Precision Medicine

DATA SCIENCE - MULTIOMICS - BIOMARKERS - TARGETED THERAPY

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Editorial

LLUÍS DONOSO BACH

Director Clinical Advanced Technologies Initiativel Hospital Clínic Barcelona | University of Barcelona. LEITAT Technological Center | Spain | HealthManagement.org Editor-in-Chief, Imaging

Precision Medicine

Precision medicine, also called personalised medicine, involves tailoring medical treatment and interventions to the individual characteristics of each patient. These characteristics may include genetic makeup, molecular profiles, environmental factors, lifestyle choices, and personal preferences. The goal of precision medicine is to optimise the effectiveness of healthcare by providing treatments that are tailored to the unique characteristics of patients. This approach contrasts with traditional medicine, which often relies on a one-size-fits-all approach based on general population averages.

Precision medicine represents a paradigm shift in healthcare, moving towards a more individualised and proactive approach to diagnosis, treatment, and prevention. It can potentially improve patient outcomes, enhance patient satisfaction, and reduce healthcare costs. It offers the promise of revolutinising healthcare through tailored treatment plans, improved diagnosis, targeted therapies, reduced adverse reactions, cost savings, and patient empowerment.

At the same time, it presents several challenges related to patient data privacy and security, data integration and interoperability, ethical and social implications, implementation costs and access, physician education and training, patient education and engagement and validation and reproducibility.

In this cover story, our contributors explore precision medicine and its benefits and application in healthcare while addressing the challenges associated with its implementation. They also discuss the need for collaboration among major stakeholders in healthcare to ensure the responsible and equitable implementation of precision medicine.

Begoña San José talks about the transformative potential of personalised wellbeing within the framework of precision health and disucsses practical strategies for optimising individual health.

Sara Green discusses the benefits of precision medicine, the challenges associated with it and the impact of its use on healthcare costs, testing and monitoring, and the inequality in access to healthcare services.

Carlos Larrañeta discusses Procure4Health, a community tasked with enhancing healthcare services across healthcare organisations and highlights the seven areas of focus where innovation could alleviate challenges associated with the implementation of precision medicine.

Paula Amorim, Gabriel Pires and Henrique Martins discuss the benefit of customizing rehabilitation based on individualized patient assessment using Human-Machine Systems (HMS) and how this could improve accuracy in assessment, monitoring and supportive tasks to increase productivity across fields of rehabilitation.

Sergey Ivanov talks about the rise of smart devices, telecare, and Internet of Things (IoT) healthcare apps to facilitate diabetes diagnostics and management and how this techonolgy opens opportunies for simpler and earlier diagnosis, prevention, symptom management, and minimisation of the consequences of diabetes.

Harvey Castro talks about new technologies, what they mean for healthcare in 2024 and what leaders need to know before they can fully embrace innovation.

Somashekara Koushik Ayalasomayajula and Kim Rochatexplore the current applications of AI in the MedTech sector, its key areas of utilisation, the challenges encountered in AI integration, and gain insights into the ongoing evolution of the regulatory framework.

Miguel Ángel Martínez Sánchez provides an overview of the experience of the Green Hospital project by Fundació Sanitària Mollet (Barcelona), which has successfully achieved the goal of becoming a net zero hospital in direct emissions.

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

Happy Reading!
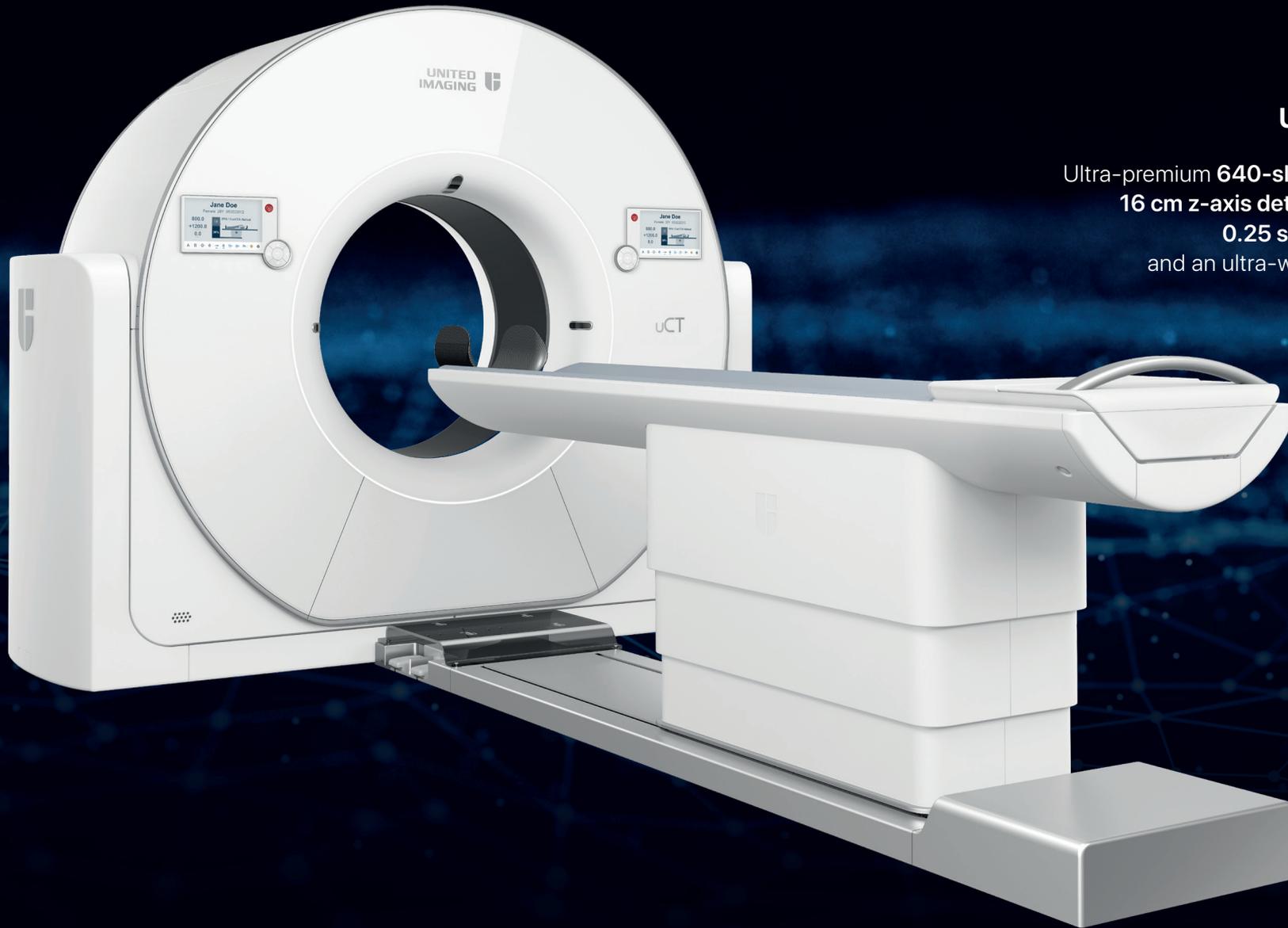
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Paula Amorin is a physical and rehabilitation doctor at the Center of Rehabilitation Medicine of the Central Region of Portugal. She is a member of the Board of Directors of the Iberic Society of Telemedicine and Telehealth and the Board of Directors of the College of Physical Medicine and Rehabilitation of the Portuguese Order of Physicians.

Harvey Castro, USA

Harvey Castro is an emergency room physician and healthcare leader. His passion is in balancing innovative healthcare approaches with individualised patient care. He consults for several healthcare companies, served on various medical boards and started more than 20 successful businesses. Recognised as a LinkedIn Top Voice, he is leading in the AI healthcare revolution, developing & advising the use of AI. As a GPT Advisor and global keynote speaker, he is dedicated to driving positive change through technology and fostering innovation.

Lluís Donoso-Bach, Spain

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.

Somashekara Koushik Ayalasomayajula, Germany

Somashekara Koushik Ayalasomayajula is a quality and regulatory affairs professional with 11+ years of experience in regulated industries. He leads the digital health team at Veranex Switzerland and actively supports medical devices (incl. IVD) and software manufacturers with regulatory strategy, design and development, V&V, management system deployment, auditing, safety and security, lifecycle management, cybersecurity and AI.

Jonathan Christensen, USA

Jonathan Christensen, Senior Insights Director, is leading a team of KLAS analysts focused on imaging research, clinical software and medical research for international markets. His role led him to engage with executive leaders from around the world to identify research needs for the industry that will benefit vendors, providers and investors. His goal is to identify gaps in market understanding and then help close those gaps to spur the industry forward and ultimately deliver better healthcare for patients.

Sara Green, Denmark

Sara Green is an Associate Professor at the Section for History and Philosophy of Science, Department of Science Education, at the University of Copenhagen. Her research focuses on the epistemic and social implications of datafication in science and medicine, with special focus on precision medicine.

Sergey Ivanov, USA

Sergey Ivanov is the Head of the Healthcare Center of Excellence at Itransition. He has more than a decade of experience in software development. Now specialising in the healthcare sector, he has vast expertise in EHR and EMR, telehealth solutions, mHealth, medical data analytics, healthcare IoT, medical device software development, and healthcare BI. His primary responsibility is to lead healthcare software development projects and ensure the successful implementation of products or services for customers.

Henrique Martins, Portugal

An Internist MD, Management PhD and Master in Law, Prof Henrique Martins headed SPMS (Portugal) leading numerous nationwide eHealth projects and co-chaired the EU eHealth Network. He consults and teaches on digital health, health transformation, management and leadership.

Kim Rochat, Switzerland

Kim Rochat brings over 15 years of expertise to the healthcare innovation sector, specialising in active devices and software. He has secured market access for numerous medical devices driven by innovative technologies, demonstrating proficiency in navigating data protection and cybersecurity challenges in the digital realm. Kim holds an MBA in Information Security, a CAS in Medical Informatics, and a CAS in Medtech Ventures Management.

Carlos Larrañeta, Spain

Carlos Larrañeta is an industrial professional holding a Bachelor's degree in Mechanical Engineering and a master's in Renewable Energy Engineering from the University of Seville. He embarked on his journey as a researcher at the Centre for New Energy Technology (CENTER) and subsequently assumed the role of R&D manager for 17 years at the Industrial Research and Cooperation Association of Andalusia (AICIA). Presently, Carlos serves as the Coordinator of the European Network Procure4Health, a role based at the Regional Ministry of Health of Andalusia.

Gabriel Pires, Portugal

Gabriel Pires leads the brain-computer interface (BCI) group in the Human-Centered Mobile Robotics Lab at ISR-UC. He conducts research on human-machine interfaces, assistive robotics and telehealth and teaches signal processing and machine learning at IPT.

Miguel Ángel Martínez Sánchez, Spain

Miguel is the current Director of Environment, Safety, and Health at Fundació Sanitària Mollet and holds a degree in Industrial Chemistry and a Bachelor's in Environmental Sciences. With over 18 years of experience, he specialises in implementing management systems and has a significant background as an auditor and consultant. He was formerly the head of the Climate Change and Sustainability Services (CCaSS) department at EY. He leads the Green Hospital and Healthy Entity projects. Both received the Silver Award at the IHF Awards in 2021 and 2022, with additional recognition for the Green Hospital project's communication at IHF 2023.

Contributors

Begoña San José, Austria

Begoña San José is a clinical psychologist with a PhD in Health Services Research from Erasmus University in The Netherlands. She developed her professional career with large multinational insurance companies and specialised in healthcare provider management, digital health and health innovation. In 2018, she established her own firm, Beandgo, and dedicates her time and effort to making high-quality mental health and wellbeing support accessible and affordable. She actively engages with corporations, insurance companies and healthcare providers to provide customised solutions in the mental health space.
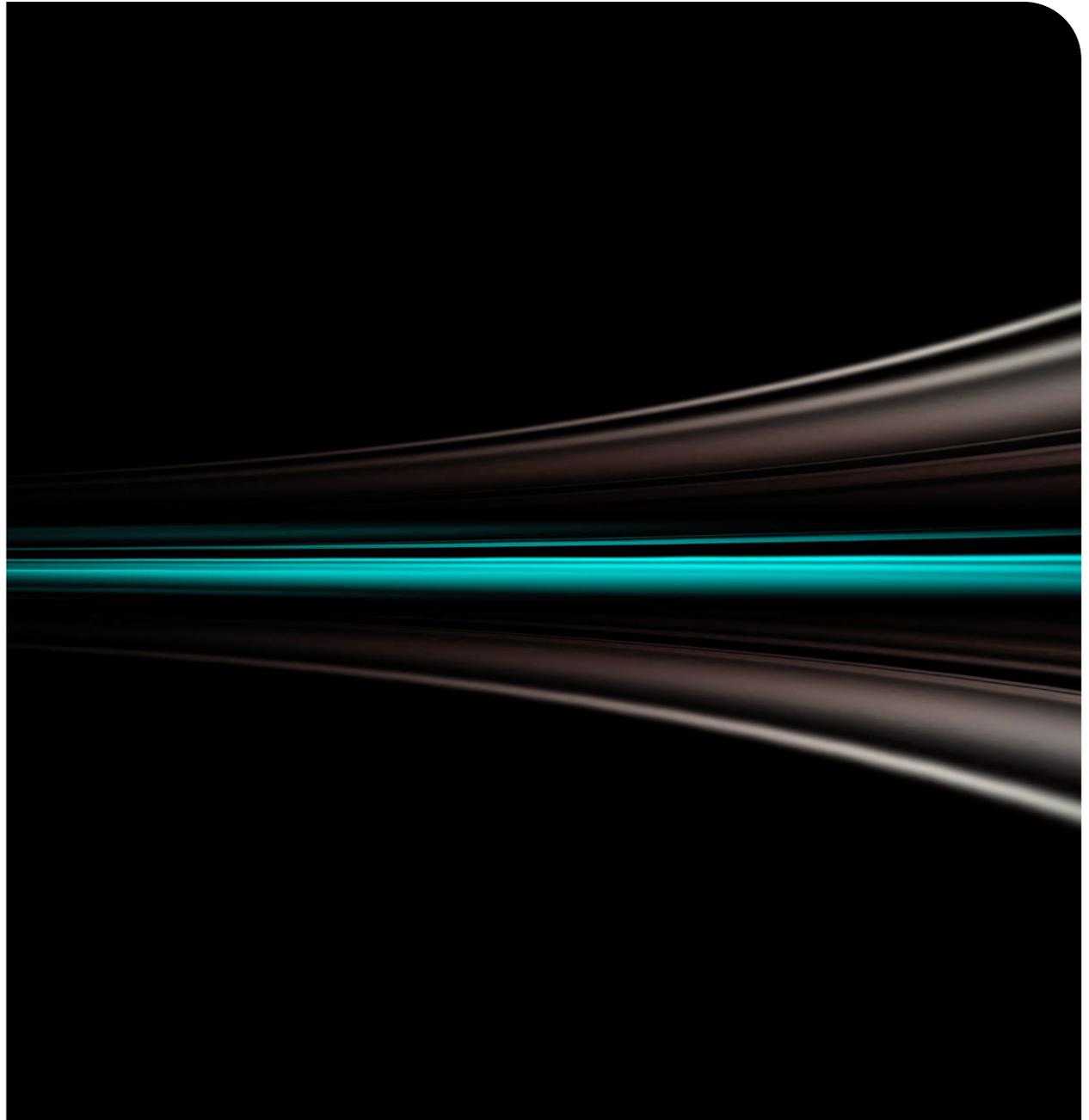
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Spotlight

United Imaging First Mobile Digital PET/CT in Europe

United Imaging Healthcare Europe announces the introduction of its first mobile digital PET-CT solution in Italy, Europe. It is now fully operational under the Azienda Unità Sanitaria Locale Piacenza (AUSLP) Hospital.

key points

- The first mobile digital PET-CT system in Europe is a result of a successful collaboration between United Imaging Healthcare, Fora Spa and AUSLP Hospital.
- This digital PET-CT leverages the powerful capabilities of artificial intelligence.
- The PET reconstruction algorithm is constructed with the CNN-based iterative reconstruction engine trained from uEXPLORER® total-body PET data and AI-empowered workflow.
- The technology enables the unit to produce low-noise PET images, improve image contrast and enable high-speed-scanning while maintaining outstanding PET image quality.

United Imaging Healthcare Europe, a leading company in advanced medical imaging and radiotherapy equipment, proudly announces the introduction of its first mobile digital PET-CT solution in Italy Europe, now fully operational in the Piacenza province under the auspices of the Azienda Unità Sanitaria Locale Piacenza (AUSLP) hospital Italy.

The first mobile digital PET-CT system in Europe is a result of a successful collaboration between United Imaging Healthcare, Fora Spa and AUSLP Hospital, the premier mobile diagnostic services company in Italy. The mobile unit has been equipped with uMI 550 digital PET-CT system. It is a top-edge digital technology system integrated with 24cm wide PET AFOV,

industry fine 2.76mm LYSO, TOF features, digital SiPM detector and the finest 2.9mm NEMA resolution with the added benefit of air-cooled detector technology ideally suited for mobile solutions. This digital PET-CT leverages the powerful capabilities of artificial intelligence. The PET reconstruction algorithm is constructed with the CNN-based iterative reconstruction engine trained from uEXPLORER® total-body PET data and AI-empowered workflow to predict low-noise PET images, improve image contrast,, and enable high-speed-scanning while maintaining outstanding PET image quality. As a result, the uMI 550 allows for a whole-body PET-CT scan within 6

minutes with 4 to 5 bed positions. uMI550 is also equipped with a unique solution of a data-driven head motion correction algorithm, which results in overcoming the need for repeat scans. The digital detector design with low-voltage power uses less energy, whereas its programmed mobile-specific workflow maximizes patient throughput to enable the ability to scan at multiple locations on the same day. On CT technology, an 80-slice CT scanner with ultra-low noise Z-Detector technology reduces the radiation dose without compromising the quality of imaging. Overall, with its unique features, including automated radioactive source less quality control programmes, multiple radiopharmaceutical support, and United Imaging's unique collaborative lifecycle approach, uMI 550 is a highly reliable machine designed to withstand the needs of large-volume treatment centres.

The partnership between United Imaging, Fora Spa, and AUSLP Hospital is bound to have a significant impact on the healthcare landscape of the Piacenza Province, providing its 285,943 inhabitants with improved access to state-of-the-art advanced imaging modalities.

Prior to the introduction of the mobile digital PET-CT unit, as many as 1200/1300 patients annually travelled out of the province to obtain PET/CT scans. However, now, thanks to the creation of a fully autonomous mobile digital PET-CT unit equipped with the essential devices for preparing the radiopharmaceutical necessary for carrying out the test and its administration, patients will no longer be forced to make long distances to undergo advanced imaging. Considering the paramount role of digital PET-CT imaging in the diagnostic process and subsequent planning and monitoring of the oncological, neurological and cardiological treatment management. The oncology, neurology and cardiology patients will particularly benefit from the mobile digital PET-CT unit. Moreover, besides facilitating access to cutting-edge imaging modalities, this pioneering solution encourages the work of multidisciplinary groups and shared decision-making as the medical personnel can share PET-CT studies in the company system.

The mobile unit is located in front of the Piacenza hospital, and the tests are managed by the Nuclear Medicine team directed by Massimiliano Casali, in close coordination with the other activities of the department. Since its launch, fifty patients have had the opportunity to undergo PET-CT scans, with estimated 1,800 services per year once the mobile unit becomes fully operational.

United Imaging is confident that the integration of the state-of-the-art uMI550 digital PET-CT system will provide the highest quality imaging and diagnostic confidence for every patient from the Piacenza province of Italy.

United Imaging takes great pride in the fact that patients from the Piacenza province will now have the opportunity to undergo precise diagnosis and receive tailored treatment from the first mobile digital uMI550 PET-CT system.

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.

Affidea's Pioneering Contributions to Radiology: Showcasing Innovation and Quality at ECR 2024

Affidea's impactful participation at the European Congress of Radiology 2024 highlights its forefront position in enhancing radiological practices and patient care. With 8 insightful clinical presentations, the clinical team demonstrated a strong commitment to quality, safety, and innovation in diagnostic imaging across Europe.

Dr Charles Niehaus, Executive Director for Affidea Group, said: "Our significant contributions to the European Congress of Radiology this year show our focus on innovation and clinical excellence. These presentations are a testament to our commitment to advancing healthcare standards, improving patient safety, and fostering a culture of continuous improvement in quality."

Dr Alessandro Roncacci, SVP Chief Medical Officer for Affidea Group, added: "The content of our presentations at the congress reflects our holistic approach to healthcare delivery. By emphasising quality, safety, and efficiency, we are not only enhancing patient care but also contributing to the evolution of radiological practices. Our efforts across Europe highlight the transformative power of collaborative innovation in the field of diagnostic imaging."

Here's a more detailed look at each presentation and the strides Affidea is making in the field.

1. Clinical audit in the Radiology department. 5-year experience in 14 European countries

Authors: A. Papachristodoulou , A. Roncacci , C. Paraskevopoulou;

Presented by Nasia Papachristodoulou, Director of Clinical Governance and Quality for Affidea Group, this study underscored the breadth and depth of implementing clinical audits in 127 radiology departments across 14 European countries. It provides an elaborate overview of how structured audits based on the ESR tool can systematically improve quality and safety in radiology services. The methodology addressed key operational aspects, including patient workflow, consent procedures, emergency preparedness, and personnel training. The audits' outcomes have significantly shaped policies, demonstrating Affidea's proactive stance on clinical governance and risk mitigation.

2. CT radiographers play crucial part in Dose Management: from CT modalities to Dose Team activities - EuroSafe Imaging Poster

Authors: C. Colmo , Z. Barbócz , I. Turos , A. Curtin , M. Vaišvilaite , M. Kostaridakis , A. Papachristodoulou , A. Roncacci , C. Paraskevopoulou;

Cristian Colmo, Lead Specialist for Affidea's Dose Excellence Programme, will present at ECR an innovative model showcasing the pivotal role of CT radiographers in enhancing dose management across various imaging modalities.

This initiative illustrated the strategic shift towards a radiographer-led approach in dose optimisation, highlighting the creation of standardised CT protocols, the establishment of diagnostic reference levels, and the implementation of a radiation dose monitoring system. The success of this program in meeting and surpassing key performance indicators showcases Affidea's commitment to leveraging team expertise for patient safety.

3. Introducing a multi-institutional organisation Dose Management Program in a country with 21 CT centres - Poster presentation

Authors: C. Paraskevopoulou , I. Turos , C. Colmo , A. Papachristodoulou , A. Roncacci

This presentation, led by Chryssa Paraskevopoulou, Group Dose Management & Radiation Protection Manager for Affidea, highlights the challenges and successes of implementing a Dose Management Program across 21 CT centres in Romania.

Using the example from Romania, Chryssa emphasised through this study the critical role of data benchmarking, educational initiatives, and protocol optimisation in achieving significant dose reductions and enhancing compliance with established diagnostic

reference levels.

The concerted efforts led to a remarkable improvement in radiation safety and patient care, reflecting Affidea's dedication to setting new standards in diagnostic imaging practices.

4. Monitoring performance indicators for Quality improvement in Radiology: experience from 15 European countries

Authors: *A. Papachristodoulou , K. C. B. Santana, A. Roncacci , C. Paraskevopoulou*

Karla Santana, Quality and Risk Manager for Affidea Group, will present at ECR the use of performance indicators to monitor and enhance quality in over 341 radiology and radiotherapy departments. This approach provided a structured framework for assessing and improving quality metrics, highlighting the importance of continuous monitoring, multidisciplinary collaboration, and context-sensitive analysis.

The findings offer valuable insights into the dynamic nature of quality improvement, reinforcing Affidea's role in pioneering patient-centered care.

5. Needlestick injuries in Diagnostic Imaging Department. Analysis of causes and impact of safety strategy in 15 European countries

Authors: *A. Papachristodoulou , C. Domingos Filho , A. Roncacci , C. Paraskevopoulou;*

This study presented a thorough analysis of needlestick injuries, illustrating Affidea's comprehensive strategy to mitigate such incidents. The deployment of targeted training, educational campaigns, and a focused safety strategy led to a notable reduction in needlestick injuries, enhancing the safety culture within diagnostic imaging departments. This initiative demonstrates Affidea's commitment to protecting patients, personnel, and third parties from preventable hazards.

6. Preventable risks in Radiology and Radiotherapy department: analysis of patient falls and impact of quality improvement actions in 15 European countries

Authors: *A. Papachristodoulou , E. Virág , C. Paraskevopoulou , A. Roncacci*

Affidea's focused analysis on preventing patient falls in diagnostic imaging and radiotherapy departments revealed a targeted approach to improving patient safety.

By categorising the severity of falls and implementing specific training and support measures, the team significantly reduced incidents, particularly post-procedure. This presentation highlights the organisation's dedication to creating a safer care environment through pre-emptive action and continuous safety education.

7. Standardisation of CT procedures as first step of Dose Management: different Countries and different approaches

Authors: *C. Colmo , I. Turos , C. Ekmekçi , Z. Barbócz , M. Kostaridakis , A. Papachristodoulou , A.Roncacci , C. Paraskevopoulou ;*

The effort to harmonise CT procedures across 15 countries represents a critical milestone in dose management. By establishing standardised protocols and diagnostic reference levels, Affidea has effectively optimised radiation doses, ensuring patient safety and enhancing the quality of care. This initiative underscores the importance of standardisation in achieving consistent, high-quality diagnostic imaging services.

8. Results of MR fusion transrectal ultrasound-guided prostate biopsy in single center

Authors: *G. Volford, F. M. Márványkövi, H. Groszeibl, T. Beöthe, P. Dombóvári, I. Buzogány, L. Kardos;*

Prostate cancer is the second most common malignant neoplasm in men. MRI plays a significant role in the diagnosis of prostate cancer. In Hungary, transrectal ultrasound-guided systemic biopsy is the common practice to verify suspected prostate cancer cases. MRI fusion-ultrasound guided targeted biopsy (MRI-TBx) is a novel technique that may aid the better detection of prostate cancer. This presentation aims to report the results of MRI-TBx or MRI-TBx combined with systemic biopsy performed in Affidea Hungary.

Affidea's dynamic presence at the European Congress of Radiology 2024 showcases its leadership in radiology and healthcare innovation. The organisation's initiatives in clinical audits, dose management, quality improvement, safety strategies and innovative methodologies underscore its pivotal role in setting new benchmarks for healthcare excellence.

Cover Story

Innovation Procurement - Meeting the Needs of Precision Medicine Implementation Challenges

An overview of the Procure4Health working group for precision medicine and the key areas of focus where innovation could alleviate challenges associated with its implementation.

CARLOS LARRAÑETA

Coordinator,
European Network
Procure4Health |
Fundacion Progreso y
Salud | Seville, Spain

key points

- Procurement of innovation is about improving public services by adopting innovative solutions to tackle the challenges faced by public services.
- The Procure4Health approach involves embracing innovative solutions to address the challenges faced by healthcare organisations.
- The Procure4Health community focuses on building capacities within healthcare systems regarding PI, facilitating collaboration among procurers of innovation in the health sector and shaping policies to influence the future of the PI instrument.
- The Procure4Health working group for precision medicine uncovered seven areas of focus where innovation could alleviate challenges, and three topics related to the market analysis phase.

Procurement of innovation is about improving public services by adopting innovative solutions to tackle the challenges faced by public services. Procure4Health is a community tasked with enhancing healthcare organisations including hospitals, regional and national public health systems, private health systems, and central purchasing bodies.

The Procure4Health approach involves embracing innovative solutions to address the challenges faced by healthcare organisations. Adopting innovations translates to procurement of innovations (PI) for healthcare systems. Recognising the potential of the PI instrument to drive significant change in healthcare systems across Europe, the European Commission has entrusted the Procure4Health community with the mission to promote its adoption. To fulfil this mandate, the Procure4Health community focuses on building capacities

within healthcare systems regarding PI, facilitating collaboration among procurers of innovation in the health sector and shaping policies to influence the future of the PI instrument.

Procuring Innovation: A Collaborative Approach to Co-Creating Healthcare Solutions

In today's landscape, enhancing healthcare and care services requires embracing innovations that address existing challenges. This entails procuring innovations tailored to specific needs for healthcare systems rather than settling for off-the-shelf solutions that may only partially meet requirements. The procurement of innovation instrument begins by defining needs and engaging with the market/innovation ecosystem, inviting them to develop solutions. Moreover, potential developers are incentivised by not only the procurement

of the outcome but also by being supported in the later stages of development. This collaborative approach underscores the paradigm of co-creation, a journey requiring joint efforts from both the demand and supply sides to achieve success.

Procurement Innovation - Concrete Impact on Healthcare

Procurement innovation is all about meeting the needs of end-users, clinicians, and patients, ultimately enhancing their experiences. Successful procurement innovation results in concrete solutions for diagnosis, treatment, or procedures that improve the daily lives of clinicians and, consequently, patients. Key steps for adopting the PI instrument within an organisation include:

- Allocating human resources to oversee the process, establishing a technical office for procurement of innovation.

- Defining organisational strategy and priorities.

- Engaging internally with end-users to identify unmet needs for innovation.

- Prioritising these unmet needs.

- Sharing this information with the market/innovation ecosystem and soliciting feedback on potential solutions.

- Initiating the tender process to contract solution development.

- Evaluating proposed solutions.

- Scaling up and deploying successful solutions.

However, success hinges on obtaining high-level management endorsement for the technical office

Outcomes of P4H activities are aimed at a broad audience to which they can bring impact:

Health & Social Care (H&Sc) procurers	Any organisations (private or public) at the local, regional and European level involved in public purchases made for primary, secondary, tertiary health and social care by the EU public procurement rules.
Enablers	Organisations that regularly interact with procurers, like competence centres for innovation procurement or networks, together with experts, consultants or advisors.
Policymakers	Decision-makers at European and national level. Especially those related to the healthcare systems.
Communication multipliers	All those external stakeholders, organisations, or individuals who recognise the added value of the project and are motivated to disseminate its benefits further bringing higher visibility to the project activities and outcomes.
Health & Care ecosystem	Any organisations (private or public) at the local, regional, and European levels with an interest in public procurement of innovation in the healthcare sector in accordance with the EU public procurement rules.
Fellow projects and initiatives	Sister projects and other related initiatives with interest in the project development.
Suppliers	Economic operators that provide innovative solutions (products or services) to the unmet needs identified by healthcare procurers.
Scientific world & Academia	Academia and research groups to get informed of the results of Procure4Health. Scientific media of interest for publishing papers and scientific results from the project.
General Public	People interested in the project's topics with or without a technical background in Procurement of Innovation.

to procure innovation. Procure4Health adopts a practical, hands-on approach rooted in the real experiences and challenges of our community members. We address requirements, obstacles, and approaches to innovative solutions, culminating in joint recommendations for top management and policymakers of healthcare systems.

Participation in Procurement Innovation

The profiles of the active members of the P4H community are as follows: management, procurement, innovation and ICT departments. Organisation-wise, the core audience is the procurers in the healthcare sector. But, as the procurement of innovation journey is the paradigm of co-creation, all the stakeholders have an important role to play at various points of the journey. Thus, P4H is open to everyone: procurers of innovations, supporting organisations, and suppliers. However, depending on the nature of each activity and to improve the efficiency of a specific discussion, each activity might be directed to a more precise group of stakeholders.

Twinnings and Clinical Working Groups: Structure for Uptake of Innovation

P4H has two main ways to structure the work and enable joint discussions between stakeholders:

- Twinnings. Partnerships among procurers to share best practices, expertise and strategy.

- Working groups (WG). There are four clinical working groups dedicated to agreeing on common

unmet needs of innovation, performing the market analysis of those needs, exploring the requirements for the development, scaling and deployment of the innovative solution in our organisations and delivering recommendations for top health management and policy maker to foster the uptake of the innovative solution developed. These working groups are:

> The future of medicine lies in providing the right treatment for the right patient at the right time, emphasising personalised interventions based on biomarker responses

- o Precision and Predictive Medicine

- o Digital Health and ICTs

- o Sustainability in Procurement of Innovation

- o Integrated Care

Two working groups focus on how to improve the efficiency of the PI instrument:

- o Value-based healthcare WG tackles how to incorporate value base criteria in the tender

process to acquire the development of innovative solutions.

- o Impactful innovation WG studies the impact and how to overcome the final "valley of death" of the innovation process. How to go from a successfully piloted solution to deployment in our healthcare systems.

Precision Medicine Challenges and Unmet Needs: A Call for Innovation

Precision medicine represents a paradigm shift in healthcare, aiming to customise treatment strategies according to individual patient characteristics, encompassing genetics, environment, and lifestyle factors.

At the heart of precision medicine lies the concept of genomic profiling. Genomic profiling entails the comprehensive examination of an individual's genetic composition, including variations in their DNA sequence. Recent advancements in high-throughput DNA sequencing technologies have made obtaining a person's complete genomic profile increasingly feasible and affordable. These profiles provide valuable insights into an individual's predisposition to certain diseases, their treatment response, and their susceptibility to adverse drug reactions.

The future of medicine lies in providing the right treatment for the right patient at the right time, emphasising personalised interventions based on bio-marker responses. Within the broader scope of personalised healthcare, precision medicine integrates genomic, proteomic, and lifestyle data to create tailored prognostic, diagnostic, and therapeutic interventions, revolutionising the landscape of modern medicine.

The Procure4Health working group for Precision Medicine uncovered seven areas of focus where innovation could alleviate challenges, and three topics entered the market analysis phase to be selected to enter the next phase of the procurement of innovation journey, the Open Market Consultation (OMC).

- **Genomic neonatal screening:** This need is based on what is known as "diagnostic opportunity" and would be framed within a population screening programme for secondary prevention. The main problem detected in the public domain is that many patients affected by rare diseases are diagnosed with an average delay of 4 years. The reasons for this diagnostic delay are diverse: little knowledge of the disease, non-specific symptoms, few specialists trained in this field, poor access to highly complex genomic tests, etc. This means that, in many cases, when patients are diagnosed, they are no longer candidates for treatment because they are at a too-advanced stage of the disease. These patients often present sequelae or irreversible deterioration, manifesting incapacity, dependence, hospitalisation or frequent medical visits, entailing a high cost to the health system and society. Detecting all treatable rare diseases at birth through genetic newborn screening would significantly accelerate and improve the percentage of patients diagnosed (on time). Patients could then access treatment in the pre-or paucisymptomatic phase, improving their survival, morbidity and quality of life. It would also bring considerable savings to the healthcare system (less or less expensive treatments, fewer hospitalisations, fewer re-

sources in general, etc.). There is currently no market solution to address this need. It would be necessary for the genetic panel adapted to DNA extraction in dried blood to be flexible and updatable (genes can be easily added) and for the response time for results to be less than ten days.

- **Preservation of fresh biological samples:** New molecular techniques in research (and increasingly in clinical practice) require the availability of biological material from patients preserved in a system that does not modify the nucleic acids, proteins or metabolites of the sample and that does not require freezing and the associated infrastructure. Frozen tissue is the best biological sample for current molecular biology techniques, but the costs of frozen storage are very high. The widespread method of storing patient samples is by fixation and embedding in paraffin, but this system does not allow us to get the most out of patient samples. Therefore, there is a need to develop other techniques to keep the sample as close as possible to the original state (at low costs, preferably).

- **Improved monitoring and optimisation of resources for personalised lung cancer care:** Nowadays, lung cancer is the paradigm of personalised medicine. Only 15-20% of cases are diagnosed at a limited stage, and surgery can be an active part of patient treatment. Therefore, speaking of curability, there has been a real diagnostic and therapeutic revolution in patients diagnosed at a locally advanced and/or metastatic stage in the last ten years. On the one hand, the possibility of

genomic sequencing of patients, especially with non-small cell lung carcinoma (NSCLC) subtype adenocarcinoma, and their access to targeted therapy, as well as the development of immunotherapy, have increased patient survival in this setting from 5-10% to a 35-60% probability of being alive at five years. We can now speak of long survivors, with and/or without disease, with and/or without active treatment. Patient follow-up has never been protocolised other than consensus guidelines based on expert recommendations. The current challenge presented by this new scenario makes the need to standardise this follow-up a priority, which would have a clear impact on the continuity of patient care and the optimisation of resources. Therefore, the challenge here would be integrating data from patients' clinical histories with the results of their complementary tests (analytical, imaging tests, pathological anatomy-molecular biology studies, etc.) and developing predictive models based on the same.

Measuring Success: Impact, Widespread Implementation and Standardisation

Our measure of success aligns with our ability to make tangible improvements in the lives of end-users, clinicians, and patients. In our context, efficiency hinges on our capacity to effectively scale up and deploy successful pilots developed within our organisations.

While technological failures are inevitable in innovation activities, our focus remains on ensuring that solutions demonstrating technological success

are seamlessly integrated and expanded across our healthcare settings. Efficiency means not only achieving technological milestones but translating those achievements into widespread implementation and meaningful impact on patient care and outcomes.

Standardisation streamlines processes and enhances efficiency. By establishing standardised procedures for assessing, defining, and prioritising innovation needs, we can ensure a systematic and proactive approach to innovation development and uptake. This shift from reactive to proactive engagement allows us to strategically allocate resources and maximise the impact of our initiatives.

Standardisation also fosters scalability and replicability. By standardising procurement processes and methodologies, we pave the way for the mass production of innovation projects. This transition from bespoke, handcrafted projects to standardised, replicable models holds the potential to significantly enhance the efficiency and effectiveness of innovation procurement.

Ultimately, by embracing standardisation as a core principle, P4H aims to revolutionise the landscape of healthcare innovation, driving widespread adoption and amplifying impact on a global scale.

High-Level Endorsement to Scaling Up and Reach Critical Mass

The strategy to scale up and achieve the critical mass necessary for global impact revolves around a comprehensive action plan developed within Procure4Health (P4H). This action plan encapsulates the approach, requirements, and recommendations

for effectively adopting innovations to enhance health care services.

The next pivotal objective for the Procure4Health community is to garner endorsement for this action plan, particularly from policymakers and top healthcare managers. Securing their support is essential to drive widespread adoption of our initiatives and ensure that our efforts are integrated into broader healthcare policies and strategies.

By gaining endorsement at the highest levels of governance within the healthcare sector, we aim to create an enabling environment conducive to scaling up our initiatives and reaching the critical mass needed to deliver meaningful global impact. This strategic approach underscores our commitment to driving positive change and transforming healthcare delivery on a global scale.

Best-in-class Methodology to Navigate Innovation Needs

The assessment and prioritisation of innovation needs is the first step of the procurement of innovation journey. A combination of two methodologies is used for this process:

1. EAFIP methodology https://eafip.eu/ Developed by one of our core partners CORVERS https://corvers.com/

2. The Early Detection Map methodology developed by the coordinators of Procure4Health, the Andalusian Public Health System (APHS)

The main aim of the Early Demand Map is to obtain a portfolio of needs and opportunities for innovation that will transform the future Health Systems.

The initiative is based on co-creation models that stand for open innovation and design thinking methods to collect ideas and innovation needs. In this process, two levels of collaboration are very much promoted:

- Internal collaboration between professionals from the Andalusian Public Health System: researchers, clinicians, project technicians, managers, top managers and professionals with different expertise.

- External collaboration between professionals from external organisations who actively collaborate with the APHS professionals to contrast and define the needs identified and to offer guidance on possible solutions to the proposed challenges:

  a. Public sector (professionals from the Andalusian Public Health System).

  b. Private sector (companies, SMEs and start-ups).

  c. Academic sector (research centres, universities).

  d. Patient´s associations.

This collaboration happens along the different phases of the process, as is shown in the graphic below:

Professionals from all these sectors gather in the OPEN and MIND workshops to define the innovation needs of the Andalusian Public Health System. With the support of the Technical office, the needs are turned into challenges which, later on, will be implemented as public procurement of innovation projects which, ultimately, will contribute to the modernisation of the public system.

Communication and Advocacy Efforts to Raise Awareness

Engaging with high-level healthcare stakeholders to secure endorsement for our initiatives presents certain challenges, primarily due to the multifaceted nature of our approach and the need for collaboration across diverse departments and stages of the innovation journey.

The precision medicine ecosystem, encompassing patients, clinicians, researchers, technologies, genomics, and data sharing, requires a concerted effort from various stakeholders. Integration of precision medicine with innovation procurement, ICTs, legal considerations, and technology transfer further adds complexity to the engagement process.

Securing high-level endorsement is crucial to mobilise this diverse ecosystem and ensure collaborative action. While top management typically prioritises short-term objectives, our strategy represents a mid to long-term approach with inherent uncertainties. However, with clear support from the European Commission and numerous national governments for implementing the procurement of innovation instruments, there is a compelling rationale for swift adoption. Delaying adoption risks missing out on valuable opportunities to leverage public resources for fostering innovation and enhancing public services.

Join in Driving Innovation and Transformation in Healthcare

We invite you to participate actively in Procure4Health and join us in driving innovation and transformation in healthcare delivery. Here's how you can get involved:

1. Register on our platform: https://community.procure4health.eu/home Procure4Health welcomes new members and organisations to join our community. Registering on our platform gives you access to funding opportunities and resources to support your initiatives.

2. Explore funding opportunities: Participate in our call for twinnings, which is open until June 17th, 2024. We offer up to €30,000 for partnerships between healthcare service providers interested in adopting the procurement of innovation instruments within their organisations.

3. Engage in work groups: Members are encouraged to join our work groups and contribute actively to discussions. These groups focus on sharing practical experiences and addressing challenges encountered in ongoing projects. By collaborating with peers, you can gain valuable insights and find solutions to obstacles you may face in adopting innovative solutions.

Raising awareness about the importance of our project is paramount to its success. By highlighting the potential benefits of precision medicine and innovation procurement, we aim to garner support and foster collaboration among stakeholders. Emphasising the alignment of our objectives with broader healthcare priorities and policy initiatives underscores the relevance and urgency of our endeavours. Through strategic communication and advocacy efforts, we seek to drive awareness and build momentum for transformative change in healthcare delivery.

Procure4Health is a platform for exchanging knowledge, sharing best practices, and fostering collaboration among healthcare stakeholders. Together, we can overcome challenges and drive positive change in healthcare delivery. Join us in shaping the future of healthcare innovation.

Conflict of Interest

None.

Socio-Political Costs of Implementing Precision Medicine

The benefits of precision medicine, the challenges associated with it and the impact of its use on healthcare costs, testing and monitoring, and the inequality in access to healthcare services.

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key points

- Precision medicine personalises disease treatment and preventive care by taking into account individual characteristics.
- Precision medicine will improve treatment outcomes, but its high costs and uncertainties about cost-saving measures pose challenges.
- Precision medicine raises concerns about healthcare costs, over-testing, and unequal access to services, challenging the principle of equal healthcare access.
- Precision medicine shows great potential, but important steps remain needed to ensure development and implementation are realised in a clinically useful and socially robust way.

Precision medicine holds great promise in revolutionising healthcare by leveraging new technologies in genomics and beyond to develop more precise biomedical models for understanding, treating, and predicting human diseases. This visionary approach aims to personalise disease treatment and preventive care by taking into account individual characteristics such as genetic variation, environmental factors, and lifestyle. Unlike traditional evidence-based medicine, which relies on statistical evidence from large populations, precision medicine seeks to improve treatment effectiveness by predicting individual responses. However, while precision medicine offers potential benefits such as improved treatment outcomes and better management of rare diseases, it also presents challenges. Concerns arise regarding its impact on healthcare costs, the risk of over-testing and over-monitoring, and the potential for increased inequality in access to health-

care services. Additionally, the principle of solidarity and equal access to healthcare services may be challenged by the implementation of precision medicine, highlighting the need for careful consideration and inclusive practices in its development and deployment.

How is precision medicine expected to revolutionise healthcare?

Precision medicine, often called personalised medicine in the European context, can be considered a vision to utilise new technologies in genomics and beyond to construct more precise and detailed biomedical models for comprehending, addressing, and forecasting human diseases. The goal is to tailor disease treatment and preventive care to the specific characteristics of each individual by considering factors such as genetic variation and other molecular markers, environmental factors, and life-

style. Traditional evidence-based medicine has emphasised statistical evidence based on large populations, but being right on average does not always predict what is best for the individual. By improving the ability to predict treatment response at the individual level, it is hoped that medicine can improve the effectiveness of treatments and reduce adverse effects experienced with current treatment forms. Precision medicine also holds the potential to improve the treatment of rare diseases that are highly influenced by specific molecular traits. Another aspect of precision medicine that holds many promises is individualised risk profiling, which is hoped to enable healthcare professionals to improve disease prevention and early intervention. It is envisioned that precision medicine will identify individuals at high risk for certain health conditions and that returning such risk information to them will motivate their commitment to adopt preventive measures. The underlying assumption is that informing individuals about their genetic risk motivates them to change their lifestyle more than general health recommendations. It is too early to tell which of these hopes can be realised, but important discussions have already started on which attainable priorities should be investigated first and what it takes to realise these promises from what we already know about the challenges.

The philosophy of science is a crucial asset to approach questions about whether and how medical uncertainty can be overcome with new scientific developments and also to understand challenges beyond science and technology. Realising the aims of precision medicine also means facing the social complexity of specific healthcare structures where socio-economic issues and data biases can greatly impact who will benefit from the new developments.

Is the higher effectiveness of precision medicine a reliable indicator of future cost-efficiency?

Policy reports often give the impression that precision medicine will inevitably lead to reduced healthcare costs. If successful, precision medicine can indeed reduce the administration of ineffective or

> Precision medicine utilises new technologies in genomics and beyond to construct precise and detailed biomedical models for comprehending, addressing, and forecasting human diseases

unnecessary interventions. However, this approach also requires large-scale investments that may have uneven returns for different stakeholders. Precision medicine requires substantial investments in large data infrastructures, omics technologies, workforce training, clinical trials, and development

and price setting of targeted therapies. Rather than blockbuster drugs developed for large populations, the precision approach requires pharmaceutical companies to invest in smaller niche markets of patients with specific molecular variants. This means that the increased efficacy for individual patients often comes with a much higher price tag. As a result, precision medicine treatments are often very expensive and may significantly increase the spending of public healthcare systems and health insurance premiums. It is, therefore, important not to equate higher effectiveness with overall higher cost-efficiency. Whether precision medicine will decrease or increase healthcare costs ultimately depends on how drug pricing models will develop at the regulatory level. Uncertainties also exist in the context of preventive precision medicine. If disease prevention can be improved for those at the highest risk, it is clear that cost savings would occur due to a reduction of downstream treatments of developed diseases, making investments in data collection and analysis worthwhile. However, there are substantial uncertainties about whether data-intensive risk profiling will succeed in identifying and helping those at the highest risk while avoiding overmedicalisation of others due to over-testing. These problems can only be addressed by governance bodies providing a robust pricing and reimbursement framework and healthcare research providing benefit-risk insights on generalised risk profiling.

Can the generalisation of individualised risk profiling lead to over-testing and over-monitoring?

Data-intensive risk profiling tends to not only pick out high-risk individuals who will benefit from pre-

ventive interventions but also to redefine many as being "at risk". As pilot projects in precision medicine show, big data screening identifies some risk factors among all individuals (Vogt et al. 2019). However, that does not mean that we all would benefit from having that information and taking preventive actions, especially if the latter involves medical treatments. We all have risk factors for developing various diseases, but many abnormalities will not develop into significant, symptomatic health problems. For example, not all individuals with hypertension will experience cardiovascular problems later in life, and not all people with cellular changes identified as cancer will develop symptoms or die from it. The problem of overdiagnosis is the risk of unnecessarily turning healthy individuals into patients with diagnoses or "at-risk individuals". Precision Medicine efficiency in this context revolves around the difficult balance of estimating how many individuals we are willing to overdiagnose per each successful case of prevention. Healthcare professionals refer to this as "the number needed to treat" to have a positive impact on one person, i.e., how many we – statistically – have to unnecessarily diagnose to prevent one death or disease case (e.g., stroke). The problem is, therefore, that good intentions to catch more diseases at earlier stages can come with the drawback of overmedicalising and overtreating patients who will not benefit from the interventions.

Overdiagnosis is a persistent problem in the history of medicine, and it is a very interesting question whether precision medicine can help reduce overdiagnosis or whether the problem may be aggravated through over-testing. This question may not have a simple answer. For hereditary diseases with strong genetic causes, precision medicine can pro-

vide more accurate risk predictions (e.g., ovarian cancer), which can help stratify which populations would benefit from earlier intervention. However, whenever we start measuring an increasing number of risk factors for common diseases in the general population, both in greater detail and via continuous monitoring, more anomalies are often identified.

> Precision information is only beneficial if it gives the individual access to better healthcare preventative and treatment services

This will often lead to an increase in follow-up testing and the need for healthcare counselling, thus increasing healthcare utilisation and cost impact, often with unclear benefits. Because individuals can be harmed by "too much medicine", it is crucial to establish more firm evidence for the benefits of data-intensive risk profiling instead of assuming that risk information will straightforwardly lead to better health outcomes. This is particularly important because risk information can be experienced as both empowering and disempowering, depending on the context of the individual receiving it.

What are the concerns regarding increased inequality in access to healthcare due to precision medicine?

Generally speaking, precision information is only beneficial if it gives the individual access to better healthcare preventative and treatment services, such as more effective precision treatments or targeted interventions for disease prevention. However, not everyone has equal access to healthcare services or options for complying with the imperative of health optimisation. This is particularly the case in countries like the US, where access to healthcare is largely based on private health insurance plans and where expensive targeted treatments or preventive tests may increase health disparities. Healthcare systems with universal coverage, such as many EU countries, can mitigate this risk by ensuring that individuals have the same level of access, regardless of their financial status. However, the increasing prices of precision treatments can also cause problems in public healthcare systems, as they make it increasingly important to prioritise treatment access to those that benefit the most. In some cases, this can result in only some patients with a specific disease being offered a new treatment because their relative predicted gain is higher. Thus, with limited price regulation, existing systems can also be put under pressure to increase treatment costs (Green et al. 2023; Green et al. 2024).

Moreover, it is crucial to ask whether the suggested strategies for individualised disease prevention cater to the relevant patient group. There are currently several important initiatives to increase inclusivity in research by involving underserved populations in data donation. This is crucial for mitigating the problem of data biases that negatively impact

the accuracy of diagnostic tests and evidence of treatments for some population groups. But addressing the problem of unrepresentative data is insufficient, as it is deeply tied to issues of trust and reciprocal gains for data donors (Sabatello et al. 2018). We also have to ask who will have access to the products of precision medicine, the technologies and treatments that were developed from all the data and work that is currently being done. Thus, developers and policymakers must work together with health professionals to ensure that health technologies are developed in a way that also improves healthcare access for underserved populations.

Can you provide an example of how precision medicine challenges the principle of solidarity and equal access to healthcare services?

Solidarity in healthcare means a collective share of risks and costs despite the fact that each person has different risks and capacities for contributing. It is well known that some are at higher risk for developing diseases, either because they have specific genetic risk factors or because of the way they live their lives. But a solidaristic system should even out such differences by collectively sharing healthcare resources. From one perspective, precision medicine may have an equalising effect because some risks can be identified and intervened on before they develop into a health problem. If you are genetically disposed to develop cardiac problems, earlier interventions might save you from downstream health problems and give you more equal opportunities for improved health outcomes. But the crucial question is how to ensure that these technologies can target the right audience and in the right way (Prainsack 2017). Precision medicine must help those at the

highest risk to have a real impact. It is well known in public health research that high-risk individuals often have complex problems that are not easily solved by giving them more information about their disease risk. It is not empowering to know your individual risk if you do not have access to genetic counselling and other preventive healthcare services, or if you do not have the resources to implement

> Developers and policymakers must work together with health professionals to ensure that health technologies are developed in a way that improves healthcare access for underserved populations

lifestyle challenges. There is a risk that precision prevention increases the responsibilities of individuals while invisibilising factors that the individual has no or limited control over. Therefore, we must take sufficient time to understand the problem we want to solve before expecting too much of the potential of the new tools. This does not mean that precision

medicine does not have the potential to revolutionise healthcare, but turning this promise into measurable action requires thinking carefully about how we can implement it in a socially robust and economically sustainable way.

A related challenge has to do with opportunity costs and how we prioritise healthcare resources. In our research project, called PROMISE, we interviewed Danish and American primary care doctors (GPs), who often face the difficult challenge of evaluating whether or not to act on their patients' worries. In addition to experienced symptoms, worries can come from the results of online genetic tests or anomalies detected by wearables such as smart watches (e.g., irregular heart rhythm). Acting on all detected anomalies is not advisable as it can lead to overdiagnosis and overtreatment. It can also lead to a waste of healthcare resources and opportunity costs, as there will be less time for other patients and other tasks in primary care. The current marketing of health technologies, such as wearables and online testing, speaks primarily to consumers with the resources to invest - financially and through lifestyle changes - in health optimisation. They are often also inaccessible to certain marginalised populations, such as blind/low vision people, who would have wanted to make behavioural and lifestyle changes. While it is great if technologies can further support a healthy lifestyle, increasing testing and monitoring often give rise to new worries even among healthy individuals. This is partly a development also caused by the opportunities of various health tech companies capitalising on the hope and hype of precision medicine. Companies behind wellness technologies are not required to document the clinical benefits of their devices as long as they are not marketed as diagnostic devices, but

they often encourage patients to consult with their physicians if they have concerns about their results. This could cause the increased burden of counselling demands on GPs or other health professions, a demand they are unprepared for and do not have sufficient resources to meet. Therefore, we need awareness of the risk of "medical Matthew effects", where healthcare resources are shifted further towards those already well.

The Matthew effect, also known as the Matthew principle, refers to the tendency for individuals to accumulate social or economic success based on their initial level of popularity, friends, and wealth. In other words, those who already have more will get more. Coined by sociologists Robert K. Merton and Harriet Zuckerman in 1968, this phenomenon can largely be attributed to preferential attachment. This means that attention, wealth, or credit is distributed among individuals based on their existing level of resources. Consequently, it becomes increasingly challenging for individuals with lower rankings to increase their resources over time, as they have fewer to start with. Conversely, those with higher rankings find it easier to maintain their advantage due to their larger initial resources.

Mitigating these problems is not easy. Important steps could include making more transparency about which applications are backed by evidence of health benefits and are properly validated, as the current market and product promises are difficult to navigate for consumers and health professionals alike. Moreover, for evidence-backed applications, there is a need for proper guidelines and procedures to implement these in healthcare systems so that more patients can benefit, regardless of their financial status. Finally, I would highlight the importance of including health professionals in the development phase of new technologies and policymaking. Policy reports that initiate large-scale investments are often written by consultant companies with limited insight into what is most needed and what is feasible in practice. As a result, we may fail to address the most pressing clinical problems or end up with unrealistic expectations of precision medicine. There is no doubt that precision medicine holds great potential, but important steps remain needed to ensure that the development and implementation are realised in a clinically useful and socially robust way.

Conflict of Interest

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Enhancing Precision Health with Personalised Wellbeing

The transformative potential of personalised wellbeing within the framework of precision health. Practical strategies for optimising individual health.

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key points

- Precision wellbeing shares similarities with precision medicine while presenting distinct challenges and opportunities.
- Precision wellbeing recognises the interconnectedness of multidimensional aspects of wellbeing.
- Factors such as physical health, mental wellbeing, social support, environmental context, cultural beliefs, personal preferences, and past experiences must be considered to implement precision wellbeing.
- While precision medicine typically focuses on acute interventions delivered at specific points in time, precision wellness emphasises the importance of precision wellness emphasises the importance of continual adaptation and refinement of wellness practices integrated into daily life.
- Fostering a culture that values and prioritises precision wellbeing involves promoting awareness, education, and advocacy regarding the significance of personalised wellbeing practices and their positive impact on individual health.

Introduction

You would easily agree with me when I tell you that you are unique. There is no second human being, even if you have an identical twin that is just like you. Yet, when it comes to health and wellness, why do we often settle for one-size-fits-all solutions that fail to recognise our individuality? In today's ever-evolving landscape of wellbeing, a new concept is gaining traction—a concept that challenges the status quo and dares to ask: What if your wellbeing was as unique as your fingerprint?

Much like its counterpart in medicine, precision medicine, which meticulously tailors treatment to the specific genetic makeup and characteristics of each patient, precision wellbeing applies a similar rationale. Just as precision medicine recognises that what works for one patient may not work for another due to genetic variations, precision wellbeing acknowledges that individuals have unique physical, mental, emotion-al, and social characteristics that require personalised approaches.

At its core, precision wellbeing challenges the status quo and dares to ask the question: Why settle for generic solutions? It's time to move beyond the outdated notion of one-size-fits-all wellbeing programmes and embrace a new era of tailored interventions.

Understanding Precision Wellbeing

Have you ever noticed how the little choices you make each day can have a ripple effect, sometimes positive and sometimes negative, on your overall sense of wellbeing? Perhaps you've felt recharged and uplifted after engaging in a heartfelt conversation with a friend or spending quality time with loved ones. Conversely, you may have experienced a sense of loneliness or disconnection after engaging in negative social interactions.

Have you ever felt empowered and strong after completing a challenging workout session? On the flip side, have you ever experienced aches and pains after neglecting your **body's** need for movement and exercise?

Reflect on your **mental** wellbeing as well. Have you ever found peace and clarity of mind through mindfulness practices or engaging in activities that bring you joy? Conversely, have you ever felt overwhelmed and stressed from constantly juggling work and personal responsibilities without taking time to rest and recharge?

Think about your **emotional** wellbeing too. Have you ever felt uplifted and supported after opening up to a friend about your feelings? On the other hand, have you ever felt drained and emotionally exhausted from suppressing your emotions or maintaining toxic relationships?

Consider your **social** connections as well. Have you ever experienced a sense of belonging after participating in group activities? Alternatively, have you ever felt isolated and disconnected from others due to social conflicts or feelings of loneliness?

And don't forget about your **environment**. Have you ever felt refreshed and rejuvenated after spending time in nature or tidying up a few drawers? Conversely, have you ever felt stressed and overwhelmed by a messy room or by a lack of access to green spaces?

Finally, reflect on your overall **sense of purpose** and spirituality. Have you ever felt a deep sense of fulfilment and meaning in life from aligning with your values and beliefs? On the other hand, have you ever experienced feelings of existential emptiness or disconnection from your sense of purpose?

Now that you've taken a moment to reflect on your own experiences in these different areas of wellbeing, consider how they compare to those of other people around you. Have you noticed similar patterns of positive and negative impacts on their wellbeing with similar activities? Or perhaps you observe differences in how certain activities affect them compared to you. These differences highlight the unique nature of individual wellbeing and the importance of personalised approaches.

> Precision wellbeing encompasses not only physical health but also mental, emotional, social, and environmental dimensions

This is not just the case for you. It is the case for each and every one of us. And these dimensions of wellbeing are not silos but interconnected aspects of the human experience. Changes in one dimension can have ripple effects across others, highlighting the need for a holistic approach.

Factors Influencing Personalised Wellbeing:

So, what are the factors influencing precision wellbeing? As we explore the multifaceted concept of personalised wellbeing, it's crucial to acknowledge the factors that influence our individual experiences and also outcomes. From cultural beliefs to past experiences, access to resources, and personal preferences, each aspect plays a role in shaping our unique paths to wellbeing.

Firstly, consider the influence of **cultural beliefs and values.** Different cultural backgrounds and traditions may dictate varying approaches to wellbeing. For instance, practices such as meditation or herbal remedies may be deeply rooted in certain cultures. Individuals who resonate with these cultural practices may find comfort and efficacy in traditions passed down through generations. However, for those whose cultural backgrounds diverge from these norms, accessing culturally specific wellness strategies may pose challenges.

Past encounters with wellness practices, whether positive or negative, can inform our choices and preferences moving forward. These experiences shape our perceptions and attitudes towards different interventions, guiding us towards strategies that align with our needs and goals. For instance, imagine someone who had a challenging experience with arts and crafts during childhood, perhaps feeling pressured to excel in artistic endeavours or facing criticism for their creations. As a result, they may develop an aversion to engaging in creative activities later in life, associating them with stress or in-

adequacy. Conversely, another individual may have fond memories of crafting with loved ones, finding joy in the process. These contrasting experiences significantly shape their attitudes towards creative outlets as adults, with one person feeling hesitant to explore artistic pursuits while the other embraces them as a source of comfort and expression.

Access to resources is another critical factor that can drive interpersonal differences in wellbeing. Considerations such as geographic location, socioeconomic status, and availability of support networks can significantly impact the options available to individuals. For instance, someone living in a busy urban area may have access to a diverse range of activities, including fitness centres, cultural events, and social gatherings, which cater to different aspects of wellbeing. Conversely, individuals in rural areas may have fewer options for structured activities but may benefit from abundant outdoor spaces for activities like hiking or gardening, which promote physical, mental, and emotional wellbeing.

Furthermore, factors such as **personality traits**, temperament, and lifestyle choices can influence our wellbeing preferences but also outcomes. Introvert individuals, for example, may find peace in solitary activities like reading or journaling, while extroverts may thrive in social settings and group activities.

Lastly, consider the role of **societal norms, expectations, and cultural trends** in shaping our perceptions of wellbeing. Societal pressures to conform to certain standards of beauty, success, or achievement can impact our self-esteem and overall sense of wellbeing. For example, cultural norms that prioritise productivity and busyness may contribute to feelings of stress and burnout as individuals strive to meet these expectations.

> The key to taking precision wellbeing forward lies in empowering individuals with insights and personalised strategies

Contrasting Approaches: Precision Medicine vs Precision Wellbeing

While precision medicine focuses on treating specific diseases or conditions using targeted interventions tailored to individual genetic, environmental, and lifestyle factors, precision wellness takes a broader approach. Precision wellbeing encompasses not only physical health but also mental, emotional, social, and environmental dimensions. It acknowledges that each individual is unique, reinforcing the need for personalised strategies to optimise overall health and wellbeing.

Precision medicine often involves diagnosing and treating illnesses based on genetic markers, biomarkers, and other measurable factors. In contrast, precision wellbeing aims to prevent illness and promote health by understanding and addressing the diverse range of factors influencing an individual's wellbeing.

While precision medicine typically focuses on acute interventions delivered at specific points in time, precision wellness emphasises the importance of continual adaptation and refinement of wellness practices. It recognises that wellbeing is dynamic and subject to change based on life circumstances, experiences, and evolving goals.

In summary, while precision medicine targets specific diseases, precision wellbeing takes a holistic approach by considering the interplay of various factors and promoting personalised strategies.

As we've explored the intricacies of personalising wellbeing, it's become evident that achieving optimal health and happiness requires a tailored approach that considers a multitude of factors unique to each individual. In our comparison with precision medicine, we've seen how precision wellbeing extends beyond targeting specific diseases or conditions at a particular moment in time. Instead, it involves continuous adjustment and refinement of practices to align with evolving personal needs, circumstances, and goals.

This understanding underscores the importance of the way forward in implementing precision wellbeing. By carefully examining each element of individual wellbeing and incorporating sustainable practices into daily routines, individuals can navigate the complexities of personal wellbeing with precision -thus the name- and efficacy. Let us look now into practical strategies for incorporating precision well-

being into our lives and ensuring the sustainability of our wellbeing practices over the long term.

The Way Forward in Precision Wellbeing

The key to taking precision wellbeing forward lies in empowering individuals with insights and personalised strategies. By leveraging data from various sources such as their past experiences, their social context and norms, but also wearable devices, health apps, and genetic testing, individuals can gain valuable insights into their unique health profile, identify areas for improvement, and track progress over time.

Additionally, promoting collaboration between individuals and healthcare professionals is essential. Professionals can offer personalised guidance, support, and interventions tailored to everyone's specific needs and circumstances. This approach enables healthcare professionals to identify trends, patterns, and potential risk factors more effectively, leading to more targeted and efficient interventions.

Furthermore, integrating precision wellbeing practices into various aspects of life is crucial for sustainability and long-term success. Encouraging individuals to incorporate wellbeing into their daily routines, habits, and lifestyles ensures that these practices become ingrained and enduring. This integration also promotes consistency and continuity, allowing individuals to maintain their wellbeing efforts over time and adapt them as needed in response to changing circumstances.

Ultimately, fostering a culture that values and prioritises precision wellbeing is key. By promoting awareness, education, and advocacy around the importance of personalised wellbeing practices and their positive impact on individual health, happiness, and overall quality of life, we can collectively advance the cause of precision wellbeing and empower people to live their best lives.

Conflict of Interest

None.

Non-Human Partners in Rehabilitation: How Healthcare Can Embrace Human-Machine Systems

In conventional rehabilitation care, doctors and therapists interact with the patients in a human-human interaction to customise rehabilitation based on an individualised assessment. Human-Machine Systems (HMS) offer accuracy in assessment, monitoring and supportive tasks and contribute to heightened productivity across various fields of rehabilitation. The objective of this study is to describe some of the HMS and raise awareness for their potential usage in the management of rehabilitation services and the quality of care offered.

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key points

- Human-Machine Systems (HMS) integrate multiple sensors, robotic systems, virtual reality and machine learning algorithms.
- HMS promote accuracy in assessment, monitoring and support in rehabilitation.
- Improvement in rehabilitation services productivity, patient safety, and overall quality of care can be obtained by wise use of HMS.
- In more complex clinical contexts, HMS may be the only viable resource in aspects that are fundamental to quality of life, such as communication, wheelchair control or even entertainment.

Introduction

An ageing population sees increased physical disability in the elderly and high longevity for people unfortunate to have such disabilities from a young age due to multiple causes. Such is a medical and social problem in many countries (Chen et al. 2016). Rehabilitation medicine is about restoring or compensating for the individual's lost or diminished abilities (Akdoğan and Adli 2011). Demand for quality of care in rehabilitation is increasing; health managers and clinicians want to offer more and better but often face challenges to justify treatment effectiveness to payors and other regulatory entities. Usually, rehabilitation practitioners customise rehabilitation plans for their patients based on an individualised assessment of physical, cognitive, emotional, and social systems in order to diagnose their specific needs, supports, and barriers (Wagner 2014). Traditionally, this task is performed manually by doctors and therapists in a human-human interaction involving physical and non-physical interactions (e.g., audiovisual interactions) (Küçüktabak et al. 2021). In more dependent patients, rehabilitation treatments are very work-intensive and often demand several therapists together to support one patient manually to perform the training (Diaz et al. 2011), making it even more difficult to meet the requirements of high-intensity forms of training. Therefore, there is an increasing demand to develop new

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techniques and assistance methods to recover lost or impaired motion control and to release therapists from the intensive labour of rehabilitation training (Brown-Triolo et al. 2002).

One way to controllably customise the interaction between the patient and the rehabilitation professional is to connect them to a robot (Baur et al. 2019). Besides controlling the desired interaction dynamics between the humans, the robots could display a virtual external environment, more engaging (Ganesh et al. 2014; Takagi et al. 2018).

It is also possible to use passive mechanical devices to transmit physical information between humans or sensors to collect information for transmission between them. These passive-device-mediated systems are not robots. The term human-machine-human (HMH) interaction includes both robot-mediated and passive-device-mediated systems (Küçüktabak et al. 2021).

Human-Machine Interaction (HMI) encompasses the communication and interaction between humans and machines; several interfaces and systems could be used with the primary aim of facilitating effective and accurate information exchange, commands, and feedback, empowering users to control and interact with technology effortlessly. In Human-Computer Interaction (HCI), the former is used to control a computer. HMIs and HCIs both serve as an interface for controlling a device. HCI is general for screen users. HMI is for any

tool, object, or robot that can interact with humans; it could involve hand-held end-effector type manipulators, haptic devices, sensorised objects, virtual environment (VR) or robotic tools.

HMI technology can be broadly categorised into the following five categories (Kaur 2021):

1. **Optical technology:** Utilising cameras as the primary hardware for computer vision, this technology enables users to interact with devices through hand gestures without any physical contact.

2. **Acoustic technology:** Primarily employing speech recognition, this technology converts spoken words into text, facilitating device control and communication. It is commonly applied in home automation systems and voice-operated wheelchairs.

3. **Bionic technology:** Combines biology, robotics, and computer science. Generally, there are two forms of bionic systems: invasive and non-invasive. In the non-invasive form, the bioelectric signals are recorded using electrodes connected outside the body. Examples include Electromyographic (EMG), Electro-oculographic (EOG), and Electroencephalographic (EEG) signals generated from different parts of the body, which can be utilised as control signals to interpret

the user's intention. EEG signals, representing brain activity, are obtained by placing electrodes on a person's scalp and include four types of waves – delta, theta, alpha and beta – along with event-related potentials (ERP) and steady-state visual evoked potentials (SSVEP), commonly used in Brain-Computer Interfaces (BCI). In the EMG technique, signals are monitored from muscles, whereas EOG measures eye movements by placing electrodes around the eye. In the invasive form, electrodes are surgically implanted in the human body, such as intracortical and electrocorticography, to monitor brain activity, and implantable myoelectric sensors combined with targeted muscle reinnervation to collect electromyographic signals. Both invasive and non-invasive bioelectric signals can play a crucial role in controlling different devices, including neural prostheses, robotic limbs, exoskeletons, and wheelchairs, within the contexts of rehabilitation and assistive technology.

4. **Tactile technology:** This method necessitates physical touch, such as button pressing, for interaction with devices. It finds utility in various applications like environmental control systems, touch-based light controls, and pressure-sensitive interfaces. Additionally, tactile technology extends to innovative uses, such as artificial

skin with sensory feedback, enabling remote communication between individuals.

5. **Motion technology:** This category encompasses all HMIs that detect motion, often utilising gyroscopes and accelerometers or their combination to achieve precise motion detection. Applications include motion-sensitive mouse capable of responding to various hand gestures, as well as wheelchair controllers where input is provided through head rotation.

A successful HMI is characterised by intuitive and user-friendly interfaces that enable efficient and pleasant interactions, allowing humans to operate and engage seamlessly with machines, devices, or software.

In HCI systems, many interface-related factors must be considered, including the type of interaction, screen resolution, display size, and even colour contrast. The ultimate goal is not only to enhance communication between users and computers but also to personalise the context and environment in which the system is accessed.

There are three interaction types in HMHs (Küçüktabak et al. 2021): (1) physical interaction, (2) non-physical interaction, and (3) a combination of both. Physical interaction is usually obtained by rendering a spring/damper system between subjects via robotic devices. Non-physical interaction includes auditory or visual interaction. Visuo-physical interaction generally results in better performance than visual interaction alone.

The choice of interaction mode has a significant impact on task performance and engagement. According to Küçüktabak et al. (2021), it involves four options:

- **Collaborative:** Partners share a common task goal and collaborate to achieve it, with roles not predetermined.

- **Cooperative:** Partners have a shared task goal but are assigned distinct roles (e.g., teacher and student).

- **Co-active:** The task is divisible, and each individual works independently, yet there is still interaction.

- **Competitive:** Each individual strives to achieve their own goal, which may conflict with the goals of others.

Having a highly skilled partner tends to enhance dyadic task performance to a greater extent than partnering with someone less skilled.

The production of «smart» HMI involves adaptive learning to understand user preferences and behaviour over time, coupled with efforts to reduce the complexity of the design, increasing ease-of-use for operators and their ability to connect to the Internet, as well as share and receive data the HMI itself to digital and online platforms such as Bluetooth and the Cloud. Additionally, applications that could benefit from hardware upgrades can have their HMIs roll out with that hardware already part of the system at a low cost, ready and waiting to be activated with the appropriate update. The Internet of Things (IoT) demands more connectivity between machines and their operators.

- The trend is moving towards smaller devices with enhanced functionality in consumer electronics, influencing HMI design. Technologies such as 3D printing simplify production at low cost. In the realm of production, HMIs are available in three distinct forms: custom-designed HMI platforms, open HMI platforms, and ruggedised HMIs (Kalkal et al. 2022).

- Custom-designed HMI platforms are typically favoured by companies necessitating proprietary hardware and software, such as those in the military and medical sectors. While custom solutions entail greater development expenses, they can yield reduced per-unit costs during production, thereby diminishing overall expenses with larger production quantities.

- Open HMI platforms, on the other hand, offer universality and are capable of running various software packages across popular operating systems. These platforms are well-suited for companies seeking to develop their own custom application software. However, due to elevated costs, they may not be the most economical choice for applications requiring extensive production runs.

- Rugged HMIs are engineered to function in the harshest and most perilous environments. The design of rugged HMIs is heavily influenced by anticipated exposures in such environments.

Technology Used in HMS for Rehabilitation and Assistance

The broad concept of HMS includes the use of different technologies that can be used to promote an increase in the efficiency and quality of rehabilitation in the near future. These are: 1. Sensors; 2. Robotic devices; 3. Brain-computer interfaces (BCI) and Brain-machine interfaces (BMI); and 4. Virtual reality.
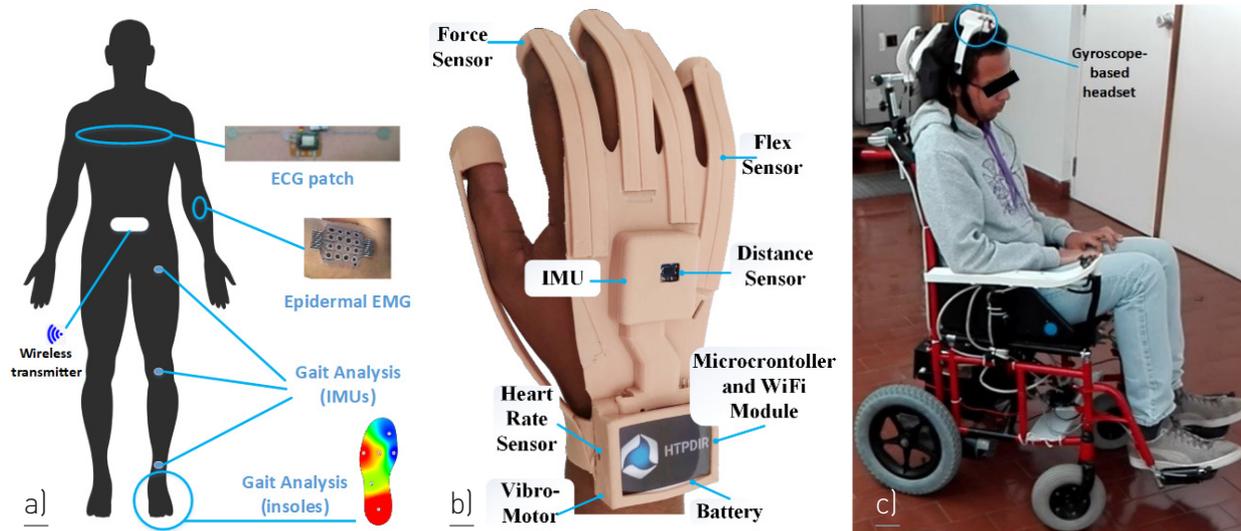
Figure 1: Wearable sensors. a) Examples of body sensors for EMG and ECG monitoring and gait and joint motion analysis (using inertial motion units and force sensors); b) Wearable glove designed for hand movements and finger bending, as well as to sense fingertips pressure (Almeida et al. 2019); c) Motion sensors (gyroscopes) used to control a wheelchair with head movement (Gomes et al. 2019).

1. Sensors

There are two categories of sensors: wearable sensors (WS) and non-wearable sensors (NWS). Wearable sensors (depicted in **Figure 1**) are typically compact, cost-effective, and inconspicuous devices that offer precise, quantitative, and uninterrupted data concerning motor activity across various settings. In clinical contexts, wearable sensors have been employed for evaluation purposes, including the instrumentation of common mobility assessments, detection of abnormal movement patterns, characterisation of disease progression, management of falls, and recognition of different activities. Moreover, they have been utilised to enhance therapeutic interventions, such as facilitating gait training through biofeedback. Clinical uses of wearable sensors encompass remote monitoring, mobile health initiatives, and broadening the scope of health metrics beyond conventional clinical environments. The portability of wearable sensors enables their deployment in everyday environments, thereby yielding more realistic and comprehensive health-related data. Wearable sensors present an opportunity for the aggregation of extensive data across clinical and real-life scenarios, fostering the advancement of personalised and precise medical practices (Porciuncula et al. 2018; Dhawan 2016).

Gate analysis is very important for the clinical assessment of patient rehabilitation (Prasanth et al. 2021). It usually includes force-based sensors and inertial motion units (IMU). Force-based sensors, commonly integrated with footwear, measure the interaction of the body with the ground during walking. Gyroscopes detect the rate of change of angular motion by sensing Coriolis forces within a rotating reference frame, reflecting the limb's angular rotation speed. Accelerometers monitor body movements based on speed changes. Additionally, magnetometers detect the Earth's gravitational vector, providing compass heading data and a reference for body orientation relative to gravity (Rueterbories et al. 2010).

Individuals experiencing hemiparesis often need to monitor and assess hand movement performance throughout their rehabilitation regimen. Hence, wearable sensors that don't impede limb mobility can be utilised for tracking and monitoring purposes. Insight into joint movement data is pivotal for refining and adapting the rehabilitation protocol (Yao et al. 2018). Machine learning technology can amalgamate and forecast data collected by sensors employed in disease rehabilitation, thereby enhancing the precision of stroke and other disease diagnoses and aiding rehabilitation practitioners in forecasting the patient's recovery path (Mainali et al. 2021; Mennella et al. 2023; Liao et al. 2020).

In addition to wearable sensors, non-wearable sensors (NWS) offer another avenue for movement monitoring, divided into two main categories: those employing image processing (IP) and those utilising floor sensors (FS). IP systems utilise optic sensors, including cameras and laser range scanners, to capture subject movements and analyse various parameters through digital image processing. FS systems, on the other hand, rely on sensors embedded in floor-based force platforms to measure gait information, including pressure and ground reaction forces exerted by the subject's feet during walking (Muro-de-la-Herran et al. 2014).

2. Robotic Devices

Rehabilitation robots play a vital role in therapy by offering high-intensity treatments and objective assessments. They have the capability to evaluate irregular movement patterns and boost motivation through interactive games and tasks displayed graphically (Baur et al. 2019; Veerbeek et al. 2017). Typically, therapists oversee robot-assisted training and assessment, setting parameters and supervising the process. However, advancements include robots connected to both patient and therapist, incorporating three-dimensional haptic systems. The potential of robotic systems lies in their ability to enhance sensitivity during patient assessments and offer valuable biofeedback (Lambercy et al. 2012).

Two main types of robotic rehabilitation devices are available: wearable devices and platform-based devices. Wearable devices, such as robotic orthoses and exoskeletons, cater to upper limb support (see example of hand exoskeleton in Figure 2) and gait correction while enhancing ankle performance during walking. On the other hand, platform-based devices primarily focus on improving ankle performance (Payedimarri et al. 2022). In recent years, exoskeleton robotic devices, also known as wearable robots, have emerged as practical tools for therapists to assist with impaired joints or limbs.
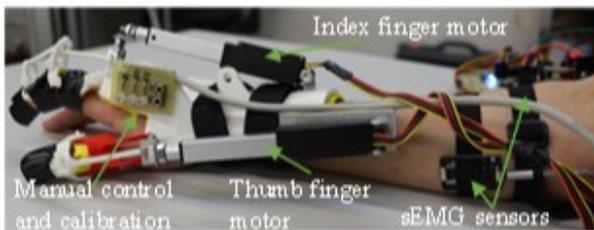
Figure 2: Upper limb exoskeleton example (Farinha et al. 2019)

These devices have evolved to encompass full-limb exoskeletons, including support for shoulders, elbows, wrists, and ankles (Shi et al. 2019).

Robotic gait devices (depicted in Figure 3) provide electromechanical support to help individuals achieve a natural walking pattern. These devices have the potential to address practical challenges and facilitate intensive gait training by reducing the need for therapist intervention. With robotic assistance, users can undergo high repetitions of the gait cycle while experiencing reduced reliance on therapists to guide limb movements or assist with trunk stabilisation (Mehrholz et al. 2017). Additional benefits encompass decreased spasticity and pain. Nonetheless, their effectiveness is restricted by the substantial expenses associated with walking assistance, challenges in acquiring necessary skills and strength, and the inability to sustain therapy outside clinical settings.

3. Brain-Computer Interfaces (BCI) and Brain Machine Interfaces (BMI)

The enhancement of assistive restoration greatly relies on electrophysiological signals, which are essential for evaluating human movement capacity and behaviour in ongoing research. EMG is commonly utilised in device control techniques due to its ability to directly reflect the user's movement intention or muscular action (Lalitharatne et al. 2014). However, when patients exhibit minimal or no motor activity, EMG may prove ineffective in detecting the user's intention, necessitating alternative solutions. Brain activity measured through EEG stands out as a non-invasive and promising method suitable for motor neurorehabilitation applications, especially for stroke survivors, when utilising BCIs/BMIs

Figure 3: Lower limb rehabilitation exoskeletons (Source: authors)

as a facilitator for neuroplasticity (Soekadar et al. 2015). In this context, one of the most common BCI relies on the modulation of sensorimotor rhythms (SMR) through motor imagery or intention of movement (with no overt motor output/execution). These BCIs have been tested in combination with different types of feedback, such as proprioceptive (hap-
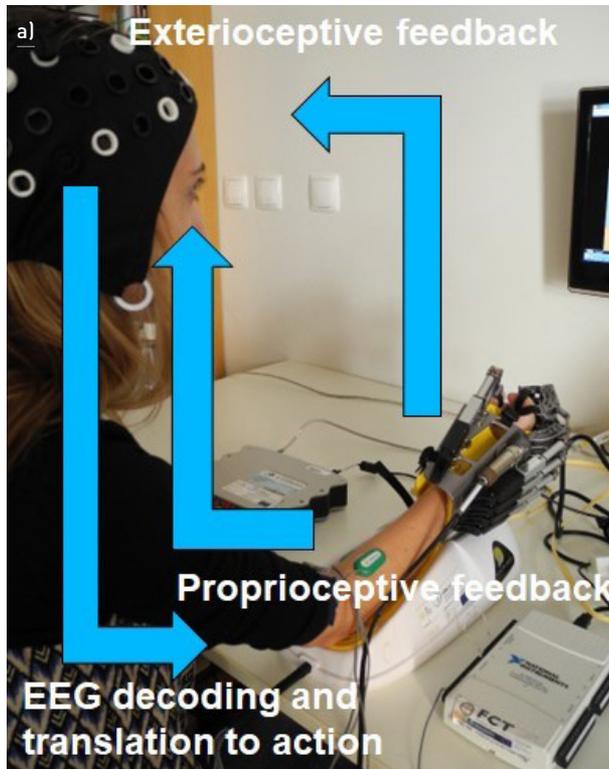
Figure 4: a) Robotic hand for neurorehabilitation combining EMG and EEG; b) A BMI system used to control a wheelchair (Cruz et al. 2021).

tic) obtained with robotic devices or exteroceptive (visual) feedback, as depicted in Figure 5a), or based on peripheral stimulation such as functional electrical stimulation (FES). A recent comprehensive analysis of BCI usage in motor rehabilitation following strokes highlighted studies where BCIs were utilised to command robotic or orthotic devices (Mansour et al, 2022). These studies showed considerable to moderate improvements in motor impairment. Additionally, emerging evidence in upper limb rehabilitation indicates that BCI-assisted robotic training after a stroke is superior to robotic training alone in facilitating motor recovery (Mansour et al. 2022). Other studies (Lennon et al. 2020) explored the direct neural interfacing with robotic gait devices in stroke rehabilitation with promising results, although with a wide heterogeneity. Non-invasive brain stimulation, including transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS), are also currently being researched as promising tools to enhance motor learning (Soekadar et al. 2015).

BCIs/BMIs can also play a crucial role for stroke survivors as assistive technology. In addition to facilitating neural plasticity, BCIs can be used to substitute lost motor functions, for example, by controlling devices like exoskeletons or powered wheelchairs (Cruz et al. 2021) (Figure 4b) in daily life activities. Furthermore, for stroke survivors in a locked-in state, BCIs can serve as a vital communication channel (Pires et al. 2022).

4. Virtual Reality

Neuroplasticity, a fundamental concept in neuroscience, underscores the regenerative capacity of the central nervous system (Garraway et al. 2016). Task repetition is crucial for establishing movement patterns, activating neural circuits responsible for motor patterns, enhancing sensory functions, and regulating afferent input, mirroring daily activities (Smith and Knikou 2017; Rosly et al. 2017). Active patient participation in motivating environments is key to enhancing rehabilitation outcomes (Weber and Stein 2018). Emerging technologies like robotic devices, BMI systems, and virtual reality (VR) address these aspects. VR, for instance, activates the mirror neuron system, fostering cortical reorganisation and functional recovery (Puyuelo-Quintana et al. 2017). VR systems vary in immersion level, ranging from semi-immersive or non-immersive setups using screens to immersive setups integrating users fully into virtual environments (Figure 5). Immersive systems, like VR caves or head-mounted displays, can incorporate additional sensory devices for enhanced feedback (Henderson et al. 2007). Combining VR with telemedicine shows promise for rehabilitating motor impairment from neurological disorders (Putrino 2014). VR is often integrated into robotic devices, such as Lokomat®, to provide complementary and motivating therapy modules (Agudo 2019). These systems have seen significant development over the past 15 years, offering high-intensity repetition-based therapies that have shown efficacy and cost-effectiveness in conditions like stroke (Iman and Jarus 2014; Sin and Lee 2013; Kim et al. 2009; Dominguez-Tellez et al. 2019), cerebral palsy (Booth et al. 2018; Johansen et al. 2019), Parkinson's disease (Feng et al. 2019; Lei et al. 2019), and multiple sclerosis (Moreno-Verdu et al. 2019; Norouzi et al. 2021; Maggio et al. 2019).

Advantages and Challenges of HMS

Several advantages and challenges of using HMS in rehabilitation medicine can be identified. While
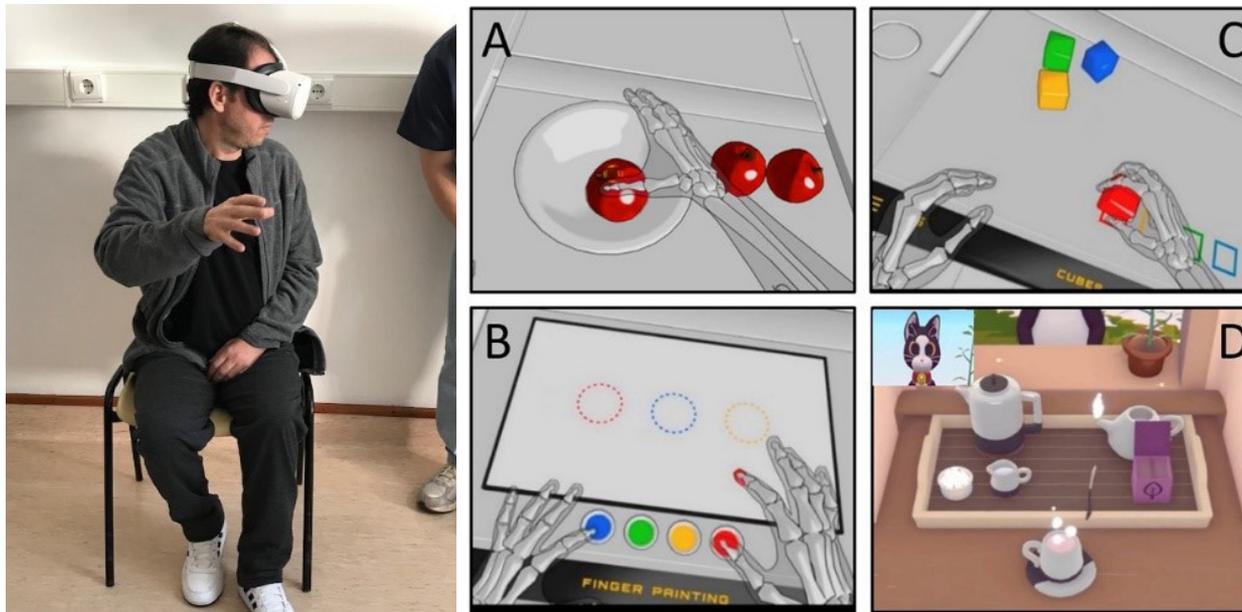
Figure 5: Examples of virtual reality in upper limb rehabilitation after stroke (Amorim et al. 2023)

the advantages can motivate management to discuss with clinicians how and when to invest and investigate further their usage, the challenges are presented to bring awareness that, like in any quality-of-care innovation, it is important to be open and transparent about the limitations and risks to best overcome them. As such, some of the advantages of Human-Machine Systems (HMS) are:

1. **Improved Usability:** HMS prioritise creating interfaces that are intuitive and user-friendly, facilitating seamless interaction between humans and machines. This leads to quicker learning, effortless navigation, and optimal utilisation of technology.

2. **Error Prevention and Recovery:** With clear instructions, visual cues, and informative feedback, HMS minimise the chances of user errors or critical mistakes. Furthermore, effective error recovery mechanisms and intuitive interfaces help users promptly resolve issues.

3. **Enhanced Safety Alerts:** HMS play a pivotal role in averting accidents and safeguarding user well-being. By providing clear warnings, alerts, and feedback, users gain better awareness of potential risks associated with machine operation, enabling them to take necessary precautions.

The challenges associated with Human-Machine Systems in rehabilitation may include:

1. **Reduced Human Interaction:** The increasing reliance on digital communication and virtual interfaces may diminish face-to-face interactions, potentially affecting social connections.

2. **Skill and Training Requirements:** Despite efforts to simplify interactions, certain machines or systems may still demand specialised skills and training for effective operation. Users may need to acquire new knowledge or undergo training programmes, adding to initial costs and time investments.

3. **Ethical and Privacy Concerns:** The integration of advanced technologies in HMS raises ethical and privacy considerations. Issues like data privacy, security breaches, surveillance, and unintended consequences of automation must be addressed to uphold individual rights, ensure confidentiality, and maintain ethical standards.

In the dynamic realm of human-machine interface (HMI), it is essential for designers, developers, and researchers to acknowledge these advantages and disadvantages to optimise benefits while mitigating potential challenges. An ethical and inclusive approach to deploying HMI systems is imperative for fostering a positive and sustainable relationship between humans and machines (Herington et al. 2023).

Conclusion

Human-Machine Systems offer an intuitive and effective means of interacting with complex machinery and processes, streamlining control, monitoring, and configuration tasks. By minimising user effort, HMS contributes to heightened productivity across various fields. Human-Computer Interaction

practices identify and address potential sources of errors and user frustration. Despite requiring additional hardware and software components for operation and maintenance, such as computers, monitors, keyboards, and operating systems, the benefits in productivity and efficacy often outweigh these costs. The future of interaction design will prioritise a human-centric approach, emphasising accessibility, inclusivity, security, and privacy. As HMIs continue to advance, the lines between humans and machines will blur further, ushering in a more interconnected and technologically empowered era.

Instead of fearing automation and AI, organisations should embrace them as integral tools for enhancing productivity and efficiency.

Conflict of Interest

None.

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IoT for Diabetes: More Than Just Glucometers

Rise of smart devices, telecare, and IoT healthcare apps to facilitate diabetes diagnostics and management.

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key points

- The number of people living with diabetes worldwide amounted to 529 million in 2023.
- Internet of Things (IoT) technology has opened many opportunities for simpler and earlier diagnostics, prevention, symptom management, and minimisation of the consequences of diabetes.
- Applications that help diabetic patients manage their diet and water intake, keep track of body weight, and control temperature and humidity in their homes are part of the favourable environment.

According to The Lancet, the number of people living with diabetes worldwide amounted to 529 million in 2023. And this number is projected to grow in the coming decade. The prognosis seems daunting, but healthcare professionals and specialists from multiple industries are actively working on controlling this condition.

The rise of smart devices, telecare, and IoT healthcare apps has aided in diabetes diagnostics and management immensely. Although glucometers are indispensable in the fight against diabetes, the Internet of Things technology has opened many more opportunities for simpler and earlier diagnostics, prevention, symptom management, and minimisation of the consequences. For example, a 2021 RELIEF study asserts that patients with type 1 diabetes who started using continuous glucose monitoring systems instead of usual glucometers had a 49% lower risk of diabetes-related hospitalisation (Roussel et al. 2021).

Smart Continuous Glucose Monitoring System

Patients with cognitive and memory problems, which are not uncommon among people living with diabetes, often forget to use their glucometers. The continuous glucose monitoring system tests its wearers' blood without requiring any action from the patient. It has to be implanted and tuned by the doctor every few months, and then it does the job automatically. Moreover, the recent models of such a system alert patients and care providers in case of any abnormalities in measured metrics.

Smart Insulin Pens

Managing diabetes puts a strain on patients, mainly because of the amount of information they have to remember all the time.

Figure 1: An example of the CGM system

Figure 2: An example of smart insulin pens

Many smart devices focus on storing relevant data so patients don't have to. An excellent example is smart insulin pens that connect to a smartphone or tablet application. These applications store the history of insulin injections transmitted from the pen, including the date and time of the injection and the amount of insulin delivered. This information is vital for patients and their doctors to prevent overdose and hyperglycaemia.

Automated Closed-Loop Insulin Delivery System

An automated closed-loop insulin delivery system works as an artificial pancreas because it almost takes over the endocrine functions of this organ. These systems consist of three main components:

- A continuous glucose monitoring device
- A remotely controlled insulin pump
- A software solution that enables their coordination

The monitoring device regularly checks a patient's blood glucose levels and quickly delivers the results to the software installed on the user's smartphone or a special controller. The algorithm determines whether the patient's glucose levels correspond to the recommended parameters and,

if not, triggers the insulin pump to dispatch the dose of insulin needed to normalise the glucose levels. This device makes life much easier for people living with type 1 diabetes, as they don't have to constantly perform glucose checks, count the amount of insulin they need, and manually inject it with an insulin pen they have to bring with them everywhere.

> Patients who used glucometers at least four times daily had a 37% lower risk of diabetes-related hospitalisation than those who used the device sporadically

Wearable Sensors

One of the many dangers of diabetes is its frequent company of other disorders that include nerve and soft tissue damage, hypertension, and vascular problems. On top of managing their blood glucose levels to avoid unpleasant and dangerous symptoms of diabetes itself, patients have to control their blood pressure and nerve activity to identify any complications early.

Devices like blood pressure and heartbeat trackers, pulse oximeters, portable ECG monitors, and skin conductance sensors simplify this task. Such gadgets can be used separately but bring more value if integrated into one IoT ecosystem. This way, an additional healthcare analytic system can use data gathered from all the devices more effectively to discover patterns and trends in patients' conditions. Based on such findings, doctors can prevent potential issues faster with more positive outcomes.

Diabetic Ulcer Prevention and Rehabilitation Footwear

Diabetic ulcers are wounds or sores that can occur anywhere on the skin but usually affect diabetic patients' feet. Up to 25% of people with diabetes
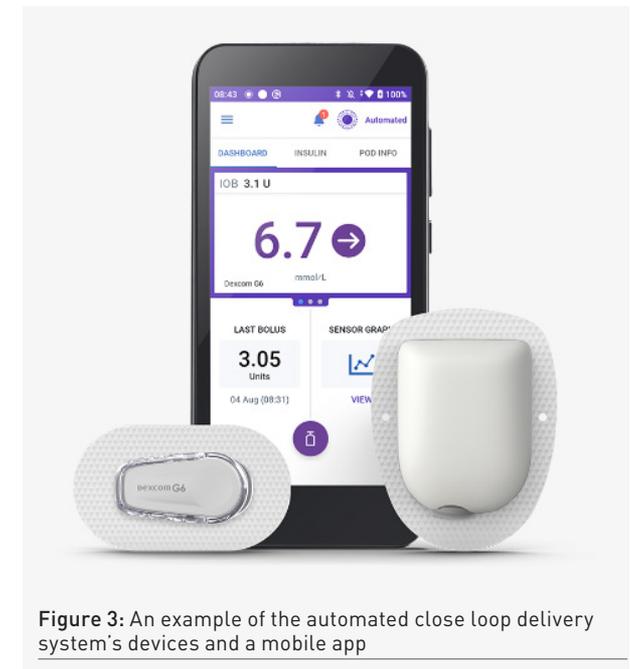
Figure 3: An example of the automated close loop delivery system's devices and a mobile app

Figure 4: An example of smart anti-ulcer footwear

Conclusion

Healthcare device manufacturers and software engineers develop, test, and put newer, more intelligent IoT devices into production every year. Besides, many general practice gadgets improve life for people with diabetes, even though they aren't connected to this condition directly. Applications that help users manage their diet and water intake, keep track of body weight, and control temperature and humidity in their homes are all a part of the favourable environment for people with diabetes. It is up to medical professionals and patients themselves to actively use such devices to improve health outcomes.

Conflict of Interest

None.

suffer from this complication, which leads to limb amputation if untreated. Therefore, multiple devices were developed to prevent and treat this condition:

- Smart socks can be worn on their own or under regular socks. They monitor skin temperature, moisture levels, and pressure in foot blood vessels. Doctors use this data to identify areas at risk of developing sores or ulcers.

- Smart insoles are inserted into shoes just like regular ones. They perform the same functions as smart socks but focus more on foot pressure and movement, helping identify the beginning of diabetic neuropathy.

- Smart wound management footwear that is currently being developed and tested looks like a heavy boot and is used for diabetic ulcer treatment assistance rather than prevention. It has the same capabilities as smart socks and insoles but also can normalise the temperature and moisture inside the boot according to its readings. This footwear also has a built-in vibration system that provides feedback to the wearer when some adjustments in walking patterns are necessary.

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Sustainability

A Net Zero Hospital: The Challenges of Establishing a Net Zero Emissions Healthcare Centre

Human health is linked to the planet, and climate change poses a serious risk. Healthcare contributes 4.4% to global CO_2 emissions. This article provides an overview of the experience of the Green Hospital project by Fundació Sanitària Mollet (Barcelona), which has successfully achieved the goal of becoming a net zero hospital in direct emissions.

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key points

- Human health is at serious risk due to climate change, affecting vulnerable groups and exacerbating global health inequalities.
- Fundació Sanitària Mollet (FSM) initiated the Green Hospital project, achieving net zero in direct emissions and committing to eliminate indirect emissions by 2050.
- Governance is the starting point for decarbonisation, focusing on institutional policies, values, and working with a vision of continuous improvement focused on tangible results.
- Defining a route to total net zero is crucial for impactful and efficient emissions reduction, with measurable goals across environmental, health, equity, governance, and education aspects.
- The Mollet University Hospital emphasises long-term vision and strategic planning for successful decarbonisation, acting as a model for sustainable healthcare.

Introduction

For a long time, it has been widely known that human health is inseparable from the health of the planet, although it is true that in recent times, much more visibility has been given to this global crisis.

The latest report, The Lancet Countdown 2023, revealed a "serious risk" to human health (Romanello 2023). With global temperatures at their highest in over 100,000 years, vulnerable groups such as the elderly and young children face increased exposure to heatwaves, droughts jeopardise water and food security, and infectious diseases spread. Economic losses and strained healthcare systems compromise our resilience and amplify global health inequalities. Projections indicate that delaying climate action will significantly worsen health outcomes, leading to increased deaths from heat-related illnesses and infectious diseases.

Similarly, at the recent COP28 held in Dubai, 123 countries signed the Climate and Health Declaration. This initiative places health at the centre of climate action and recognises the need to reduce emissions and pollution to safeguard it. The WHO Director-General, Tedros Adhanom Ghebreyesus, emphasised that it is a historic and crucial moment. The Director of the WHO Department of Environment, Climate Change, and Health, Maria Neira, stated that *"The climate crisis is a health crisis,"* and the signing of the Declaration is *"the realization of a dream that the global health community has been fighting for years"*.

Adding to all this is the fact that healthcare facilities are responsible for 4.4% of global net CO_2 emissions, highlighting that the healthcare sector is one of the major contributors to the impact of climate change.

In this context, our institution, Fundació Sanitària Mollet (FSM), a non-profit organisation providing public health and social

services, managing six different centres approximately 18 km from Barcelona, acknowledges the significant environmental impact of hospitals. This led to the initiation of the Green Hospital project.

The purpose of FSM is *"improving our people's lives"*, in the broadest sense, encompassing not only the people we attend but also the professionals, the community, and the environment. Recognising the significant environmental impact of hospitals, Mollet University Hospital made a conscious decision to be part of the solution rather than adding to the problem. To align with this vision, the Green Hospital project was initiated during the conception phase of the hospital's construction, culminating in its opening in July 2010.

The project, active for a decade, prioritises sustainable facilities, processes, and green culture. For these reasons, in the last 12 years the Mollet University Hospital has achieved a net zero in direct emissions (scope 1 and 2). Our commitment extends beyond this milestone as we have devised a route to net zero by 2050, targeting the elimination of indirect emissions.

What Should be the Starting Point in Decarbonisation?

In my opinion and in line with our experience, any organisation intending to embark on a decarbonisation strategy, the starting point must be governance.

The fight against climate change must emanate from the top management of institutions and should materialise in institutional policies, values, strategic plans, and set objectives. It should not only be documented on paper but also manifested through disseminating institutional green culture, awareness and training of professionals, efficient resource management at the organisational level, and tangible results.

> With global temperatures at their highest in over 100,000 years, vulnerable groups such as the elderly and young children face increased exposure to heatwaves, droughts, water and food shortages and the spread of infectious diseases

In this context, a results-oriented strategy and commitment to quality and continuous improvement have been key to achieving our goals.

Integrating green culture into healthcare institutions has only recently become a significant focus. However, this commitment has been evident at the University Hospital Mollet since its opening in July 2010. In 2011, it certified the safety and health management system (OSHAS 18001, currently ISO 45001). A year later, in 2012, it certified environmental management systems (ISO 14001) and energy management (ISO 50001). These management systems were followed by certifications in Social Responsibility (SR10), laboratory quality (ISO 9001), healthy company model (SIGOS), EFQM 600 seal, and Joint Commission accreditation.

Furthermore, the hospital joined the voluntary agreements to reduce CO_2 emissions of the Catalan Office of Climate Change (OCCC) in 2013. This commitment mandates the annual calculation of the hospital's carbon footprint and the development of an action plan to mitigate environmental emissions, allowing for the implementation of high-impact actions over the years to reduce the carbon footprint effectively.

As a healthcare centre providing public services, precision in implementing actions and correctly and efficiently using budgetary resources is crucial. Having implemented management systems and focusing on continuous improvement, from results analysis and indicator tracking, allows us to carry out actions that will have a significant impact, as in the Green Hospital project's decarbonisation of our activities. It also enables the proper and efficient use of the economic resources available. Thanks to this, we have become more sustainable in all environmental, healthcare, and economic aspects, demonstrating that environmental sustainability impacts healthcare and economic sustainability, even if results are sometimes seen in the medium term.
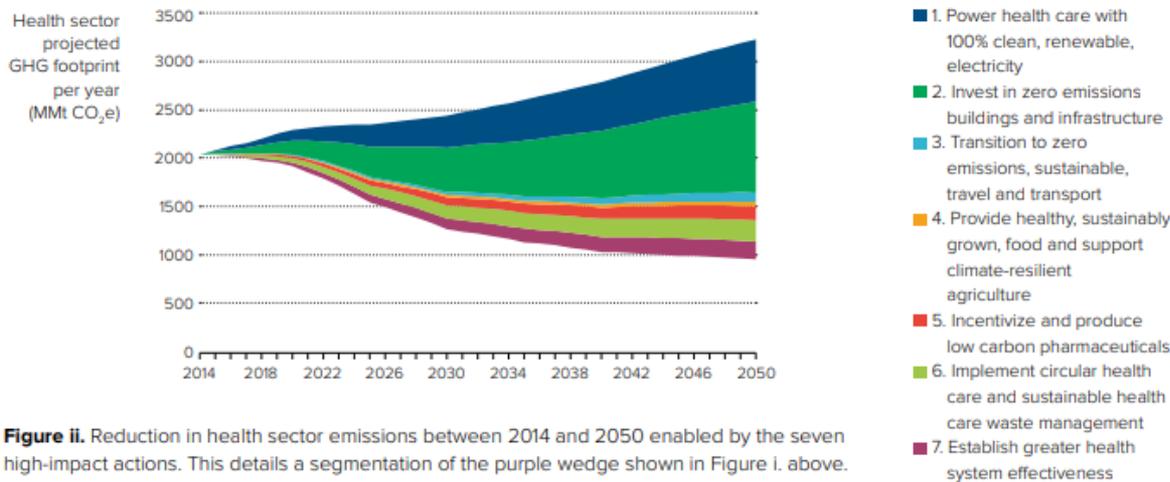
Figure ii. Reduction in health sector emissions between 2014 and 2050 enabled by the seven high-impact actions. This details a segmentation of the purple wedge shown in Figure i. above.

Legend:
1. Power health care with 100% clean, renewable, electricity
2. Invest in zero emissions buildings and infrastructure
3. Transition to zero emissions, sustainable, travel and transport
4. Provide healthy, sustainably grown, food and support climate-resilient agriculture
5. Incentivize and produce low carbon pharmaceuticals
6. Implement circular health care and sustainable health care waste management
7. Establish greater health system effectiveness

Source: Global Road Map for Health Care Decarbonisation - HCWH

How to Accelerate Decarbonisation

According to the Health Care Without Harm - Global Road Map for Health Care Decarbonization report, there are seven high-impact actions to decarbonise the healthcare sector: 1. Power health care with 100% clean, renewable, electricity 2. Invest in zero emissions buildings and infrastructure 3. Transition to zero emissions, sustainable travel and transport 4. Provide healthy, sustainably grown food and support climate-resilient agriculture 5. Incentivise and produce low-carbon pharmaceuticals 6. Implement circular health care and sustainable health care waste management 7. Establish greater health system effectiveness.

In our Green Hospital project, the starting point was to invest in a zero-emission building and infrastructure. Since 2017, 100% of the electricity consumed comes from certified 100% renewable sources. As seen in the image, these two actions have the most significant impact on reducing CO_2 emissions in a healthcare facility.

Likewise, we have implemented actions related to the other five high-impact actions and have many more planned on our journey toward total net zero.

Currently, with the majority of actions related to infrastructure and facilities already implemented, we are conducting a process-by-process analysis, which we believe is necessary to ensure that all our activities are as sustainable as possible.

The Importance of a Climate-Smart Building

In addressing the emerging challenges posed by climate change, it is imperative to adopt a climate-smart approach in designing healthcare facilities. A climate-smart hospital building not only needs to be sustainable and low-emission but also resilient, capable of confronting the evolving challenges of climate change, such as heat waves and emerging tropical diseases, and ensuring uninterrupted operations in the face of meteorological phenomena like droughts and floods.

Key elements of a climate-smart building encompass energy-efficient systems with low consumption, complemented by the integration of renewable energy sources. Sustainable infrastructure components, including landscaped roofs, rainwater collection systems, and vegetation to enhance biodiversity, play a crucial role.

Efficient water consumption systems, incorporating low flow, recirculation, or reuse mechanisms, are equally vital. Leveraging natural ventilation and light reduces consumption and enhances overall environmental efficiency. Constructing with sustainable materials, preferably sourced from local companies, contributes to the building's eco-friendly profile.

Moreover, in terms of resilience, the building should be adaptable to the dynamic challenges posed by climate change. Employing durable materials that can be modified according to evolving needs without generating waste is crucial. An illustrative example is the rapid adaptation of hospitals during the pandemic, where many facilities had to modify their structures within 24-48 hours to accommodate a surge in patients.

The Mollet University Hospital Climate-Smart Building

Situated adjacent to the protected natural and rural area of Gallecs, encompassed within the Plan of

Areas of Natural Interest of Catalonia, our hospital was purposefully designed to minimise visual impact and seamlessly integrate into the natural surroundings.

In the designated building area, a Centennial Oak Tree stood. This tree became an integral part of the project design, with the building being meticulously adapted to the terrain's volume to preserve its natural state.

The hospital also has a Geothermal System, which at the time was the fourth-largest project in Europe. Comprising 148 wells, each 146 meters deep, and utilising over 20km of subterranean pipelines, this system taps into underground energy, resulting in an impressive 30% reduction in air conditioning energy consumption on average.

Incorporating natural courtyards and sustainable architecture is a hallmark of our hospital. Internal and natural courtyards and green light wells optimising natural light in workspaces have led to a significant 40% reduction in average light consumption. Gravel and plant rooftops enhance thermal insulation and acoustic comfort. According to the Gallecs Natural Park, our green courtyards serve as resting and nesting spots for various bird species, contributing to the well-being of healthcare professionals.

The building was designed with radiant ceilings featuring a circular plumbing system circulating hot water on the roof at a controlled temperature. This reduces daily energy consumption, promoting efficiency and providing patients with a serene, quiet environment.

Rainwater collection posed a significant challenge, and over the past decade, we have achieved a remarkable 36% reduction in water consumption on average despite increased normal activity. An 80m3 cistern collects rainwater for the courtyards.

> In addressing the emerging challenges posed by climate change, it is imperative to adopt a climate-smart approach in the design of healthcare facilities

Four years ago, a major installation was completed: the photovoltaic plant. Designed with horizontal architecture, 80% of the roof was designated for solar panel installation. In 2023, energy production represented over 13% of the total, substantially reducing approximately 120 annual tons of carbon emissions, equivalent to planting 240 trees per year.

Process Improvement in Healthcare Sustainability

Process analysis is a critical element in diminishing the environmental impact within a healthcare institution. A meticulous examination of each area and activity is indispensable to optimize efficiency. This is imperative because, for example, the environmental impact varies significantly between the surgical area and the hospitalisation process, with distinctions in factors such as energy consumption, consumable material usage, and waste generation.

Outlined below are key points and actions integral to our consideration in each of the processes:

- Recycling and Waste Management Enhancement: Over the past 11 years, a comprehensive revision of recycling and waste management has elevated the number of waste segregation types from 9 to 29, showcasing a commitment to more sustainable practices. The ongoing focus remains on refining recycling and waste management strategies.

- Reduction of Inpatient Stay Duration: Addressing the length of stay in inpatient units is a crucial action since each day of hospitalisation generates 7kg of waste. By minimising unnecessary stays, both the environmental impact and waste generation are curtailed. Prioritising home hospitalisation and implementing streamlined processes such as the Fast Track for knee and hip replacement effectively reduce hospital stays.

- Avoidance of Unnecessary Travel and Mobility: Acknowledging that 7% of indirect emissions result from transportation, we are actively working on process improvements to minimise hospital visits. The adoption of online consultations has surged by 24%. Additionally, introducing a high-performance urology outpatient visit

A SUSTAINABLE HOSPITAL
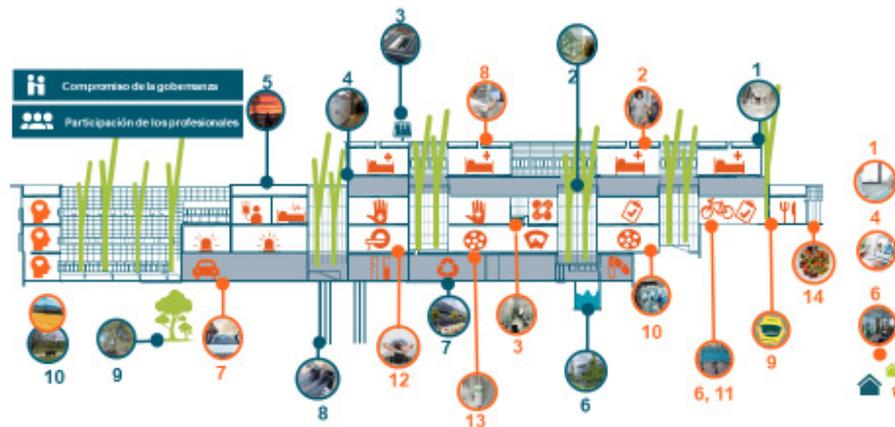
more sustainable, we have a sustainable hospital today. In any of its areas, actions can be observed, as depicted in the following infographic, where actions related to structures are represented in blue, and those related to processes are represented in orange.

The Green Culture

Establishing a green culture within an institution is another key element in advancing healthcare decarbonisation. The active engagement of professionals is crucial, as they play a central role in the battle against climate change, contributing improvement proposals to enhance the sustainability of their work processes.

The decisive involvement of all professionals played a crucial role in identifying the most viable actions with the greatest impact on reducing the carbon footprint. Effectively communicating senior management's commitment to sustainability posed a notable challenge. Consequently, in 2012, it was mandated that environmental training become mandatory for all professionals, ensuring the organisation's dedication to environmental stewardship resonates throughout the entire staff.

Moreover, organisations need to assess professionals' perceptions of climate change, their training, and the implementation of best practices. In our specific case, this information is validated through periodic surveys, providing insights into the high level of engagement among our employees.

The Need to Define a Route to Total Net Zero

Some might wonder if defining a route to net zero is truly necessary. In response to that question, my

and a Rehabilitation Service YouTube channel enhances treatment follow-up from the comfort of patients' homes.

- Preventing Unnecessary Duplication of Diagnostic Tests: The high environmental impact of diagnostic tests on energy consumption and waste generation underscores the need to scrutinise processes to avoid unnecessary tests. This not only benefits patients but also contributes to environmental and economic sustainability.

- Implementing More Efficient Systems: Considering new, more efficient systems is crucial in decision-making. In our case, we have implemented different projects focus on sustainable

initiatives such as the recovery and treatment of anaesthetic gases harmful to the ozone layer, improvements in sterilisation circuits for water conservation, the utilisation of recyclable materials in the surgical block, and the treatment of dialysis plant waters. Additionally, implementing a new Semi-automated drug-dispensing system has reduced medication waste by 29%, concurrently enhancing patient safety and process efficiency.

A Sustainable Hospital

As a result of the actions and policies implemented by governance, the improvement of structures and facilities, and the analysis of processes to make them

ACTION PLAN 2023
NET ZERO DIRECT EMISSIONS
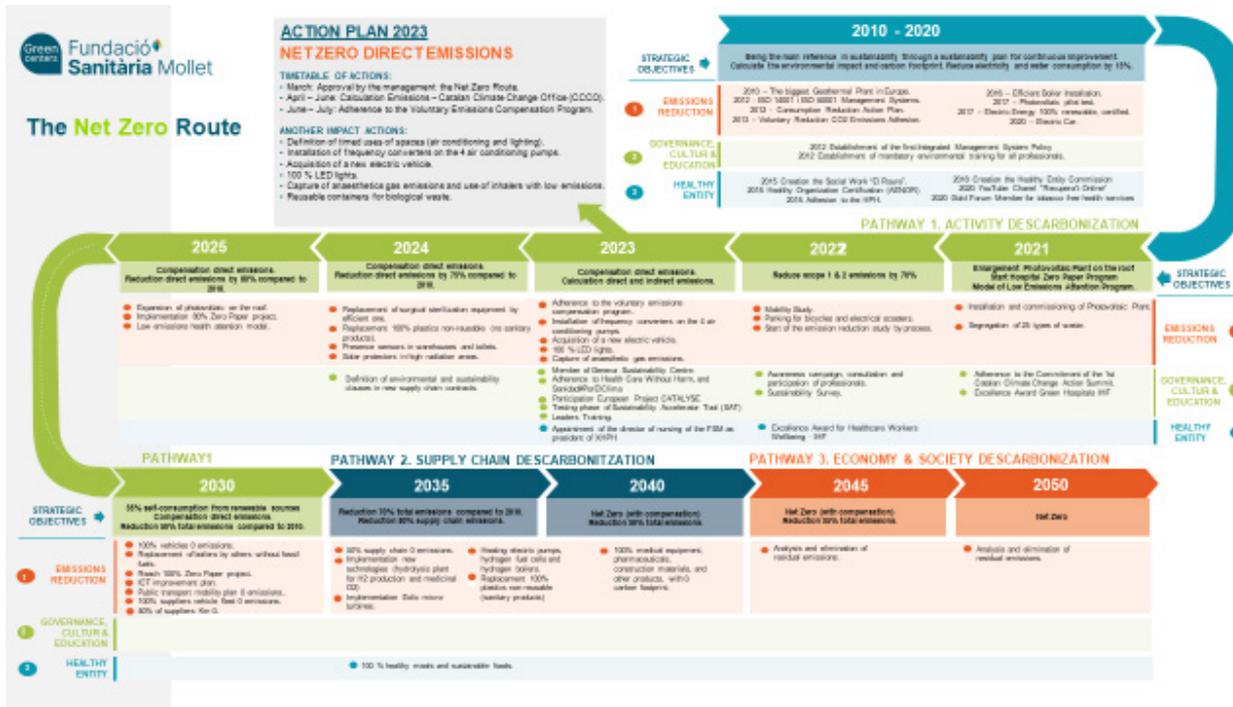
answer would be affirmative. Defining a net zero roadmap is necessary to identify the key aspects that will have the greatest impact on both health and the environment. Likewise, establishing coherent planning of the actions with the greatest impact will allow the reduction of emissions more efficiently.

In our case, as an entity providing a public service and operating within a public budget, we cannot implement all the actions or measures we would like due to a lack of incentives from the authorities. For this reason, having a route to net zero allows us to establish a realistic and purposeful action plan, prioritising those that will have a greater impact on

emissions reduction. It ensures that we do not overlook or forget important actions that cannot be materialised at the present moment.

Our strategy relies on three pillars: Governance, Culture, and Education; Environmental Impact Reduction; and Healthy Entity Project. We actively engage professionals and stakeholders and share knowledge on our path to net zero.

Similarly, three paths have been defined. Pathway 1 is the decarbonisation of our activity; pathway 2 is the decarbonisation of our supply chain, where we are already taking actions with the goal of becoming a total net zero Hospital by 2040 (including indirect

emissions), pathway 3 involves eliminating any residual emissions through the decarbonisation of the economy and society. Our plan includes measurable goals for environmental impact, health, equity, governance, and education.

Conclusion

The climate crisis is also a health crisis for people. Considering that healthcare centres are one of the activities with the greatest environmental impact, we cannot stand idly by; we must act quickly to reduce our emissions.

To meet the challenge of zero emissions in healthcare centres, the starting point should be governance. This challenge should be reflected in the policies, objectives, and strategic plans of the organisation.

Furthermore, although not mandatory, having implemented management systems and focusing on continuous improvement, analysing results, and monitoring indicators will enable us to carry out actions with a greater impact on decarbonising our activity. This approach ensures the correct and efficient use of the economic resources at our disposal. As a result, we can be more sustainable in all environmental, healthcare, and economic aspects, demonstrating that environmental sustainability affects healthcare and economic sustainability, even if results are sometimes seen in the medium term.

Regarding the implementation of actions, transforming centres into climate-smart buildings, using energy from renewable sources, and conducting a thorough analysis of each process (sustainable and

zero-emission mobility, healthy and sustainable nutrition, low-carbon pharmaceuticals, circular economy, system efficiency) is crucial.

Similarly, for a decarbonisation project to be successful, as in the case of our Green Hospital project, implementing a green culture among all stakeholders involved, including professionals, patients, suppliers, the community, etc., should be considered.

Without all the aspects above, the Mollet University Hospital could not have achieved the challenge of being a net zero centre in direct emissions.

On the other hand, any viable strategy must include a long-term vision, which is why we have outlined a route to total net zero, including indirect emissions, by the year 2050. We have planned future actions and strategic objectives based on the three key pillars mentioned above.

Conflict of Interest

None.

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Digitalisation

From Generative AI to Apple's Vision Pro - How Digital Innovations Are Revolutionising Healthcare

A conversation with Harvey Castro, author of "ChatGPT and Healthcare: Unlocking The Potential Of Patient Empowerment," about new technologies, what they mean for healthcare in 2024 and what leaders need to know before they can fully embrace innovation.

HARVEY CASTRO

Assistant Professor l University of Texas, San Antonio l ER Physician l AI in Health Expert, Keynote Speaker and Author l Texas, USA

key points

- By leveraging the power of generative AI, hospital systems can improve scheduling patients and help optimise appointment workflows.
- Physicians can turn to AI tools to help them with their differential diagnosis or as a feedback loop to ensure they haven't missed anything.
- Many different platforms are now available with different flavours of generative AI technology, but ChatGPT has cemented its place as the leader of the pack.
- The synergy between human expertise and AI promises exceptional results, setting a new standard in healthcare provision.

In the rapidly evolving landscape of healthcare, digitalisation continues to revolutionise how patients receive care, professionals deliver services, and organisations manage operations. The momentum of digital transformation in healthcare shows no signs of slowing down. From ChatGPT to virtual reality, the trends shaping this new technological era are diverse and impactful. In our conversation with Harvey Castro, we went over what these new technologies mean for healthcare in 2024 and what leaders need to know before they can fully embrace innovation.

What was your first impression of ChatGPT technology, and how does it relate to healthcare today?

I started playing with ChatGPT when the tool first came out in November 2022. My initial amazement quickly evolved into a need to share my experience on this new subject with the world. I published my book "ChatGPT and Healthcare: Unlocking The Potential Of Patient Empowerment" in February 2023.

ChatGPT is like a person trying to be the smartest and most helpful they can be. You can talk to them anytime, you can ask any question, and this AI will always reply with an answer. ChatGPT is literally a database, consolidated with everything the internet has to offer, and the AI went through all this data. However, the problem with this technology is it can make mistakes. Much like a very intelligent but very proud friend, ChatGPT can *not* come back with an answer to your question, and that answer might be correct or wrong; the tool doesn't have the capability to say it doesn't know. If the human user is unaware that some answers can be mistakes, they will fall into traps and rabbit holes and start taking incorrect data at face value. In my eyes, a human expert is always needed in the equation to weed through ChatGPT answers to dissect and filter the informational output.

As for applications to healthcare, the low-hanging fruit is just using ChatGPT for virtual assistance or telemedicine. By leveraging the power of generative AI, hospital systems will be better at scheduling patients and help optimise appointment workflows. Another use I witnessed is clinical support. Even if healthcare administrators might not have approved this specific clinical use, physicians can turn to AI tools to help them with their differential diagnosis or as a feedback loop to ensure they haven't missed anything. ChatGPT offers supplemental help to some physicians after a long shift when fatigue sets in.

What sets ChatGPT aside from other forms of AI that already exist in healthcare?

ChatGPT, or the generative AI technology in general, didn't come out of the blue; it was actually invented by Google years ago. OpenAI's originality comes from the fact that leveraging its partnership with Microsoft enabled it to scale up its tool very quickly and bring it first to the next level. OpenAI was the first to put this technology in the hands of the general public, and their tool's popularity soared. Even though this technology existed before, nobody from the public got to experiment with it first-hand. This explains the sudden viral popularity and then adoption, and this sets aside ChatGPT's strategy from its competitors. Many different platforms are now available, different flavours of generative AI technology, but to my eyes, ChatGPT cemented its place as leader of the pack, as it brings so many different technology aspects to one single website.

Do users need specific expertise to use ChatGPT? Are there any pitfalls they should be aware of?

Generative AI is a good tool, but a strong educational background is needed to use this technology in the best way. If users do not know how the technology works or are not equipped to recognise the best practices, they'll rush into it without even realising they're doing it wrong.

> A human expert is always needed in the equation to weed through ChatGPT answers to dissect and filter the informational output

First comes the issue of bias. Whereas AI algorithms do not experience bias per se, the information that was trained into this AI might have introduced some bias from the human opinions that went into establishing the knowledge database. The geography and time range of knowledge can also introduce bias and warrant the need for human expertise when using ChatGPT. For example, if the data used to build ChatGPT capabilities was focused on Europe and North America, the relevance of AI's answers would change depending on the user's location. Whereas a European physician would recognise their situation in the answers provided, an African physician would be confronted with the right answers, but for the wrong population, in terms of culture, available resources, and health care access, the tool would ultimately be useless. The passing of time can also be a source of bias, and knowledge evolves, but stored data doesn't. When asking ChatGPT how to perform a specific medical procedure, answers could be dated and not reflect the current or latest recommendations. Answers *were* right at some point, but ChatGPT might not have had access to the most recent data, leading to partially incorrect information with potential adverse consequences. Essentially, ChatGPT can only be as good and its answers as relevant as the information the tool can access.

Generative AI should be used carefully, and users must be made aware of these technological limitations. Patients should not replace their physicians with ChatGPT queries, as medical expertise is needed as a guardrail for information quality.

Do you have examples of hospitals or health systems using generative AI?

In New York, a network of hospitals utilised predictive analytics through their AI system. What's notable is that they trained their AI with data from their specific population and hospital visitors, tailoring their tools specifically to their patients. Each hospital caters to a unique demographic, influencing their perspectives and actions, leading to varied outcomes. They aggregated patient data into their

AI, resulting in a tool for doctors to access predictive analytics. This tool analyses past patient data to categorise current patients and predict their likelihood of readmission. This empowers providers to reconsider discharge decisions, potentially preventing unnecessary returns. Conversely, it can also support confident discharge decisions for lower-risk patients. This integration of AI into healthcare delivery is ground-breaking, enhancing doctors' capabilities rather than replacing them. The synergy between human expertise and AI promises exceptional results, setting a new standard in healthcare provision.

What would be the best partnership between AI and physicians - clinician augmentation rather than replacing them?

To put it simply, AI plus humans is better than just AI. Leveraging the full power of AI needs the human element, especially in healthcare. Healthcare is about empathy, and the human feelings physicians experience when they see a patient are hard to put into an algorithm. Touching a patient, feeling their skin, and looking at their eyes, all the anamnesis brings a lot of data that ChatGPT can't access. However, if this data is put into AI, then we can benefit from the predictive analysis capabilities of ChatGPT but tailored to a specific patient and their own data points. Associating the strong predictive analysis capabilities of AI with the data collected during physician-led clinical anamnesis is the key to bringing out the maximum potential of AI and delivering better healthcare to patients.

What can be done by health organisations to ensure proper data governance?

Data quality is crucial for AI tools, as answers provided by AI can only be as good as the knowledge the algorithms can have access to. In the example provided by New York hospitals, the data is tailored to the use case, collected from the same population as the one the AI will be used for. Quality data collection is the needed stepping stone towards quality answers from the AI tool.

> Generative AI should be used carefully, and users must be made aware of these technological limitations

Also, governance is needed to ensure that data quality remains on time. There is something called data drift: past or current relevance of an AI tool does not guarantee that results will stay true in three or six months. Data evolves, and to ensure that AI tools keep delivering their best outputs and are of use to patients and physicians, data scientists need to keep an eye on the data. Governance procedures must put guardrails and feedback loops in place to continuously check if the AI keeps validat-

ing what it should be validating and is not drifting. ChatGPT users and healthcare organisations must continually analyse the data and understand that data changes over time. Special attention should be given to AI tools provided by start-ups, who might not have the necessary resources to keep refining their tool and counteract data drift.

There is a dilemma to mitigate between innovation speed and necessary governance. Moving forward quickly towards new technologies and evolving out of outdated healthcare methods is crucial for improving patient outcomes; however, technological adoption should not go unchecked. Patient safety, data security, and ethical responsibility must be prioritised when adopting new technologies while also steering away from a government intervention that is too heavy-handed and could impede progress.

Ethical guardrails are already in place: HIPAA, recommendations, and best practices. Healthcare professionals are already aware of these and have their patients' interests at heart. Physicians and nurses should be leveraged as patient advocates in all new technology implementation projects, and they need to be involved in decisions at the board level to ensure that new technologies serve patients effectively. Collaboration between healthcare professionals, boards, and vendors is key. Ultimately, this inclusive approach can mitigate the need for additional layers of governance. Healthcare tends to be conservative, favouring gradual change over sudden upheaval. Therefore, healthcare professionals will naturally apply brakes when necessary, taking the time to understand the risk-benefit profile before rushing into implementing change.

What are the regional disparities and legal complexities for AI adoption in healthcare?

Adopting AI in hospital systems is not uniform and depends on factors like region and demographics. In tech-savvy areas like Silicon Valley, California, hospitals are more receptive to AI tools due to frequent exposure to such innovations. Conversely, rural hospitals may resist change and view AI tools with scepticism. Different medical specialties also have varying attitudes towards AI. For instance, radiology embraces AI for interpreting scans, while other fields may be more cautious.

Hospital systems aim for a balance between adopting cutting-edge tools for competitive advantage and ensuring patient welfare and financial viability. However, navigating the legal implications of AI use presents a dilemma. Depending on the circumstances, there's a risk of litigation whether AI is employed or not.

For example, a colleague's ER uses AI to detect stroke symptoms from CT scans, alerting doctors in real time. While this aids in prompt intervention, it also raises legal questions. If a hospital lacks such technology and a patient suffers adverse outcomes, legal repercussions may follow, alleging negligence.

Moreover, the American Medical Association advocates for healthcare professionals' involvement in AI adoption decisions. Transparency about AI's capabilities, risks, and benefits is crucial for informed decision-making among medical staff.

As AI technology advances rapidly, regulatory bodies like the FDA also play a role in overseeing its use in healthcare. The evolving landscape of AI integration into medical practice presents complex ethical, legal, and professional considerations that require careful navigation.

The governance of AI in healthcare requires collaboration between healthcare professionals, hospital leadership, and vendors. Education also plays a crucial role in the successful adoption of AI. Hospital executives and healthcare professionals need to be taught what this technology can do, how to use these new tools and the associated risks. For example, cloud data storage can be at increased risk of a breach: understanding this could prompt health organisations to develop their AI solutions on local servers instead. Education and knowledge transfer between stakeholders can help mitigate many risks while implementing AI tools.

What do you think the rapid evolution of AI can bring to healthcare in the future?

The rapid evolution of technology in healthcare promises ground-breaking advancements that may soon revolutionise patient care. Imagine a future where robots with advanced AI capabilities, such as those developed by ChatGPT, can analyse vital health metrics in real-time. These robots could seamlessly integrate into medical settings, providing instant feedback to healthcare providers during patient interactions. For example, during a conversation with a patient, a healthcare provider could inquire about their health metrics, and the robot would promptly provide accurate information without the need for additional tests or examinations.

Additionally, recent developments from the Ambient.AI platform, which aims to act as a scribe during doctor-patient interactions, offer further insights into the potential of AI in healthcare. Although current technology may still require some refinement, the pace of innovation suggests that we could witness significant improvements in clinical decision support and note-taking tools within the next few years.

These advancements have the potential to transform healthcare delivery, allowing healthcare professionals to focus more on patient care and less on administrative tasks. With AI support, healthcare providers could receive valuable insights in real time, enabling them to make more informed decisions and provide better patient outcomes. As technology continues to evolve, the possibilities for improving healthcare are limitless, offering hope for a future where patient care is more efficient, accurate, and personalised.

Apple's Vision Pro is 2024 hot news; how will it impact healthcare?

Apple's latest virtual reality computing device, the Apple Vision Pro, holds immense potential for transformative impact within the realm of digital health. Apple has consistently disrupted various industries with innovative tech, and the healthcare sector is no different. The Vision Pro merges a high-resolution display with voice, hand, and eye-controlled interfaces, offering to dismantle the barriers between our physical and digital worlds. Embedded within this technical and engineering progress lies an extensive potential for transforming healthcare.

The emergence of Vision Pro could herald a new era of telemedicine, making it more interactive and immersive. This tool would enable patients to ac-

cess their digital doctor's office effortlessly from the comfort of their home or on the go. Inclusivity is also at stake, as the headset could allow better access to medicine from underserved or remote communities. Immersive VR could also tackle the issue of patient education and engagement by elucidating complex medical terminology using interactive 3D models. Aided by the device, patients could explore and learn about medical procedures, health conditions, or treatment plans, sharing a common virtual space with their physician. Vision Pro has the potential to revolutionise how doctors share and discuss health data with patients using real-time health data visualisation in both virtual and physical consultations. Areas of concern could be highlighted and annotated in real-time, and even surgical procedures could be demonstrated by healthcare professionals in virtual reality. The integration of Apple Vision Pro into healthcare could be as impactful as the introduction of electronic health records or the dawn of telemedicine. It paths the way towards an unparalleled level of interaction and comprehension between patients and their health data.

Reimagining patient care in this new light, far away from 2D screens and obsolete interfaces, is paving the way for more meaningful, interactive patient-doctor interactions, but the transition presents challenges. As for many emerging technologies, issues of accessibility, cost, and widespread adoption will need to be addressed, and a common sustainable framework for implementation will be co-created among all stakeholders, medical voices, and

tech innovators united to better patients' standard of care and tailored even more individualised treatment pathways.

The implications of VR for doctor-patient interactions are endless, but it's not the only area that could benefit from this promising technology. Medical education, and more generally, knowledge transfer, could be radically changed by the irruption of virtual reality. Virtual reality can now serve as an active training tool for aspiring surgeons and a platform for practicing operations in a simulated environment. Enterprises such as Osso VR and ImmersiveTouch provide VR solutions for surgeon training and skill refinement, surpassing conventional methods. A pivotal Harvard Business Review study revealed a 230% performance enhancement among VR-trained surgeons compared to their traditionally trained counterparts. These VR-trained surgeons demonstrated superior speed and precision in surgical procedures. VR has the potential to enhance medical education significantly, both in performance and inclusivity, as only a limited number of students could observe surgeries first-hand, hindering comprehensive learning and widening the differences between local curriculums.

With VR cameras, surgeons can livestream operations globally, enabling medical students to immerse themselves in the operating room through VR headsets. Case Western University pioneered this approach, utilising devices like the HoloLens to teach human anatomy without cadavers, albeit employing Mixed Reality technology. 2023 has seen

numerous examples showcasing the integration of VR (and/or AR, XR, etc.) in medical training.

Even the traditional world of medical conferences could be shaken up by VR. Dr Brennan Spiegel, a fervent VR advocate in medicine, delivered an entire MedEd lecture in VR in 2017. He continues to utilise VR in presentations at the annual Virtual Medicine conference. The use case for VR headsets in medical conferences for increased audience engagement and content quality is well established, with interactivity, 3D visualisation, and gamification. Yet, the adoption of extended realities remains limited and is still seen as a futuristic gadget.

Conclusion

The year 2023 witnessed a profound transformation in healthcare, powered by digitalisation, and the trend will keep strong in 2024, ushering in an even deeper bond between healthcare and digital innovations. Like Apple's Vision Pro, many technological innovations will have long-lasting impacts on how we manage patient care. As healthcare stakeholders continue to embrace these innovations, collaboration, innovation, and a commitment to patient-centricity will be critical for realising the full potential of digitalisation in healthcare and delivering on the promise to enhance access, efficiency, and quality of care.

Conflict of Interest

None.

Machine Learning and Medical Device Regulations

MedTech sector is in the midst of a digital revolution, with AI leading the way. In the tightly regulated realm of MedTech, there's an increasing demand for a well-established regulatory framework that emphasises the equilibrium between innovation and patient safety. Let's explore the current applications of AI in the MedTech sector, its key areas of utilisation, the challenges encountered in AI integration, and gain insights into the ongoing evolution of the regulatory framework.

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key points

- Machine learning intersects with medical device development, driving innovation, treatment personalisation, and overall patient care.
- Adequately addressing the hurdles and complexities associated with integrating machine learning into medical devices translates to tangible benefits for patients, from enhanced diagnostics to personalised treatments.
- Regulatory frameworks are essential for adapting to the challenges and opportunities posed by machine learning in medical devices, ensuring safety and performance.

Introduction

The rapid evolution of information technology over the past 50 years is transforming our healthcare institutions from paper-based organisations into smart hospitals, a term outlined by European Union Agency for Cybersecurity (ENISA) where integration of technology enhances healthcare services, efficiency, and patient outcomes while addressing cybersecurity challenges. Machine learning (ML), a subset of Artificial Intelligence (AI) plays a crucial role in realising the vision of a smart hospital by leveraging data-driven insights for improved diagnostics, treatment personalisation, and operational efficiency. Systematic reliance on medical devices by both patients and healthcare providers accelerate technological advancements which have played a pivotal role in enhancing patient outcomes, improving diagnostics, and revolutionising treatment methodologies. Enabling healthcare professionals to make faster and more accurate decisions and/or automate monitoring processes have been among the main improvement objectives for many stakeholders. In the last years, machine learning has been one of the most transformative technologies within this sector. ML has emerged as a game-changer, particularly within the realm of medical devices where the development of algorithms enables computers to learn from data and make predictions or decisions without explicit programming. In healthcare, the utilisation of machine learning has been a paradigm shift, allowing for the analysis of vast amounts of medical data to derive meaningful insights. From predictive analytics to image recognition, machine learning has demonstrated its prowess in augmenting clinical decision-making processes, thus fostering a new era in healthcare.

The development of ML based system offers tremendous opportunity to improve patient care, diagnostic reliability and address healthcare professionals' shortage. Adequately trained ML algorithms can

accurately identify, and classify abnormalities based on radiological scans, sonograms, video streams or any form of image or sound. This has led to enhanced diagnostic accuracy and efficiency, particularly in areas such as mammography, radiology, cardiology, pathology, oncology and neuroimaging. In radiology, AI algorithms have been developed to help in the detection and classification of different conditions such as lung nodules, breast cancer and brain abnormalities. In pathology, AI has been shown to improve the accuracy and efficiency of disease diagnosis through the automatic analysis of histopathological samples (Strohm et al. 2020). In cardiology, AI-powered tools analyse electrocardiograms (ECGs) to swiftly identify patterns indicative of cardiac issues. In oncology, AI aids in the interpretation of complex genetic data to personalise cancer treatment plans. The Molecular Oncology journal (2020) showcased how AI algorithms can predict patient responses to different cancer therapies by analysing genetic and clinical data.

In pneumology, sounds recognition through AI algorithm are applied in order to detect and classify respiratory disease which increase the capacity and automate stethoscope.

At the time of writing this article, the internet site "AI for Radiology" lists over 60 ML base systems which have been granted CE Mark according to the Medical Device Regulation. On the contrary, the FDA curates a registry of medical devices incorporating AI/ML technology that are authorised for sale in the United States. Upon scrutinising this registry, it becomes evident that the initial FDA approval for an AI/ML-enabled device occurred in 1995. As of July 30, 2023, approximately 692 devices have received clearance or approval from the FDA.

Revolutionising healthcare, machine learning enhances medical devices for precise diagnostics, personalised treatments, and improved outcomes

Challenges with AI in Healthcare

The integration of artificial intelligence (AI) in healthcare, particularly in the realm of medical devices, presents both promising advancements and notable challenges. While AI holds the potential to revolutionise diagnostics, treatment, and patient care, several hurdles must be addressed to ensure its effective and ethical implementation.

One major challenge is the need for robust regulatory frameworks to govern the development and deployment of AI-powered medical devices. Ensuring the safety, efficacy, and data privacy of these devices is crucial to prevent potential harm to patients and maintain public trust. Striking a balance between innovation and regulation is essential to foster the responsible use of AI in healthcare.

Another central challenge lies in the quality and representativeness of data sets used for training and validating AI algorithms. Comprehensive and diverse data sets are essential to ensure the accuracy and reliability of medical devices. Inadequate or biased data can compromise the performance of AI models, leading to inaccurate diagnoses and treatment recommendations. For e.g., let us consider an AI algorithm trained on a dataset that lacks diversity in terms of demographic representation, featuring primarily tumours from a specific subset of the population. This limitation poses a risk to the model's ability to generalise effectively across diverse patient profiles. For instance, the algorithm may perform well within the constraints of the training data but could exhibit inaccuracies or biases when presented with cases from a more varied patient population. Therefore, the development and use of robust data sets that encompass a wide range of demographics and medical scenarios are critical to the success of AI in healthcare.

The issue of bias in AI poses another substantial hurdle. Biases present in training data or algorithms can perpetuate disparities in healthcare outcomes. Mitigating bias requires a meticulous examination of data collection processes and ongoing monitoring and adjustment of algorithms to ensure fairness and equity in medical decision-making thereby ensuring adequate performance. The healthcare industry must prioritise efforts to address and eliminate biases in AI systems to promote safe and effective healthcare practices.

Trustworthiness is a critical factor in fostering the adoption of AI in healthcare. Establishing trust among healthcare professionals and patients is challenging, particularly when dealing with complex AI algorithms. Transparency in AI decision-making processes, clear communication of the limitations and capabilities of medical devices, and adherence to rigorous ethical and scientific/ technical standards are essential to build and maintain trust in AI technologies and to safeguard their safety and performance. Ensuring that AI systems are explainable and interpretable by healthcare practitioners further contributes to their acceptance and integration into clinical practice.

Interoperability issues pose another significant challenge. Integrating AI technologies into existing healthcare systems and ensuring seamless communication between different devices and platforms is complex. Standardisation efforts are necessary to facilitate interoperability and enable the efficient exchange of information, promoting a cohesive and integrated healthcare ecosystem.

Healthcare professionals also face challenges related to the integration of AI into their workflow. Adequate training and education are crucial to empower clinicians to effectively use AI tools and interpret their outputs. Additionally, fostering collaboration between technologists and healthcare practitioners is essential to develop solutions that align with real-world clinical needs.

In conclusion, while AI in healthcare, particularly in the context of medical devices, holds immense potential for improving patient outcomes, the challenging nature of ensuring the safety and performance of AI systems arises from a combination of ethical, educational, regulatory, and technological factors like ensuring privacy and security, monitoring of updates, quality of data and bias etc., Addressing these challenges requires a multidisciplinary approach involving collaboration between technologists, healthcare professionals, regulators, and policymakers.

> Harmonising machine learning and medical device regulations is crucial for advancing innovation while upholding the highest standards of patient safety in healthcare

Regulatory Landscape: Medical Devices and Artificial Intelligence

European Union (EU)

EU Medical Device Landscape

The medical device regulatory landscape in the European Union (EU) is governed by two key regulations: the Medical Device Regulation (MDR; EU 2017/745) and the In Vitro Diagnostic Regulation (IVDR; EU 2017/746). These regulations, implemented to enhance patient safety and ensure the effectiveness of medical devices, have replaced previous directives (MDD 93/42/EEC; AIMDD 90/385/EEC; IVDD 98/79/EEC).

While the Medical Device Regulation (MDR) focuses on various medical devices, including implants, diagnostic equipment, and software, In-Vitro Diagnostic Regulation (IVDR) specifically addresses in vitro diagnostic medical devices, such as laboratory tests, diagnostic reagents and IVD software.

Both regulations introduce stricter requirements for pre-market, post-market surveillance, and quality management systems. Notably, they place a greater emphasis on transparency, traceability, and market surveillance emphasising the importance of ensuring the safety and efficacy of medical devices in the EU market. Manufacturers must adhere to specific conformity assessment procedures, demonstrate compliance with general safety and performance requirements, and actively engage in post-market surveillance. The EU's regulatory framework for medical devices aims to align with technological advancements while maintaining a strong focus on patient safety and public health.

EU Artificial Intelligence Act (AIA)

The EU AI Act is a comprehensive legislative framework proposed by the European Union to regulate the development and use of AI technologies within its member states. First draft was introduced in April 2021 with an intention to address ethical and legal challenges associated with AI, the Act aims to establish a harmonised framework for the development, deployment, and use of AI technologies across diverse sectors (horizontal legislation). As of December 9, 2023, the Members of European Parliament (MEPs) reached a political deal with the council

and the final agreed text is currently awaiting adaptation by both Parliament and Council to become EU law.

Key provisions include establishing risk-based categorisation for AI systems, outlining requirements for high-risk applications, promoting transparency and human oversight, and establishing a European Artificial Intelligence Board to oversee and enforce compliance.

The Act categorises AI applications into four risk levels—unacceptable risk, high risk, limited risk, and minimal risk—and introduces specific requirements and obligations based on these risk levels. For high-risk AI systems, the Act mandates conformity assessments, data and record-keeping obligations, transparency requirements, and human oversight. Furthermore, medical devices using AI and requiring the involvement of a notified body for conformity assessment under the respective EU regulations are categorised as high-risk AI systems, thus mandating manufacturers of AI systems to comply with additional requirements set out in the Act.

Although the EU AI Act seeks to balance innovation with ethical considerations, it poses challenges for medical device manufacturers. Key challenges include increased scrutiny on safety and transparency requirements, considerations for data privacy, effective allocation of resources, and adapting to evolving regulations. Striking a balance between compliance and innovation is crucial for manufacturers to navigate this intricate regulatory landscape successfully.

United States of America

U.S. Medical Device Landscape

Medical device regulations in the U.S. fall under the authority of U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS). FDA regulates food, drugs, biologics, cosmetics, veterinary medicine, and tobacco, while Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device regulation, with assistance from the Center for Biologics Evaluation and Research (CBER).

As identified by Medical Device Amendments (MDA) of 1976, medical devices are classified and regulated in 3 classes based on risk posed to consumer. Each regulatory classification comprises different regulatory controls and become stringent with increasing risk class i.e., class III devices are most highly regulated due to the risk involved and require premarket approval from FDA while class I devices can be listed with FDA by the manufacturer. Manufacturers upon classifying the risk class of their device shall determine the appropriate regulatory pathway. High-risk devices (Class III) typically undergo the premarket approval (PMA) process, involving comprehensive scientific evidence to ensure safety and efficacy. Moderate-risk devices (Class II) often qualify for the 510(k) pathway (PMN; Pre-Market Notification), requiring substantial equivalence to a predicate device. Low-risk devices (Class I) are usually exempt from PMN and/or other quality systems requirements and can be self-listed.

Next to the conventional pathways, there exists a De Novo pathway. De Novo process is a regulatory pathway for novel medical devices with no clear predicate. Manufacturers submit evidence to establish the device's safety and effectiveness, leading to a new classification. It provides a route for innovative technologies with moderate risk, facilitating market entry for devices that don't fit the criteria for the 510(k) pathway. Lastly, expedited options like the Breakthrough Devices Program and the Accelerated Approval Program accelerate access to innovative technologies, streamlining regulatory processes for devices addressing critical unmet medical needs.

Medical device manufacturers are subjected to a range of regulatory controls i.e., requirements to ensure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness for their intended use. These requirements include, for example, premarket review, labelling, establishment registration and device listing, and quality system regulation (good manufacturing practices for devices).

One of the biggest challenges in regulating AI/ML enabled medical devices is the rapidly evolving nature of the technology that requires constant adaptation to keep pace with emerging advancements and uphold standards of safety and effectiveness. Another challenge is the lack of clear guidelines and standards for AI/ML in medical devices, causing confusion for manufacturers regarding the required regulatory measures and hindering regulators' ability to assess the safety and effectiveness of such devices.

Artificial Intelligence

There isn't a comprehensive standalone regulation specifically for artificial intelligence (AI) in the United States. However, various existing laws, regulations, and agencies address certain aspects of AI applications, depending on the context and industry. Following points must be considered:

- **Sector-Specific Regulations:** Certain sectors, such as healthcare, have specific regulations that indirectly apply to AI systems. For example, the safety and performance of AI in medical devices will be evaluated by the FDA during its clearance/approval process.

- **Consumer Protection and Privacy Laws:** Regulations like the Federal Trade Commission (FTC) Act and state-specific data protection laws govern consumer protection and privacy. They may be applicable when AI systems involve personal data.

- **Ethical and Fairness Considerations:** While not regulatory in nature, there is a growing emphasis on ethical AI practices. Various organisations, including the National Institute of Standards and Technology (NIST), are developing guidelines and principles to promote ethical AI development.

- **National AI Strategy:** The U.S. government has shown interest in AI development through initiatives like the National Artificial Intelligence Initiative Act of 2020, which focuses on advancing AI research and development.

- **Congressional and Agency Inquiries:** There have been discussions and inquiries within the U.S. Congress and federal agencies about the need for AI regulation. Proposals and discussions vary, including considerations for transparency, accountability, and bias mitigation in AI systems.

It's essential to stay updated on developments, as the landscape of AI regulation is dynamic, and new initiatives may emerge. As of now, there isn't a singular, comprehensive federal law dedicated solely to regulating AI in the United States.

State of the Art Considerations

The field of AI is advancing at an unprecedented pace, with continual breakthroughs in machine learning algorithms, computational power, and data analytics. In this dynamic landscape, to integrate artificial intelligence into medical devices and to harness the full potential of AI in medical devices, it is crucial to prioritise "state-of-the-art considerations." This approach not only reflects ongoing advancements in technology but also addresses critical factors that contribute to the effectiveness, safety, and ethical deployment of AI in healthcare.

Use of Regulatory Sandboxes

The term 'regulatory sandbox' can be traced back to the financial technology, where regulatory sandboxes have existed since 2014. The UK Financial Conduct Authority (UK FCA) has been a leader in this concept, establishing its regulatory sandbox in 2014, and since then it has been replicated in about 40 jurisdictions.

The term can be generally defined as a testbed for a selected number of projects where certain laws or regulations are set aside, and the project receives guidance and monitoring from a competent authority.

According to a World Bank study, more than 50 countries are currently experimenting with fintech sandboxes. Japan introduced in 2018 a sandbox regime open to organisations and companies both in- and outside Japan willing to experiment with new technologies, including blockchain, AI, and the internet of things (IoT), in fields such as financial services, healthcare and transportation. In Europe, both Norway and the United Kingdom (UK) have developed AI sandboxes. Norway established a regulatory sandbox as part of its national AI strategy, to provide guidance on personal data protection for private and public companies.

In scope of a sector specific legislation, EU's AI Act introduces the concept of 'AI regulatory sandboxes', with an objective to foster AI innovation by establishing a controlled experimentation and testing environment for innovative AI technologies, products, and services during development phase, before their placement on the market. To this end, Spain has announced that they will be piloting a regulatory sandbox aimed at testing the requirements of the legislation (EU AIA), as well as how conformity assessments and post-market activities may be overseen. Deliverables from this pilot include documentation of obligations and how they can be implemented, and methods for controlling and following-up that can be applied by those supervising national

authorities responsible for implementing the regulation. Reflecting the cross-state approach desired by the Act, other member states will be able to follow or join the pilot. As accessing such AI regulatory sandboxes typically involves collaboration with regulatory agencies or member States that offer such environments, it is suggested that manufacturers of AI systems closely monitor and stay connected to the respective regulatory agencies in their member state.

Finally, usage of regulatory sandboxes not only supports manufacturers of AI based systems, develop their products in a regulation compliant way, but also support them in avoiding potential legal risks and help them to better understand the regulatory and/or statutory expectations. Furthermore, testing in a controlled environment also mitigates the risks and unintended consequences (such as unseen security flaws) when bringing a new technology to market, and can potentially reduce the time-to-market cycle for new products.

Guidance on AI/ML Practices

The U.S. FDA (Food and Drug Administration), Health Canada and UK's MHRA (Medicines and Healthcare products Regulatory Agency) jointly identified 10 guiding principles for the development of Good Machine Learning Practices. These guiding principles will help promote safe, effective and high-quality medical devices that use AI/ML.

FDA in its discussion paper 'Proposed Regulatory Frameworks for Modifications to Artificial Intelligence/ Machine Learning (AI/ML) – Based Software as a Medical Device (SaMD)', presented their thoughts for reviewing changes performed to SaMDs involving AI/ML technology and also requested the feedback from the industry [15]. Similarly, guidance from other regulators and/or industry trade associations on medical devices incorporating AI/ML technologies must be taken into consideration wherever possible. Complying with guidance proposed by regulatory not only supports for regulatory compliance but helps in better understanding the expectations of the regulators and can benefit in reducing the regulatory review times needed for product's market entry.

International Standards

International standards are globally recognised guidelines and specifications developed to ensure the consistency, safety, and quality of products, services, and systems across borders. They provide a common language and framework for organisations to meet specific requirements, fostering interoperability and facilitating international trade.

ISO, or the International Organization for Standardization, is a non-governmental international body that develops and publishes these standards. Comprising representatives from various national standards organisations, ISO sets standards in diverse areas, including technology, healthcare, manufacturing, and more. ISO standards contribute to innovation, efficiency, and the assurance of quality on a global scale.

At the time of writing this document, there are a few standards published by the standardisations committees that can be used by the manufacturer of AI systems to demonstrate the robustness and performance of their AI system. Out of 24 published standards and 32 standards under development by ISO/IEC JTC1/SC 42 Artificial Intelligence, **Table 1** identifies some key standards that must be considered by manufacturers of AI enabled medical devices.

Proposed Method for Regulatory Compliance for an AI-Based Medical Device

Achieving regulatory compliance for medical devices involves a meticulous approach to development, validation, and documentation. This is often achieved by implementing a quality management system and by establishing and maintaining a technical documentation throughout the lifecycle phases.

Implementing a Quality Management System (QMS) is essential for medical device manufacturers due to various regulatory, safety, and operational considerations. A QMS provides a structured framework for managing and continually improving the processes involved in the design, development, manufacturing, and distribution of medical devices. Manufacturers of AI systems should consider the newly published standard ISO/IEC 42001:2023.

Secondly, manufacturers of AI systems shall wherever possible resort for a hybrid approach for integrating requirements of ISO/IEC 62304 – Medical device software – Software lifecycle processes with ISO/IEC 5338 – AI system lifecycle processes. Furthermore, for AI systems based on machine learning, manufacturers of AI systems shall align the AI development practices with the recommendations of Good Machine Learning Practices (GMLP). Adhering to this approach should support

ISO #	Title
ISO/IEC TR 24027:2021	Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
ISO/IEC TR 24028:2020	Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence
ISO/IEC TR 24029-1:2021	Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview
ISO/IEC TS 4213:2022	Information technology — Artificial intelligence — Assessment of machine learning classification performance
ISO/IEC 23894:2023	Information technology — Artificial intelligence — Guidance on risk management
ISO/IEC 24029-2	Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
ISO/IEC 42001	Information technology — Artificial intelligence — Management system
ISO/IEC 5338	Information technology — Artificial intelligence — AI system life cycle processes

Table 1: Published standards on AI by ISO/IEC JTC 1/ SC 42

manufacturers of AI systems to meet the expectations of the regulatory authorities and facilitate for market entry.

Thirdly, segregation of data for training and validation in healthcare machine learning models takes on heightened significance, particularly considering the necessity to validate models in clinical trials. Rigorous validation is crucial to ensure that the model's performance is robust and clinically relevant. By separating training and validation datasets, the model undergoes assessment against diverse, unseen data, mirroring the conditions it would encounter in real-world clinical settings. This process not only guards against overfitting but also enhances the model's generalisability and reliability in practical healthcare applications. The careful segregation of data for training and validation is thus an indispensable step in the development and validation of machine learning models that can meet the stringent standards of clinical practice and trials in the healthcare domain.

Another key consideration is the adequate definition of Performance parameters which are indispensable in evaluating the efficacy of machine learning algorithms based medical devices. These quantitative metrics, including accuracy, precision, repeatability, and others, form a critical foundation for assessing how well a model fulfils its intended use and associated claims. Clear and well-defined performance endpoints are necessary to guide the development, fine-tuning, and assessment of machine learning models. Safety considerations, such as identifying errors and false predictions, are paramount to ensuring the reliability and clinical suitability of these algorithms.

The aforementioned considerations, coupled with the diligent implementation of systematic monitoring approaches and the application of state-of-the-art concepts, collectively empower manufacturers of AI-enabled medical devices to align with regulatory expectations. This proactive approach not only ensures compliance but also facilitates the incorporation of state-of-the-art technologies, allowing medical device manufacturers to navigate the complex regulatory landscape effectively while delivering innovative and high-quality solutions.

Conclusion

In summary, the integration of Machine Learning (ML) in medical devices offers transformative benefits for healthcare, enhancing diagnostics, personalised treatment, and operational efficiency. Despite its potential, many challenges have to be addressed when integration ML in Medical devices such as technical, scientific and ethical constraints. The regulatory frameworks developed in the US and in the European Union provide general rules and principles that are designed to ensure the use of ML result in safe and effective products such as medical devices.

While ML offers a tremendous opportunity for innovation and growth for Medical Devices Manufacturers, the systematic applications of good practices in the development of state-of-the-art devices is a necessity to ensure that their products will achieve not only the regulatory expectations but also foster trust among healthcare professionals and patients which is crucial for the successful deployment of AI in healthcare.

Conflict of Interest

None.

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The Global Best in KLAS® Rankings: Increased Insights from Europe

An overview of the 2024 Best in KLAS Awards – Global Software report providing insight on the most effective software solutions in healthcare.

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key points

- The Best in KLAS® awards serve as a guide, helping stakeholders easily see the most effective software solutions that elevate the standard of care.
- The research directly represents the provider voice in each region an award is given and acts as a catalyst for improving vendor performance.
- The 2024 Global Best in KLAS report reflects expanded research in Europe by KLAS, with subregional awards given in the UK and Ireland, Northern Europe, DACH, France, and Southern Europe.
- The 2024 Best in KLAS – Global Software report is a big step forward in Europe – and the world.

In the realm of healthcare technology, the Best in KLAS® awards serve as a guide, helping stakeholders easily see the most effective software solutions that elevate the standard of care. The 2024 Best in KLAS Awards – Global Software report represents a big step forward into the European healthcare IT market as more feedback enabled KLAS to present more Best in KLAS awards than ever before.

KLAS is a research and insights firm on a global mission to improve healthcare delivery by amplifying the provider's voice. Working with thousands of healthcare professionals and clinicians worldwide, KLAS gathers data and insights on software and services to deliver timely reports, trends, and statistical overviews. The research directly represents the provider voice in each region an award is given and acts as a catalyst for improving vendor performance.

2024 Awards Given in More European Market Segments

The 2024 Global Best in KLAS report reflects expanded research in Europe by

KLAS, with subregional awards given in the UK and Ireland, Northern Europe, DACH, France, and Southern Europe. Jonathan Christensen, senior insights director at KLAS, shared, "KLAS continues to see more feedback from and engagement in Europe. This year is the first that KLAS

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has been able to highlight vendor performance at a more granular, subregional level for Europe. Publishing this more granular look is better for provider organisations because it gives increased clarity on which vendors are selling in the region that have an established presence. More importantly, it shows which vendors are performing well.

KLAS' goal is to continually refine and to get better as we increase our research efforts to try and make the report as relevant and applicable as possible for the providers in their own geography. The 2024 Best in KLAS – Global Software report is a big step forward in Europe – and the world, and we're going to continue to grow our presence and feedback from other regions in the future."

Selected Best in KLAS Award Winners – Global

Global Acute Care EHR

Outside of the US, KLAS defines Electronic Health Record (EHR) software products as providing core inpatient functionality, including a clinical data repository, order entry, ePrescribing, results reporting, and/or clinician charting and documentation.

To see Best in KLAS winners in different regions for Digital Pathology, PACS, and Shared Care Records/ HIE, please see the full report.

Key Takeaways and Trends from 2024

Increased Focus on Patient Engagement: Healthcare organisations worldwide are placing greater emphasis on engaging patients throughout their healthcare journey. According to KLAS interviews, nearly two-thirds of organisations prioritise

Region/Subregion	Solution	Score and unique orgs	Market average	Trend 2023-2024
Asia/Oceania	**IQVIA Arcus Air HIS**	82.7 (n=14)	73.8	-3%
Canada	**Epic EpicCare Inpatient EHR**	87.5 (n=7)	77.8	-2%
Europe/DACH	**Dedalus ORBIS**	67.8 (n=14)	65.0	n/a
Europe/France	**Softway Medical HOPITAL MANAGER**	77.6 (n=12)	70.5	n/a
Europe/Northern Europe	**Epic EpicCare Inpatient EHR**	84.0 (n=9)	72.5	n/a
Europe/Southern Europe	**Dedalus Care (HCIS) (Mostly Spain)**	79.7 (n=6)	73.3	n/a
Europe/UK & Ireland	**Epic EpicCare Inpatient**	85.0 (n=6)	71.8	n/a
Latin America	**MV SOUL (Mostly Brazil)**	79.9 (n=11)	76.3	+13%
Middle East/Africa	**Oracle Health Millennium PowerChart**	82.5 (n=16)	82.0	-3%

patient engagement technology for IT investment in the next one to two years. Many are already utilising such technologies, with future plans to consolidate functionalities through patient portals and streamline access to healthcare services.

Continued Emphasis on EHR Optimisation and Expansion: Healthcare organisations globally are persistently investing in optimising existing technologies, particularly Electronic Health Records (EHR). This involves enhancing adoption and usability across clinical areas and harnessing data-driven capabilities from EHR vendors to improve operations. KLAS will release reports in 2024 focusing on EHR adoption and performance in the Middle East/Africa and the UK/Ireland regions.

Migration Towards Cloud-Based Solutions: Simultaneously with EHR optimisation, many healthcare organisations are modernising and lightening their IT infrastructure by embracing cloud technologies. While still in the early stages, over two-thirds of organisations are in the process of adopting cloud solutions. Moreover, cloud strategy and transformation rank high among the areas where healthcare organisations seek advisory services from firms.

Why Granularity Matters and Factors Impacting Best in KLAS Vendor Scores

Producing a meaningful international report can be a challenge thanks to the vast amounts of data required, but KLAS feels it is worth the effort. Christensen makes it clear that the goal with the global Best in KLAS report has always been to acknowl-

edge strong vendor performance at a more sub-regional or even country level because "KLAS recognises the diversity in the vendors and their performance based on language, regionality, and local regulations and support. So, we have continued to push to get more granular to better highlight these differences."

> Nearly two-thirds of healthcare organisations prioritise patient engagement technology for IT investment in the next one to two years

Depending on the region, various factors make an impact on customer satisfaction with their solutions, which can set the winners apart. Christensen shares a few: "One factor that influences how well a vendor does in a region is how they, or their reseller, meet basic support requests from customers in country. What we generally see is that vendors who are Best in KLAS are better able to deal with those support requests. They're also better at meeting the

local regulations. As we look at these regional Best in KLAS awards in Europe, it allows for an apples-to-apples comparison of vendors against the same regional expectations. It is still not perfect, but these changes have allowed us to better highlight feedback from like-minded organisations on how well vendors meet their local needs."

Ironclad Methodology: sampling selection, data thresholds and ranking criteria

At the core of the Global Best in KLAS report is a methodology aimed at evaluating software solutions on their overall performance. The data, for both the US and global reports, is based on over 26,000 conversations each year with the customers of over 1,100 tracked products from more than 5,000 healthcare organisations. To avoid relying on vendors to obtain client lists, KLAS makes proactive calls to tens of thousands of healthcare professionals. Data is also obtained from user groups, referrals, and online.

KLAS makes every effort to build strong, mutually beneficial relationships with providers, and this helps produce a higher response rate. So, when randomly selecting a sample within known customer bases, KLAS cannot fully control for the nonresponse bias when customers do not participate. However, many do respond. Additionally, to allow for the representation of differing perspectives within any customer organisation, samples may include individuals from the same organisation. The evaluation period spans

either 13 or 19 months, depending on the solution type, ensuring a comprehensive analysis of performance trends.

While data thresholds are higher for research gathered in the US, to be considered fully rated data in non-US regions, solutions needed a sample size of 6 or more unique organisations. Meanwhile, sample sizes of 3-5 unique organisations are marked as limited data.

Nearly two-thirds of healthcare organisations prioritise patient engagement technology for IT investment in the next one to two years Nearly two-thirds of healthcare organisations prioritise patient engagement technology for IT investment in the next one to two years

Customer Experience Pillars and Eligibility Criteria

To accurately reflect the sentiment of customers and offer readers an at-a-glance overview of vendor performance, evaluation is segmented into six customer experience pillars: culture, loyalty, operations, product, relationship, and value. Scores on a 100-point scale are translated into alphabetical grades from F to A+.

Not all solutions are eligible for a Best in KLAS ranking. In these cases, overall performance scores and customer experience pillar grades are still displayed, along with the reason for ineligibility among the following:

- **Limited Data:** Solutions with sample sizes below required thresholds, though they may meet lower "limited data" thresholds.

- **Newly rated [NR]:** Solutions rated after the Best in KLAS report deadline.

- **Not eligible [NE]:** In regions outside of the US, Acute care EHR solutions must have evaluations from two or more countries within the region, and at least one customer must be a HIMSS Level 6+ as verified by KLAS. PACS systems must have the same number of evaluations, and at least one customer in the region needs to manage 300,000+ images per year.

- **Not primary [NP]:** Solutions that are not a vendor's lead offering in a market segment.

- **Regional [R]:** Solutions with data primarily sourced from a small, specific geographical area.

In the realm of healthcare technology, the KLAS Rankings serve as a beacon guiding stakeholders towards the most effective software and services solutions that elevate the standard of care. Within this expansive landscape, understanding the intricacies of the ranking system is paramount for informed decision-making.

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