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Opportunities in Transformation

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Penilla Gunther

Prioritising Patient Safety and Combatting Fatigue in Healthcare











Editorial



LLUÍS DONOSO BACH

Director Clinical Advanced Technologies Initiative I Hospital Clinic Barcelona I University of Barcelona. LEITAT Technological Center I Spain I HealthManagement.org Editor-in-Chief, Imaging

Opportunities in Digital Transformation

The COVID-19 pandemic accelerated the digital transformation of health systems, prompting a shift in focus towards improving patient experiences and innovative forms of care delivery. Healthcare leaders are responsible for delivering improved, more effective care, but they face challenges in navigating the complexities of digitalisation. In this context, effective leadership is crucial for ensuring a seamless organisational transition to digital culture.

Key trends in this digital transformation benefit both patients and healthcare professionals. Some trends showcase notable advantages: wearables empower doctors and patients to track health data, enhancing preventive medical efforts; Al tools efficiently analyse vast datasets, streamlining patient diagnostic and treatment, alleviating time-consuming tasks for staff; and telehealth technology improves healthcare access, especially for populations facing accessibility challenges.

As healthcare professionals integrate digital solutions, new experiences unfold, streamlining workflows, improving efficiency, and alleviating workforce pressures. This showcases how technology enhances the overall healthcare professional experience and contributes to improved quality of care.

In this ongoing digital transformation, the collaborative use of these technologies refines communication and care quality. Our latest cover story, "Opportunities in Digital Transformation," delves into the key digital transformation trends in healthcare. The goal is to highlight the influence of technological advancements on the interaction between patients and clinicians while assessing how effectively healthcare has adapted to the digital model of care.

Isabel Page talks about the impact of technology and AI on executive leadership in healthcare. She highlights the need for AI to remain an enhancer rather than a replacement for highly skilled practitioners and to support and ease the predicted global shortfalls in healthcare practitioners.

Monsterrat Codina and Jaume Ribera highlight the crucial role of healthcare managers in the ongoing digital transformation and discuss a role-play simulation methodology called HALIGN and how it can assist healthcare managers in navigating the complexities of this transformative journey effectively.

In light of the 2023 European Patient Safety conference, Oliver Kimberger sheds light on the evolving relationship between AI and the established medical culture. He explores the implications of this evolution for both patients and health professionals.

Interoperability is pivotal in facilitating the sharing and integration of health information among systems, applications, and healthcare providers. Josep Vilata Marzo discusses the types of interoperability, outlining the benefits they offer healthcare providers. He emphasises the critical impact of interoperability on medical outcomes while addressing the challenges in achieving interoperability in healthcare.

Penilla Gunther explains the importance of patient safety in healthcare and highlights the Fight Fatigue campaign, emphasising its role in supporting staff and improving overall patient safety.

We hope you enjoy reading this issue and welcome any feedback.

Happy Reading!



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2. Hologic Data on File. CS-00335. Rev 001 ** According to Norton Healthcare/Dr Callahan.

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Oliver Kimberger, Vienna



Montserrat Codina's interests encompass new and innovative education models and concepts, exploring how training, capacity building, and skills development can be adapted in the health sector. She leads international innovation and training projects, guiding them from idea to conclusion. They are implemented in collaboration with global partners that represent the stakeholders of the health innovation ecosystem. She holds a PhD in biology and has served as adjunct faculty at the University of Barcelona.

Oliver Kimberger is the interim head of the Department of General Anaesthesiology and Intensive Care Medicine at the Medical University of Vienna and a Professor of Perioperative Information Management. His scientific focus includes microcirculation & fluid management, patient temperature management technology, big data, artificial intelligence, data science and the digital transformation of medicine.

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Lluís Donoso-Bach, Spain



Josep Vilalta Marzo, Barcelona



Lluís Donoso-Bach is the Director of the Clinical Advanced Technologies Initiative at the Hospital Clínic of Barcelona and a Professor of Radiology at the University of Barcelona. He has served the European Society of Radiology in various capacities, including as President in 2015–2016. Prof Donoso-Bach is HealthManagement.org Editor-in-Chief of the Imaging Chapter.

Josep Marzo is an interoperability healthcare systems expert. He is the managing partner at Vico Open Modeling & Clinical Document Engineering and specialised in conceptual modelling of information systems. He leads interoperability projects, focusing on how the standards promoted by the European Health Data Space will empower citizens as proactive agents of their clinical information. This involvement extends to decision-making about their healthcare processes and their involvement with biomedical research teams and clinical trials.

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Penilla Gunther, Brussels



Penilla Gunther is a former Member of Parliament in Sweden, the Board of the Nordic Council and Chair of the Committee on Welfare. She is President of the European Patient Safety Foundation, which plays an important role in the work for patient rights and sustainable healthcare. She is appointed by the European Commission as a Member of the Cancer Mission Board and is the Founder of FOKUS Patient® - a platform for life science and healthcare with a patient perspective.

Charles Niehaus, Affidea



Charles Niehaus serves as Executive Director of Affidea Group since September 2022. A seasoned medical professional with 27+ years of global healthcare expertise, Charles combines clinical, operational, and management skills. He has driven excellence in healthcare across Sub-Saharan Africa, the UK, and Europe, focusing on continuous improvement. Dedicated to delivering high-quality, cost-effective care, he advised The Nelson Mandela Foundation on population health, including HIV. With 18+ years in public-private partnerships, he has transformed surgical and diagnostic businesses, aligning strategies and enhancing performance.

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countries in
Europe

20 million examinations / year

+12
million
patients / year

+7500 doctors



Contributors

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Jaume Ribera, Barcelona



Isabel Page specialises in advising and coaching high-achieving board members, C-suite, equity partners, senior executives and professionals, focusing on sustainable wellness and strategic business at the core of their achievements. Her international client base operates at the forefront of disruptive change across various industries. With a career that spans organisational development for a 6,000+ organisation, MBA/M.Sc. HR business school lecturing and coaching leaders from global companies at MIT's Presencing Institute, Isabel ensures a robust quality in her approach.

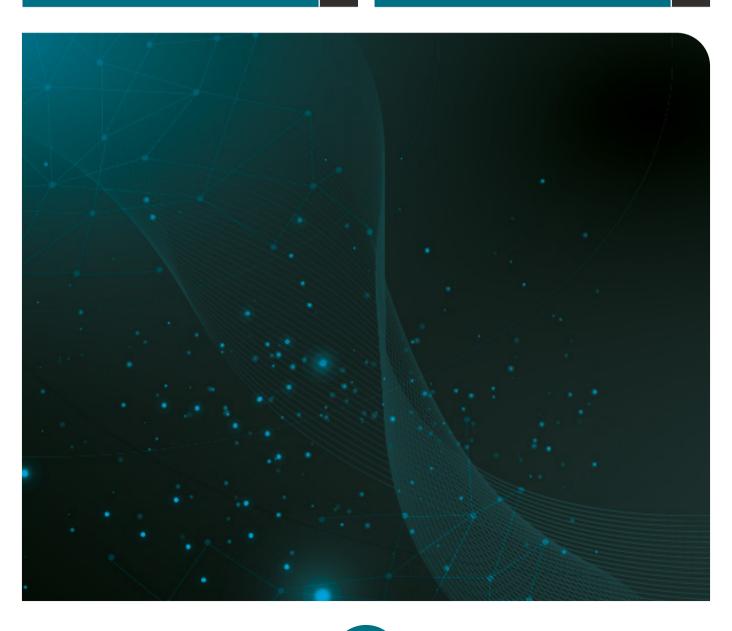
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United Imaging's uMR Omega Revolutionises MRI at Military Clinical Hospital, Ełk

An overview of the collaboration between United Imaging and the Military Clinical Hospital in Ełk and the shared dedication to ensuring that a wide spectrum of patients can benefit from the highest standards of diagnostic accuracy and safety in medical imaging.



On the 11th of October, 2023, the Military Clinical Hospital in Ełk officially became a new member of the international family of United Imaging. The hospital has decided to expand its diagnostic capabilities by opening a state-of-the-art magnetic resonance imaging (MRI) laboratory, which will involve the world's first Ultra-Wide-Bore 3T MRI.

This comprehensive hospital has eleven highly specialised departments, including an operating room and an emergency room. In addition to providing a wide range of healthcare services to the local population, the Military Clinical Hospital in Ełk has established a close relationship with the Poland-based multinational

battalion Battle Group. The hospital is actively involved in handling a variety of <u>emergency cases</u> and taking care of soldiers.

The Military Clinical Hospital in Ełk is the first hospital in Poland and the third in Europe to have such a unique diagnostic tool.

The addition of the uMR Omega to the diagnostic arsenal of the hospital will significantly improve the access of the local population to advanced imaging modalities, thereby ensuring that all patients have the possibility of obtaining precise diagnosis and, subsequently, adequate treatment plan.



The uMR Omega[™] has been deliberately designed to satisfy all requirements of contemporary healthcare institutions. This includes the highest-quality imaging supporting the diagnostic process, the option of intraoperative use, as well as option of radiotherapy planning of unparalleled precision.

In order to provide patients with a more comfortable experience during an MRI exam while ensuring the highest image quality and scan speed, United Imaging introduced a revolutionary design reflecting the most recent advances in MRI technology. The unique combination of ACS (Artificial Intelligence Compressed Sensing) and DeepRecon technologies has allowed the time of the MR examination to be reduced by as much as 70%. Thanks to the 75 cm ultra-wide bore construction, patients have 25% additional space, which, together with a unique starlight environment, not only increases the overall comfort but also reduces the potential risk of a panic attack in claustrophobic patients. The additional space not only guarantees that all patients, regardless of their sizes, can undergo MRI but also opens up new ways of patient positioning, expanding diagnostic possibilities for joint examinations, large patients, and pregnant women. With painstaking attention to detail, United Imaging came up with nextgeneration ultra-flexible soft RF Coils to offer patients a blanket-like feeling. Last but not least, the Dual-Source Millimeter-Wave Radar is the industry's first dualsource phased-array millimeter-wave radar solution for contactless sensing of patients' respiratory motions that renders the need for a respiratory belt obsolete.

Fully integrated within the MRI bore and unobstructed by clothing, the Dual-Source Millimeter-Wave Radar empowers the Free-breathing Renal non-contrast enhanced MRI or free-breathing liver MRI.

The diagnostic process has been significantly improved through the development of higher-density coils, which allow for the hyper-resolution MR imaging of the musculoskeletal system or Ultra-short echo time (UTE) MR imaging in pulmonary metastases from liver cancer.



Leveraging the unique advantages provided by artificial intelligence, United Imaging introduced the ACS (Al-assisted Compressed Sensing) to best balance speed and image quality, combining CS (Compressed Sense), HF (Half Fourier), and PI (Parallel Imaging). What is more, the reconstruction procedure is actively supported by a state-of-the-art deep-learning neural network.

Besides an approximately 97% reduction in acoustic noise, the Qscan, coupled with AI technologies such as ACS and DeepRecon, offers whole-body quiet scanning without increasing the scanning time. As a consequence, radiologists are provided with higher acceleration levels for MRI imaging and improved depiction of small anatomical structures, allowing them to perform rapid breast MRI, rapid whole Spine scans, high-resolution MSK, or, in the case of brain MRIs, significantly facilitating the diagnosis of acute cerebral infarction.

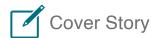
The collaboration between United Imaging and the Military Clinical Hospital in Ełk reflects the shared dedication to ensuring that a wide spectrum of patients, regardless of their background or medical condition, can benefit from the highest standards of diagnostic accuracy and safety in medical imaging.

About United Imaging Healthcare

United Imaging Healthcare was founded in 2011 with a commitment to provide high-performance medical imaging products, radiotherapy equipment, life science instruments, and intelligent digital solutions to global customers. With a mission "To Bring Equal Healthcare for All" and a vision to "lead healthcare innovation", United Imaging is continuously devoted to creating more value for its customers and improving the accessibility of high-end medical equipment and services worldwide through close collaborations with hospitals, universities, research institutions, and industry partners.



Cover Story



Artificial Intelligence and Healthcare Leadership

The impact of technology and artificial intelligence (AI) on executive leadership in healthcare is a multifaceted and dynamic subject that has garnered significant attention in recent years. In an interview with CNN in April 2023, Elon Musk warned that artificial intelligence could lead to the destruction of civilisation. What does AI mean for healthcare leaders, and do they need to take this warning seriously?



Principal I Isabel Page Business Advisory and Leadership Development I Senior Adjunct Lecturer I University of Luxembourg I Luxembourg

key points

- The widespread adoption of artificial intelligence have reshaped the business landscape, requiring healthcare executives to navigate a complex and ever-changing environment.
- Al-driven analytics provide a deeper understanding of market trends, customer behaviours, and competitive landscapes, enabling healthcare leaders to formulate agile and adaptive strategies.
- Healthcare leaders have the task of communicating and demonstrating the vision, objectives and strategy, including the use of AI in that process.
- Leveraging AI capabilities to augment human potential rather than replace it will need to be monitored to prevent unintended consequences.

The Healthcare Landscape

Globally, healthcare spending is not keeping up to remain sustainable, and systems also need a larger workforce. According to the World Health Organization, even if 40 million new health-sector jobs could be created by 2030 there is still a projected shortfall of 9.9 million physicians, nurses and midwives globally over the same period (WHO 2016). Healthcare leaders, therefore, need to attract, train and retain more healthcare professionals and ensure their time is used where it adds the most value - caring for patients. The rapid advancement of technology and the widespread adoption of artificial intelligence (AI) have reshaped the business landscape, requiring healthcare executives to navigate a complex and ever-changing environment. As the sector increasingly integrates advanced technologies into operations, executive leaders are faced with both unprecedented opportunities and challenges. So what are the perceived profound effects of technology and Al on executive healthcare leadership, taking account of

key aspects such as decision-making, strategic planning, organisational culture, and the evolving role of leaders in the digital age?

Let's start with a definition of AI. According to the European Parliament, "AI is the capability of a computer programme to perform tasks or reasoning processes that we usually associate with intelligence in a human being" (European Parliament 2016). According to a report drawn up on proprietary research and analyses undertaken by EIT Health and McKinsey & Company, including work by the McKinsey Global Institute (MGI) on the future of work in the era of automation and AI, the following areas of healthcare may be served by AI (Spatharou et al. 2020):

- Self-care/prevention/wellness
- · Triage and diagnosis
- Diagnostics
- · Clinical decision support
- Care delivery



· Chronic care management

The <u>main areas of AI</u> applicable to the health sector are purported to be:

- Machine Learning (ML): the use and development of computer systems that are able to learn and adapt without following explicit instructions by using algorithms and statistical models to analyse and draw inferences from patterns in data; and
- Natural Language Processing (NLP): the application of computational techniques to analyse and synthesise natural language and speech.

Current Challenges for Healthcare Leadership

The main challenges for healthcare leadership (non-exhaustive) include:

Enhanced Decision-Making

Al is capable of providing boards and executive leaders with advanced analytics and data processing capabilities, potentially improving the quality and accuracy of decision-making. Real-time insights from machine learning algorithms may support leaders in making informed and strategic choices. However, the

been to visit the emergency department, who has the responsibility? Is it the AI system itself, the developers of the system or the county council? (Peterson et al. 2022). In this respect, laws need to be developed rapidly to ascertain liability and accountability.

Strategic Planning in the Digital Age

Healthcare boards must take into account that strategic change processes are long-term. Executives need to factor in the rapid pace of technological change, digital disruption, and emerging challenges and opportunities in their strategic frameworks. Al-driven analytics may provide a deeper understanding of market trends, customer behaviours, and competitive landscapes, enabling healthcare leaders to formulate agile and adaptive strategies. However, the potential lack of intuition and creativity in Al systems is a concern, particularly in fields that require innovative thinking.

The change process design is a crucial task for strategic leadership, and careful use of AI in the planning phase may provide a more in-depth, real-time and accurate business environment and competitive analysis for the orientation of a visioning process and strategic implementation. However, before any AI soil is tilled and seeds planted, leaders must reach a common understanding of AI itself (AI, machine learning and deep learning) to define an objective for how

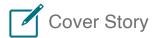
Executive and clinical leaders must set, oversee and implement the challenging complexities of balanced human-Al skills when integrating Al into current or innovative workflows

green pastures of analytics and data processing depend, as ever, on the quality of the statistics gathered and the way the data is processed. And we all need to remain aware of a natural bias to find statistics that suit our personal position or argument.

Further, accountability held among individuals, organisations, and AI systems regarding decisions based on support from an AI algorithm is perceived as a risk that needs to be addressed. However, accountability is not addressed if advice turns out to be incorrect. For example, if a patient is given AI-based advice from a county council-operated patient portal for triage-suggested self-care, and the advice instead should have

Al can be applied in the future (Pokorni et al. 2021).

Healthcare leaders also have the task of communicating and demonstrating the vision, objectives and strategy, including the use of AI in that process. Communication strategy must be inclusive to have any chance of success - employees, employee representatives or external stakeholders must be included in the formation of the change process and will be one of the key success factors. Through participation, stakeholder doubts and concerns may be addressed and included during the design process and along the implementation milestones. Stakeholders should understand both the why and how they may participate, and transparent discussions on proposed designs of AI hardware and



software systems are crucial to have any chance of seamless technological integration with partners.

Cultural Integration

Successful integration always involves a shift in the cultural paradigm of thinking, mindset, attitudes, behaviours, and knowledge acquisition. The challenge lies in balancing the implementation of new technologies with the preservation of core organisational values, and the chance of unintended consequences derailing a cultural change is high.

Both for healthcare leaders and stakeholders, new technology is one of the most frightening aspects of strategic change involving, as it does, substantial economic and capital commitments and implementation decisions with far-reaching implications for growth and success. Usually, a very steep, innovative

appropriate, both ethically and substantively.

Leveraging AI capabilities to augment human potential rather than replace it will need to be monitored to prevent unintended consequences. This will involve an extremely sensitive approach to managing talent, organising and encouraging appropriate reskilling to foster change that creates collaborative working environments. In a sector where empathy and emotional intelligence are core to patient care, assessing patients with our human senses, including paying attention to our intuitive thinking and feeling, means taking an extremely careful and balanced approach to supporting or disconfirming technological diagnosis.

The potential loss of human touch in healthcare leadership due to AI is significant, and, in the context of increasing medical litigation, the risk of beginning to over-rely on technology in an attempt to shift accountability and responsibility for human decision-

The aim of AI must remain that of an enhancer rather than a replacement for highly skilled practitioners

and continuous learning curve has to be culturally assimilated, and the cultural expectation that 'this is the way we do things around here' may be fragmented, in some cases, almost beyond recognition. This may lead to heavy resistance and reticence to adopt AI, the severity depending on the organisational culture and success, or lack of success, of communication strategy. In the rather hierarchical, bureaucratic and silo organisational culture prevalent in the healthcare sector, championing a digital mindset and creating an environment conducive to experimentation and learning may be extremely challenging.

Human-Al Collaboration

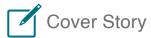
As decisions are made around the use and implementation of AI technologies in the healthcare sector, executive and clinical leaders must set, oversee and implement the challenging complexities of balanced human-AI skills when integrating AI into current or innovative workflows. Human oversight is critical. The greatest skills involve understanding deeply the limits and potentialities of AI, neither over nor underestimating the power of these new tech tools, while making absolutely certain that data inputs are trustworthy and

making may be tempting.

This means all leaders, whether in healthcare or other sectors, will need agile leadership skills to be resilient, cope with ambiguity and navigate the uncertainty of change. They will need to learn fast and flexibly as the landscape and legislative challenges change rapidly and foster innovation as they guide their teams through digital transformation.

Ethical Considerations

Increased deployment of AI in the healthcare system will give rise to ethical dilemmas that executive and clinical healthcare leaders must address. Issues such as data privacy, bias in algorithms, and the societal impact of AI applications require thoughtful consideration and ethical decision-making. AI, therefore, needs to be established and implemented responsibly: ethical challenges need to be raised and discussed in the strategic planning stages, with the participation of patients and their appropriate representatives. In this way, patient care stays at the heart of healthcare decision-making, allowing ethical challenges and their solutions to be jointly analysed, assessed and addressed.



Both executive and clinical leaders must establish ethical frameworks within their organisations and specialist departments, ensuring that technology aligns with both medical values and society at large. In addition, increased reliance on data collection and analysis means that concerns about privacy and AI need to be addressed in the context of increasing reliance on data collection and analysis.

Impact on Talent Acquisition and Development

Talent acquisition and development initiatives will be hugely impacted by increased uptake in Al. One of the criteria that may slow the adoption of AI into healthcare may be the lack of suitably qualified candidates with the skills, competencies, and drive needed for Al digital transformation. In addition to finding candidates who are experts in relevant AI, the ability to learn and upskill continuously right across the organisation needs to be addressed. Further, the cost of implementing AI in small healthcare practices may be a barrier to entry, which may force greater collaboration and consolidation in the sector. The downside across the sector may be the replacement of highly skilled practitioners, trained at huge cost, rendered obsolete by Al applications, which may cause unintended unemployment, where a more optimal balance of supporting highly-trained practitioners rather than replacing them would have been more appropriate.

Conclusion

In conclusion, the impact of technology and artificial intelligence on executive leadership is expected to be profound.

 To ease the predicted shortfall of practitioners, increased controlled and monitored use of AI in the healthcare sector may play a substantive role in bridging that gap, as long as it is directed towards patient care and not used as a tool to deflect responsibility or accountability;

- The demands of integrating AI for healthcare boards, executive leaders and clinicians are multifaceted, requiring leaders to adapt their decision-making, strategic planning, collaboration, ethics, and talent strategies to thrive in the digital era;
- The traditional hierarchical and bureaucratic organisational culture with a tendency to create silos, may slow down or derail digital projects. The chances of unintended consequences are high, particularly if all relevant internal and external stakeholders are not included in early discussions to streamline compatibility across digital hardware and software;
- The impact of AI may be very costly in terms of talent attrition, costs that will undoubtedly affect the whole of society, requiring very careful consideration and a balanced approach towards the development of AI to complement rather than replace the human skills of diagnosis, treatment and care.

Referring to our original question: should we take Elon Musk's warning that AI could lead to the destruction of civilisation seriously? To avoid this warning becoming anywhere near reality, it seems essential that:

- Al be regulated at a global, country, local and organisational level.
- The aim of AI must remain that of an enhancer rather than a replacement for highly skilled practitioners who have very sophisticated human skills in terms of bringing extremely complex elements together to form a reasoned judgment, including sense, gut feeling and intuition.
- Al efforts must also be developed in low- and middleincome countries, along with high-income countries, to ensure global equity in enhancing and supporting the roles of health professionals to ease the predicted global shortfalls in healthcare practitioners.

Conflict of Interest

None

references

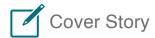
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How Role Play Advances Innovation/ Digital Transformation Adoption

Digital transformation in healthcare is inevitable, accelerated by the COVID-19 pandemic. Implementing digital healthcare innovations requires stakeholder collaboration but faces challenges due to differing agendas and perspectives. Role-play simulation games provide a safe learning environment to enhance stakeholder engagement skills. HALIGN, a methodology using a role-play simulation game, aligns stakeholders for healthcare innovation.



Project Lead I IESE Business School I Barcelona, Spain

Jaume Ribera I Emeritus Professor I IESE Business School I Barcelona, Spain

key points

- Digital transformation in healthcare is inevitable due to technology advancements and increased demand for patientcentred care.
- Healthcare innovations require collaboration among diverse stakeholders, but stakeholder engagement can be challenging due to varying interests.
- Role-play simulation games provide a safe, experiential learning environment to enhance stakeholder engagement and address complex healthcare processes.
- HALIGN, a role-play simulation methodology, aligns complex health ecosystem stakeholders for successful healthcare innovation implementation, focusing on leadership, communication, negotiation, and change management.

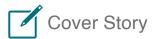
Introduction

Digital transformation in healthcare is an unavoidable reality driven by the rapid evolution of technology and the ever-increasing demand for more efficient, accessible, and patient-centred healthcare (Parish 2015). The integration of digital tools, such as electronic health records, telemedicine, wearable devices, and data analytics, has already begun to revolutionise the sector and seen to contribute to addressing these challenges by improving access to care, reducing inefficiencies, and providing personalised treatment options (WHO Guideline 2019).

The COVID-19 pandemic served as a catalyst, accelerating the adoption of telehealth and digital health solutions to ensure continuity of care. As society's reliance on technology continues to grow, so does the healthcare sector's need to embrace this digital shift to enhance patient outcomes, reduce costs, improve patients' and professionals' experiences, achieve equity (Nundy et al. 2022), and stay competitive in an increasingly data-driven world. In essence, digital

transformation is no longer a matter of choice but an essential journey for healthcare providers to deliver better, more responsive, and more effective care (WHO 2021).

Introducing healthcare innovations into the healthcare system and modifying the usual care is a challenging task. If there is a permanent topic when discussing the challenges faced by executives and professionals in any industry, it is the ability to get things done and manage change within the organisation. In the healthcare sector, the situation is much more complex. Healthcare managers must confront multifaceted challenges as they oversee digital transformation initiatives in their institutions. These challenges encompass not only technical obstacles but also the intricacies of organisational change, having to address the complex adaptive shift in human expertise and capabilities, and the imperative of fostering innovation and ensuring efficient resource allocation. But there is another level of complexity, as impactful change in the healthcare sector relies on effective collaboration among different



stakeholders in the healthcare innovation ecosystem (Granstrand and Holgersson 2020).

Stakeholder Alignment for Innovation/ Digital Transformation Adoption

There is ample literature on managing change within organisations (Kotter 1995; Pendlebury et al. 1998; Heath and Heath 2010), but the scope is very limited when discussing multi-stakeholder changes in an industry as regulated as healthcare. It is also helpful to understand that in a health system, there is no single authority that can enforce changes. Rather, comprehensive planning is essential to optimise integration and ensure the future success of any healthcare innovation. The planning process of healthcare innovations typically follows a set of sequential phases (McKenzie et al. 2016), which should

engagement, healthcare innovations can better address the complex and interconnected challenges facing the healthcare ecosystem and boost innovation outcomes (Segarra-Oña et al. 2020).

However, putting this into practice is a complex endeavour. Engaging with stakeholders can be challenging. While it may appear that all healthcare ecosystem stakeholders share overarching goals, such as enhancing the health and well-being of citizens and patients, for example, by implementing a home care unit in a hospital with remote patient monitoring, each stakeholder possesses distinct agendas, potentially conflicting interests, unique challenges, and predefined boundaries that can differ from one another. These factors can limit their ability to align actions in a singular direction and successfully implement or adopt the proposed digital healthcare innovation.

Digital transformation is no longer a matter of choice but an essential journey for healthcare providers to deliver better, more responsive, and more effective care

address not only the effectiveness of the innovation but also other factors that are essential for successful scale-up and integration, such as behavioural change of part of the different stakeholders.

Reforms in health systems fall into the complex space in the Cynefin framework (Snowden and Boone 2007). This means that reforms are parts of the unordered space, where no best practices and even good practices are available, and where the professionals and executives that lead the change have to work together to explore emerging practices since what worked well in a particular set of circumstances will fall short on others. Therefore, the involvement of stakeholders who have an interest, influence, or are affected by the innovation is crucial for achieving successful integration and better outcomes. The planning process of any transformation (digital or not) in the healthcare sector must include the perspectives, experiences, and opinions of these stakeholders (Franco-Trigo et al. 2020). By strengthening stakeholder

Role-Play Simulation Games: An Experiential Environment to Enhance Stakeholder Engagement

Successfully engaging and aligning with different stakeholders for the implementation and adoption of a healthcare innovation requires a set of skills and abilities that are not easy to teach and most often are acquired after multiple attempts at both successful or failed interactions with stakeholders in the real world. There is almost no option for real stakeholders to interact in a learning-by-doing safe environment and get to understand each other perspective. Here is where role-play simulation games can be the most useful tools for professionals and executives to learn, develop and practice. Management simulation games bring an experiential aspect to learning about complex systems. Simulation games offer novel opportunities for addressing complex and risky real-life processes in a safe training context (Lukosch et al. 2018). Research



indicates that simulation games can effectively enhance learning in areas such as complex problem-solving (Tennyson and Breuer 2002), decision-making (Tena-Chollet et al., 2017), and negotiation and collaboration skills (Fisher and Fisher-Yoshida 2017).

IESE Business School has used simulation games to teach executives and MBAs since the early 1970's. Over the years, we have explored different types of simulation games. The availability of simulation games and their growth is a confirmatory signal that there is value in their use in education and training. Most existing simulators focus on the simple cause-effect relationship that can be induced/deduced from the running of the simulation. In other cases, there are more choices for the participant, but there is still an underlying ordered structure that defines good practices in the participants' actions. They cover a wide variety of topics, but no one has the scope of the health ecosystem.

negotiation, change management, and leveraging networks. These modules serve as the foundational building blocks offering the context and insights needed to navigate the intricate landscape of stakeholder collaboration effectively.

The HALIGN simulation game covers the different profiles of the healthcare ecosystem stakeholders to address selected complex system situations. It merges elements of the traditional case method with principles drawn from the multi-stakeholder collaboration initiative as outlined by Fred Krawchuk in 2013. Krawchuk recognised that no single organisation possesses all the necessary knowledge, influence, connections, or resources to effectively tackle intricate issues involving multiple stakeholders. In an effort to facilitate multi-stakeholder collaborations, Krawchuk proposed a comprehensive 5P approach designed to address the challenges inherent in such initiatives while encompassing the key attributes that successful initiatives commonly exhibit.

By strengthening stakeholder engagement, healthcare innovations can better address the complex and interconnected challenges facing the healthcare ecosystem and boost innovation outcomes

HALIGN Methodology: Aligning Complex Health Ecosystem Stakeholders

HALIGN is a methodology based on a role-play simulation game developed over the last three years as a research-educational project with co-funding from EIT-Health (HALIGN: Making High-Value Care Solutions a Reality 2023). HALIGN is about aligning complex health ecosystem stakeholders to achieve a common goal, which is crucial in the implementation of healthcare innovations. The HALIGN methodology consists of a structured framework comprised of various training modules, each meticulously designed to equip participants with essential knowledge and practical tools necessary for fostering improved alignment among stakeholders, such as an overview of healthcare innovation ecosystems, leadership, communication,

The 5P approach consists of:

- Purpose: This denotes a specific issue, challenge, opportunity, or potential that unites all participants and serves as the driving force behind their gathering.
- 2. People: Involves the active participation of a diverse mix of stakeholders, encompassing both governmental and non-governmental actors, including representatives from government, businesses, non-profit organisations, academia, and civil society.
- **3. Place:** Refers to the physical or virtual space where participants come together to engage in meaningful dialogue and collaborative efforts.



- 4. Process: Encompasses a collaborative approach involving shared inquiry, learning, problem-solving, and, when needed, decision-making, all conducted in innovative ways to address the concerns of stakeholders effectively.
- 5. Practice: Signifies the ongoing commitment of stakeholders to nurture and enhance the essential skills, mindsets, and values required for successful collaboration.

The HALIGN role-play methodology divides the participants into different teams, each one representing a different stakeholder group (People) that may or may

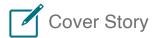
The HALIGN methodology, honed and validated in workshops featuring an array of professionals, including medical experts, healthcare administrators, startup innovators, and policymakers, has received significant recognition for its efficacy in enhancing their grasp of alignment challenges and methods to address them. Additionally, healthcare organisations have effectively employed this methodology to cultivate their managers' awareness of other stakeholders' perspectives and equip them with the ability to collaborate towards shared, acceptable solutions (WHO Regional Office Europe 2023).

HALIGN is about aligning complex health ecosystem stakeholders to achieve a common goal, crucial in the implementation of healthcare innovations

not match their real role in life. Each team discusses a common case related to a digital transformation initiative, such as the implementation of a home care unit in a hospital with remote patient monitoring (Purpose), from the point of view of the stakeholder they are role-playing, with objectives and red lines unknown to the other participants. The discussion can take place in-person or virtually in a specifically designed platform (Place), and teams are asked to try to reach a common agreement on how the home care unit is to be implemented (Process). The results of the game are not predefined and are determined by the actions proposed by the stakeholders, the conversations held among the teams, their negotiation abilities, their interpersonal skills and the degree of conviction each team is able to convey. In this context, HALIGN fosters an environment where participants work towards comprehending the perspectives of other stakeholders, enabling them to craft a solution that garners consensus and can be effectively implemented (Practice).

HALIGN to Support Healthcare Managers in Navigating Digital Transformation in Healthcare

In the context of digital transformation in healthcare, healthcare managers play a pivotal role in steering the industry through this inevitable change. They are responsible for orchestrating the adoption of digital technologies and ensuring that these innovations are seamlessly integrated into the healthcare ecosystem. Healthcare managers must assess the specific needs of their institutions, make informed decisions regarding technology investments, and establish a strategic roadmap for implementation. They also need to navigate regulatory and compliance challenges to safeguard patient data and ensure that digital systems adhere to industry standards. Additionally, healthcare managers must lead change management efforts within their organisations, as resistance to digital transformation can be a significant obstacle. This includes facilitating



training and education for healthcare staff to empower them with the necessary skills and knowledge to leverage digital tools effectively. Furthermore, they should promote a culture of innovation and continuous improvement to keep up with the ever-evolving landscape of digital healthcare.

The HALIGN methodology could be a resourceful tool to support healthcare managers at different stages of this challenging journey and facilitate a conducive

atmosphere where the different stakeholders actively seek to understand the viewpoints of their fellow stakeholders, enabling the development of solutions that garner consensus and can be smoothly put into practice.

Conflict of Interest

None.

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MEDICAL IMAGING



Elevating Healthcare: Affidea's Commitment to Patient Safety

Affidea recognises the pivotal role of innovation and patient-centric care in transforming the healthcare experience and is committed to setting new benchmarks that prioritise patient safety while offering best-in-class care



Executive Director I Affidea Group

key points

- Radiation safety is not a matter to be taken lightly. Numerous studies highlight the rising concerns regarding cumulative radiation exposure.
- Affidea is dedicated to pioneering safe imaging while maintaining the highest diagnostic standards, and its Dose Excellence Program is a testament to this commitment.
- The Dose Excellence Program represents a harmonious blend of cutting-edge technology and unwavering commitment to patient well-being.
- Affidea's dedication to safety and radiation protection has earned it prestigious recognition from the European Society of Radiology (ESR), and its medical centres have been awarded a 5-star certification.

In the ever-evolving landscape of modern medicine that aims to improve the healthcare of our patients, where ground-breaking advancements continually redefine the industry, one fundamental principle remains unshakable: the commitment to patient safety and the delivery of high-quality care.

Radiation safety is not a matter to be taken lightly. Numerous recent studies in radiology highlighted the rising concerns regarding cumulative radiation exposure in patients due to the increased use of diagnostic ionising imaging procedures such as CT scans and X-rays, emphasising the necessity of optimising doses without compromising diagnostic accuracy.

Affidea Group's commitment to patient safety has been our proactive response since 2014 to this growing concern. It is not only about meeting the European regulatory guidelines but also about exceeding them to ensure the utmost safety and quality of care for our patients.

At Affidea, we are dedicated to pioneering safe imaging while maintaining the highest diagnostic standards, and our Dose Excellence Program is a testament to this commitment. As a company, we are hugely impressed by the remarkable professionalism and high standards of our clinical colleagues, who are guided daily by a high responsibility to keep our patients safe while offering the best possible care.

The Dose Excellence Program represents a harmonious blend of cutting-edge technology and unwavering commitment to patient well-being. It prioritises patients' safety and minimises the radiation exposure associated with CT scans while preserving diagnostic accuracy.

Our medical centres are dedicated to setting new standards in the industry, and they actively participate in the EuroSafe Imaging Stars initiative—an endeavour by the European Society of Radiology to create a network of top-tier medical providers with stringent safety protocols related to radiation protection. Here, patient safety lies at the heart of the medical practice, striking the optimal balance between radiation dose and diagnostic confidence.

Our dedication to safety and radiation protection has earned us prestigious recognition from the European



Society of Radiology (ESR), and our medical centres have been awarded a 5-star certification, a symbol of excellence proudly displayed on the Eurosafe
Wall of Stars. 90% of the centres recognised for their commitment to radiation protection and patient safety across Europe are part of the Affidea Group. We salute and welcome the efforts made by the other stand-alone imaging providers who joined us in investing resources to ensure patient safety where ionising imaging procedures are performed.

- staff, ensuring they are equipped with the latest knowledge and best practices in patient safety.
- Modern Equipment: We consistently invest in stateof-the-art equipment, guaranteeing that the latestgeneration technology is employed for diagnostic procedures.
- Continuous Monitoring: Our commitment extends beyond the program's implementation; it actively monitors its performance and takes corrective actions whenever necessary.

Affidea's Dose Excellence programme is vast, spanning 13 European countries... each month, over 75,000 examinations are conducted under the Dose Excellence Program

The reach of Affidea's Dose Excellence programme is vast, spanning 13 European countries. Each month, over 75,000 examinations are conducted under the Dose Excellence Program. The primary objective here is clear - to perform ionising imaging procedures with the lowest possible radiation dose while upholding diagnostic image quality.

Real-Time Data Monitoring

What truly distinguishes Affidea is its commitment to realtime data monitoring by experts in physics and imaging. Affidea proudly stands as a unique healthcare provider in Europe to record and monitor radiation dose data for all CT systems, patients, and the countries in which we operate. This commitment extends beyond data collection to determining personalised radiation doses for each patient, enabled by innovative digital software.

Furthermore, Affidea has set radiation dose reference levels by anatomical region, clinical indication, and body mass index in all CT examinations, surpassing the guidelines established by European regulatory authorities. Notably, an impressive 92% of the examinations for anatomical regions such as the chest, heart, brain, and abdomen adhere to Affidea's lower radiation dose limits, surpassing national reference levels.

The success of the Dose Excellence Programme rests upon four pillars:

 Continuous Training: We are placing great importance on the ongoing training of our medical

- Cross-Specialty Collaboration: Patient safety is the driving force behind Affidea's clinical practices, underpinned by rigorous standards and medical protocols that enable the highest level of care. This is made possible through collaboration among all specialities, fostering the best possible outcomes.
- Peer Review: We ensure not only the continuity of our high standards but also the constant refinement of our practices. This internal scrutiny fosters an environment of continuous improvement, where the collective expertise of our medical professionals ensures that every aspect of patient care is meticulously reviewed, analysed, and enhanced to guarantee a high level of safety and quality.

As we move forward, we recognise the pivotal role of innovation and patient-centric care in transforming the healthcare experience. We're not content with merely meeting standards; we are driven to exceed them, setting new benchmarks that prioritise patient safety while offering best-in-class care.

The success of our Dose Excellence Programme is not solely measured by awards; it's reflected in the lives we touch and the care we provide. Every patient who walks through our doors can trust that their well-being is at the core of everything we do.



Cover Story



Integration of Artificial Intelligence in Healthcare: Understanding Changes and Impact

Oliver Kimberger, Professor at the Medical University of Vienna, shared his insights with HealthManagement.org, highlighting the evolving relationship between Artificial Intelligence (AI) and the established medical culture. These insights were shared in the context of his session at the 2023 Patient Safety Conference, titled "Culture in organization and AI: Is it compatible with current medical culture?"



Professor I Deputy Head of Department I Director of Trauma Anaesthesia I Department of Anaesthesia, Intensive Care Medicine and Pain Medicine I Medical University of Vienna I Vienna, Austria

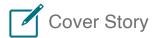
Is there potential for AI to enhance and safeguard the safety and quality of healthcare delivery?

Yes, I'm quite certain there is. However, we currently face a slight challenge in terms of the limited presence of AI in the ICU and OR. While there are few approved and commercially available applications that offer decision support in the ICU, the options are still limited. In the OR, there is, for example, one available application based on an AI algorithm to inform you in advance if there will be hypotension in patients. Although the availability is currently limited, the potential is exceptionally promising. I'm confident that we will see a rise in the development and deployment of such applications in the near future. In the first instances, they will primarily serve as helpers for busywork and quality assurance tools. Secondly, they will play a role in the prediction of disease trajectories and the optimisation of therapy.

How willing are healthcare professionals to embrace Al technologies in their daily work, and what is their level of trust in Al?

The current level of trust in AI is moderate to low, primarily because people tend to view AI as a black box algorithm, unsure of how it works. Moreover, health professionals are not used to working with them and have not received education during their medical study about AI and how it works. Consequently, trust-related concerns arise, including fears that the data collected during daily treatment may compromise privacy, both for patients and physicians.

Some individuals also worry that failing to follow Al recommendations might lead to legal problems. Furthermore, they are unsure about Al being forensically responsible for its own decisions. A possible future role for Al might be that of an informed advisor who acts like a senior colleague whom you also do not blindly trust.



And, just like experienced colleagues, Al can also make mistakes, though it may often be right.

How do patients and the general public feel about using Al in healthcare?

I'm not entirely certain if people are fully aware of this concern. From the patient's perspective, there's a fear that increasing AI involvement might result in further alienation from doctors. They worry that they may no longer see a doctor as the first point of contact but, for instance, an AI for initial triage. If you were to ask people on the street about their fears regarding AI, some might express concerns about the growing distance between physicians and patients.

On the other hand, physicians are afraid of the potential for de-skilling. They worry that people might

Furthermore, it's crucial for them to recognise that Al isn't something you can blindly trust, but it is also not something you need to be able to distrust.

Developing a critical approach to AI is key, and this should be integrated into their education. This educational shift isn't limited to physicians alone; it should extend to all healthcare professionals, including nurses, physiotherapists, and others. It's a cultural change that involves everyone. It's not sufficient for AI to learn from a limited dataset because that would make it applicable only to a specific population. Instead, AI should be trained on diverse datasets to ensure it optimises its algorithms comprehensively. This way, there won't be any problems where underprivileged or underrepresented groups are disproportionately affected by AI.

It is important that AI is not regarded as a substitute for physicians but as a supplement and improvement to medical practice

lose essential skills, just as we've become reliant on GPS in cars and can barely navigate without it. Similarly, there could come a day when people can't interpret medical data because it was always done by AI, and should AI not be there anymore, they no longer possess the skills. This is why I believe it is important that AI is not regarded as a substitute for physicians but as a supplement to medical practice.

What strategies can be employed to ensure the safe and effective integration of AI in medical practice and to ensure the culture in healthcare organisations is compatible with AI technology?

I believe that education is paramount. Doctors and healthcare professionals need to know what AI is, what it can and cannot do and how it functions. They don't need to grasp the actual programming or algorithm formulas, but they should have knowledge of the basic concepts.

How are issues related to patient privacy and bias in Al algorithms being addressed?

They are not addressed enough. The limited availability of open databases is indeed a problem. Many algorithms learn from these databases, but as they are limited, they inherently carry societal biases. These biases reflect the limited database and may not represent the diversity we need.

We must be aware of this problem. You can address it by seeking larger and more diverse databases. However, it is important to note that if a database already includes bias, no amount of calculation can completely eliminate this bias. The only option is to work with even larger and more diverse databases. This doesn't mean we should avoid using these databases altogether, but we must be aware of this limitation and address these biases in publications and the development of algorithms.



Are medical schools and healthcare institutions providing adequate education and training in Al for healthcare professionals? Is this something that we will see progress?

A medical university in Vienna is taking steps to incorporate digitalisation of medicine and AI into its curriculum. This reflects a growing recognition of the importance of these topics in modern healthcare. We are also working on a master's programme in digital medicine (https://digital-skills-jobs.europa.eu/en/ds4health). Starting such a programme demonstrates a commitment to staying at the forefront of medical education. It's an exciting development for students who can choose to do it after their medical studies.

liberates healthcare professionals from time-consuming paperwork. It will allow doctors to do some actual healthcare professional work, concentrating on delivering patient care without being glued to the paperwork.

How will the roles and interactions of healthcare professionals change and evolve with the integration of AI in healthcare?

There are two options. On the one hand, the less favourable option is that, overall, there's a global shortage of healthcare professionals, and AI and digital medicine will just compensate for this workforce shortage. In such a scenario, the improvement in patient care may not be there at all. On the other hand, AI will

All should be trained on diverse datasets to ensure its algorithms work for everyone

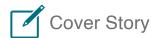
What changes in medical culture are expected as a result of the integration of AI into healthcare?

The integration of AI in healthcare brings about improvements in various aspects, including quality, adherence to guidelines, and administrative efficiency. However, I think we just have to take care that we do not see too much de-skilling when these methods are implemented.

One notable benefit of AI in healthcare is the reduction of administrative burdens. Tasks such as coding for patients and generating patient summaries, which take up a lot of the doctors' time, can be automated with AI. AI not only streamlines processes but also improve the quality of care, adherence to guidelines, and efficiency, freeing healthcare professionals from mundane work like coding and administrative tasks. In turn, they will have more time to spend with patients, and it will not just be about making AI a workforce compensation but a valuable tool for improving patient outcomes and experiences.

Conflict of Interest

None.



Interoperability and Healthcare: **Key Aspects, Pitfalls and Evolution**

Interoperability outcomes in healthcare refer to improving patient care, reducing medical errors, and increasing efficiency in healthcare delivery by enhancing the necessary coordination of all the agents involved.



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key points

- Interoperability oriented towards care continuity.
- Empowerment of the patient over their clinical information.
- Greater visibility and transparency about the results of the clinical practice.
- Optimising the available resources for the benefit of the patient and population health.
- Improving the coordination of care.
- · The critical impact of interoperability on medical outcomes.

Introduction

Interoperability implies data, information, knowledge and intelligence exchange, including their free usability between a range of components from several different technologies, based on open standards, plainly defined, and subject to transparent conformance of their structure and algorithms. A broader definition takes into account organisational factors that impact system-to-system business process performance. When a vendor is forced to adapt its system to a dominant system that

Interoperability Levels

From Data to Information, Knowledge and Intelligence



Consequence of an interaction of objects (events), during an interval of time, in a location (facts).

Outcome of combining a finite set of objects in a context, interpreting them, and determining their coherence and truthfulness

Effect of understanding information from the categories of a conceptual scheme

It arises from the ability to ask





Knowledge



questions, solve problems, recognize mistakes, and learn



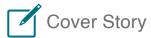


Intelligence



*Patterns of reality that have the potential to be read and interpreted

Figure 1: Interoperability Levels. Source: https://vico.org/Interoperability/InteropHealthcarePaper/InteropLevels.png



is not based on open standards, we are talking about compatibility, not interoperability. Types of interoperability include syntactic level, where several systems can communicate with each other, and semantic crossdomain level, where multiple organisations work together and exchange information assets based on a shared reference information model.

Interoperability outcomes in healthcare refer to improving patient care, reducing medical errors, and increasing efficiency in healthcare delivery. Interoperability allows healthcare providers to access patient data regardless of the system or platform where the data is stored. This means that a patient's electronic health record (EHR) can be accessed by different healthcare providers and systems, such as hospitals, clinics, and pharmacies, in order to provide coordinated care and continuity of the care process. However, achieving interoperability in healthcare can be challenging due to a variety of factors, such as multiple healthcare organisations involved, differences in data and terminology standards, the multiplicity of regulatory concerns on privacy, and technical limitations on coexistence between legacy and new systems. Efforts to improve healthcare interoperability are ongoing and involve collaboration between healthcare providers (public and private entities), government agencies, research institutions, and technology vendors.

Why Healthcare Interoperability

By "health system", we mean a network of organisations that brings together people, institutions and resources. Its mission is to provide services aimed at meeting the health needs of citizens and a target population.

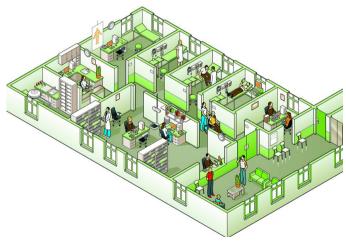


Figure 2: Healthcare Organisation

Its rules act on the basis of fair conditions and respect for people's dignity, with sustainable funding and accountability for the results of their actions.

The health organisation is a space of collaboration where several agents share the responsibility of solving, maintaining and improving the functional state of health and the quality of life of the citizens. These tasks require an organisational structure that is sustainable with a risk, quality and cost that we must manage and measure.

We will fulfil these requirements effectively only if we share standardised clinical information through the care processes and if we apply an interoperability scheme oriented towards care continuity and the empowerment of the patient over his clinical information. Both actions generate greater visibility and transparency about the results of the clinical practice of our professionals and help to optimise the available resources for the benefit of the Patient and Population's health.

Let's review the main agents involved in the delivery of healthcare services in a health system. Here are some examples:

- 1. Physicians: Doctors who diagnose and treat illnesses, injuries, and diseases.
- Nurses: Healthcare professionals who provide patient care and assist physicians in medical procedures.
- Pharmacists: Healthcare professionals who dispense medications and provide drug information to patients and healthcare providers.
- Allied health professionals: These include a variety of healthcare professionals who work in fields such as physical therapy, occupational therapy, speech therapy, respiratory therapy, and radiology.
- Health administrators: These are the people who manage healthcare facilities, such as hospitals and clinics.
- Health educators: These are professionals who
 provide education and information to patients and
 the general public about various health issues and
 disease prevention.
- Medical researchers: These are scientists who conduct research to develop new treatments and cures for diseases.
- Health insurers: These are organisations that provide insurance coverage for healthcare services.

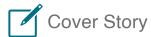




Figure 3: Healthcare Organisations Interoperability Scenarios

- Government agencies: These are entities that regulate and oversee healthcare services, such as pharmacovigilance management and health programmes.
- Patients: We consider that patients themselves are healthcare agents, as they play a role of greater empowerment in their own healthcare and treatment decisions.

In the context of healthcare, interoperability has a significant impact on medical outcomes by improving the necessary coordination of all the agents involved:

- Improved coordination of care: When different healthcare providers and systems can exchange patient data easily, it can improve the coordination of care. The lack of clinical information sharing kills more than the improper access to medical data.
- More accurate diagnosis and treatment:
 Interoperability can enable healthcare providers to access a patient's complete medical history, including information from different providers and systems. This can help providers make more accurate diagnoses and develop more effective treatment plans.

- Reduced errors: Interoperability can reduce errors that occur when information is not shared or is shared inaccurately. For example, a pharmacist can access a patient's medication history from different providers and systems, which can help prevent adverse drug interactions or duplicative prescriptions.
- 4. Better patient engagement: Interoperability can improve patient engagement by allowing patients to access their own health information from different providers and systems. Patients could check their medical information available, and they could also act as a controller of the quality of the clinical sources and detect potential misunderstandings that affect their healthcare process.

Standards Portfolio

We have different sorts of organisations with complementary accountability. For example, HL7 International (Health Level Seven) is a "Standards Development Organisation" (SDO) for the field of health. Founded in 1987, their standards have been accredited by ANSI and ISO. It operates internationally, and its mission is to provide global information standards for



clinical practice, healthcare organisations, administration and logistics to achieve real interoperability between the different information systems and technology applied in selected healthcare domains. On the other side, IHE (Integrating the Healthcare Enterprise) is a "Standards Implementing Organisation" (SIO), an initiative that aims to improve the interoperability of healthcare information systems. It defines a set of standards and implementation guidelines for the exchange of health information that can be tested in a real-time context to prove their efficacy and correct alignment with stakeholder requisites (Rules of Conformance).

To best understand how the information standards thrive inside the healthcare ecosystem, we share a reading of a conceptual model (Figure 4).

By convention, we have rendered the main process in the middle of the model. The background colour of the concept means a stereotype of the process corresponding to a patient encounter. The primary goal of each encounter is to provide appropriate care, address the patient's needs, and improve their overall health outcomes.

A patient encounter refers to any interaction or meeting between a healthcare provider and a patient.

It involves the exchange of information, assessment of the patient's condition, and the delivery of healthcare services. Patient encounters can take place in various healthcare settings, such as hospitals, clinics, doctor's offices, emergency rooms, or even through telemedicine platforms.

During a patient encounter, healthcare providers aim to gather relevant information about the patient's medical history, current symptoms, and concerns. They may perform physical examinations, order diagnostic tests, prescribe medications, provide treatments, or offer counselling and education regarding the patient's condition. The specific nature and depth of the encounter depend on the purpose, urgency, and complexity of the patient's situation.

Reading the model, we can represent the diverse range of patient encounters that can occur across different healthcare settings and specialties (longitudinal register) and establish the following business rules through the different relationships between concepts (cardinality):

 All patient encounters must be performed in one healthcare facility (the salmon colour of the concept implies that it is a process, and the

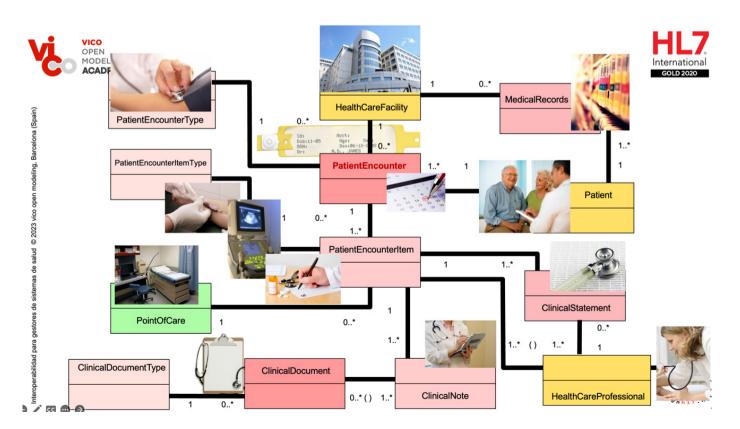
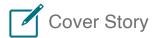


Figure 4: Patient Encounter Conceptual Model. Source https://vico.org/Interoperability/InteropHealthcarePaper/HealthCareSystemModel.png



- yellow colour of the facility means the role of an entity healthcare organisation, with requisites and constraints associated).
- The healthcare facility could house none or several patient encounters.
- Every patient encounter must indicate their patient encounter type (see the examples of patient encounters above).
- The patient encounter type could define none or several patient encounters.
- All patient encounters must contain one or more activities detailed as patient encounter items.
- Every patient encounter item belongs to a patient encounter.
- Every patient encounter item must indicate their patient encounter item type (see the examples of patient encounters above).
- 8. The patient encounter item type could define none or several patient encounter items.
- All patient encounters are referred to one patient.
- Every patient must have one or more patient encounters (The yellow colour of the concept means the role of an entity person, with requisites and constraints associated).
- 11. Every patient must have one or more entries in their medical record.
- 12. The medical record belongs to one patient.
- The medical record must be custodied by a healthcare facility (on behalf of a healthcare organisation).
- A healthcare facility could have custody of none or several medical records.
- 15. Every patient encounter item must be performed in a point of care (the green colour of the concept implies a concrete ubication of the healthcare facility with requisites and constraints associated).
- 16. The point of care could house none or several patient encounter items.
- Every patient encounter item must generate one or more clinical statements (we'll explain this concept below).
- Every clinical statement must be associated with a patient encounter item.
- Every clinical statement must be authored by one healthcare professional.

- 20. A healthcare professional could be the author of none or several clinical statements (The yellow colour of the concept means the role of an entity person, with requisites and constraints associated).
- 21. A healthcare professional must record their clinical statements in one or more clinical notes.
- 22. Every clinical note must be authored by one or more healthcare professionals.
- 23. A clinical document must gather one or more clinical notes.
- A clinical note could be gathered in none or several clinical documents.
- Every clinical document must indicate its clinical document type and a clinical document type could define none or several clinical documents.

About Clinical Statements

Clinical statements capture key information about the patient's condition, allowing healthcare professionals to make informed decisions and provide appropriate care.



Use of the model

The Clinical Statement Pattern represents a standard, high-level structure intended to support specific business functions. Although not intended to CMET A, SupportingClinicalIstatement), the Clinical Statement Pattern can communications regarding clinical information. The process of modification both) in order to achieve the needs of a particular domain. There is one ma (A, SupportingClinicalIstatement universal)

COCT_MT530000 (HL7 V3)



Figure 5: HL7 Clinical Statement Pattern. Source: https://vico.org/HL7_RIM/index.html - clinical-statement-pattern

A clinical statement refers to a concise and structured piece of information that describes a patient's health status, medical condition, diagnosis, treatment, or any other relevant clinical details. Clinical statements are commonly used in healthcare settings to document patient encounters, communicate information among healthcare professionals, and ensure accurate and standardised documentation for medical records.



Clinical statements typically follow a specific format and include essential elements such as:

- 1. Patient identification.
- Date and time when the statement was documented or when the relevant clinical event occurred.
- 3. Clinical context: Provides an overview of the patient's medical history, presenting problem, or reason for the statement.
- Objective findings: Are factual and observable information gathered through physical examinations, laboratory tests, imaging studies, or other diagnostic procedures.
- Subjective information: Includes the patient's selfreported symptoms, complaints, or other relevant information shared during the encounter.
- Assessment and diagnosis: The healthcare professional's evaluation and determination of the patient's medical conditions based on the presented information.
- Treatment plan: Outlines the recommended interventions, therapies, medications, or procedures for managing the patient's condition.
- 8. Prognosis: An estimation of the expected course and outcome of the patient's condition or disease.

Clinical information standards are centred on electronic data interchange, clinical document sharing, interoperability artefacts, and the platforms that manage exchange and communication.

It's very important not to confuse the levels of accountability that conditions every information standard. In our model, we'll solve the different interoperability scenarios with data, documents, and messages to fulfil the requisites of the sender and receiver on their electronic data interchange and documents to share the Clinical Statements authored by Healthcare Professionals.

Data interchange doesn't need a context or an author, but clinical documents are fully constrained by a context, by one or more authors of the content, a legal authenticator of the clinical statements, and a healthcare organisation that must act as a custody of the documents by law.

Please remember that an Electronic Health Record is a "Clinical Document Related Group" (not a simple clinical data gathering), and each clinical document is:

- · An act of clinical knowledge.
- A clinical statement about the functional health status of a patient
- A collaboration tool between health professionals and communication with the patient.

Scenarios, Actors and Transactions

Interoperability scenario refers to a situation or context where multiple systems, devices, or software applications are able to work together and exchange information seamlessly. It involves the ability of different components or entities to communicate, interact, and share data effectively, despite being developed independently by different vendors or organisations. When we talk about interoperability Use Cases (UC), we understand that each UC is a package that contains one or more scenarios. The exact number of contained scenarios depends on our UC granularity criteria.

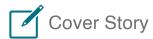
In an interoperability scenario, the various systems involved should be able to understand and interpret the data and commands shared between them, regardless of their underlying technologies, protocols, or standards. This enables them to collaborate and achieve common goals without encountering compatibility issues or barriers.

Interoperability scenarios can occur in various domains of healthcare, for example, allowing different electronic health record (EHR) systems to exchange patient data securely and accurately, enabling healthcare providers to access comprehensive medical information regardless of the system they use.

IHE (Integrated Healthcare Enterprise) is our best reference for specifying scenarios with actors and transactions. It will be useful to browse the contents of the ATNA (Audit Trail and Node Authentication) infrastructure profile to learn, with examples, the relevance of identifying actors and transactions when we define an interoperability scenario.

One of the key concepts in IHE is the notion of actors and transactions. An actor is a functional component within a healthcare information system that plays a specific role in the exchange of health information. A transaction is a specific type of exchange that occurs between two actors, is implemented by interoperability artefacts and is managed by interoperability platforms.

Transactions are specific types of exchanges that occur between actors. For example, one common



transaction in the IHE framework is the Patient Identifier Cross-Reference (PIX) transaction, which is used to query a cross-reference of patient identifiers maintained by the PIX actor. Another example is the Retrieve Imaging Information (RII) transaction, which is used to retrieve information about medical images stored in an Image Archive (IA) actor. The concept of actors and transactions is a key part of the IHE framework, and understanding these concepts is essential for building interoperable healthcare information systems that can exchange information seamlessly across different applications and systems. For example, between a PACS (Picture Archiving and Communication System) and a DACS (Document Archiving and Communication System).

About Interoperability Artefacts

We consider the interoperability artefacts as a set of tools, standards, and guidelines used to ensure that different systems, applications, and devices can work together seamlessly. These artefacts are essential in achieving interoperability. Some examples of interoperability artefacts include:

- Application Programming Interfaces (APIs): These are sets of protocols, routines, and tools used by developers to build software applications. APIs allow different applications to communicate and exchange data with each other. FHIR® is the most recent example of success in healthcare interoperability.
- Data and Document exchange formats: These are standardised formats for exchanging data and documents between different systems. Examples include XML, JSON, and CSV.
- Standards and protocols: These are guidelines and rules that ensure that different systems can communicate with each other effectively. Examples include HTTP, TCP/IP, and LDAP.
- Middleware: This is software that acts as a bridge between different systems and applications.
 Middleware can translate between different protocols, data formats, and APIs, enabling interoperability between different systems.

About Interoperability Middleware

Enterprise Service Bus (ESB) and Message-Oriented Middleware (MOM) are technologies used for asynchronous communication between different systems or components. However, they have significant differences that we must take into consideration if we are facing complex scenarios where a choreography of processes or fault-exception rules are needed.

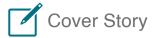
ESB is a cloud-based messaging service and process manager that enables communication between different applications and services in the cloud or on-premises. It offers a reliable and scalable platform that supports multiple protocols, message patterns and Business Process Execution Language (BPEL) services. On the other hand, MOM is a middleware technology that enables communication between different applications or services using only messaging patterns. MOM is typically used in enterprise environments where different systems need to communicate with each other only through electronic data interchange.

We can find solutions to this kind of middleware, both open-source and freeware. For example, OpenESB provides a powerful and flexible platform for building and managing complex integration solutions that can help organisations streamline their business processes and improve overall efficiency. It is a Java-based enterprise service bus (ESB) that supports a platform for integrating enterprise applications and services.

Healthcare Decision-Makers View

Let me share some ideas on why decision-makers should embrace interoperability services in their healthcare domains. There are several compelling arguments that healthcare decision-makers can consider when it comes to adopting interoperability in healthcare systems.

- Enhanced Patient Care: Interoperability enables seamless sharing of patient health records and information across different healthcare providers, improving care coordination and patient outcomes.
 Access to comprehensive and up-to-date patient information allows healthcare professionals to make informed decisions and provide more personalised, timely, and effective treatments.
- Patient Safety and Reduced Errors: Interoperability helps prevent medical errors by ensuring an accurate and complete exchange of patient data, including medications, allergies, and medical history. Access to real-time patient information can help avoid duplicate tests, medication errors, and adverse drug interactions, ultimately improving patient safety.



- Increased Efficiency and Cost Savings:
 Interoperability streamlines workflows and reduces administrative burdens associated with manual data entry, paperwork, and faxing. It improves operational efficiency by eliminating redundant processes and automating data exchange, which saves time and reduces costs for healthcare organisations.
- Improved Population Health Management:
 Interoperability enables comprehensive data aggregation and analysis, which supports population health management initiatives. By having access to integrated patient data, healthcare decision-makers can identify trends, monitor health outcomes, and proactively address public health concerns such as disease outbreaks, chronic disease management, and preventive care strategies.
- Empowered Patient Engagement: Interoperability
 promotes patient engagement by allowing individuals
 to access and control their health information
 securely. Patients can actively participate in their
 care decisions, access their medical records,
 and share information with other providers. This
 engagement leads to increased patient satisfaction
 and better health outcomes.
- Research and Innovation: Interoperability facilitates data and document sharing for research purposes, enabling large-scale analysis and the discovery of new insights. With interoperable systems, decisionmakers can leverage big data analytics, machine learning, and artificial intelligence to drive research, develop innovative treatments, and advance medical knowledge.
- Regulatory Compliance and Incentives: Many countries are enacting regulations and policies that promote interoperability as a means to improve healthcare outcomes. Adopting interoperable systems ensures compliance with these regulations and opens up opportunities for healthcare organisations to qualify for incentive programmes and funding related to interoperability implementation.
- Collaboration and Continuity of Care: Interoperability allows for seamless communication and collaboration between healthcare providers, promoting a continuum of care. Sharing patient data across different care settings, such as hospitals, clinics, and long-term care facilities, enables care

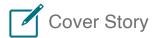
teams to work together effectively, reducing gaps in care and ensuring smoother transitions for patients.

By embracing interoperability, healthcare decisionmakers can unlock the potential for better patient care, improved efficiency, and transformative advancements in healthcare delivery, ultimately leading to better health outcomes for individuals and populations as a whole.

Again, the most appropriate starting point for a decision-maker is the review of the implementation guides published by IHE. The guides represent a distillation of interoperability best practices, and the events organised under the heading of "connectathon" are a very valuable source of reference for knowing the level of quality of technology providers in the health systems market and to what extent they are in compliance with the most accredited clinical information standards.

It is also highly recommended to follow up on the market showcases. An interoperability showcase is an event or demonstration that highlights the ability of different systems, technologies, or platforms to work together seamlessly and exchange information effectively. It aims to showcase how different components, devices, or software can communicate and interact with each other, even if they are developed by different vendors or utilise different standards. Interoperability showcases are commonly organised in the technology industry to promote collaboration, innovation, and compatibility among various products or solutions. These showcases often involve live demonstrations or simulations where different systems or products are integrated to demonstrate their interoperability capabilities. The main goals of an interoperability showcase are:

- Compatibility: To demonstrate that different systems or technologies can work together and exchange data without any issues, regardless of their underlying specifications or protocols.
- Collaboration: To encourage collaboration among different vendors, developers, or organisations by showcasing how their products can integrate and complement each other to provide enhanced functionalities or services.
- Standardisation: To promote the adoption of common standards, protocols, or frameworks that facilitate interoperability and create a unified ecosystem where various technologies can seamlessly interact.



 Innovation: To inspire innovation by showcasing how interoperability can enable the development of new applications, services, or solutions that leverage the strengths of multiple systems or technologies.

Interoperability showcases are often organised by industry associations (HIMSS), technology consortia, or standards organisations. They provide a platform for companies to demonstrate their products or solutions to potential customers, partners, or stakeholders, fostering collaboration and driving the adoption of interoperable technologies. These showcases can cover various domains, such as healthcare, telecommunications, smart cities, Internet of Things (IoT), financial services, and more. They may focus on specific interoperability standards or technologies, or they can have a broader scope to encompass multiple areas. Interoperability showcases play a crucial role in promoting compatibility and collaboration within the technology industry, ultimately leading to more integrated and interconnected systems that benefit end-users and drive technological advancements.

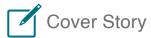
Patient: A New Interoperability Actor

Patient engagement plays a crucial role in achieving interoperability in healthcare. By involving patients in their own care and empowering them to access and share their health information, interoperability can be enhanced, leading to improved healthcare outcomes. Here are some use cases that demonstrate how patient engagement can promote interoperability:

- Personal Health Records (PHRs): Patients can maintain their own PHRs, which consolidate their medical information from various healthcare providers. By actively updating their records, patients ensure that their health information is accurate and up to date. PHRs can be accessed by different healthcare providers, facilitating interoperability and seamless information exchange.
- Patient Access to Health Information: Patients can be given access to their electronic health records (EHRs) through secure patient portals. This allows them to review their medical history, test results, diagnoses, and treatment plans. By having access to their own health information, patients can actively participate in care decisions, seek second opinions, and share the information with other healthcare providers as needed.

- Patient-Generated Health Data (PGHD): Patients
 can collect and contribute their health data using
 wearable devices, mobile apps, or other monitoring
 tools. This includes information such as activity
 levels, heart rate, blood pressure, sleep patterns,
 and more. Integrating PGHD with EHRs allows
 healthcare providers to have a comprehensive
 view of patients' health, enabling better-informed
 decisions and personalised care plans.
- Appointment Scheduling and Reminders: Patient engagement can be enhanced through interoperable systems that enable online appointment scheduling and automated reminders. This helps patients stay informed about their upcoming appointments, reduces no-show rates, and improves overall care coordination.
- Secure Messaging and Telehealth: Interoperable
 messaging platforms and telehealth solutions
 enable patients to communicate securely with their
 healthcare providers. Patients can ask questions,
 discuss concerns, share updates, and receive
 guidance remotely. By facilitating these interactions,
 interoperability supports patient engagement and
 strengthens the patient-provider relationship.
- Medication Management: Interoperable systems can integrate medication lists, prescription history, and medication adherence data. Patients can access this information to ensure they are following the prescribed treatment plan correctly. Interoperability enables medication reconciliation during care transitions, preventing errors and promoting patient safety.
- Health Education and Decision Support:
 Interoperable health information systems can deliver personalised educational resources and decision-support tools to patients. These resources can help patients understand their conditions, treatment options, and potential risks. By being well-informed, patients can actively participate in shared decision-making with their healthcare providers.

By leveraging patient engagement and interoperability, healthcare organisations can create a more patient-centred and collaborative care environment. These use cases foster information exchange, enable better care coordination and empower patients to take an active role in their own health management.



Blue Button is a healthcare industry initiative that provides patients with secure and easy access to their personal health information. It allows patients to download and share their health data with healthcare providers, family members, or other authorised individuals. The Blue Button was initially launched by the U.S. Department of Veterans Affairs (VA) in 2010 and has since been adopted by several other healthcare organisations, and many private and public health plans.

The Blue Button is typically accessible through a patient portal or mobile app and allows patients to download their health records in a standardised format, such as PDF, XML, or JSON. This data can include information on medications, allergies, lab results, immunisations, and other clinical data. The Blue Button initiative aims to empower patients to take control of their healthcare by giving them greater access to their health information and promoting interoperability and data sharing among healthcare providers. By making it easier for patients to access and share their health data, the Blue Button can help improve the quality and coordination of care, reduce medical errors, and enable patients to make more informed healthcare decisions.

Another initiative that will trigger a breakthrough in patient empowerment is The European Health Data Space (EHDS). It is an initiative of the European Union (EU) aimed at facilitating the secure exchange and sharing of health data across borders within the EU. It is part of the broader European Commission's Data Strategy, which aims to unlock the potential of data-driven technologies and services while protecting individual privacy and ensuring the highest standards of security.

The EHDS seeks to address challenges related to fragmented health data systems and data silos across European countries. It aims to enable healthcare providers, researchers, and innovators to access and use health data more effectively and efficiently for the purposes of research, innovation, and improving healthcare outcomes.

Key objectives of the EHDS include:

 Interoperability and standardisation: Promoting the adoption of common technical and semantic standards to ensure that health data can be exchanged and understood across different systems and countries.

- Data governance: Establishing a framework for data governance that defines the rights, responsibilities, and accountability of all stakeholders involved in the sharing and use of health data while respecting individual privacy and data protection laws.
- Data quality and integrity: Ensuring the quality, reliability, and integrity of health data shared within the EHDS to support evidence-based decisionmaking and research.
- Access and reuse of health data: Facilitating secure access to health data for authorised users, such as healthcare professionals, researchers, and innovators, while implementing stringent privacy and security measures.
- 5. Citizen empowerment: Empowering individuals to have more control over their health data through mechanisms such as consent management, allowing them to actively participate in datasharing decisions and benefit from innovative healthcare solutions.

The EHDS aims to promote cross-border collaboration, accelerate medical research, foster innovation, and enhance healthcare delivery by leveraging the vast amount of health data available across the EU. It also seeks to address ethical, legal, and technical challenges associated with data sharing, ensuring that privacy and data protection rights are upheld.

The implementation of the EHDS involves close collaboration between EU member states, relevant stakeholders, and the European Commission. It builds upon existing initiatives and regulations, such as the General Data Protection Regulation (GDPR) and the EU's Electronic Health Record Exchange Format, while seeking to harmonise standards and practices across different countries.

In Catalonia, the Healthcare Department has recently implemented a joint service of Blue Button and European Health Data Space rules, focused on sharing clinical documents and generating European patient summaries from a DACS (Document Archiving and Communication System) through a Patient Portal "La Meva Salut" (My Health). Empowered patients can now download all their medical reports and patient summaries on their mobile devices and share them with research institutions in a collaborative effort with non-governmental organisations like Salus-Coop.



Interoperability Pitfalls and Evolution

Current prevalent standards are evolving without any intention of unifying their artefacts. It is missed that the ambitious UMLS initiative regarding the mapping and harmonisation of all biomedical terminology standards, is not also applied with regard to the clinical information modelling standards.

FHIR® (Fast Healthcare Interoperability Resources) and openEHR (open Electronic Health Record) are two prevalent standards in the healthcare domain, specifically focusing on interoperability and electronic health records (EHRs). While they have similar goals, they approach interoperability and EHRs from different perspectives and have different design principles. Here's an overview of the relationship between FHIR and openEHR:

Purpose and Scope

- a). FHIR: Is a standard developed by HL7 (Health Level Seven International) and aims to provide a framework for exchanging healthcare information electronically. It focuses on data exchange, allowing different healthcare systems to share information using a standardised set of resources and APIs.
- b). openEHR: Is an open standard developed by the openEHR Foundation. It aims to define a common information model and architecture for EHRs that support lifelong, shared healthcare records. openEHR focuses on creating semantically rich and computable EHRs with a strong emphasis on clinical content and decision support.

Data and Reference Information Models

- a). FHIR: Utilises a resource-based data model, where healthcare information is represented as discrete resources such as Patient, Observation, Medication, etc. These resources have predefined structures and can be exchanged using RESTful APIs and formats like JSON or XML.
- b). openEHR: Employs an archetype-based data model. It defines a set of archetypes that capture the clinical knowledge and semantics of various types of health data. These archetypes are used to create templates for capturing and storing EHR data. The templates can be customised to accommodate local requirements and are designed to be computable and interoperable.

Interoperability

- a). FHIR: Focuses on facilitating interoperability between different healthcare systems and applications. It provides a set of well-defined resources, standards, and APIs that allow for easy data exchange and integration. FHIR is widely used for implementing interoperability at the application level and enables plug-and-play integration of different healthcare systems.
- b). openEHR: Aims to achieve semantic interoperability by providing a standardised information model and clinical knowledge representation. It focuses on capturing structured and semantically rich EHR data that can be shared and processed by different systems. openEHR provides a foundation for creating interoperable EHRs with consistent clinical content and decision-support capabilities.

Relationship

FHIR and openEHR are not mutually exclusive and can complement each other in certain use cases. They can be used together to achieve comprehensive interoperability and EHR capabilities. For example:

- a). FHIR can be used as a transport mechanism for exchanging data between openEHR-based systems or as a mechanism to expose openEHR data to external applications.
- b). openEHR can provide the underlying information model and clinical content framework for storing and managing EHR data, while FHIR can provide the standardised APIs and resources for interoperability with other systems.

In summary, FHIR and openEHR have different approaches and design principles but share the common goal of improving interoperability and electronic health records. They can be used together to leverage the strengths of each standard and create comprehensive solutions for healthcare information exchange and EHR management.

Clinical intelligence (AI in the healthcare domain), thanks to global clinical information access through interoperability services and the application of public and transparent algorisms, must help to generate relevant and pertinent questions, and at the same time, it must answer the key questions that our daily clinical practice generates:



- 1. How can I be thorough yet efficient in considering the possible causes of my patient's problems?
- 2. How do I rate the information I have gathered during the medical interview and physical examination?
- 3. How do I interpret new information aimed at establishing a diagnosis?
- 4. How do I select the most appropriate diagnostic examination?
- 5. How do I choose between several alternatives on treatment with risk of error and harm to the patient?
- 6. How can I improve my relationship and communication with the patient?

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Conflict of Interest

None.

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Clinical Care Management

Prioritising Patient Safety and Combatting Fatigue in Healthcare

Penilla Gunther, President of the European Patient Safety Foundation, shares her insights with HealthManagement.org, explaining the importance of patient safety and its growing significance in healthcare. She also highlights the potential impact the Fight Fatigue campaign could have on patient safety and overall healthcare outcomes.



President I The European Patient Safety Foundation I Brussels, Belgium

Why is it important to take a closer look at patient involvement in the context of safety?

It is important for everyone to work together and play their part in patient safety. Patients, too, bear some responsibility in being properly informed and prepared about their treatment or surgery or observing how the procedures are followed in healthcare settings. While patients shouldn't be made responsible for checking equipment functionality, it is the responsibility of healthcare systems to do everything so that patients feel safe and encouraged to ask questions, as this can provide access to relevant information regarding their medical condition. I would say that patient safety is a shared responsibility, and patients play a crucial role in this regard.

Would you agree that it is important for doctors to engage continuously with patients in discussions about their safety?

I believe it's the best way to achieve patient safety. Open dialogue makes it possible to discuss and address aspects of patient safety, ranging from the simplest to the most complex. When we attended the Global Patient Safety Ministerial Summit in Montreux, Switzerland, in February this year, the emphasis was still on the most essential and basic aspect of patient safety: hand hygiene. It's a simple yet fundamental practice that everyone can contribute to. There are no excuses to overlook discussions about patient safety, as it spans from basic practices, like handwashing, to the utilisation of highly advanced medical equipment and facilities. But as these discussions are not always fostered by local or medical culture or habits, we need to ensure that opportunities are created by incrementing them along the various patient pathways within healthcare settings or by providing the patients with information or tools such as a checklist detailing all the patient safety checks they should go through.

As AI continues to play a more significant role, what factors do you believe need addressing to ensure the responsible use of AI technologies in patient care?

Al from a patient safety perspective has been discussed in detail during our last Patient Safety conference

in Vienna. The least we can say is that AI provides opportunities to identify the health risks of patients, which can positively influence patient safety and outcomes. For example, AI algorithms can continuously analyse patient vital signs, electronic health records, and other real-time data to detect early signs of deterioration or potential medical errors, and that is, of course, a good thing. But it also comes with risks and implementation conditions, such as the need to ensure that patient data is transmitted and stored in such a way that patients feel safe sharing them.

Remote monitoring is becoming more significant, and we've seen that patients enjoy the empowerment it brings, allowing them to take control of their health into their own hands. How might the implementation of remote monitoring impact patient safety?

The impact of remote monitoring is clearly conditioned by how individuals handle their aids, apps, or any MedTech at home. It is, therefore, important that patients know how to handle these tools, and this knowledge should also extend to friends and families.

Sometimes, as private individuals, we may overlook instructions for product use. In healthcare, it's not only about MedTech but also about pharmaceutical products because the line between pharma and MedTech is very thin today. We need to consider pharmaceutical products and MedTech in the same context for patients. In both cases, incorrect use will result in not achieving the best health effects that one expects.

From your perspective, how has patient safety changed since the pandemic? What are the anticipated developments in the future?

I believe that the issue of patient safety has reached an incredibly high level of attention, particularly in discussions about ensuring a safe vaccine or adequate intensive care beds and staff capacities and providing the right treatment and conditions for healthcare workers. This heightened awareness spans the entire life science industry and society, presenting an opportunity for substantial improvements. Governments and other policymakers have recognised the need for development in this area. With collaborative efforts, which we observed during the pandemic, I hold an optimistic view of the future of patient safety.

The pandemic witnessed a significant surge in remote consultations. How do you perceive the impact of remote consultations on patient safety, and do you anticipate further improvements?

Coming from Sweden, recognised for its high level of digital maturity, I've observed a notable increase in digital doctor consultations. Interestingly, these companies providing digital healthcare providers are also establishing physical healthcare facilities for in-person appointments. There's been a shift from exclusively virtual meetings to a combination of virtual and in-person consultations. Virtual consultations provide convenience and cost-effectiveness, and in certain situations, an in-person visit to a real doctor is necessary. The goal is to strike a balance, leveraging the advantages of both approaches.

Patient safety is a shared responsibility, and patients play a crucial role in this regard

And again, as for any patient safety issue, proper implementation of remote monitoring is a shared responsibility. Healthcare professionals have to deliver user-friendly information and instructions about the product to the patient, and patients have to do their best to follow the instructions. Ultimately, it's all about ensuring patient safety to genuinely achieve the expected health outcomes.

In any case, what we need to avoid, from a patient safety point of view, is disconnected medicine, where the personal link between doctor and patient is lost, as is in-depth knowledge of the patient's medical history. The provision of quality care goes beyond brief, virtual discussions, which should only be there to take care of specific cases, such as following up on treatment at a distance or dealing with a question relating to that treatment, for example.

Patient communities have adapted to the unique challenges and opportunities presented by the pandemic. How are patient communities interacting now?

The awareness of patient safety has significantly grown, yet there is still much to be done. It's still difficult for communities or patient organisations to organise or link up in a more structural way around global challenges such as pandemics. What can be said, however, is that the pandemic showed just how ill-prepared healthcare systems in Europe were to cope with and absorb the impact of a disaster that was relatively predictable. In other industrial sectors, such as chemicals or nuclear power, railroads or airlines, risks are constantly analysed and reassessed to adapt the organisation to whatever may happen. Perhaps patient communities should now join forces and take the lead in importing such approaches from outside healthcare and promoting their implementation at all levels of healthcare systems.

outlined that, to achieve that, we need a new impetus for patient safety and some kind of a new vision. The healthcare systems have become more complex, and the changes patient safety improvement requires have to be embedded into a wider approach, considering the complexity of these systems.

The conference was also the opportunity to highlight the Fighting Fatigue Together campaign, which our Foundation launched to alert on the risks related to the fatigue of healthcare workers, and I'm very happy and very proud to witness the increased interest surrounding this campaign.

We announced that we have started to support the implementation of the campaign in Austria, Croatia, Georgia and Spain. These are the first countries, but it's essential for every country to address the shortage of healthcare workers, understand the reasons for them quitting their jobs and strive to create a healthier working environment in healthcare.

There is a strong link between the well-being of healthcare workers and patient outcomes

Can you highlight the key takeaway messages, or the main themes introduced at the 2023 Patient Safety Conference?

Several speakers at the conference have addressed patient safety from various perspectives, including people from medical companies, pharma and hospitals, healthcare professionals, and the patient side. I love this diverse representation because it allows for collaborative discussions and the exchange of innovative practices, which is key to accelerating the implementation of patient safety improvements. But I hope it won't stop in Vienna; it must go on so that we can achieve positive outcomes across Europe.

A very interesting thing which was outlined was the link between patient safety and the resilience of healthcare systems. In a way, improving the quality of care through better patient involvement organisation or ensuring the well-being of healthcare workers can contribute to healthcare settings that are better prepared to face crises, ranging from local disasters to global challenges such as pandemics or climate change. But it was also

We are all reliant on healthcare, and it's vital to retain and support the dedicated professionals working in the field. Additionally, we must focus on training more individuals for these roles and consider changes in working hours and conditions. This is something that concerns all of society because we are all patients sometimes.

Could you explain the objectives of the Fight Fatigue campaign in more detail?

The campaign originated in the U.K. several years ago following a tragic incident involving a nurse who, after working excessively long hours, lost his life in a car accident while driving home. This was the starting point to highlight the urgent need to address the fact that you cannot have people working too long hours in healthcare, as this comes with inherent dangers.

So, the first goal of the campaign is to raise awareness across Europe about the risks related to the fatigue of healthcare professionals, both for themselves and their patients. As a priority, we aim to encourage healthcare

professionals to protect themselves from the effects of fatigue and to rest properly during night shifts or before driving home. We also want to equip them to explain to hospital management the importance of accessible and convenient on-site rest facilities.

But, of course, ultimately, our long-term goal is to improve the working conditions of healthcare professionals because, in many countries, the border of what can be reasonably expected from human beings has been crossed. Numerous stories have surfaced of patients feeling distressed and terrified when they hear that their healthcare providers have been working maybe 48 hours, recognising it is not safe. It is dangerous for both healthcare professionals and patients. It has to change for the benefit of the whole society.

What impact do you anticipate the Fighting Fatigue Together campaign having on patient safety and healthcare outcomes?

I strongly believe in the importance of engaging with people to understand their experiences in healthcare. How do you experience healthcare? Have you something to share with us that we can use as a good or bad example? We need to collect this knowledge to improve healthcare but also to strengthen the link between the patients we all are and the healthcare professionals who are taking care of us.

I'm so pleased that our campaign has gathered support from across the life science sector and healthcare, including patient organisations, so that we can make a change. Care is not solely the responsibility of healthcare workers; the broader environment and society need to provide support and acknowledgment for the good work being done.

This support is a key objective of the campaign — to demonstrate solidarity with healthcare workers. During the pandemic, people were clapping their hands outside on the streets. However, they need more than clapping hands; we need to create a supportive and nurturing environment to help them in their daily work.

Let's not overlook either that there is a strong link between the well-being of healthcare workers and patient outcomes. We like people who really meet our expectations of knowledge, experience, and service. Patients nowadays would like to have more personalised care that matches their specific needs and demands, and that's not easy to achieve in a world where we also lack the workforce and the resources. At least, what we could aim for is a better level of well-being for healthcare professionals, ensuring that they are taken care of and feel recognised for their continuous dedication.

The story often has two different sides, and it's essential for us to come together, acknowledge these perspectives, and collectively work to solve the problem. While the challenges may not be entirely resolved with a conference or even a campaign, it's an ongoing journey we are all on, and any contribution to improve the situation is welcome.

What can you say about the importance of increasing retention and recruitment?

Beyond the high levels of burnout due to the pandemics and pre-existing shortages, I believe that the current generation of young professionals pays much more attention to the balance between private and professional life and that it is a reason why it is so difficult to recruit and retain young professionals. Medical schools find it hard to attract new students, and the rates of persons leaving the medical professions have never been so high. If we combine these trends with the ageing of the medical staff, we are now facing a major crisis in staffing healthcare, and that is why extra efforts must be invested in recruitment and retention.

These efforts involve ensuring that the hospital's environment aligns with the candidate's expectations and values. An example highlights the significance of a positive interview experience: imagine a nurse seeking his first job interview at different hospitals. While the first hospital offered a position, the atmosphere during the interview lacked warmth and welcome. In contrast, the second hospital expressed enthusiasm about having him on board, making him feel valued and part of a cohesive team. Of course, it is not just about marketing; the recruitment process must be truly aligned with the working conditions offered by the hospital.

This example highlights the impact of a hospital's culture and emphasises the importance of fostering a supportive and welcoming environment to attract and retain talented healthcare professionals.

Are we seeing more efforts to try and increase loyalty, retention, and recruitment of employees?

Unfortunately, I see that in many countries, we are taking the simplest route out of the crisis: solving the staff shortage by recruiting staff from another EU Member State or from a third country. It may solve the problem in quantitative terms in the short term, but we have to be aware that it also represents a risk in terms of the quality of the healthcare professional-patient relationship with communication errors for linguistic reasons and failures due to specific national or local cultural characteristics, which could impact the patient safety and outcomes.

Another way to look at it is to do our best to address the needs of the healthcare staff and prevent them from leaving the medical profession. For example, I believe it is important for healthcare professionals to meet, benefit from mutual collaboration, and exchange experiences and knowledge. There needs to be a collective effort to bring about the desired change in valuing those dedicated to vital work. Many times, healthcare professionals have been underpaid compared to other industries. Recognising and adequately compensating is essential for their well-being and motivation, as well as showing they are valued.

Is there anything else that you would like to add?

I'm very happy that patient safety is also one of the patient's rights, and I try to work according to the European Charter of Patients' Rights. Patient safety is a fundamental aspect of healthcare, encompassing various elements outlined in the charter. I'm very happy that we have achieved more, at least since the pandemic.

I see the need to tackle fatigue among healthcare workers. I'm really looking forward to seeing the road ahead and what the future will bring. I believe that through collaborative efforts to address this issue, we can achieve more and truly make an impact at the European level.

Conflict of Interest

None.



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