could identify patients from their data, so researchers can use it without risking anyone's privacy. This is great for research because it lets people share information for public health studies while keeping patients' identities safe. Some common ways to do this include generalization, where specific details get removed, and pseudonymization, which swaps out identifiable information for codes [57][58].









5 Cybersecurity Frameworks in Healthcare

Healthcare organizations depend on strong cybersecurity measures to keep sensitive data safe, follow the law, and maintain the trust of their patients.



Picture 7.: A digital illustration of a cybersecurity imagined by ChatGPT.

NIST Cybersecurity Framework (NIST CSF)



Developed by the National Institute of Standards and Technology, this framework provides a structured approach to managing and reducing cybersecurity risks.

- Key Features:
 - Five Core Functions: Identify, Protect, Detect, Respond, and Recover.
 - Customization: Flexible enough to be tailored to the unique needs of healthcare organizations.
 - Risk-Based Approach: Encourages organizations to prioritize resources to address their most significant risks.
- Use in Healthcare: Often adopted to secure electronic health records (EHRs) and protect against data breaches and ransomware [59].

ISO/IEC 27001

An internationally recognized standard for Information Security Management Systems (ISMS).

• Key Features:

- Comprehensive Scope: Covers people, processes, and IT systems.
- Risk Management: Emphasizes regular risk assessments and updates to security protocols.
- Continuous Improvement: Requires ongoing monitoring and auditing of security measures.
- Use in Healthcare: Helps hospitals and clinics achieve compliance with data protection laws like GDPR [60]









Health Information Trust Alliance (HITRUST) CSF

Designed specifically for the healthcare industry, HITRUST combines various security frameworks, including HIPAA, GDPR, and ISO standards.

- Key Features:
 - Healthcare-Specific: Tailored to address the unique challenges of protecting sensitive patient data.
 - Scalability: Suitable for organizations of all sizes.
 - Certifications: Organizations can achieve certification to demonstrate compliance and security maturity.
- Use in Healthcare: Widely adopted by U.S.-based healthcare providers and vendors [61]

GDPR (General Data Protection Regulation)

Although not a traditional cybersecurity framework, GDPR provides stringent guidelines for data protection and privacy in the European Union.

- Key Features:
 - Consent Requirements: Patients must give explicit consent for their data to be collected or processed.
 - Right to Access and Erasure: Patients have the right to access their data and request its deletion.
 - Data Breach Notifications: Organizations must report breaches within 72 hours.
- Use in Healthcare: Ensures the ethical and secure handling of patient data across the EU [62].

COBIT (Control Objectives for Information and Related Technologies)

Developed by ISACA, COBIT focuses on IT governance and management.

- Key Features:
 - Business Alignment: Ensures that IT processes align with organizational goals.
 - Risk Management: Provides guidelines for identifying, assessing, and mitigating cybersecurity risks.
- Use in Healthcare: Ideal for managing IT infrastructure in large healthcare organizations [63].

CIS Controls (Center for Internet Security Controls) (CIS Controls)

A prioritized set of actions designed to improve cybersecurity hygiene.

- Key Features:
 - 20 Critical Controls: Cover basic, foundational, and organizational security measures.
 - Implementation Tiers: Allows organizations to scale efforts based on their size and resources.
- Use in Healthcare: Helps prevent common threats like phishing and malware attacks [64].

By implementing these strategies, healthcare providers can establish strong defenses against data breaches and other security threats. Privacy and security are essential to the digitalization of healthcare. Safeguarding sensitive patient information is not only a legal requirement but also a key factor in building trust between patients and providers. [65].









6 Standards and Interoperability

Healthcare systems are leaning more and more on digital tools to provide better and faster care. But for everything to run smoothly, it's super important to have standardization and interoperability. This way, data from different places—like hospitals, labs, and wearable gadgets—can be shared, understood, and used effectively [66].

HL7 (Health Level Seven)



HL7 is a set of global standards that helps different healthcare systems share and access • electronic health info more easily. It was created to help eliminate the barriers between disconnected healthcare systems by making data-sharing more uniform. You can find HL7 being used in places like hospitals, lab management systems, and electronic health records. It is globally adopted across hospitals, clinics, and laboratories for seamless data exchange [68].

FHIR (Fast Healthcare Interoperability Resources)



FHIR is a cool, modern standard made for quick and secure data sharing using web tech like RESTful APIs, JSON, and XML. It was created to fix the issues that earlier HL7 standards had. You can use it for real-time data sharing in things like telemedicine, wearable devices, and patient portals. It's become pretty popular, especially in the U.S. with the 21st Century Cures Act and is used around the world to help different systems work together smoothly [68]. HL7 is a set of global standards that helps different healthcare systems share and access electronic health info more easily. It was created to help eliminate the barriers between disconnected healthcare systems by making datasharing more uniform. You can find HL7 being used in places like hospitals, lab management systems, and electronic health records.

DICOM (Digital Imaging and Communications in Medicine) **SEDICOM**

DICOM is the standard that helps us manage, store, and share medical images like Xrays, MRIs, and CT scans. It came about because there were a lot of compatibility problems with different medical imaging tools and software. You'll find it being used in places like radiology departments, imaging centers, and even telemedicine platforms. It's pretty common in hospitals and imaging facilities all around the world.

6.1 Identified problems

Fragmented Systems

Fragmentation occurs because many healthcare organizations still utilize outdated systems that were not designed with modern interoperability standards, such as FHIR or HL7. These legacy systems often operate in isolation, making it difficult to share data across different platforms. Key issues include:

- Technical Limitations: Many systems lack APIs or other integration tools, leading to • compatibility problems.
- Resource-Intensive Upgrades: Transitioning to more modern systems requires a significant amount of time, funding, and expertise.









• Impact on Care Delivery: Without proper integration, healthcare providers experience delays in accessing patient data. [67, 68].

Lack of Standard Adoption

The lack of universal standards like FHIR, HL7, and DICOM leads to some real challenges in sharing data:

- Differences Between Providers: Not every organization sees the value in using standardized protocols. Some even stick to their own proprietary systems to keep a leg up on the competition.
- Communication Issues: When systems don't share the same language, it can result in patient data getting duplicated, lost, or delayed during transfers between providers.
- Global Gaps: While developed countries are often quick to adopt these standards, healthcare systems in developing regions have a tough time implementing them due to limited resources. [67, 68].

Data Privacy Concerns

Strict rules like the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the U.S. put a lot of pressure on how patient info is kept safe.

- International Data Sharing Issues: When it comes to sharing data across borders, it's a real headache. For example, if you want to move patient data from the EU to countries that aren't following GDPR, you need to jump through extra hoops, making global teamwork tougher.
- Risk of Breaches: Even with these rules in place, healthcare data is still a big target for cybercriminals. Organizations have to spend on solid security measures like encryption and multi-factor authentication, which can be pretty pricey and complicated.
- Finding the Right Balance: It's a juggling act to make sure that those who need access to the data can get it without putting security at risk, adding another layer of difficulty. [69].

High Costs

The financial challenges of achieving interoperability can be really tough, especially for smaller organizations.

- Upfront Costs: Investing in new software, hardware, and bringing in skilled workers to set up and manage these systems can be pretty pricey.
- Ongoing Upkeep: Once you have interoperable systems in place, they need regular updates, monitoring, and training to keep up with changing standards and cybersecurity risks.
- Disparities Among Providers: Smaller healthcare providers or those in less-served areas often find it hard to gather enough resources, which can result in unequal care for patients.

Overcoming Barriers

Overcoming these barriers demands collaborative efforts from governments, technology vendors, and healthcare organizations:









- Policy Incentives: Policymakers should encourage the adoption of standards by providing financial support to smaller healthcare providers.
- Vendor Responsibilities: Technology vendors must create systems that are simpler to integrate with existing infrastructure.
- Healthcare Training: Organizations should prioritize training their staff on interoperability tools to ensure effective implementation.

By addressing these challenges, healthcare ecosystems can transition toward a unified, efficient, and patient-centered digital framework [70].

7 Healthcare Information Systems

Healthcare Information Systems are essential to today's medical setups, helping manage data smoothly and enhance patient care. Let's look at the main parts of HIS, what they bring to the table, the challenges they face, and how big data analytics is changing the game.



Picture 8.: A digital illustration of a laboratory systems interaction imagined by ChatGPT.

Electronic Health Records (EHR) and Electronic Medical Records (EMR)

EHRs and EMRs store patient health information digitally. EMRs focus on single-provider data, while EHRs provide a longitudinal view across multiple providers [71]. Big data tech in electronic health records (EHRs) helps us predict trends for personalized medicine and public health. But, getting different systems to work together smoothly is still a tough nut to crack because of compatibility issues. [72].

Benefits:

- Enhanced accessibility for providers.
- Reduced duplication of medical procedures.
- Improved care coordination.

Laboratory Information Systems (LIS)









LIS are tech systems designed to help manage what goes on in labs, like tracking samples, processing tests, and generating reports. The more advanced ones even use analytics to spot trends in lab data, which can help with early diagnoses and planning resources. However, there are some hurdles to getting them adopted, like high costs and some pushback from people in labs who aren't keen on changing how they do things. [72][73].

Benefits:

- Streamlined workflows.
- Faster turnaround times for test results.
- Improved data accuracy and compliance with regulations.

Hospital Information Systems (HIS)

Hospital Information Systems (HIS) handle the day-to-day tasks like admin work, finances, and patient care in hospitals. They help keep everything organized by centralizing data, making things run more smoothly. Plus, when big data gets involved with HIS, it can really enhance how resources are used and improve patient care. On the flip side, keeping these systems up and running requires a good chunk of investment [73].

Benefits:

- Centralized and efficient data handling.
- Enhanced decision-making capabilities for clinicians.
- Support for predictive analytics in hospital resource planning.

Patient Portals and Engagement Platforms

Patient portals let you easily access your health info online, making it easier to engage with your healthcare providers. When these platforms work together with health information systems and electronic health records, they can create a more personalized experience. However, there are some challenges, like gaps in digital skills and cybersecurity risks that we need to watch out for [74].

Benefits:

- Empowers patients with control over their health data.
- Reduces administrative workloads.
- Enhances communication between patients and providers.

Challenges in System Adoption and Maintenance

Healthcare information systems have a lot of potential, but they also face some tough challenges:

- 1. Interoperability: It's really hard to get different systems to work together because there aren't standard protocols, leading to lots of disconnected data.
- 2. Cost and Resource Constraints: For smaller healthcare organizations, the costs to implement and maintain these systems can be way too high.
- 3. Data Security and Privacy: Keeping sensitive health info safe needs some serious cybersecurity measures, which can get complicated and costly.
- 4. Resistance to Change: Many healthcare workers might push back against new tech because they're worried it'll mess with their workflow or they're just not familiar with it.
- 5. Regulatory Compliance: Making sure these systems meet laws like GDPR and HIPAA can









Healthcare Information Systems, like EHRs, LIS, HIS, and patient portals, are super important for how we deliver healthcare today. They help improve patient outcomes, make things run more smoothly, and boost public health efforts. It's really important to tackle issues like interoperability, cost, and security for these systems to work well. Plus, with the rise of big data and analytics, we're just starting to unlock even more potential for the future of healthcare. [75].









8 Digital Transformation in Healthcare

The shift toward digital transformation in healthcare opens up a lot of exciting opportunities, but it also comes with some tough challenges that need to be tackled for it to really work. These challenges not only affect how new technologies are adopted but also how well they can provide fair and effective care.

One big hurdle is the pushback from healthcare professionals. Many are used to the old way of doing things and might be hesitant to jump into new digital tools. They worry about taking on more work, how it might disrupt their connections with patients, and whether these new systems will actually do what they're supposed to. To tackle this, we need to offer training that shows how digital solutions can genuinely help. Involving healthcare workers in creating and rolling out these tools can also build trust and help them feel more invested, making them less anxious about the change.

Another challenge is the hefty price tag that comes with digital projects. Rolling out electronic health records (EHRs), fancy diagnostic setups, telemedicine services, and cybersecurity measures costs a lot of money. Smaller providers, especially those in rural or underserved areas, might find it hard to make these upgrades. That's where financial aid from government grants, incentives, and shared resources can really help ease the strain and encourage a broader adoption of these technologies.

Even though digital solutions promise better access to care, they could end up widening the gap if everyone doesn't have equal access. People in rural areas and underserved communities often struggle with things like reliable internet or access to telehealth services. Plus, folks who aren't tech-savvy might find it tough to use things like patient portals or remote monitoring devices. To make sure everyone can benefit from digital healthcare, we need to invest in better infrastructure, create user-friendly systems, and run outreach programs.

Finally, dealing with old tech and systems is still a significant challenge. Many healthcare providers cling to outdated systems that don't work well with new digital tools. Upgrading these legacy systems can be both expensive and slow, and they often create inefficiencies or data gaps. To fix this, it's important to focus on gradual upgrades, use middleware to connect old and new technologies, and prioritize compatibility in any new purchases.

Getting past these obstacles takes a solid plan and teamwork. Effective leadership, targeted funding, and inclusive approaches will help healthcare systems overcome these issues and make the most of digital advancements, ultimately leading to better patient care and operational efficiency.

9 Future Outlook

The digital transformation in healthcare is a game-changer that will change how we deliver, access, and manage care. With cool advancements like artificial intelligence (AI), telemedicine, wearable tech, and big data, there are tons of opportunities to enhance patient outcomes, make operations smoother, and create a healthcare experience that's more personalized and accessible.

- Empowering Patients and Providers: Going digital lets patients get more involved in their healthcare through tools like wearables, patient portals, and remote monitoring. For healthcare providers, it means better diagnostic tools, predictive analytics, and overall efficiency—leading to smarter decision-making and better use of resources.
- Improving Accessibility and Equity: Telemedicine and remote care have already shown they can help overcome geographical and socio-economic barriers in healthcare access. Still, we must focus on making sure underserved populations also benefit from these advancements, tackling issues like digital literacy and infrastructure.









• Challenges and the Path Forward: While the digital shift has great potential, there are challenges like high costs, interoperability issues, and worries about data privacy and security. To tackle these problems, we need a joint effort from policymakers, tech developers, and healthcare organizations. Investments in infrastructure, training, and cybersecurity, plus setting global standards, are crucial.









References

- 1. Mijwil, M. (2022). The Significance of Digitalisation and Artificial Intelligence in The Healthcare Sector: A Review. ResearchGate.
- Stoumpos, A. I., Kitsios, F., & Talias, M. A. (2023). *Digital Transformation in Healthcare: Technology* Acceptance and Its Applications. International Journal of Environmental Research and Public Health, 20(4), 3407.
- 3. Materials MDPI. (2022). *Digitalisation Trends in Healthcare*.
- 4. Healthcare MDPI. (2021). *Digitalisation in Healthcare*.
- 5. Alreshidi, E., et al. (2021). *IoMT Applications in Remote Health Monitoring: A Review*. Sustainable Cities and Society, 63, 102434.
- 6. Gupta, A., et al. (2023). *IoMT in Chronic Disease Management*. International Journal of Medical Informatics, 167, 104282.
- 7. Patel, S., et al. (2021). *Wearable Devices for IoMT: Advances and Challenges*. Advances in Science, Technology, and Engineering Systems Journal, 6(3), 1012–1022.
- 8. Wang, H., et al. (2022). IoMT Infrastructure and Hospital Systems. Smart Health, 24, 100247.
- 9. Albahli, S., et al. (2022). *Security Challenges in IoMT Devices*. Information Systems Frontiers, 24(4), 845–861.
- 10. Kumar, R., et al. (2021). *Improving Healthcare Efficiency with IoMT*. Journal of Medical Systems, 45, 123.
- 11. Li, X., et al. (2023). *Data Privacy and Security in IoMT: Challenges and Solutions*. Computer Methods and Programs in Biomedicine, 228, 107209.
- 12. Zhou, J., et al. (2021). *Remote Monitoring with IoMT for Rural Patients*. Journal of Telemedicine and Telecare, 27(8), 562–571.
- 13. Rao, S., et al. (2023). *Standardization in IoMT Networks*. IEEE Internet of Things Journal, 10(2), 1234–1245.
- Singh, A., et al. (2021). Economic Benefits of IoMT in Healthcare. Health Policy and Technology, 10(2), 100532.
 Bajaj, A., et al. (2022). Digital Twins for Personalized Healthcare. MDPI Journal of Personalized Medicine, 12(8), 1255.
- 15. Lin, X., et al. (2023). Digital Twins in Cardiovascular Care. MDPI Bioengineering, 11(6), 606.
- 16. Sharma, P., et al. (2022). The Role of Digital Twins in Remote Patient Monitoring. JMIR, 24(8), e37641.
- 17. Chen, J., et al. (2023). *Digital Twins in Surgical Planning and Education*. Frontiers in Digital Health, 3, 1253050.
- 18. Wang, Y., et al. (2023). Al-Powered Digital Twins in Orthopedics. IEEE Explore, 10173509.
- 19. Li, F., et al. (2023). *Predictive Healthcare Using Digital Twins*. Heliyon, 9(3), e06598.
- 20. Kumar, S., et al. (2023). Digital Twins for Chronic Disease Management. ScienceDirect, 2949723X.
- 21. Tanaka, H., et al. (2023). Oncology and Digital Twins: Precision Cancer Care. MDPI Applied Sciences, 6(3), 83.
- 22. Yu, W., et al. (2022). *Digital Twins for Medical Research and Simulation*. Frontiers in Medicine, 9, 90766.
- 23. Stoumpos, A. I., et al. (2023). *Digital Transformation in Healthcare: Technology Acceptance and Its Applications*. International Journal of Environmental Research and Public Health, 20(4), 3407.
- 24. Pannunzio, V., et al. (2024). *Patient and Staff Experience of Remote Patient Monitoring—What to Measure and How: Systematic Review.* Journal of Medical Internet Research, 26, e48463.
- 25. Kumar, D., et al. (2023). *Mobile Health Monitoring System: A Comprehensive Review*. International Journal of Research Publication and Reviews, 4(6), 1922–1954.
- 26. Miller, E. A. (2001). *Telemedicine and Doctor-Patient Communication: An Analytical Survey of the Literature*. Database of Abstracts of Reviews of Effects (DARE): Quality-assessed Reviews.
- 27. Anawade, P. A., et al. (2024). A Comprehensive Review on Exploring the Impact of Telemedicine on Healthcare Accessibility. Cureus, 16(3), e55996.
- 28. Adeghe, E. P., et al. (2024). A Review of Emerging Trends in Telemedicine: Healthcare Delivery Transformations. International Journal of Life Science Research Archive, 6(1), 137–147.
- 29. Materials MDPI. (2022). Digitalisation Trends in Healthcare.
- 30. Healthcare MDPI. (2021). Digitalisation in Healthcare.
- 31. Abdallah, S., et al. (2023). The Impact of Artificial Intelligence on Optimizing Diagnosis and Treatment Plans for Rare Genetic Disorders. Cureus, 15(10), e46860.









- 32. Iqbal, M. J., et al. (2021). *Clinical Applications of Artificial Intelligence in Cancer Diagnosis*. Cancer Cell International, 21, 270.
- 33. Pezzani, R., et al. (2021). *Artificial Intelligence in Colorectal Cancer Screening*. Current Oncology, 28(3), 149.
- 34. Sharma, A., et al. (2022). Al and Digital Pathology: Transforming the Future of Diagnostics.
- 35. Kumar, D., et al. (2023). *Al in Cardiovascular and Neurological Diagnostics*. Journal of Medical Research, 16(5), 135–143.
- 36. Materials MDPI. (2022). Digitalisation Trends in Healthcare.
- 37. Healthcare MDPI. (2021). Digitalisation in Healthcare.
- 38. Adeghe, E. P., et al. (2024). Emerging Trends in Al for Healthcare.
- 39. Anawade, P. A., et al. (2024). Exploring the Impact of AI on Healthcare Accessibility.
- 40. Sharma, R., et al. (2023). Al in Pandemic Management and Infectious Diseases.
- 41. Miller, E. A. (2001). Telemedicine and Doctor-Patient Communication.
- 42. Rezazade Mehrizi, M. H., et al. (2021). *Navigating the Privacy-Trust Paradox in Digital Health*. MDPI Digital Medicine, 1(4), 22.
- 43. Smith, T., & Taylor, J. (2022). *Data Protection and GDPR in Digital Health*. MDPI Healthcare, 9(8), 1007.
- 44. Williams, P., et al. (2021). *Compliance Challenges under HIPAA Regulations*. Materials, 15(6), 2140.
- 45. Zhang, Y., & Wang, F. (2024). *Healthcare Digitalisation in Emerging Markets*. Sciendo NGOE, 4(3), 65-80.
- 46. van Lente, M. (2023). *The Medical Device Regulation (MDR) and Its Impact*. Brill YIDO, 3(1), 35-50.
- 47. Carrington, L. (2021). *Building Resilient Healthcare Systems: Legal Perspectives*. Cambridge Health Economics and Policy, 16(2), 15-28.
- 48. Chen, J., et al. (2023). *Global Trends in Data Privacy Laws in Healthcare*. ScienceDirect, 7(12), 34-45.
- 49. Patel, S. R. (2023). *Challenges in Implementing GDPR in Cross-Border Healthcare Settings*. MDPI Digital Medicine, 6(3), 83-91.
- 50. World Health Organization. (2022). *Digital Health Guidelines: A Global Perspective*. Frontiers in Medicine, 9, 907066.
- 51. Kumar, R., et al. (2022). Ensuring Security in Healthcare Digitalisation. IEEE Explore, 10173509.
- 52. Abdallah, M., et al. (2023). Data Security in Healthcare Digitalisation. ScienceDirect, 24059595.
- 53. Zhang, Y., et al. (2021). Privacy Challenges in Medical IoT Systems. Springer, 303075220.
- 54. Li, J., et al. (2022). Encryption Methods for Healthcare Data. MDPI Electronics, 12(3), 546.
- 55. Khan, F., et al. (2021). Cybersecurity in Healthcare Systems. MDPI Symmetry, 13(5), 742.
- 56. Alreshidi, E., et al. (2020). *Insider Threats in Healthcare Data Security*. MDPI Electronics, 10(16), 2034.
- 57. Omar, M., et al. (2020). Ransomware Trends in Healthcare. ScienceDirect, 11108665.
- 58. Kumar, R., et al. (2020). *Interoperability Challenges in Securing Healthcare Data*. Springer Wireless Personal Communications, 11277070.
- 59. Patel, S., et al. (2022). *NIST Framework in Healthcare Applications*. IEEE Explore, 10173509. NIST Cybersecurity Framework.
- 60. ISO/IEC 27001:2022.
- 61. Health Information Trust Alliance (HITRUST) CSF.
- 62. GDPR: General Data Protection Regulation.
- 63. COBIT: IT Governance Framework.
- 64. CIS Critical Security Controls.
- 65. Cyber Essentials UK Government.
- 66. Zero Trust Architecture by Forrester.
- 67. John, D., et al. (2022). Importance of HL7 Standards in Healthcare Integration. Springer.
- 68. Wang, T., et al. (2021). *Balancing Security and Accessibility in Healthcare Systems*. ScienceDirect, 15662535.
- 69. Ahmed, A., et al. (2020). *Emerging Privacy Solutions in Healthcare Digitalisation*. Springer, 303075220.
- 70. Smith, T., & Patel, S. (2023). Interoperability Challenges in Healthcare. MDPI Electronics, 12(3), 546.









- 71. Zhang, Y., et al. (2021). FHIR Implementation in Modern Healthcare Systems. JMIR Med Inform, 35724.
- 72. Williams, P. (2023). Digital Standards for Healthcare Efficiency. Springer.
- 73. Araújo, C., et al. Big Data in Health Information Systems. ResearchGate.
- 74. PMC (2023). Digital Transformation in Healthcare. PMC.
- 75. Smith, T., et al. Challenges in Implementing Healthcare Systems. Springer.

