

Medical Device & AI Regulations

THE JOURNAL 2023

Anita Sands, Agnes Kijo, Agnès Leotsakos

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

Stephen Gilbert

Improving the Regulation of Medical Devices and Artificial Intelligence

Gabriella M. Racca

Digital Transformation in Healthcare Procurement

Penny Pinnock

Growing Pressures Driving the Shift to Healthcare Digitalisation

Elena Demosthenous

Standards in Support of the EU Medical Devices Regulations

Susana Álvarez Gómez

Effective Management in Times of Health Crisis



Editorial



STEPHEN
LIEBER

Chief Analytics Officer, CHIME, U.S,
HealthManagement.org, Editor-in-Chief,
Health IT

Medical Device and AI Regulations

The quickly evolving major presence of Artificial Intelligence in healthcare means the current regulatory landscape is changing. AI-based medical devices are rapidly revolutionising the industry across the globe, but along with the many positive developments made in healthcare delivery, calls for more regulatory oversight are growing. Many countries are rethinking and re-tooling their regulatory protocols to account for AI-based medical technologies to achieve effectiveness and ensure patient safety.

In this issue, our contributors discuss **Medical Device and AI Regulations**, particularly the measures needed for improved regulation of devices and AI tools, some ongoing regulatory reforms, and what can be expected in the future.

Elena Demosthenous discusses the use of harmonised standards as a proven and trusted way of ensuring medical devices comply with regulations and safety standards for patients, healthcare professionals and others. Stephen Gilbert shares his insights and thoughts regarding the need for improved and balanced regulation of medical devices and artificial intelligence.

Agnès Leotsakos, Agnes Kilo and Anita Sands highlight that effective regulatory systems are a vital component of health system strengthening, particularly in the age of AI/ML-enabled medical devices.

Gabriella Racca explores the potential of AI coupled with digital innovation for future healthcare procurement.

Medical digital algorithms have the potential to transform healthcare and improve patient outcomes. Taner Ozcan delves deeper to uncover what medical digital algorithms are, how they work, and the benefits

they offer in healthcare.

Generative AI is one of the powerful tools in radiology and has the potential to revolutionise the field. Josep Munuera and Arnau Valls discuss its role and contributions across the field, yet cautioning us that the multiple uses of generative AI imaging also carry limitations that need to be solved before this being ready for wide adoption.

Penny Pinnock highlights the need for healthcare organisations to refresh their existing technology and accelerate the adoption of digital and AI-driven technologies to improve patient outcomes, reduce costs and improve care delivery.

Emily Zampella and Michele Klain discuss radionuclide therapy and how it represents a valid, highly specific therapy option in paediatric patients. Valeria Guadieri and Alberto Cuocolo talk about peptide receptor imaging and PRRT as a new frontier in personalised medicine, allowing for tailored treatment plans.

Susana Álvarez Gómez shares the strategies and experiences of the public procurement department of Madrid Health in facing the recently ended pandemic, as well as the innovative actions taken to respond to this worldwide health crisis.

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

Happy reading!

A handwritten signature in black ink that reads "Stephen Lieber". The signature is written in a cursive, flowing style.

Contents

EDITORIAL

65 Medical Device and AI Regulations

Stephen Lieber, USA

SPOTLIGHT

79 Latest Advances in MRI

United Imaging Healthcare

Point-of-View

81 Mindray Resona R9 Platinum Edition – A new leap for precision ultrasound

Mindray

Point-of-View

COVER STORY

84 How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

Agnes Sitta Kijo, Anita Sands, Switzerland

Agnès Leotsakos, United Kingdom

88 Improving the Regulation of Medical Devices and Artificial Intelligence

Stephen Gilbert, Germany

92 Standards in Support of the EU Medical Devices Regulations –

Elena Demosthenous, Cyprus

DIGITAL TRANSFORMATION

97 Growing Pressures Driving the Shift to Healthcare Digitalisation

Penny Pinnock, United Kingdom

100 Digitisation for DSOs

Joerg Aumueller, Switzerland – Straumann Group

Point-of-View

DISCLOSURE OF CONFLICT OF INTEREST:

Point-of-View articles are the sole opinion of the author(s) and they are part of the HealthManagement.org Corporate Engagement or Educational Community Programme supported by educational grants.

Contents

103 Digital Transformation in Healthcare Procurement

Gabriella M.Racca, Italy

106 Revolutionising Medicine: The Power of Digital Algorithms in Healthcare

Taner Ozcan, Turkey

MEDICAL IMAGING

111 Radionuclide Therapy in Paediatric Patients

Emilia Zampella, Michele Klain, Italy

113 One Ring to Rule Them all in In

Stéphane Maquaire, France - Affidea

Alessandro Roncacci, Italy - Affidea

Point-of-View

116 Central Role of Nuclear Medicine in Personalised Medicine

Valeria Gaudieri, Alberto Cuocolo, Italy

GOVERNANCE AND LEADERSHIP

120 Business Continuity Management in Medical Technology: Ensuring Uninterrupted Healthcare Services

Thomas Jäschke, Germany

Point-of-View

123 Effective Management in Times of Health Crisis

Susana Álvarez Gómez, Spain

AI & ROBOTICS

128 How Imaging Generative AI Will Transform the Medical Radiological Practice

Josep Munuera, Arnau Valls-Esteve, Spain

DISCLOSURE OF CONFLICT OF INTEREST:

Point-of-View articles are the sole opinion of the author(s) and they are part of the HealthManagement.org Corporate Engagement or Educational Community Programme supported by educational grants.

Contributors

Joerg Aumueller, Switzerland



In his role as Vice President, Global Head of Enterprise Solutions at the Straumann Group, Joerg Aumueller focuses on developing enterprise solutions for dental service organisations (DSOs) by enhancing customer co-creation in digital transformation of DSO business and dental delivery models, and establishing transformational services to streamline dental operations.

Digitisation for DSOs

100

Valeria Gaudieri, Italy



Valeria Gaudieri, MD, PhD, Researcher at the Department of Advanced Biomedical Sciences, University of Naples Federico II. Author of more than 60 scientific publications on peer reviewed international journals indexed by Pub Med. Her field of research are theragnostic approach of malignancies and radionuclide therapy, nuclear medicine applications in neurodegenerative diseases, and risk stratification and outcome prediction using cardiovascular imaging.

Central Role of Nuclear Medicine in Personalised Medicine

116

Alberto Cuocolo, Italy



Alberto Cuocolo, MD, Full professor of Diagnostic Imaging and Radiotherapy, Director of the Department of Advanced Biomedical Sciences, University of Naples Federico II. Author of more than 540 scientific publications on peer reviewed international journals indexed by Pub Med and of more than 50 book chapters. He has organised, directs and coordinates a group of young researchers and scholarship holders from the Department of Advanced Biomedical Sciences of the University of Naples Federico II and the Bioimaging Section of the Institute of Biostructures and Bioimaging of the National Research Council.

Central Role of Nuclear Medicine in Personalised Medicine

116

Stephen Gilbert, Germany



Stephen Gilbert is Professor for Medical Device Regulatory Science at the Else Kröner Fresenius Center for Digital Health at Dresden University of Technology. His research goal is to advance the regulatory science of software as a medical device and AI enabled medical devices. Innovative digital approaches to healthcare must be accompanied by innovative approaches in regulation to ensure speed to market, to maximum access of patients to life saving treatments whilst ensuring safety on market.

Improving the Regulation of Medical Devices and Artificial Intelligence

88

Elena Demosthenous, Cyprus



Elena Demosthenous currently works at the Cyprus Organisation for Standardisation (CYS) as the National Member of the Technical Board of the European Standardisation Organisation (CEN) and as the officer responsible for standardisation in the sectors of Healthcare, Occupational Health & Safety, Consumer Safety, and Food & Feed. Elena is a Certified Lead Auditor for Quality Management and Environmental Management Systems as well as an auditor in a wide variety of sectors.

Standards in Support of the EU Medical Devices Regulations

92

Susana Álvarez Gómez, Spain



Susana Álvarez Gómez is a health management professional with experience in management positions in public and private centers for the last 20 years. Susana is currently Deputy Director for Public Procurement for Madrid Health Service in Madrid, Spain.

Effective Management in Times of Health Crisis

123

Thomas Jäschke, Germany



Thomas Jäschke is a renowned expert in data privacy and information security in healthcare. He is a board member of the Dr. Jäschke Group, a network of companies specialising in digitalisation, consulting, and information security in healthcare. Jäschke is also a professor at FOM University of Applied Sciences, teaching courses on IT security and knowledge management. He has authored and edited several books, including “Data Privacy and Information Security in Healthcare.”

Business Continuity Management in Medical Technology: Ensuring Uninterrupted Healthcare Services

120

Agnès Leotsakos, United Kingdom



Agnès Leotsakos has a Ph.D. in Biomedicine and Biochemistry, and over 25 years’ experience in global public health. Agnès is a consultant for WHO and Strasys UK. She is an expert on Patient Safety and Quality Improvement. She was Leader of Global Capacity Building and Education in Safety and Quality of Health Services, at WHO. Since her appointment at WHO Headquarters, in Geneva, in 1998 she has led projects within several WHO programmes including communicable diseases and macroeconomics and health.

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

84

Agnes Sitta Kijo, Switzerland



Agnes Sitta Kijo, is a Technical Officer, at the Facilitated Products Introduction (FPI) Team in WHO-HQ, Geneva, Switzerland. She is responsible for the Collaborative Registration Procedure for in vitro diagnostics and medical devices. Agnes has an extensive experience in medical devices regulation and regulatory harmonisation initiatives for medical devices. During her career she held different technical, advisory and leadership roles allowing her to provide sound guidance to regulators and regional harmonisation initiatives globally.

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

84

Stéphane Maquaire, France



Stéphane Maquaire is Director Europe at Incepto Medical, a platform of AI solutions for medical imaging. With an engineer degree, he has over 20 years of experience in technical leadership and commercial management of molecular solutions. In 2014, he became General Manager MRI imaging solutions for Europe. His medical imaging knowledge and his expertise in European business development are fostering the market expansion of Incepto Medical.

One Ring to Rule Them all in AI

113

Michele Klain, Italy



Michele Klain, MD, Associate Professor of Diagnostic Imaging and Radiotherapy, Department of Advanced Biomedical Sciences, University of Naples Federico II. Author of more than 100 scientific publications on peer reviewed international journals indexed by Pub Med. He organises and coordinates a group of young researchers and scholarship holders from the Department of Advanced Biomedical Sciences of the University of Naples Federico II.

Radionuclide Therapy in Paediatric Patients

111

Josep Munuera, Spain



Josep Munuera is a senior consultant radiologist (MD, PhD) sub-specialised in diagnostic neuroradiology (ED-iNR). He is currently Director of Radiology at the Hospital de Sant Pau (Barcelona, Spain). He is the scientific head of the Spanish Society of Radiology (SERAM) and vice president of the Catalan society of radiology (Radiòlegs de Catalunya). His specific areas of interest are cerebrovascular pathology and MRI, as well as innovation in medical imaging, especially in the field of Artificial Intelligence and 3D.

How Imaging Generative AI Will Transform the Medical Radiological Practice

128

Taner Ozcan, Turkey



Taner Ozcan is a graduate of medical school and has a master's degree in health management. He worked as a medical doctor in several hospitals and clinics, and as a manager in the Ministry of Health, Private Hospitals Association (OHSAD) and leading hospital groups in the health sector. He is still continuing his doctorate program at Istinye University. He has been working as a process analysis director in the Digital Transformation Office of MLPCARE.

Revolutionising Medicine: The Power of Digital Algorithms in Healthcare

106

Alessandro Roncacci, Italy



Dr Alessandro Roncacci is Senior Vice President and Chief Medical Officer at Affidea Group. He has 15 years of experience as a radiologist and holds a PhD in Surgical Physiopathology and Gastroenterology at the University "La Sapienza". He has presented his work at several conferences. Dr Roncacci also holds a master's degree in Healthcare Management from Bocconi University. He is an expert in resource management and outsourcing services in radiology.

One Ring to Rule Them all in AI

113

Penny Pinnock, United Kingdom



Penny Pinnock is Business Development Manager at Siemens Financial Services (SFS). Penny is an Asset Finance expert and focuses on building relationships and understanding customer requirements to intelligently tailor our solutions and deliver clear outcomes. Outside of work, she's a proud wife and busy mum to two beautiful boys – and loves to socialise with friends.

Growing Pressures Driving the Shift to Healthcare Digitalisation

97

Anita Sands, Switzerland



Anita Sands is a technical officer at World Health Organization, where she works on post-market monitoring of quality, safety and performance of medical devices. She joined WHO in 2004 working in the WHO Prequalification Team on IVDs. In 2014, she took on the role to establish WHO's area of work to support post-market surveillance and market surveillance of medical devices.

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

84

Gabriella M. Racca, Italy



Gabriella M. Racca is a full Professor of Administrative Law at the Department of Management of the University of Turin (Italy). She coordinates the IUS Publicum Network Review (Class A Ranking) and is a member of the Board of Directors of the Italian Institute of Administrative Sciences. She is the Director of the Master on Efficiency, Integrity and Innovation in Italian Public Contracts (Master SEIIC). She has been Head of Research Units of several EU projects and is a Member of the Advisory Board of the EURIPHI project.

Digital Transformation in Healthcare Procurement

103

Arnau Valls Esteve, Spain



Arnau Valls-Esteve is a BSc, MSc, Telecommunications Engineer from the Polytechnic University of Catalonia (UPC-BarcelonaTECH). Since 2014, he works at the Innovation and Research Department of Sant Joan de Déu Barcelona Children's Hospital as engineer and Head of Innovation leading national and European projects in the field of digital technologies applied to health. He is co-founder and Technical Manager of the 3D Planning Unit 3D4H of the same hospital. In 2020, Arnau co-founded the Paediatric Innovation Hub i4KIDS as a member of the coordinating team.

How Imaging Generative AI Will Transform the Medical Radiological Practice

128

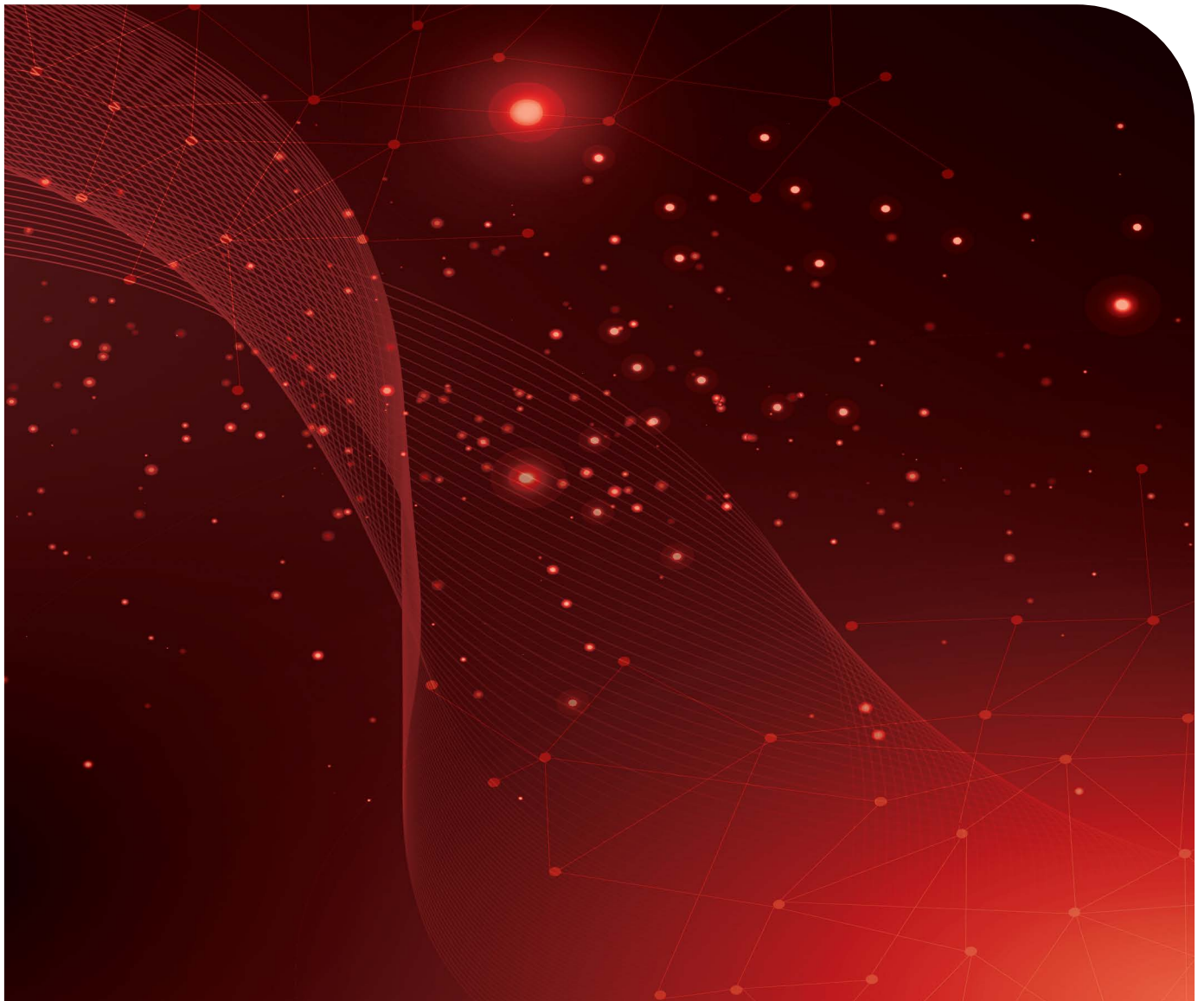


Emilia Zampella, Italy

Emilia Zampella, MD, PhD, Researcher at the Department of Advanced Biomedical Sciences, University of Naples Federico II. Author of more than 90 scientific publications on peer reviewed international journals indexed by Pub Med. Her field of research are theragnostic approach of malignancies and radionuclide therapy, and risk stratification and outcome prediction using cardiovascular imaging.

Radionuclide Therapy in Paediatric Patients

111



Get your free subscription!



Subscribe here for FREE

Subscription Rates (6 Issues/Year)

One year: Euro 106 + 5% VAT, if applicable
Two years: Euro 184 + 5% VAT, if applicable

Distribution

Total circulation 60,000
ISSN = 1377-7629a

© HealthManagement.org is published eight times per year. The Publisher is to be notified of any cancellations six weeks before the end of the subscription. The reproduction of (parts of) articles is prohibited without the consent of the Publisher. The Publisher does not accept any liability for unsolicited material. The Publisher retains the right to republish all contributions and submitted materials via the internet and other media.

Legal Disclaimer

The Publishers, Editor-in-Chief, Editorial Board, Ambassadors and Editors make every effort to ensure that no inaccurate or misleading data, opinion or statement appears in this publication. All data and opinions appearing in the articles and advertisements herein are the sole responsibility of the contributor or advertiser concerned. Therefore the Publishers, Editors-in-Chief, Editorial Board, Industry and Regional Ambassadors, Editors and their respective employees accept no liability whatsoever for the consequences of any such inaccurate or misleading data, opinion or statements.

Press Accreditation

According to the standards of International Business Press Audits.

HealthManagement.org
is independently audited by TopPro Audit



Editorial Board



Prof. Alexandre Lourenço

Editor-in-Chief EXEC

Centro Hospitalar e
Universitário de Coimbra,
Portugal
al@healthmanagement.org



Prof. Lluís Donoso Bach

Editor-in-Chief Imaging

Hospital Clinic – University
of Barcelona, Spain
ld@healthmanagement.org



Prof Fausto J. Pinto

Editor-in-Chief Cardiology

President, World Heart
Federation (WHF), Head
of the Heart and Vascular
Department, Santa Maria
University Hospital,
Lisbon, Portugal
fp@healthmanagement.org

Board Members

Susana Álvarez Gómez

Servicio Madrileño de Salud, Spain

Prof. Octavian Andronic

Carol Davila University of Medicine, Romania

Dr. Gilbert Bejjani

CHIREC Hospital Group, Brussels, Belgium

Philippe Blua

Hospital Center of Troyes, France

Prof. Edward I. Bluth

Ochsner Healthcare, USA

Prof. Frank Boudghene

Hôpital Tenon, France

Miguel Cabrer Gonzalez

Son Espases University Hospital, Spain

Prof. Davide Caramella

University of Pisa, Italy

Richard Corbridge

Boots, UK

Prof. Marc Cuggia

Pontchaillou Hospital, France

Prof. Alberto Cuocolo

University of Naples Federico II, Italy

Prof. Johan de Mey

Free University of Brussels, Belgium

Prof. Rachel Dusnscombe

Imperial College London, UK

Prof. Nevra Elmas

Ege University, Turkey

Prof. Joan Marques Faner

Son Dureta University Hospital, Spain

Prof. Mansoor Fatehi

Medical Imaging Informatics Research Center, Iran

Eugene Fidelis Soh

TTSH & Central Health, Singapore

Prof. Guy Frija

Georges-Pompidou European Hospital, France

Prof. Juraj Gemes

F.D. Roosevelt University Hospital, Slovakia

Prof. Frederik L. Giesel

University Hospital Heidelberg, Germany

Dr. Peter Gocke

Charité, Germany

Marc Hastert

Federation of Luxembourg Hospitals, Luxembourg

Sean Hickey

Chief Digital Information Officer InHealth, UK

Priv.-Doz. Philipp Kahlert

Universitätsklinikum Essen, Germany

Prof. Peter Kearney

Cork University Hospital, Ireland

Prof. Ekaterina Kldiashvili

Tbilisi Medical Academy, Georgia

Heinz Kölking

Lilienthal Clinic, Germany

Prof. David Koff

McMaster University, Canada

Nikolaus Koller

President EAHM Editorial Board, Austria

Prof. Elmar Kotter

University Hospital Freiburg, Germany

Prof. Aleksandras Laucevicius

Vilnius University Hospital, Lithuania

Prof. Heinz U. Lemke

CARS; University of Leipzig, Germany

Dr. Agnes Leotsakos

WHO, Switzerland

Prof. Lars Lönn

National Hospital, Denmark

Prof. Manu Malbrain

Medical University of Lublin, Poland

Chris McCahan

IFC, World Bank Group, USA

Prof Geraldine McGinty

Weill Cornell Medicine, USA

Louise McMahon

Health and Social Care Board, Northern Ireland

Prof Henrique Martins

SPMS, Portugal

Pierre-Michael Meier

Eco System ENTSCHIEDERFABRIK, Germany

Prof. Iris Meyenburg-Altward

Com-P-Tense Germany, Germany

Dr. Sergej Nazarenko

Estonian Nuclear Medicine Society, Estonia

Prof. Juan Carlos Negrette

University of Utah - Health Sciences, USA

Lucy Nugent

Tallaght University Hospital, Ireland

Dr Reem Osman

Saudi German Hospital Group, UAE

Dr. Taner Özcan

MLPCare, Turkey

Prof. Hacer Özgen Narci

Istinye University, Turkey

Prof. Josep M. Picas

WAdaptive HS, Spain

Prof. Piotr Ponikowski

Clinical Military Hospital, Poland

Prof. Silvia G. Priori

University of Pavia, Italy

Dr. Donna Prosser

Vizient, USA

Mike Ramsay MD

Patient Safety Movement Foundation, USA

Prof. Amiran Revishvili

AV Vishnevsky Institute of Surgery, Russia

Prof. Denitsa Sacheva

National Parliament, Bulgaria

Prof. Massimo Santini

San Filippo Neri Hospital, Italy

Prof. Elisabeth Schouman-Claeys

European Standardisation Organization, Belgium

Prof. Ernst R. Schwarz

Cedars Sinai Medical Center, USA

Prof. Valentin Sinityn

Moscow Lomonosov State University, Russia

Prof. Karl Stroetmann

University of Victoria, Canada

Jean-Pierre Thierry

Synsana, France

Prof. Dan Tzivoni

Hebrew University Hadassah Medical School, Israel

Prof. Alex Vahanian

University Paris-Descartes, France

Prof. Vlastimil Valek

Masaryk University, Czech Republic

Prof. Wilfried von Eiff

Uni Münster, Germany

Prof. Pascal Verdonck

MEDIVA, Belgium

Dr. Rafael Vidal-Perez

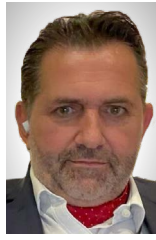
Hospital Clinico Universitario de A Coruña, Spain

Diane Whitehouse

EHTEL, Belgium



Stephen Lieber
Editor-in-Chief IT
 Chief Analytics Officer, College of
 Healthcare Information Management
 Executives (CHIME), USA
sl@healthmanagement.org



Christian Marolt
Executive & Editorial Director
 HealthManagement.org, Cyprus
cm@healthmanagement.org

Industry Ambassadors

Alper Alsan
 Siemens Healthineers, Germany
Chiara Cavallo
 Russels Reynolds, France
Dan Conley
 Beacon Communications, USA
Prof. Okan Ekinçi
 Roche, USA
Prof. Mathias Goyen
 GE Healthcare, Germany
Dr. Rowland Illing
 Amazon Health Services, USA
Alessandro Roncacci
 Affidea, Netherlands
Christina Roosen
 Dedalus, Spain
Gregory Roumeliotis
 Orgenesis, USA
Dr. Jan Schillebeeckx
 Meerkant, Belgium

Regional Ambassadors

Dr. Thomas Kaier
 King's College London, UK
Dr Charles Kamotho
 The International Clinic, Kenya
Dr. Mahboob Ali Khan
 Private Healthcare Providers, KSA
Mercedes Puente
 Renovatio Biomédica, Portugal
Dr. Nadya Pyatigorskaya
 Pitié Salpêtrière Hospital, France
Andreas Sofroniou
 Limassol General Hospital, Cyprus
Dr. András Vargha
 National Centre for Patients' Rights, Hungary
Rita Veloso
 University of A Coruña, Spain

Team

CM (Christian Marolt)
 Executive Director cm@healthmanagement.org
Anastazia Anastasiou
 VP MarCom aa@mindbyte.eu
Iphigenia Papaioanou
 VP Customer Experience ip@healthmanagement.org
Katya Mitreva
 VP Client Service km@healthmanagement.org
Neovi Lenou
 Client Service Director nl@healthmanagement.org
Samna Ghani
 Senior Editor sg@healthmanagement.org
Prof. Hans Blickman
 Senior Editor hb@healthmanagement.org
Tiffany Hionas
 Staff Editor th@healthmanagement.org
Evi Hadjichrysostomou
 Creative Director
Andreas Kariofilis
 Head AudioVisual studio@mindbyte.eu
Natalia Sokolova
 Social Media Manager
Tania Farooq
 Communication Assistant
Sandip Limbachiya
 Head of IT
Mahjabeen Ahmed
 Communications Assistant
Sergey Chygrynets
 Front-end Developer



EU Office:
 Rue Villain XIV 53-55
 B-1050 Brussels, Belgium
 Tel: +32 2 286 85 00
brussels@mindbyte.eu

EMEA & ROW Office:
 166, Agias Filaxeos
 CY-3083, Limassol, Cyprus
 Tel: +357 25 822 133
emea@mindbyte.eu

Headquarters:
 Kosta Ourani, 5 Petoussis Court, 5th floor
 CY-3085 Limassol, Cyprus
hq@mindbyte.eu

[@HealthManagement.org](https://www.facebook.com/HealthManagement.org)
[@ehealthmgmt](https://twitter.com/ehealthmgmt)
[HealthManagement.org](https://www.linkedin.com/company/HealthManagement.org)
[healthmanagement.org](https://www.youtube.com/channel/UC...)

HealthManagement.org is a product of





Spotlight

Latest Advances in MRI

State-Of-The-Art uMR Omega™ Installed in IRCSS Sacro Cuore Don Calabria Hospital



The IRCSS Sacro Cuore Don Calabria Hospital exterior photo

Thanks to a partnership with FORA S.p.A., United Imaging Healthcare's first OMEGA uMR is now present in Europe. The uMR Omega™, the first ever 75cm, Ultra-wide-bore 3.0T MRI, has been recently installed in the world-renowned IRCSS Sacro Cuore Don Calabria hospital. Since the hospital's establishment in 1922, this impressive 549-bed institution has been the Veneto Region Medical Reference Centre for Tropical Diseases, Radiotherapy, Nuclear Medicine, Ob-Gyn, Orthopaedics, and Ophthalmology, routinely providing medical, surgical, intensive care, paediatric, and rehabilitation services to the north Italian population. Being at the forefront of scientific advancements, the hospital was recognised as a leading research institution in the field of Infectious and Tropical Diseases.

Aiming to improve patients' comfort during the MRI exam, as well as offer the highest image quality and scan speed, United Imaging came up with a unique design reflecting the latest advances in MRI technology. Thanks to the combination of ACS (Artificial Intelligence Compressed Sensing) and DeepRecon technologies, the time of the MR examination can be reduced even by 70%. The 75 cm ultra-wide bore offers patients 25% of additional space with a unique starlight environment, not only increasing the overall comfort but also minimising the potential risk of a panic attack in claustrophobic patients. Taking into consideration every detail, United Imaging introduced next-generation ultra-flexible soft RF Coils to offer patients a blanket-like feeling.

In order to make cutting-edge MRI imaging widely

available, the IRCSS Sacro Cuore Don Calabria hospital decided to rely on the uMR Omega™ for its ultra-wide construction. As a result, the hospital could offer the MRI for a larger number of patients without excluding any specific populations, therefore setting an equal standard of diagnosis for all.

From the highest-quality imaging facilitating the diagnostic process, through the option of intraoperative use, to radiotherapy planning of unprecedented precision, the uMR Omega™ offers limitless possibilities to doctors. The vast space attributable to the wide construction opens up new ways of patient positioning, considerably expanding diagnostic potential for joint examinations, large patients, and pregnant women. The diagnostic process has been significantly improved through the development of higher-density coils, which allow for the hyper-resolution MR imaging of the musculoskeletal system or Ultra-short echo time (UTE) MR imaging in Pulmonary Metastases from Liver Cancer.

Recognising the value of artificial intelligence, United Imaging introduced the ACS (AI-assisted Compressed Sensing) to best balance speed and image quality, combining CS (Compressed Sense), HF (Half Fourier), and PI (Parallel Imaging). Moreover, the reconstruction procedure is supported by a state-of-the-art deep-learning neural network.

Besides an approximately 97% reduction in acoustic noise, the Qscan, coupled with AI technologies such as ACS and DeepRecon, offers whole-body quiet scanning with no sacrifice of the scanning time and brings it into a clinical setting for the first time. As a result, radiologists are provided with higher acceleration levels for MRI imaging and better depiction of small anatomical structures, allowing them to conduct rapid breast MRI, rapid whole spine scans, high-resolution MSK, or, in the case of brain MRIs, greatly facilitating the diagnosis of acute cerebral infarction.

Fully integrated within MRI bore and unobstructed by clothing, the Dual-Source Millimeter Wave Radar is the industry's first dual-source phased-array millimeter wave radar solution for contactless sensing of patients' respiratory motions that renders the need for a respiratory belt obsolete. This pioneering technology empowers the free-breathing renal non-contrast enhanced MRI or free-breathing liver MRI.

The uMR Omega™ has been designed to address the evolving patient and doctor needs, which can be fully satisfied due to many quantum leaps in MRI technology over the last couple of years. Already improving the standard of care in the IRCSS Sacro Cuore Don Calabria hospital, the uMR Omega™ has the mission of making advanced imaging modalities widely available. ■



uMR Omega with the IRCSS Sacro Cuore Don Calabria medical team

Mindray Resona R9 Platinum Edition – A new leap for precision ultrasound

Powered by ZONE Sonography Technology, this state-of-the-art Resona R9 takes clinical intelligence to new heights, providing a complete solution for both diagnostic and interventional ultrasound needs.

Designed to streamline workflow and ensure consistent and accurate results, the Resona R9 offers advanced intelligent tools such as high frame rate CEUS, high frame rate STE, uHIT, iFusion, VFlow, and UMA in general imaging, Smart Breast, and Smart HR for obstetrics and gynecology applications. With these features, clinicians can confidently diagnose and manage routine and advanced studies in various clinical environments.

Additionally, the Resona R9 offers the innovative multi-parametric assessment solution, providing even more clinical advantages. With all these features, the Resona R9 provides a comprehensive solution for precision ultrasound diagnosis.

Experience cutting-edge ultrasound technology and enjoy a better user experience with Mindray at **EUROSON 2023**. Visit our **Booth S4** to discover how the **Mindray Resona R9 Platinum Edition** can help you elevate clinical intelligence and improve patient care.

Powered by **ZST+**





Cover Story

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

Effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, even more so in the age of medical devices that are enabled by machine learning.

ANITA SANDS



Regulation and Prequalification Department,
World Health Organization, Geneva

key points

- Without medical devices, many critical healthcare procedures would not be possible.
- WHO provides guidance to its Member States on how to regulate medical devices to ensure access to latest technologies, while minimizing risk of harm to patients and device users.
- Collectively, WHO and other regulators are seeking to ensure that machine learning-enabled medical devices are monitored quality, safety and performance throughout the life cycle.

Agnes Kijo | Regulation and Prequalification Department | World Health Organization, Geneva
Agnès Leotsakos | External consultant | World Health Organization

Introduction

Medical devices are essential in carrying out various healthcare procedures, including diagnosis, prevention, monitoring treatments, supporting people living with disabilities, and intervening in and treating of acute and chronic illnesses.

Medical devices are used in diverse settings, from personal use at home, to advanced medical facilities, or remote (small) clinics where healthcare professionals and clinicians' practise. Without medical devices, many critical healthcare procedures would not be possible. Currently, there are an estimated two million different kinds of medical devices on the world market, categorised into more than 22 000 generic devices groups. Such diversity underscores the need for freely accessible global nomenclature for medical devices (WHO Executive Board 2019).

Effective regulatory systems are an essential component of health system management and contribute

to better public health outcomes.

While national authorities have been regulating medicines for the past 70 years, the regulation of medical devices began 30 years later.

The objective of regulating medical devices is to ensure that patients have access to safe and effective medical devices of high quality, while also preventing products that offer limited clinical benefits or pose a safety risk from entering the market. Medical device regulation requires stakeholders (manufacturers, importers and distributors) to meet the requirements set down by regulatory authorities based on internationally recognised standards.

However, with the increasing digitalisation of healthcare through machine-learning-based medical devices (ML/MDs), traditional models of change assessment and post-market surveillance present some new challenges. Despite these challenges, the principles of medical device regulation still apply to ML/MDs when

they have a medical purpose (IMDRF 2023).

Many low- or lower-middle-income countries lack the resources, awareness, and commitment required to successfully transition from an unregulated market to a basic medical device regulatory framework. To this end, WHO implements various strategies to facilitate national and regional efforts to regulate medical devices.

to take enforcement actions – then progresses to expanded-level regulatory controls – such as inspection of registered establishments and oversight of clinical investigations.

Not all countries will be able to move at the same pace or devote the same levels of resources, systematic assessment and continued progress in this area. Over time, however, this will lead to greater public confidence

Delivering quality-assured medical products for all: WHO's five-year plan (2019-2023) to help build effective and efficient regulatory systems.

WHO Support for Regulation of Medical Devices

Effective regulatory oversight is a critical requirement for ensuring that products in the market continue to be of good quality, safety, and appropriate performance throughout the lifecycle from pre-market, placing on the market, to post-market and disposal or decommissioning.

However, regulatory authorities can be constrained in terms of resources, awareness, commitment and priority setting, which means legal provisions, guidelines, and/or procedures for medical devices can be inadequate. WHO supports regulatory authorities and manufacturers to ensure quality, safety and performance of medical devices through many activities.

WHO's work on regulation and safety priorities are based on a strategic plan entitled "Delivering quality-assured medical products for all 2019-2023: WHO's five-year plan to help build effective and efficient regulatory systems" (WHO 2019).

The **WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices (GMRF)** recommends guiding principles and uniform definitions and specifies the elements of effective and efficient regulations to be embodied within binding/enforceable national laws.

Many countries have neither the financial resources nor the technical expertise to move from a minimally regulated market directly to one with a comprehensive medical devices law and regulatory controls. The GMRF recommends instead a stepwise approach to regulating the quality, safety and performance of medical devices. This staged development starts from basic-level regulatory controls – such as the publication of the law, import controls, and resourcing the regulatory authority

in the regulation, as well as safety, performance and quality of medical devices including in vitro diagnostics (IVDs) used in health systems.

WHO Good Regulatory Practices help regulators to execute core regulatory functions, by leveraging the competencies of policymakers, procurers, distributors, clinicians, patients and consumers. WHO Good Reliance Practices also describe the various models of work-sharing, recognition, and reliance that may be leveraged (WHO 2021).

To evaluate the strengths and weaknesses of their regulatory systems, national authorities can use **WHO's Global Benchmarking Tool**, recently adapted for medical devices as the GBT + medical devices (WHO). The evaluation findings from GBT can be used to create plans for institutional development of regulatory system.

To assist countries adopt reliance principles for regulation, **WHO Prequalification (PQ)** can provide relevant information on products. While not used for regulatory approval, PQ offers governments and international aid agencies valuable information for procuring medical products from an approved list that has been evaluated by subject matter experts.

Further information about WHO assessment of a particular device can be found in the WHO prequalification public reports (WHO).

WHO's Support to Detect Substandard and Falsified Medical Devices

The vast majority of medical products globally circulate in markets with insufficient regulatory oversight to assure the quality of medical devices and prevent or detect the distribution of substandard/falsified medical devices.

WHO's strategy to **control substandard and falsified medical products** involves a three-pronged approach:

prevent, detect, and respond.

It is critical to empower users and patients to document the first sign that a device may be responsible for harm. Any health facility that uses medical devices should have a user feedback form available to all staff and a process to ensure the manufacturer (or their local authorized representative) is informed as soon as possible about a device failure or malfunctioning. Hospitals and other health facilities are likely to have their own systems for ensuring patient safety which can interface with medical device incident reporting for detection of substandard/falsified devices.

A crucial aspect of ensuring the quality, safety, and performance of medical devices is **post-market surveillance (PMS)**. This is a set of activities conducted by manufacturers to continuously monitor the quality, safety and performance of medical devices throughout their lifecycle (ISO). Manufacturers gather and analyse data from user feedback (through complaints, technical support calls-outs, maintenance, installation, user training), scientific peer-reviewed scientific literature, and publicly available regulatory sources.

Users in health facilities, hospitals, diagnostic centers, and community clinics should report any device-related incident such as mortality or morbidity, involving the user or other person, or any deterioration or malfunction of a device to its manufacturer.

In turn, there are certain categories of incidents that must be reported by the manufacturer to the regulatory agencies, including incidents that caused harm or might have cause harm.

As part of the post-market surveillance analysis, manufacturers may need to undertake correction (fix the problem now), corrective action (prevent the same problem recurring) or preventive actions (prevent a problem from occurring in the first instance) to address reduce risks to patients, and users. From their perspective, regulatory authorities must take appropriate regulatory actions if manufacturers' investigations or actions are inadequate or implement their own market surveillance activities, including trending of incidents. This includes overseeing any corrective actions taken by the manufacturer in the field, with the ultimate goal of safeguarding the interests of consumers and patients as part of the response to substandard or falsified devices.

WHO guidance and other internationally recognised standards encourage harmonised reporting to enhance data analysis for trends, and sharing of field safety notices in the public domain by regulators for users in healthcare facilities to freely access (WHO 2020; IMDRF please replace with:

WHO guidance and other internationally recognised standards encourage harmonised reporting to enhance data analysis for identifying trends. Additionally, they encourage the sharing of field safety notices by regulatory authorities in the public domain, ensuring that healthcare facilities and users have unrestricted access to this valuable information (WHO 2020; IMDRF 2020).

The **WHO Global Surveillance and Monitoring System (GSMS)** ([WHO Global Surveillance and Monitoring System](#)) works with regulatory authorities and other key stakeholders to improve the quantity, quality and analysis of data on SF medical products, and to use that data in the better prevention, detection and response to SF products, to protect public health. Its current scope includes medicines, vaccines and IVDs and certain medical devices listed by WHO. To date, all incidents for WHO prequalified IVDs are reported into GSMS, primarily by their manufacturers, any current field safety notices are displayed on the WHO's website (WHO 2023).

WHO is also currently assessing the need for a freely accessible global database of field safety notices for all medical devices for their users.

Regulation of Machine-Learning Enabled Medical Devices

Machine learning (ML) is a subset of artificial intelligence (AI). AI uses algorithms or models to learn, make decisions and make predictions. Machine learning allows ML models to be developed by ML training algorithms through analysis of datasets to identify patterns without models being explicitly programmed to do so.

Medical devices can make use of ML to achieve their intended use.

If a ML product meets the definition of a medical device, it is considered to be a Machine Learning-enabled Medical Device, or ML/MD and would be regulated as such. Typically, algorithms tend to be "locked" and don't change unless the regulators assess and clears any change. ML/MDs tend not to be "locked" and will continuously be updating the model. Therefore, traditional methods for change assessment of medical device in the post-market phase and post-market surveillance need to re-considered.

Regulators are aiming to converge their regulatory requirements for ML/MDs. Most recently, the **International Medical Device Regulators Forum (IMDRF) published Machine Learning-enabled Medical Devices: Key Terms and Definitions** (IMDRF 2022). A new IMDRF item is proposed for Good Machine Learning Practice (GMLP) to provide internationally harmonized principles to help promote the development

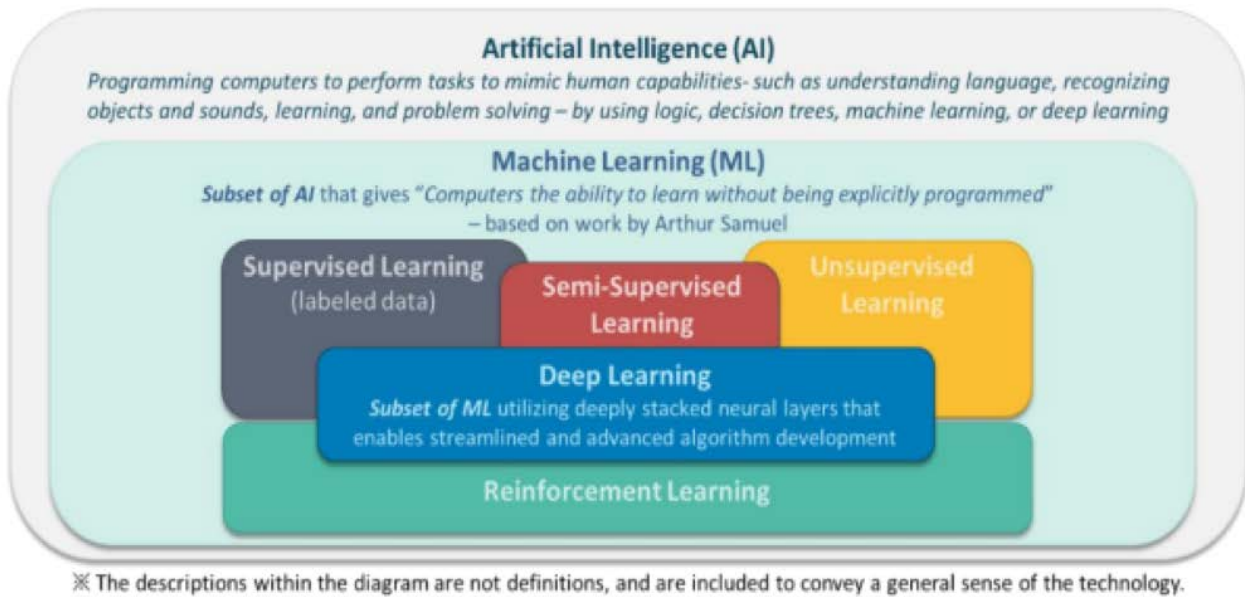


Figure 1 Overview of AI and ML Concepts, adopted from IMDRF, Machine Learning-enabled Medical Devices (IMDRF 2022).

of safe and effective ML/MDs.

ML/MDs have the potential to address poor access to quality services for prevention, treatment and care, and lack of specially trained health personnel by leapfrogging current medical devices that require visual interpretation of results.

This has been applied for medical imaging, breast cancer screening and gastrointestinal endoscopy. Through its various departments, WHO has developed guidance for how ML/MDs might be used for cervical cancer screening and computer-aided diagnosis of tuberculosis (WHO 2021; WHO 2021) WHO guidance is forthcoming on regulatory concepts on artificial intelligence for health (Naher et al. 2023; Oala et al. 2021).

Conclusion

ML/MDs are recognised as having the potential to improve health outcomes in settings where limited resources and a shortage of specialised healthcare professionals limit access to medical devices. Once any device with machine learning is used for a medical purpose, it becomes a medical device and therefore falls within the purview of the medical device regulatory system. Anticipating the need for refinement of existing regulations to handle the nuances for ML/MDs, WHO aims to provide guidance and support to its Member States on how to assure the quality of ML/MDs and monitor their quality, safety and performance throughout the life cycle.

Conflict of Interest

None. ■

references

For full references, please email edito@healthmanagement.org or <https://ii.hm/1ku5>.

Improving the Regulation of Medical Devices and Artificial Intelligence

Stephen Gilbert, Professor for Medical Device Regulatory Science at the Else Kröner Fresenius Center for Digital Health at Dresden University of Technology, spoke to HealthManagement about the need for improved and balanced regulation of medical devices and artificial intelligence, and what can be expected in the future.

STEPHEN
GILBERT



Professor of Medical Device Regulatory Science,
Else Kröner Fresenius Center for Digital Health,
Technische Universität Dresden, Germany

What is your stand on the need for better regulation of AI and machine learning medical tools?

It is, like always, a question of balance between old habits and new approaches.

A lot of the regulation that exists at the moment was not designed with AI or even modern software development practices in mind, and in our case, it was developed around implant technologies primarily. With the amount of time dedicated to designing a new hip implant and the critical importance of the materials and the mechanical functioning an implant, there had to be a very tight control of every component that goes into it and for every revision of that device.

There's a question of finding that balance with new technologies which are infinitely more adaptive by their nature.

You could take an extremist perspective and some very traditionally minded people within the regulatory space do that. They may say there needs to be a very, very tight control in the versioning and consequently the update cycle should be incredibly slow.

We're talking years, as exemplified by a hip implant, because patients are involved and oversight takes time; and there is a need for extreme caution.

However, in my mind there needs to be balanced caution. The way you should approach software is actually to allow feedback loops and to listen to and

react to data about how your product is used and how it is performing; to record and measure that performance as close to real time as possible, and then to allow the adoption of that software as close to real time as possible because software can be adapted very quickly.

If you're operating in a system where you have no feedback on the performance, on what basis are you modifying software? How do you know that it is functioning correctly? The extension of that from software to AI is the same argument.

It is not a question of not having a balance. It is not a question of saying we need to monitor exactly as we do with a hip implant and a hip replacement joint. It is not about finding a middle ground exactly. Instead, it is about finding a new ground, new approaches, new methods and new ways of monitoring.

Underregulation leads to: “insufficient oversight, irresponsible manufacturers paying insufficient attention to safety, and patient harms” (Gilbert et al. 2023) However more careful regulation can limit the availability of essential or lifesaving materials or products. How can this imbalance be avoided?

The feedback loop is about a device which is on the market. It could be an AI device or software device and how you feedback from the doctors and the patients or how that's performing. It all comes down to the design of

the device.

It is similar to the regulatory system, whereby there are feedback loops, but they don't function very well, and function very slowly. There is a need for them to be more reactive and less antagonistic in many ways.

Maybe it is the case that the regulator always feels attacked and they respond to that by asserting their authority.

There needs to be a better listening approach from regulators. However at the moment, under frameworks for assessing regulation, regulators and legislators think that they only need to produce a report that shows that the regulation is working well.

In the U.S. they have several of the leading universities linked within a program with the FDA. So the likes of Stanford and Harvard and others are carrying out data led research that really is starting to make a difference in the U.S. They are responsible for feeding data in, for studying, and actually identifying the new problems or new technologies regarding it. They are exploring the innovations that are about to come in the pipeline.

There are the innovations that scientists are delivering that the regulatory system can't yet cope with. Consider new types of cells in personalised cell therapies, new types of AI like large language models, all of which could deliver a potential benefit to patients.

How should that be regulated? It is not a question of how it should be stopped or how it should be enabled, but it is about how it should be addressed in a holistic manner, considering the aspects of patient safety, and considering the potential for patient benefit. So it is a question of how to pay closer attention to this. Now, this is harder within Europe because Europe has many member states and a very complicated governing structure, whereas a country such as the UK, Switzerland or Japan that is not subject to union oversight has the advantages of being a single system.

But it does not mean oversight cannot be done in a European setting. It is a question of having the will to do it and setting up systems to do it.

They say that medical malpractice and medical harm is huge. Will the fear/risk of malpractice be addressed, i.e., if AI 'helps' in medical decision making?

The overall question for health care systems is building an oversight approach for AI and other health software. It's not only a question of AI, but it is about ensuring the systems are not blocking progress or blocking advances towards rational and sensible approaches for oversight.

There are a few really interesting proposals in the U.S. side of regulation that are not yet fully in force for introducing oversight mechanisms or reactive

oversight mechanisms within larger hospital groups – this is not for the individual hospitals - but for the payer systems (larger ones) where there's an impact assessment before new technology is introduced. It is our fundamental responsibility to assess AI when it's introduced and even its interaction with other areas.

Regarding medical malpractice, there is a very large potential for decision support algorithms to reduce malpractices by enhancing the decision-making capabilities of clinicians and healthcare institutions.

Unfortunately, malpractice can go in a number of different directions. In certain types of health care systems, concerns about malpractice liability increases interventions and it can be an incentive to over-treat. There can be a financial incentive through profit, but it can also be an accidental incentivization through bad design of the pricing system. Medical malpractice can occur if a doctor makes an error because of substandard treatment, as a result of their fatigue and burnout. AI does not get fatigued, and costs a lot less and may be very valuable to augment clinician decision making, if correctly introduced.

Malpractice fear, as always, is the thought of have I done enough? The support algorithms have the potential to assist, if developed and implemented correctly, in providing a degree of back up to the doctors. Within a European setting, all of these would be classified as medical device areas. If they're providing decision support, they're much more tightly regulated.

However, there is certainly potential if AI is correctly applied in this area, to be considering patient needs, the health care system needs, and the doctor needs.

AI should not be considered as a single tool, but holistically across the range of tools that are introduced to enhance the workflows within hospitals, in order for there to be real benefits in this area.

Can you explain how the FDA approach to the introduction of AI-based DHT's regulation is different to that of the European Union?

There are two critical aspects which are different: the first includes oversight over medical devices which are introduced into the U.S. or which may not even arrive depending on the political progress, and the second aspect is this question of monitoring change. The latter comes under the relatively technical title of change control plans or periodic change control plans. In the UK, they're approaching this as an approach for general medical software, not only AI-based software.

We're talking about adaptability in a kind of batch sense where an AI company and a medical device developer can actually update on the basis of received

data and updated data. Their tool can better provide care and will be more enhanced with providing decision support for patients.

Europe does not have this adaptive system for AI-enabled medical devices. It has some very early discussions of such a system, but these are still some way off.

The U.S. will allow a lot of non-critical AI, in the area of broad decision support, to be outside medical device regulation. These tools use AI tools to interpret data and to make diagnostic and treatment recommendations to doctors, based on patients real-time records, use AI to improve EHRs, and to help in decision support including in a non-emergency situation. In this scenario, it creates a situation where the doctor can better and more safely make a critical decision; AI can allow that providing certain safeguards are built in.

In order for it be counted as a 'non-device' and not to be under the close scrutiny of the FDA, manufacturers need to have an approach where their AI is explainable. It must be explainable for the doctor and explained to the doctor. This is the single most transformational difference between current European approaches and U.S. approaches to the regulation of AI in medicine and digital health in general.

The basis on which the AI make their recommendations has to be made clear to the doctor, and the evidence of those decisions has to be made clear to the doctor. Additionally, the interface needs to be designed so that it does not lead the doctor to stop thinking.

There is an enormous amount of freedom gained from having support systems that are flexible to adapt without change-by-change regulatory oversight. We are already seeing the impact of that in an ecosystem of decision support built around the EHR system in the U.S. There are many plug ins and tools, and support services for doctors which are built holistically from many providers and sometimes from the big electronic health system providers themselves.

I believe the right approach needs to be a wave of innovation because there is an absolutely clear need within our health care systems and patients to want these types of tools.

Who do you think should be the final arbiter to ensure a product safety and as well that's unbiased and sufficiently powerful that it doesn't cause harm?

I do believe the U.S. program has the balance approximately right.

The U.S. overall approach is to split non-device and device tools and to ensure the companies have a responsibility to stay within the scope of what is device

and what is non-device.

The FDA have a responsibility to police those boundaries. Where a company states they are doing something which is a non-device category and they are not, it is the responsibility of market surveillance to oversee this, and in this case, it is a responsibility of the FDA.

The low level or intermediate level of support that is provided by these decision support tools to doctors requires the responsibility of a doctor to ensure the basis of information and evidence provided is reliable. It is not a question of simply making a decision. There is a critical responsibility for doctors, and that is understood within the design of the U.S. program.

There is a responsibility for the health care system to ensure that what they are introducing works with their staff: to make sure that their staff are trained to use it, and to make sure that they're overseeing what systems are in place in their hospital from a holistic view. There is a U.S. Act of Congress called the Algorithmic Accountability Act which would formally bring in responsibilities for hospital systems and for medical device developers if it was introduced in law.

The responsibilities in the U.S. system are very clear regarding the FDA needing to approve the products. The manufacturers have a responsibility or requirement to produce evidence for the safety and performance of these tools. In Europe, we have a situation where almost everything is under tighter control than the programme than the U.S. will have.

Will AI help or hinder staff particularly as they are overtasked already (burn out)?

AI has the potential to make everything worse but it also has the potential to make everything better, and we will probably see a balance.

There are very few people who are calling for no regulation whatsoever within the health care space. You may see a very small number of entrepreneurs who have a very short term, selfish perspective, - they are simply eager to bring their products onto the market. However, there are not many within the public or political scene that would say the health care system should not be a regulated space.

At the moment, medical device regulation has a focus on the individual device. However, that does not work particularly well when you're considering digital systems and interacting digital systems, and when you're considering a transformation of the workflow within the health care system for the patient, the doctor and the interaction between doctor and patient.

That needs a much wider consideration of how the overall systems are working within hospitals. At the

moment, there is so much stress on hospital systems and hospital managers in most countries. In most of Central and Western Europe where we are monitoring or trying to improve or cope with the provision, it's proven to be very challenging because the staff are always in a situation of extreme stress.

In my view, the introduction of AI technologies needs to be considered from a whole system approach rather than from an individual technology perspective.

I'm personally relatively optimistic because I believe countries will increasingly start to realise that transformative AI and software technologies are in the pipeline. As more are shown to be safer and further developed, I believe there will be a realisation that the processes to oversee the good introduction of these is to be taken seriously.

How do you envision the post-Brexit regulation will be different to that of the U.S. and EU?

The UK does plan to introduce approaches like the U.S. in terms of the algorithm change. They have an ambitious program, which may come later, that will be extended to general health software, and not only for AI based software. That will be transformative in the UK.

The UK is in an interesting position. They cannot act like Japan or the U.S, so I see them having some innovation but then always being held that they effectively have to be very similar in their regulations to Europe.

UK is not a huge manufacturer of medical devices and software medical devices compared to other countries, but their export market to Europe is very important. Therefore, they have to stay close to EU regulations.

However, a much larger challenge in the U.S. is determining whether clinical decision support is considered a device or non-device.

The FDA have traditionally been very fast to respond whereas the European regulation regulators are, in the experience of many within the industry, very slow to respond to questions, particularly in the period of the introduction of MDR. There is sometimes a reluctance to answer questions quickly and sometimes notified bodies are so busy, or there not enough regulatory bodies to approve individual devices.

Additionally, with the new regulations, there is a restriction on the ability of those notified bodies to actually give any feedback and that's been deliberately introduced in the regulations.

I believe the most important aspect for the digital area is this holistic consideration of the interaction of many tools, devices and approaches within our modern and developing health care system. This is something which is addressed in the most interesting way within the draft U.S. legislation, the Algorithmic Accountability Act, where oversight is not only provided by the medical device regulator, but it's also by the hospital system - the hospital regulators, thus by all of them together.

How much do you think the GDP regulations are actually in contrast with the needs of medical technology development regulations?

There is a transformative act (the European Health Data Space proposal) which is being discussed on a European level which would actually bring in approaches to allow patients to have access to the electronic health record. They will be able to access their record and download it, and that means they'll be able to run their own algorithms on it. They may soon be able to pay for services, that it can be provided at low cost, which will assess how their health care has been provided. They will also be able transfer their electronic health record between European countries.

Under the European Health Data Space it is likely that patients will have an opt out as to the use of their data for wider research purposes after anonymisation. In Germany there is likely to be a specific opt out approach where patients can opt out of different types of use. The evidence is that sufficient patients would remain opted in which would allow data to be collected for the purpose, for example, of post-market surveillance of medical devices or the surveillance of the health care efficiency of delivery, whilst simultaneously protecting patients' rights through the ability to opt out.

My strong belief is that this can be done with the public and with patients, explaining to them that they can opt in to sharing their data for public good, particularly as another aspect of the changing of health care systems is that health care is increasingly moving to the patient's home.

Conflict of Interest

Stephen Gilbert is an advisor/consultant for Ada Health GmbH and holds share options; has consulted for Una Health GmbH, Lindus Health Ltd, FLO Ltd and Thymia Ltd..

references

Gilbert S et al. (2023) Learning From Experience and Finding the Right Balance in the Governance of Artificial Intelligence and Digital Health Technologies J Med Internet Re.25:e43682

Standards in Support of the EU Medical Devices Regulations

The use of harmonised standards in support of the Medical Devices Regulations (MDR & IVDR) is a proven and trusted way to ensure compliance, quality, safety and efficiency of products, production processes, management systems, services and test-methods. They are developed as per the EU request to the European Standardisation Organisations (CEN & CENELEC) and cited in the Official Journal of the EU.



ELENA
DEMOSTHENOUS

Cyprus Organisation for Standardisation (CYS)
CEN Technical Board Member
Standards Officer
ISO TC 304 Healthcare Organisation Management Expert
Cyprus

key points

- European and International Standards are widely used in all sectors of economic and industrial activity, including the healthcare sector.
- Standards frequently are developed in response to market needs and assist with legislation gaps, thus the whole process is usually market driven and enhances free trade.
- The new European Regulations 2017/745 on Medical Devices (MDR) and 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) aim to ensure a robust, transparent and sustainable regulatory framework, and maintain a high level of safety while also supporting innovation.
- Using harmonised standards, is a proven way of ensuring that medical devices placed on the market comply with the regulations and are thus safe.
- The European and International standard EN ISO 13485:2016 “Medical devices - Quality management systems - Requirements for regulatory purposes” helps manufacturers comply with the requirements of the regulations regarding the implementation of a quality management system.

Useful Tools to Help Achieve MDR and IVDR Compliance

European and International Standards are widely used in all sectors of economic and industrial activity, including the healthcare sector, on which several active technical standardisation committees.

These standards are voluntary and define requirements and/or guidance regarding products, production processes, management systems, services or test-methods, ensuring quality, safety and efficiency.

They are trusted and appreciated worldwide, and as such, the European Commission uses them to assist manufacturers and economic operators to comply with EU regulations and eliminate barriers to trade.

Upon reflection, one could ask why? Why are standards so important?

As ISO, the International Organisation for Standardisation claims in one of its most popular quotes, “Great things happen when the world agrees!”. This is what standardisation is all about. It is a process based on very important principles such as consensus, transparency, accessibility, integrity, efficiency, and coherence in at the European and international level. Both International (ISO & IEC) and European (CEN & CENELEC) Standardisation Organisations, develop standards based on the above principles, with the voluntary participation of experts around the world, nominated by their members, the National Standards Bodies (e.g., BSI in the UK, AFNOR in France, CYS in Cyprus).

Additionally, across Europe all National Standards Bodies are governed by the European Regulation

1025/2012 and apart from developing and promoting the use of standards, they have the responsibility of managing the national standardisation system and participating in European & International Standardisation.

Standards usually are developed in response to market needs and assist with legislation gaps, thus the whole process is usually market driven and enhances free trade.

Removing barriers to trade was one of the main reasons why, back in 1985, the EU New Approach Directives

26th May 2022 respectively. The transitional provisions are defined in Article 120 of the MDR and Article 110 of the IVDR. However, further extensions on time of implementation are expected to be granted and for this reason the European Commission initiated a consultation concerning the extension of this transition period in January 2023.

In order to assist all relevant stakeholders in complying with the new Regulations, the European Commission issued a Standardisation Request (SReq) to CEN & CENELEC, which was accepted by their members,

Implementation of harmonised standards gives presumption of conformity to the essential requirements of the Medical Devices Regulations

were developed. Instead of specifying technical requirements, they laid down essential requirements, leaving it up to European standards to assist manufactures in complying with these directives. Then by citing these standards in the Official Journal of the European Union (OJEU), they evolve into Harmonised Standards.

Under the same philosophy, and in order to further improve this system, the EU has moved a few years ago to the New Legislative Framework, as a result of which the new European Regulations 2017/745 on Medical Devices (MDR) and 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) were developed. These new Regulations aim to ensure a robust, transparent and sustainable regulatory framework, and maintain a high level of safety while also supporting innovation.

As in the previous medical devices' directives, medical devices are classified according to their intended use and related risks, and different certification and registration requirements are set for each category. Additionally, the new regulations include several specific requirements for the economic operators of the supply chain of medical devices described in Chapter 1 in Article 2 (e.g. manufacturers, authorised representatives, importers, distributors), as well as notified bodies, expert laboratories etc. Also, the new regulations include requirements related to traceability, information provided by the manufacturer, as well as transitional provisions.

The new European Regulations 2017/745 on Medical Devices and 2017/746 on In Vitro Diagnostic Medical Devices have entered into force on 26th May 2021 and

requesting CEN & CENELEC to develop European standards in support of the regulations.

Once developed, these new standards are assessed prior to publication and, when published, they are offered to the European Commission for citation. It is important to note that compliance with harmonised standards is not compulsory (unless otherwise stated) and as per Article 8 of 2017/746 MDR, "Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof".

It is also important to note that the European Standardisation Organisations, which offer the standards for citation, cooperate very closely with the International Standardisation Organisations, under the Vienna Agreement (between CEN and ISO) and the Frankfurt Agreement (between CENELEC and IEC). This is achieved either through adoption of international standards or through development of standards in parallel.

In the healthcare sector and in relation to MDR and IVDR, most of the harmonised standards are based on or developed in parallel with ISO or IEC, leading to further coherence between European and international level.

All standards have a specific structure, however harmonised standards include some additional elements. More specifically, a harmonised standard typically contains:

- A European foreword providing the key references to the applicable EU legislation.
- The normative clauses, including scope, terms and definitions, technical methods, normative references etc.

It specifies requirements for a quality management system for organisations who need to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Implementation and certification of EN ISO 13185 can assist in the compliance with the Quality Management System requirements of MDR & IVDR

- One or more informative Annexes lettered Z (ZA, ZB,...,ZZ) describing the relationship between the clauses of the harmonised European Standard and the essential requirements of the legislation the standard aims to cover.

Finally, there is a standard, which, even though it is not harmonised yet, is very important in complying with the requirements of the regulations regarding the implementation of a quality management system by the manufacturers:

The European and International standard EN ISO 13485:2016 (+AC:2018+A11:2021) “Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)”.

In order to assist manufacturers, the standard also includes informative Annexes ZA and ZB which correlate the requirements of the standard with the relative requirements of MDR and IVDR.

Compliance with complex and demanding regulations can be challenging, both in large countries and economies but especially in smaller ones. Using harmonised standards, is a proven way of ensuring that medical devices placed on the market comply with the regulations and are thus safe, both for patients as well as healthcare professionals and others.

Conflict of Interest

None. ■

references

1. CEN-CENELEC (2023) Available from <https://www.cencenelec.eu/>
2. European Commission. Guidance – MDCG endorsed documents and other guidance. Available from https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
3. European Commission. Harmonised Standards. Available from https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
4. European Commission. Internal Market, Industry, Entrepreneurship and SMEs. Available from https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en
5. European Commission. Medical devices – transition period extension. Available from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13684-Medical-devices-transition-period-extension_en
6. International Organization for Standardization (ISO). Available from <https://www.iso.org/home.html>



Digital Transformation

Growing Pressures Driving the Shift to Healthcare Digitalisation

Digital and AI-driven technologies tangibly improve the effectiveness of healthcare delivery and access – whether holistic patient management, clinical productivity, or hospital site utilisation – all of which ultimately improves patient outcomes. Yet the sector faces financial challenges to acquire the clinical, care, collaboration and buildings technology required to make the digital transition complete. To boost the availability of capital with which to achieve digital transformation, the sector must therefore harness private sector finance to enable digital, commercial, clinical and sustainable transition.



**PENNY
PINNOCK**

Business Development Manager,
Siemens Financial Services (SFSF),
UK

key points

- Pressure is mounting for healthcare organisations to accelerate adoption of digital and AI-driven technologies – proven to deliver significant benefits to delivery of care, patient outcomes, and operational costs.
- However, the significant levels of investment required cannot typically be afforded through available healthcare capital budgets.
- Given the projected market growth and urgent need for investment, research from vendors like Siemens Financial Services, GE Healthcare, Samsung or Philips finds that specialist smart finance will play a crucial role in enabling the development and digitalisation of healthcare systems all round the world.

Introduction

In recent years, digital capabilities in healthcare technology have been shown to enable greater access and productivity, early diagnosis, and contribution to better outcomes in healthcare systems across the world.

Most healthcare organisations around the world have already embarked on digital transformation and are now looking at speed of implementation, along with providing evidence of tangible outcomes, to inspire budget holders and maintain momentum in their digital transformation journeys.

Although clinical benefits from digital transformation tend to be the first strategic targets of most organisations, the rising prices of supplies and energy are also focusing the minds of healthcare administrators on digitalisation to reduce costs in infrastructure and operations (European Commission 2019).

Digital Delivers Specific Benefits for Healthcare Organisations

According to academic (Elkefi & Asan 2022), governmental (HMI 2017), and analyst (McKinsey & Company 2021) commentators, the strategic approach to digital transformation is to establish a ‘digital thread’ running through healthcare organisations and systems. This allows digitalised capabilities to be seamlessly connected along the patient pathway, in order to achieve significant outcome improvements, clinical effectiveness, and hopefully, cost reductions.

An example of one of these digital capabilities is the use of new AI technology in healthcare. As one academic paper (Hosny et al. 2018) notes “Artificial intelligence (AI) algorithms, particularly deep learning, have demonstrated remarkable progress in image-recognition tasks... AI methods excel at automatically recognising complex patterns in imaging data

and providing quantitative, rather than qualitative, assessments of radiographic characteristics”.



Remote telesurgery is another digital capability rapidly growing in popularity. A recent study (Mohan et al. 2021) noted that while there remain some adoption obstacles, the pandemic experience shows value and viability of this remote technique. The study notes that, “Telesurgery or remote surgery is a promising surgical advancement... Zero-latency time and improvement in haptic feedback technology are required for precise and well-done surgeries. Technologies like 5G network, IoT, and tactile robotics should be integrated into telesurgery to overcome these barriers. Cost and legalisation to address legal and ethical issues remain to be addressed. Robotic surgery can demonstrate a pivotal role in the surgical procedures being performed in the... pandemic by minimising the number of surgical staff in the operation theaters, hence curtailing the risk of (COVID-19) infection that can contribute to higher morbidity and mortality”.

Additionally, **smart hospital buildings** offer improved patient experiences and outcomes, and at the same time deliver important cost savings and sustainability benefits. Equipping a hospital with an up-to-date



building management system can make the building’s operations more intelligent and energy efficient, leading to significant energy savings. In addition, built-in wastewater recycling and reclaimed water system can drastically reduce water consumption.

In the UK, the Milton Keynes University Hospital NHS Foundation Trust is piloting a solution that allows its hospital to create a digital twin of its building. This enables staff to access a huge amount of real-time data, such as room occupancy, the location of critical equipment, and even the status of paper towel dispensers in the bathrooms.



Enabling Urgent Investment

Not only are these technology investments important, they are also urgent.

In Europe, health ministers from all EU Member States have adopted the region’s first ever digital health action plan – an ambitious agenda that will leverage digital transformation in Europe and Central Asia with the aim of improving people’s health and well-being (World Health Organization 2022). The World Health Organization (WHO) highlights the requirement to “[r]ecognise the urgent need to address the major impediments faced by least-developed countries implementing digital health technologies”.

For healthcare systems the world over, enabling these investments makes a disproportionately positive contribution to efficiency and effectiveness in healthcare delivery, healthcare access, and patient outcomes (short-term and long-term, reducing the social cost of rising overall demand and lifetime healthcare costs).

Financing Digital Transformation

In general, investment in healthcare technology – and its projected growth over the next five years – is substantial, yet it cannot generally be afforded through available capital expenditure budgets in healthcare systems (The WHO Council on the Economics of Health for All 2021). This is the case both for aging equipment that



needs replacement and upgrading, as well as for newer technologies on the market whose benefits have only recently emerged.

Moreover, the healthcare sector is responsible for some 4–5% of global greenhouse gas emissions (Tennison et al. 2021) and therefore has a vital role to play in climate change mitigation efforts, which will not only result in substantial reductions in emissions, but can often lead to enhanced patient care, staff satisfaction, and cost savings (Tennison et al. 2021).

To boost the availability of capital with which digital transformation can be achieved, the healthcare sector therefore has to harness private sector finance to enable a digital, commercial, clinical, and sustainable transition. Private sector finance – usually from specialist financiers with a deep understanding of the technology and its applications – plays a crucial role in enabling the development and digitalisation of healthcare systems all around the world.

Smart finance, offered by specialist financiers, enables three key areas of technology investment: upgrade, net new technology, and smarter buildings.

These smart financing techniques are equally important for buyers and technology vendors alike. Buyers need an affordable and financially sustainable means of acquiring the equipment and technology they need to improve clinical efficiency, patient outcomes, cost optimisation, and smooth administration. Vendors need to leverage smart finance to make new technology more affordable and accessible for customers, manage cash flow, and offer a competitive value proposition to healthcare organisations.

Conclusion: The Urgency to Act Now

The need to refresh healthcare’s existing technology base goes hand in hand with the equally urgent need to acquire emerging digital technologies. The global COVID crisis is/was a harbinger: this crisis clearly demonstrated the value – in terms of both efficiency and patient outcomes – of digital transformation in the healthcare sector.

In light of these drivers of change, each month that

Case Study – Admiraal De Ruyter Ziekenhuis

Source: [Siemens Healthineers](#)

Admiraal De Ruyter Ziekenhuis (ADRZ) in the Netherlands is working with Siemens Healthineers in a 10-year-long strategic partnership that includes providing medical equipment, building works, financing, and management services. This collaboration has yielded and will continue to yield significant clinical, operational, and financial outcomes.

The partnership value at a glance:

- Design, construction, and leasing of six standardised operating rooms to improve quality of health services to patients
- Efficient primary care offered to roughly 248,000 people in the region
- 10% lower turnkey investment compared with conventional solutions
- Rapid availability of the new infrastructure (15 months from preparation to completion)

passes without progress on digital transformation is regarded by healthcare digitalisation pioneers as a month in which healthcare resources have not been efficiently deployed, people’s professional time has not been effectively managed, costs have not been optimised, and patient outcome improvements have not been implemented.

This transformation cannot be funded by public funds alone.

Private sector finance is playing a critical role in enabling the digital transition. Partnering with a smart solutions provider will allow healthcare organisations to achieve radical, data- and evidence-driven change through digital transformation – improving patient outcomes, reducing both immediate and lifetime healthcare costs, and deploying scarce clinical and care skills more efficiently and effectively.

Conflict of Interest

None. ■

references

Assessing the impact of digital transformation of health services (2019) European Commission, Luxembourg. Publications Office of the European Union. Available at: https://health.ec.europa.eu/system/files/2019-11/022_digitaltransformation_en_0.pdf

Countries in the European region adopt first-ever Digital Health Action Plan (2022) World Health Organization. Available at: <https://www.who.int/europe/news/item/13-09-2022-countries-in-the-european-region-adopt-first-ever-digital-health-action-plan>

Elkefi S and Asan O (2022) Digital Twins for Managing Health Care Systems: Rapid Literature Review. Journal of medical Internet research. U.S. National Library of Medicine. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428772/>

Financing Health for All: Increase, transform and redirect (2021) The Who Council on the Economics of Health for All. Available at: https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/who_council4a_councilbrieffinal-no2.pdf?sfvrsn=bd61dcfe_5&download=true

Health Innovation Week (2017) Health Management Institute of Ireland (HMI). Available at: <https://www.hmi.ie/wps/2017/10/health-innovation-week/>

For full references, please email edito@healthmanagement.org or visit <https://iii.hm/1ktc>



Digitisation for DSOs

Discover why dental support organisations must go digital and how they can do so.

Four guiding principles can help DSOs select and implement digital initiatives that result in optimised efficiencies, consistent treatment outcomes, and an improved experience for both patients and providers that fuels the stability and growth of organisations.



JOERG
AUMUELLER

Vice President and Global Head
of Enterprise Solutions,
Straumann Group

key points

- Digitisation is essential to the continued growth and stability of DSOs in an ever-changing industry, but the adoption and rollout of digital solutions must be done judiciously in order to provide a positive return on investment. (ROI)
- Instead of investing in new digital technology simply for the sake of being early adopters, DSOs should carefully evaluate their options and select solutions that address their organisation's unique needs.
- Careful communication with internal stakeholders and clinicians will help DSOs to ensure widespread support for the adoption and consistent utilisation of new technologies.
- The new software or equipment should facilitate, not complicate, the roles of clinical and administrative staff.
- To measure the ROI of a digitisation initiative, DSOs should determine in advance how they will assess the impact of the adoption of new digital technology.

Why Must DSOs Go Digital?

Dental support organisations (DSOs) have the unique opportunity as well as obligation to advance dentistry and shape the delivery of oral healthcare by digitising their organisations through the large-scale adoption of innovative technologies.

Digital technology benefits DSOs by reducing the time required to complete certain clinical procedures and administrative tasks, freeing up time that can be spent generating revenue by seeing more patients. The benefits don't end there; digitisation reduces variables and inefficiencies to create more standardised treatment workflows with predictable outcomes. For example, some dental technologies—such as programs that use artificial intelligence (AI) to identify radiologic pathologies—increase clinicians' confidence in their ability to make accurate diagnoses (Frontiers in Dental Medicine 2023).

Transitioning to digital solutions also provides an answer to the staffing issues currently plaguing the dental industry. There is available software that can assist with tasks that

would otherwise require an employee to spend many hours to complete. This can potentially eliminate the need to hire for certain non-clinical roles, and reduce stress for all team members by freeing up more time for them to focus on duties that cannot currently be automated.

According to a report by the American Dental Association (ADA) Health Policy Institute (HPI) published in 2022 that analysed the dental labor shortage in the United States of America, "factors associated with (staff) retention include work-life balance, positive workplace culture, and ability to help patients" (ADA Health Policy Institute 2022).

An organisation that boasts modern dental technology and optimised processes thus provides the working environment that attracts and retains dental hygienists and assistants.

Digitisation also enhances the value proposition for oral healthcare consumers who are searching for a new dental care provider with modern digital tools. Digital solutions can help make dentistry more cost-effective and convenient for patients while improving the quality



of outcomes, resulting in a treatment experience that meets consumer demand for low-cost, high-quality, and personalised care.

DSOs are well positioned to benefit exponentially from wide-scale adoption of digital technology due to their agility, economies of scale, and resources. There is a virtually limitless range of options to choose

It may be counterproductive to implement a new program or tool if utilising it makes the workday longer or more stressful for clinical and administrative staff. Consistent adoption and correct utilisation of the technology is key to ensuring the success of the investment, so the digital product or equipment should be easy to integrate into the daily workflow and the

DSOs are well positioned to benefit exponentially from wide-scale adoption of digital technology due to their agility, economies of scale, and resources

from, given the recent surge of emergent solutions for automating and digitising processes on both the clinical and administrative levels. The challenge, however, lies in recognising which digital technologies are worth investing in, and then rolling out the solutions across the network in a consistent and supported manner.

The Judicious Adoption of Digital Technology

Modern dental technology includes clinical equipment like intra-oral scanners, laboratory solutions like 3D printers, and administrative tools like practice and patient management platforms. Given the dizzying array of options, it can be overwhelming to make a financially sound technological investment that will benefit the entire network.

How can DSOs choose the right technology to invest in? The following four guiding principles may help:

The Four Fundamental Principles of Digitization for DSOs

1. Understand the needs of the organisation and its target market.

Instead of adopting new dental digital products purely for the sake of being an early adopter, a DSO would do well to select tools and technology that speak to local consumer demand and the needs of the clinicians and other staff employed at the network's practices. Digital solutions should solve real problems and make it easier for clinical team members to render treatments. This requires a careful analysis of the needs of the market and the organisation, as well as a thorough investigation of how a new piece of technology can address those needs (see box: "Questions for DSOs to Ask").

2. Choose digital solutions that will be a natural fit for the organisation's current workflows and processes.

benefits should be readily apparent to the end users. DSOs should also create and execute a strategy to ensure that the digital technology—whether in the form of a software or a clinical tool—is correctly and consistently implemented across the network.

3. Request input and feedback from the individuals who will be using the new technology.

A digitisation initiative should have full support from the team members who will be utilising it. DSOs may need to execute internal awareness campaigns and training sessions to help clinicians understand the rationale for its adoption. Dentists should also have a part in the decision-making process when it comes to digitising a treatment workflow, as this will help them feel valued and elicit their support for the digital rollout. A lack of consultation, on the other hand, could cause feelings of resentment and burnout for dentists and clinical staff, leading to under-utilisation of the technology.

4. Carefully weigh the benefits versus the costs of adopting a new digital technology or workflow.

If the tool or system under consideration does not deliver results as expected, how will the loss impact the organisation? Is the vendor or provider of the technology familiar with the complex needs of enterprise-level healthcare companies, particularly in the dental industry? Are they experienced in providing solutions and support at the scale that DSOs need? It is essential to do research to find out what other customers have used a particular solution and what their experience has been. It is also important to determine in advance what signs to look for that signal a successful execution, adoption, and utilisation of a digitisation initiative. While the ROI on a digital initiative can be difficult to measure, by setting some parameters at the outset, a DSO can



recognise signs that indicate the success or failure of the investment. In addition, a strategic partner will assist DSOs in identifying bespoke solutions and implementing them to the extent required across their network.

Conclusion

Digitisation of the delivery of oral care improves access to care for patients, helps DSOs meet the demands of oral healthcare consumers, improves efficiencies in processes at every organisational level, increases production potential, and helps sustain the standard of clinical excellence across the network. Digitisation is thus an integral part of the elixir of growth for the DSO model.

This was recently demonstrated in a DSO consisting of more than 400 practices. The DSO implemented an end-to-end strategy to digitise their single-implant delivery system and harmonise treatment processes. As a result, the DSO was able to reduce surgical appointment times by 50% and increase single-unit implant treatments by 30% (for more information please [contact us](#)).

Despite facing a vast array of digital technologies, it is possible for DSOs to make judicious selections and then strategically implement the chosen solutions across their practice geography. Partnering with experienced trusted brands with the capacity to design and execute digitisation initiatives at scale can help DSOs to leverage the benefits of going digital and achieve an ROI for the

solutions they adopt.

Visit Straumann Group's [resources page for DSOs](#) for more insights.

Conflict of Interest

None. ■

Questions for DSOs to Ask

Will the technological investment under consideration...

- make it easier for clinicians to do their job or will it add an unnecessary burden to their daily workload?
- reduce chair time?
- minimise the risk of litigation by reducing clinician errors and the possibility of misdiagnoses?
- supply aggregated data on clinician performance and consumer satisfaction that helps the organisation make informed decisions?
- standardise treatment outcomes from practice to practice?
- standardise operational processes and centralise data across the network?
- improve treatment plan acceptance rates?
- facilitate appointment scheduling and treatment payment for consumers?

references

American Dental Association Health Policy Institute, American Dental Assistants Association, American Dental Hygienists' Association, the Dental Assisting National Board, IgniteDA (2022) Dental workforce shortages: Data to navigate today's labor market. Available from: <https://www.ada.org/-/media/project/adaorganization/ada/ada-org/files/resources/research/>

[hpi/dental_workforce_shortages_labor_market.pdf](#)

Ding H et al. (2023) Artificial intelligence in dentistry—A review. *Frontiers in Dental Medicine*. Sec. Dental Materials. Vol 4. Available from: <https://doi.org/10.3389/fdmed.2023.1085251>

Digital Transformation in Healthcare Procurement

The article explores the potential of AI coupled with digital innovation as it pertains to future healthcare procurement. The importance of interoperability and qualification for the Virtual Company Dossier, and the potential benefits of cross-border procurement and digital platforms are discussed in detail. The article also highlights the need for greater involvement of academia in this and better collaboration between the public and private sectors to achieve innovation, efficiency and safety in healthcare procurement.

GABRIELLA M.
RACCA



Full Professor,
Administrative Law,
Department of Management,
University of Turin,
Turin, Italy

key points

- The impact of digitalisation and AI on health procurement should lead to a different process from other procurement sectors and be based on digital and interoperable platforms available to contracting entities and suppliers.
- Digital transformation might provide greater control of purchasing processes and its related data.
- Industry, suppliers and public buyers should work together to develop healthcare purchasing strategies.
- Academic institutions should play a crucial role in the collaboration among the European procurement community and stakeholders.

Innovation, Collaboration and Digital Trust

1. Innovations in Digital Health Procurement

The increasing demand for innovative and high-quality medical devices and healthcare services in Europe and worldwide is driving the need for digital innovation in public procurement (Racca, Yukins and De La Rosa 2022).

The recent public health crisis has also strengthened the need of public-private collaboration in the healthcare sector. Procurement under the Joint Procurement Agreement (JPA), the RescEU scheme, the Advanced Purchase Agreements (APAs) for the purchase of COVID-19 vaccines, and the establishment of the new Health Emergency Preparedness and Response (HERA), are evidence of this and highlight the need for digital trust among public buyers and suppliers (Racca and Yukins a).

A different, strategic, approach is required for the procurement of innovative pharmaceuticals and medical devices.

The impact of digitalisation and AI on health

procurement should lead to a different process from other procurement sectors and be based on digital and interoperable platforms easily available to contracting entities and suppliers (Racca and Yukins 2014).

Ongoing research projects by the University of Turin (Master SEIIC) and within international networks (European Commission, Directorate-General for Communications Networks, Content and Technology 2021, European Commission 2020, European Commission 2016), Ehppa (EHPPA), Euriphi (EURIPHI), BBG Procurement Excellence (BBG), CircPro (Interreg Europe), as mentioned by the OECD (OECD 2023) aim to support the effective digital transformation of e-procurement platforms to improve procurement in the healthcare sector (Racca and Yukins b).

2. Leveraging Qualification and Interoperability for Effective Digital Health Procurement

Digital transformation might provide greater control of purchasing processes and the related data, ensuring



transparency and accountability of public choices. This approach is in line with the EU Commission's view to encourage the full use of AI and data analytics in strategic procurement to achieve better value for money (Directive 2014/24/EU, wh. 93) and contribute to a more innovative, sustainable and competitive economy (EU Commission, DG Internal Market Industry Entrepreneurship and SMEs 2023). The digital transformation of healthcare offers scope for the expansion of e-procurement, which has the potential to increase accountability, transparency and innovation

Industry, Entrepreneurship and SMEs 2020). Digital transformation is driving towards the standardisation of contract models for all phases of the procurement cycle, including need definition, selection, and execution (Racca et al 2011). In addition, "native" digital e-forms for tenders for standardised medical contracts might be carried out on digital platforms by professional and qualified Central Purchasing Bodies through the contractual tools already provided by the EU Directives (Dynamic Purchasing Systems, Electronic Auctions and Catalogues).

The demand for innovative and high-quality medical devices and services is driving the need for digital innovation in public procurement

in procurement (EU Commission, Directorate-General for Health and Food Safety 2021).

The full digitalisation and the interoperability of National Databases collecting the Virtual Company Dossiers of suppliers might facilitate participation as well as the creation of digital platforms supporting joint and cross-border procurement and dynamic purchasing systems for medical products, as well as rapid access to the market for innovative e-health devices (Racca 2022). The issue of interoperability is still a significant challenge, with more than 300 e-procurement platforms and many different qualification systems at EU level (EU Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs 2020, p.14).

The EU TED Platform needs to be improved by means of revised and effective e-forms to facilitate data collection and the re-use of supplier qualifications in a standardised way across different countries. Also, the concept of private platforms collected in the SIMAP website as e-senders should be monitored, and addressed to better connect the TED system to assure effective transparency.

The re-use (Re-usability principle) of the European Single Tender Document (ESPD) and related exclusion and qualification criteria should also be guaranteed to simplify participation.

The economic operator's Virtual Company Dossier, as an evolution of the e-Certis system, should allow for full inter-operability among databases containing the information needed for an effective e-procurement system, applying the Once-only principle (EU Commission, Directorate-General for Internal Market,

3. Cross-border Procurement and Digital Platforms

Industry, suppliers and public buyers should work together to develop healthcare purchasing strategies to promote innovation and market access for disruptive technologies, innovations and services.

Specific platforms might foster pre-commercial procurement and Value-Based Procurement (VBP) as well to select integrated services (EU Commission, Directorate-General for Health and Food Safety 2019). The VBP approach, correctly addressed, might respond to the growing challenges of healthcare systems and actually accelerate the shift to value-based, high-quality, digital healthcare. VPB has already become the default approach applied by the Welsh National Healthcare System (NHS Wales); in addition, Catalonia is using this method in telehealth projects; Dutch authorities are making value-based procurement central in the healthcare supply chain; while in France, Resah Idf has also published a guide on VBP to support a wider use, particularly in the healthcare sector (EURIPHI 2021).

The goals of innovation, efficiency and safety in healthcare procurement require stronger public-public and public-private cooperation (also transatlantic, with U.S. GPOs) based on digitalised networks between CPBs and EU Institutions to address all issues arising in healthcare procurement, especially to face emergencies.

The organisational model of digital cooperation among CPBs could well foster a new system based on public algorithms that can operate according to measurable quality criteria based on benchmarks



and deliver fast and transparent outcomes to ensure the efficiency, integrity and sustainability of strategic procurement (Racca and Yukins 2019).

community and stakeholders by providing expertise as well as an impartial perspective while safeguarding the quality of innovative and digital transformation of

Cross-border procurement and digital collaborative purchasing platforms are needed to foster innovation and market access for disruptive technologies, innovations and services

4. The Role of Academia for a Digital Public Procurement Ecosystem in Healthcare

The common goal of efficient procurement of innovative medical devices, digital services and IT systems through enhanced digital collaboration between industry, health buyers and qualified purchasers can reduce pressure on healthcare budgets and facilitate better value for money and innovation in future digital healthcare.

Academic institutions, assuring free research without external pressures should play a crucial role in the collaboration among the European procurement

procurement systems. Academia should continue to play an active role in EU-funded and public-private projects on digital transformation to ensure evidence-based, innovative and high-quality digital procurement practices and platform solutions in healthcare. This involvement will also help industry to develop digital trust, while incorporating academic and research issues to prepare for future challenges for better healthcare.

Conflict of Interest

None. ■

references

BBG Public Procurement Excellence Programme. Available from <https://ppe.bbg.gv.at/>.

EHPPA [European Health Public Procurement Alliance]. Available from <https://www.ehppa.com/>.

EURIPHI (2021) Resah Guidebook 'Understanding Value Based Procurement: a new approach to purchasing.' Available from: <https://www.euriphi.eu/news/resah-guidebook-understanding-value-based-procurement-a-new-approach-to-purchasing/>

EURIPHI [European wide Innovative Procurement in Health and Care]. Available from <https://www.euriphi.eu/>.

European Commission (2016) Feasibility study concerning the actual implementation of a joint cross-border procurement procedure by public buyers from different Member States, written by BBG and SKI, December 2016. Available from: <https://ec.europa.eu/docsroom/documents/22102/>.

European Commission, Directorate-General for Health and Food Safety (2019) Defining value in 'value-based healthcare': opinion by the Expert Panel on effective ways of investing in Health (EXPH). Publications Office. Available from: <https://data.europa.eu/doi/10.2875/148325>.

European Commission (2020) ProcurCompEU. European competency framework for public procurement professionals. Available from: https://commission.europa.eu/funding-tenders/tools-public-buyers/professionalisation-public-buyers/procurcompeu-european-competency-framework-public-procurement-professionals_en.

European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (2020) Interoperability in end-to-end eProcurement. Publications Office, Brussels. Available from: <https://data.europa.eu/doi/10.2873/991386>.

European Commission, Directorate-General for Health and Food Safety (2021) Expert Panel on effective ways of investing in Health (EXPH): Opinion on public procurement in healthcare system, adopted on 28 April 2021. Publications Office. Available from: <https://data.europa.eu/doi/10.2875/832331>.

European Commission, Directorate-General for Communications Networks, Content and Technology (2021) The strategic use of public procurement for innovation in the digital economy: final report. Publications Office, 2021. Available from: <https://data.europa.eu/doi/10.2759/936544>.

European Commission: DG Internal Market Industry Entrepreneurship and SMEs (2023) Public Procurement: A data space to improve public spending, boost data-driven policy-making

and improve access to tenders for SMEs. Official Journal of the European Union. 981, 1-11. Available from: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023XC0316\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023XC0316(02)&from=EN).

Interreg Europe. CircPro [Smart Circular Procurement]. Available from <https://projects2014-2020.interregeurope.eu/circpro/>.

Master SEIIC. HAPPY Project [Healthy Ageing in Public Procurement of Innovation]. Available from <http://www.masterseic.it/happi/>.

NHS Wales, Value-Based Healthcare for Wales. Value Based Procurement. Available at: <https://vbhc.nhs.wales/value-based-healthcare-for-wales/value-based-procurement/>.

OECD (2023) Professionalising the public procurement workforce: A review of current initiatives and challenge. OECD Public Governance Policy Papers. No. 26. OECD Publishing, Paris. Available from: <https://doi.org/10.1787/e2eda150-en>.

Racca GM (2022) Digital Transformation for an Effective E-Procurement. In: Risvig Hamer C, Andhov M, Bertelsen E, and Caranta R. (eds.), Into the Northern Light. In memory of Steen Treumer. Ex Tuto Publishing, Copenhagen, pp. 215-228.

Racca GM, Cavallo Perin R, Albano GL (2011) Competition in the execution phase of public procurement. Public Contract Law Journal. 41(1), pp. 89-108.

Racca GM and Yukins CR (2014) Integrity and Efficiency in Sustainable Public Contracts: Balancing Corruption Concerns in Public Procurement Internationally, Droit Administratif / Administrative Law Collection. Bruylant, Bruxelles.

Racca GM and Yukins CR (eds.) (2019) Joint Public Procurement and Innovation: Lessons Across Borders. Droit Administratif / Administrative Law Collection. Bruylant, Bruxelles.

Racca GM and Yukins CR (a) (forthcoming) Emergency Procurement and Corruption, in Williams-Elegbe S and Tillipman J (eds.), Routledge Handbook of Public Procurement Corruption (Routledge, London, Forthcoming)

Racca GM and Yukins CR (b) (eds.) (forthcoming) Public Procurement and Digitalisation, Droit Administratif / Administrative Law Collection (Bruylant, Bruxelles, Forthcoming)

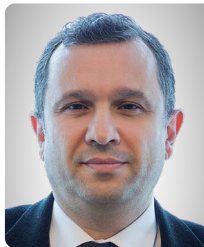
Racca GM, Yukins CR and De La Rosa S (2022) 1st Pan-European Hospital & Healthcare Procurement Summit, 20-21 September 2022, Brussels. Available from <https://www.health-procsummit.com/health-procurement-summit-2022>

Revolutionising Medicine: The Power of Digital Algorithms in Healthcare

Medical digital algorithms are computer programs that use complex mathematical equations to analyse data and make predictions about medical conditions.

These algorithms have the potential to revolutionise healthcare by improving accuracy, reducing costs, and providing personalised treatment plans. Despite their potential benefits to transform healthcare, medical digital algorithms also raise concerns about privacy and bias. It is important to approach them with caution and careful consideration.

TANER
OZCAN



Process Analysis Director,
MLPCARE,
Istanbul,
Turkey

key points

- An algorithm is a step-by-step procedure or a set of instructions that is designed to perform a specific task or solve a problem.
- Algorithms in health care can automate many (routine) tasks, freeing up medical professionals to focus on more complex cases.
- To ensure the long-term reliability and effectiveness of AI/ML-based clinical algorithms, it is crucial that we establish systems for regular monitoring and maintenance.

Enhancing Diagnostics, Treatment and Patient Outcomes through Innovative Technology

Introduction

An algorithm is a step-by-step procedure or a set of instructions that are designed to perform a specific task or solve a problem.

It consists of a series of well-defined and finite steps that can be followed to achieve a particular goal or objective. Algorithms are used in computer programming, mathematics, and many other fields.

In computer programming, algorithms are used to solve problems and automate tasks. For example, an algorithm might be used to sort a list of numbers or to search for a specific item in a database.

Algorithms can be expressed in various forms, such as natural language, flowcharts, pseudocode, or programming languages. In addition, digital algorithms can be used in a wide variety of applications, such as computer programming, data analysis, cryptography, and digital signal processing. They are typically written in a programming language and can be executed by a computer or other digital device.

Machine learning (ML) and artificial intelligence (AI) algorithms have the potential to derive insights from clinical data and possibly improve patient outcomes. The use of artificial intelligence (AI) and machine learning (ML) in the clinical arena has developed tremendously over the past decades, with numerous examples in medical imaging, cardiology, and acute care (Choudhury and Asan. 2020). Indeed, the list of AI/ML-based algorithms approved for clinical use by



the United States Food and Drug Administration (FDA) continues to grow at a rapid rate (Benjamins et al. 2020).

Well-constructed algorithms are efficient, accurate, and easy to understand. They should be designed to work correctly on all possible inputs and should produce the desired output. Digital algorithms are essential for many modern technologies and have revolutionised the way we process and analyse information. They have enabled us to solve complex problems quickly and efficiently, making them an integral part of the digital world.

Despite the accelerated development of these medical algorithms, adoption into the clinical space

real-time patient data from sensors and wearable devices.

Medical digital algorithms use machine learning techniques to “learn” from the data they analyse. They can identify patterns and correlations in the data that would be difficult or impossible for humans to detect. By doing so, they can help healthcare providers make more accurate diagnoses, develop more effective treatment plans, and monitor patient progress more effectively.

For example, an algorithm trained to detect breast cancer might analyse mammograms from thousands of patients to identify common patterns and features that indicate the presence of cancer. The algorithm can then use this knowledge to analyse new mammograms,

An algorithm is a step-by-step procedure or a set of instructions that is designed to perform a specific task or solve a problem

has been limited. The challenges encountered on the way to successful integration go far beyond the initial development and evaluation phase. Because ML algorithms are highly data-dependent, a major concern is that their performance depends heavily on how the data are generated in specific contexts, at specific times. It can be difficult to anticipate how these models will behave in real-world settings over time, as their complexity can obscure potential failure modes (Feng et al. 2022).

What Are Medical Digital Algorithms?

A medical digital algorithm is a step-by-step procedure or set of rules that is designed to help healthcare professionals diagnose, treat, or manage a specific medical condition or disease. These algorithms are typically created using computer-based models that are programmed to process large amounts of data and provide recommendations based on specific criteria.

In simple terms, medical digital algorithms are computer programs that use mathematical models to analyse patient data and provide healthcare professionals with diagnostic or treatment recommendations. These models are then trained on large datasets of patient information, such as medical records or imaging data. The algorithm then uses this training to identify patterns and correlations in the data that might be indicative of specific medical conditions. These algorithms can process vast amounts of data, including medical images, electronic health records, and

indicate the diagnosis to healthcare providers and even suggest recommendations for further testing or treatment, all based on the data analysis.

Medical digital algorithms can be used for a wide range of purposes, such as:

- **Diagnosis:** Algorithms can be used to identify potential diagnoses based on a patient’s symptoms and medical history.
- **Treatment:** Algorithms can help healthcare professionals determine the most effective treatment plan for a patient based on their individual characteristics and circumstances.
- **Monitoring:** Algorithms can be used to track a patient’s progress over time and provide recommendations for adjustments to their treatment plan if necessary.

One example of a medical digital algorithm is the Framingham Risk Score, which is used to assess a patient’s risk of developing cardiovascular disease based on various risk factors such as age, gender, blood pressure, cholesterol levels, and smoking status. Another example is the Modified Early Warning Score (MEWS), which is used to predict the likelihood of a patient experiencing clinical deterioration in a hospital setting based on their vital signs and other clinical data.

Medical digital algorithms have become a critical tool in modern healthcare, providing doctors and healthcare professionals with a powerful way to analyse and interpret complex patient data. These algorithms are designed to help healthcare providers make better



decisions, improve patient outcomes, and reduce healthcare costs.

automate many routine tasks, freeing up medical professionals to focus on more complex cases. This can lead to faster diagnoses, shorter wait times,

Algorithms in health care can automate many (routine) tasks, freeing up medical professionals to focus on more complex cases

The Benefits of Medical Digital Algorithms

Algorithms can also automate many routine tasks, freeing up medical professionals to focus on more complex cases.

Medical digital algorithms thus can offer a range of benefits in healthcare.

Here are some of the most significant advantages they provide:

- **Improved Diagnostics:** Medical digital algorithms can help healthcare providers make more accurate diagnoses by analysing patient data and identifying patterns that may be difficult or impossible for humans to detect. This can lead to earlier detection of medical conditions, more accurate diagnoses, and better treatment outcomes.
- **Personalised Treatment:** By analysing patient data, these algorithms can provide healthcare providers with personalised treatment recommendations tailored to each patient's unique medical history, genetic makeup, and other factors. This can lead to more effective treatments and better patient outcomes. For example, algorithms are being developed to analyse a patient's genetic information and identify which medications are most likely to be effective for that individual, or what disease they might be more prone to.
- **Reduced Costs:** Medical digital algorithms can help reduce healthcare costs by improving the efficiency of healthcare delivery. By providing healthcare providers with more accurate diagnoses and treatment recommendations, these algorithms can help reduce the number of unnecessary tests, procedures, and even hospitalisations, leading to cost savings for patients and healthcare providers alike.
- **Improved Patient Outcomes:** By providing healthcare providers with more accurate and personalised treatment recommendations, medical digital algorithms can improve patient outcomes and reduce the risk of adverse events. Algorithms can

and reduced costs. For example, algorithms are being developed to automate the triage process in emergency departments. These algorithms can quickly analyse a patient's symptoms and medical history to determine the level of urgency and prioritise treatment. This can lead to better patient satisfaction and improved overall health.

- **Real-time Monitoring:** Medical digital algorithms can monitor patient data in real-time, providing healthcare providers with instant alerts when a patient's condition changes or deteriorates. This can help healthcare providers respond quickly and effectively to changes in a patient's health, improving patient outcomes and reducing the risk of complications.

Challenges and Concerns

While medical digital algorithms offer many benefits, there are also challenges and concerns associated with their use. Some of these include:

- **Data Privacy:** Medical digital algorithms rely on large amounts of patient data to function effectively. As such, there are concerns about data privacy and security. Healthcare providers must take steps to ensure patient data is protected and used only for its intended purposes.
- **Bias:** Medical digital algorithms are only as unbiased as the data they are trained on. If the data is biased or incomplete, the algorithm may also be biased. Healthcare providers must ensure that algorithms are trained on diverse datasets to prevent bias. For example, if an algorithm is trained on data that primarily includes white male patients, it may not be as accurate in diagnosing or treating medical conditions in patients who are not white or male.
- **Errors or Misinterpretations in the Data.** Another limitation of medical digital algorithms is the potential for errors or misinterpretations in the data. While algorithms are designed to be highly accurate, they



can still make mistakes if the data is incomplete or inaccurate. Additionally, the interpretation of the data can be influenced by the individual who programmed the algorithm, which can lead to errors or bias in the output.

- **Transparency and Accountability:** Algorithms can be complex and difficult to understand, which can make it challenging to identify and correct errors or biases. To address this challenge, medical professionals

Conclusion

In conclusion, medical digital algorithms are already revolutionising the healthcare industry.

They can improve patient outcomes, increase efficiency, and provide personalised care. However, there are also challenges that need to be addressed, including data privacy and security, transparency and accountability, and the need to safeguard a human connection in healthcare.

To ensure the long-term reliability and effectiveness of AI/ML-based clinical algorithms, it is crucial that we establish systems for regular monitoring and maintenance

must work to ensure that algorithms are developed with transparency and that patients have access to information about how algorithms are being used in their care.

- **Lack of Human Touch:** Medical digital algorithms may not take into account the nuances of a patient's individual situation or provide the same level of empathy and emotional support that a human clinician can.
- **Reliance on Technology:** Medical digital algorithms rely on technology to function. Healthcare providers may become overly reliant on technology and algorithms, potentially leading to reduced critical thinking skills and a lack of judgment.

Finally, there is a concern that reliance on algorithms may lead to a loss of human touch in healthcare. Medical professionals must strike a balance between using algorithms to improve efficiency and accuracy while also maintaining a human connection with patients.

As the use of medical digital algorithms continues to grow, it is essential that medical professionals work to address these challenges and ensure that algorithms are used in a responsible and ethical manner.

To ensure the long-term reliability and effectiveness of AI/ML-based clinical algorithms, it is crucial that we establish systems for regular monitoring and maintenance.

Simply put, AI-based algorithms achieve high predictive accuracy by detecting correlations between patient variables and outcomes. However, when the clinical environment is highly dynamic and patient populations are heterogeneous, a model that works well in one-time period or one hospital may fail in another. To bring clinical AI into maturity, AI systems must be continually monitored and updated (Yoshida et al. 2018).

Conflict of Interest

None. ■

references

Benjamins S, Dhunoo P, Meskó B (2020) The state of artificial intelligence-based (fda-approved) medical devices and algorithms: an online database. NPJ Digit Med. 3 (118).

Choudhury A, Asan O (2020) Role of artificial intelligence in patient safety outcomes: systematic literature review. JMIR Med Inform. 8, e18599.

Feng J, Phillips RV, Malenica I et al. (2022) Clinical artificial intelligence quality improvement:

towards continual monitoring and updating of AI algorithms in healthcare. npj Digit. Med. 5 (66). Available from <https://doi.org/10.1038/s41746-022-00611-y>

Yoshida E, Fei S, Bavuso K, Lagor C. & Maviglia S (2018) The value of monitoring clinical decision support interventions. Appl. Clin. Inform. 9, 163–173.



Medical Imaging



Radionuclide Therapy in Paediatric Patients

Radionuclide therapy uses radioactive substances for the selective delivery of radiation to tumors or target organs, providing a valid alternative to surgery or traditional medical treatments in paediatric patients.

In particular, it combines the advantage of target selectivity and therapeutic strategy with curative intent or for disease control and palliation.



EMILIA ZAMPELLA

Researcher,
Department of Advanced Biomedical Sciences,
University Federico II of Naples, Italy

key points

- Radionuclide therapy is a specialised area of nuclear medicine that uses radioactive compounds able to release high-energy ionizing radiations.
- In paediatric patients, the use of radionuclide therapy is validated, safe and effective for the treatment of several benign and malignant diseases.
- The identification of patients who may benefit from radionuclide therapy is crucial in order to improve outcome and limit radiation exposure.

Michele Klain | Associate Professor | Department of Advanced Biomedical Sciences
| University Federico II of Naples | Italy

Introduction

Nuclear medicine is a branch of medicine based on the administration of radiopharmaceuticals, radioactive compounds able to reproduce biological, cellular or metabolic pathways.

The radioactive isotopes can be used individually or combined with different molecules and, according to their decay properties, may have diagnostic and/or therapeutic applications.

In particular, α - and β -emitters are able to release low-range highly ionizing radiation, allowing for therapeutic effects.

Radionuclide therapy is a specialised area of nuclear medicine that uses radioisotopes for therapeutic purposes and it is widely used for the treatment of several benign and malignant conditions. Radionuclide therapy has been demonstrated to be safe and effective also in paediatric patients.

Children are considered more vulnerable as compared to adults because of their longer life expectancy. Moreover, several malignancies typically show a more aggressive clinical behavior in paediatric patients as

compared to adults.

Therefore, the availability of concrete therapeutic options is mandatory in these patients.

Historically, Iodine-131 (¹³¹I) is the most widely used radionuclide therapy agent in children. It has the ability to be taken up into well differentiated follicular cells of thyroid epithelium.

This therapy is currently performed for the treatment of benign conditions such as hyperthyroidism or malignant diseases such as differentiated thyroid cancer (DTC).

In children, DTC accounts for 21% of all head and neck tumors, with an increasing incidence rate of approximately 1% per year. Differently from adults, they typically present with more advanced disease at diagnosis, with extensive lymph nodal involvement and distant metastases. Moreover, the rate of recurrence seems to be higher in paediatric patients, leading to frequent re-operations or additional treatments. Despite this evidence, prognosis remain excellent and it seems to be related to several prognostic factors, including tumor type and younger age. In children with DTC, the initial treatment consists of surgery, that can be



radical or more conservative determined by extent of disease. Then, in patients identified as at intermediate-high risk of recurrence, radioactive iodine treatment is recommended. In these patients, DTC are usually highly

safe, efficient and well tolerated, however several issues still remain to be addressed.

Recently, several radiotracers able to bind to specific targets of disease have been proposed and validated in

Radionuclide therapy in paediatric patients can thus be safe, efficient and well tolerated, however several issues still remain to be addressed

iodine avid, and show an excellent response to ¹³¹I therapy. Several authors reported improved survival, decreased disease progression, and lower recurrence rates in patients with advanced DTC who received postoperative radioactive iodine therapy.

Another validated application of radionuclide therapy in children is the treatment of metastatic or recurrent neuroblastoma not responding to conventional treatment. Neuroblastoma is the most common malignant extracranial solid tumor of childhood, derived from the sympathetic nervous system chain. Meta-iodobenzylguanidine (MIBG) is an analogue of the norepinephrine that, once injected, is taken up by cells rich in sympathetic neurons by an active uptake process, mediated by the norepinephrine transporter.

In order to enable therapeutic effects, MIBG can be labeled with ¹³¹I. In children with advanced disease treated with multiple administrations of ¹³¹I-MIBG, excellent results in terms of disease control have been achieved. Moreover, this radionuclide therapy seems to be well tolerated and toxicity is limited to hematological side-effects. Currently, ¹³¹I-MIBG represent the best palliative treatment in these patients; the combined administration of radionuclides and chemotherapy agents has been proposed as an additional opportunity in paediatric patients with advanced neuroblastoma. However, available data is still limited and further studies are needed.

Radionuclide therapy in paediatric patients can thus be

adults, yet not in paediatric patients as the role of these agents has not yet been elucidated.

For example, radiolabeled somatostatin analogues currently represent the main therapeutic option in adult patients with gastro-entero-pancreatic neuroendocrine neoplasms. In children, the role of these radiopharmaceuticals has not been fully clarified, but encouraging results emerged from some preliminary data (references maybe?). As mentioned above, it should be considered that paediatric patients represent a very radiosensitive category, due to growing processes and higher life expectancy. Therefore, the optimisation of therapeutic protocols and an accurate selection of paediatric patients who may really benefit from radionuclide therapy is mandatory, in order to improve outcome without significant adverse effects.

Conclusion

In the era of precision medicine in adults, radionuclide therapy may also likely represent a valid, highly-specific therapeutic option in paediatric patients. In the future, the availability of new radioactive agents, the identification of more specific disease targets and the optimisation of administration protocols will contribute to an even more effective treatment of several benign and malignant disease in children.

Conflict of Interest

None. ■

references

Carrasquillo JA et al. (2012) Radionuclide therapy of adrenal tumors. *J Surg Oncol.* 1;106(5):632-42.

Foster JH et al. (2021) Peptide receptor radionuclide therapy for treatment of metastatic neuroendocrine tumors in children. *Pediatr Blood Cancer.* Jul;68(7):e29056.

Tuli G et al. (2023) Clinical features of thyroid cancer in paediatric age. Experience of a tertiary

centre in the 2000-2020 period. *Endocrine.*

Zampella E et al. (2023) Prognostic value of 12-month response to therapy in paediatric patients with differentiated thyroid cancer. *Endocrine.*



One Ring to rule them all in AI

A Case Study On Affidea Portugal

Artificial Intelligence in radiology is growing at a rapid pace. Alessandro Roncacci, SVP and CMO of Affidea, and Stéphane Maquaire, GM for Europe at Incepto Medical, reveal the dynamic partnership in Portugal, bringing to the national level the benefits and added value of AI solutions.



Live session at the European Congress of Radiology 2023 with (from left to right) Stéphane Maquaire, Alessandro Roncacci and Oana Dumitroiu.

What is the current landscape of artificial intelligence in radiology, and what is Incepto's vision?

Stéphane: Despite several early signs of consolidation, there is a growing number of AI providers. We are aware that the pressures for medical imaging on doctors are increasing daily, and medical imaging will continue to play a key role in the patient pathway. Since Incepto's foundation in 2018, our vision was to connect those two worlds, where we provide the best AI tools for radiologists in order to improve the accuracy and scale of medical diagnosis. Our mission is to create and develop AI solutions and deploy them in healthcare institutions. It is very important that clinicians receive added value by using AI tools, whether through standardisation, efficiency or quality.

What is Affidea's objective in using AI to tackle the challenges in diagnostic imaging? And how many AI solutions is Affidea piloting across the different countries?

Alessandro: Affidea's objective in using AI is to increase quality, safety and efficiency in the services we provide. We aim to use AI to manage the amount of data we have to tailor the treatment and the diagnosis, personalise them, and increase operational efficiency, decreasing the workload of our professionals while maintaining the right workflow. We want to ensure that 7500 of our clinical professionals and 4000 radiologists are familiar with the use of AI to support their daily activity to improve our patients' clinical outcomes.

We are proud of our journey that began a few years ago, currently adopting 12 AI solutions across 10 countries working on this project.



Can you discuss the Incepto platform that Affidea is implementing in Portugal? How does the platform support Affidea’s radiologists? How is it integrated into the workflow and how does it impact the infrastructure?

Stéphane: The objective for Affidea Portugal was to scale up to the national level and to ensure we can bring the benefit and the added value of the AI solution to this level.

well as our corporate team: from legal and GDPR team to IT, clinical, operations, commercial, marketing, they all work together with the vendors. We then use clear KPIs to deploy the solution and extend them across the organisation where applicable.

The reputation of the vendor is, of course, a differentiating factor in the selection of the AI solutions, while their certifications are an essential requisite in our preliminary assessment. We also look at the market

In a couple of applications, we have saved 25%- 30% of the reporting time. However, the real impact is that you still have the same standard from the first to the last report and fewer chances of human errors.

Firstly, we are working very closely with the Affidea team in Portugal and a co-operator to ensure we connect all the sites to the Incepto platform, ensuring that any site can access any application automatically.

Secondly, we are working very closely with the medical doctors in the Portuguese team to understand which applications are the most meaningful to use and deploy in their network, and, thus, for which applications users are required to undergo training.

Radiologists and patients in Affidea Portugal can greatly benefit from the solution, for example, through detection, enhanced diagnostics confidence and during the follow-up.

What are the main benefits that the solution promises to bring to radiologists?

Stéphane: It often depends on the type of application. In this case, it can support radiologists in detecting and measuring lesions, while decreasing the reading time. It can, therefore, substantially benefit the doctors as well as the patient.

What is Affidea’s methodology for evaluating and commercialising AI solutions in diagnostic imaging? How does the company prioritise the selection criteria for AI solutions and the countries and centres?

Alessandro: We have a robust clinical governance structure and a clear AI framework with different stages that allow us to select and test a new solution, from a clinical, operational and commercial point of view. We work closely with our champions at country level as

demand, the patients, referrals and doctors’ needs, our clinical and operational capabilities, and the environment. We work in 15 countries and have different organizations, so we adopt AI solutions to different needs, from prevention, screening, emergency, and elective in neuro and MSK to oncology and in real-life environment.

How many AI solutions is Affidea Portugal currently working with using Incepto platform?

Alessandro: At the moment, we have seven different solutions and 50 radiologists involved in this project. Our team is very much KPI-driven, allowing us to evaluate the outcomes obtained and continuously improve the processes.

What have you learned about the implementation of Incepto platform in Affidea Portugal network? Can you tell us about the success factors and how can we scale this out?

Stéphane: I think the first success factor is the team. We have learnt that the real value and the power lies in having a strong team working closely together from both sides. As well, it is a success to be working with the

‘A study from the American College of Radiology highlighted that clinical adoption of AI has increased dramatically over the last five years, with 30% of radiologists indicating that they are currently using AI in their everyday practice.’



medical referral doctors for each application, alongside the IT and deployment experts.

Additionally, understanding the clinical and operational needs and the local context has been key.

Secondly, I believe the need to rapidly train, explain

co-create different solutions in partnership with a reliable AI vendor because there are some clinical needs that are not yet addressed properly by any AI solution, so why not consider this journey ourselves in a co-development model?

Artificial intelligence will support even more human intelligence without replacing it, but will continue to improve our efficiency and efficacy in the reporting activity.

and remove any small barriers is absolutely critical. We are still in the adoption phase, and here any small issue can really deter you from adopting.

We have been spending a lot of time on-site and remotely with the doctors to train them and to ensure there is a real understanding of the benefits.

But above all, I would say that one very important thing that we have established with Affidea is that we are sharing the same high standards in terms of data privacy, security and GDPR. This reflects that we can deploy geographically, face any issue, and tackle them much more quickly together.

What are the main challenges that you confronted with when implementing the Incepto platform and when trying to integrate multiple AI solutions under one single umbrella? What are the main benefits that you believe this brings to your radiologists?

Alessandro: IT integration, ensuring we are GDPR compliant, and protecting the safety of the data are always the most challenging steps, but we managed to overcome them successfully. Moreover, this is a plug-and-play model – we train our clinical teams, we pilot, and we test the solution from a clinical, operational and commercial point of view. If it brings the expected outcomes, we can then roll it out.

However, we are considering to co-develop or

How many hours can AI save from a radiologist per day?

Alessandro: In a couple of applications, we have saved 25%- 30% of the reporting time, which provides us with the support we need to face the increasing demand for examinations. Previously, we recorded around 30 examinations per day, but today we have the possibility to report 40 in the same given time. However, the real impact is that you still have the same standard from the first to the last report and fewer chances of human errors.

Can you describe in one word what the future of AI in radiology will be? How do you see AI developing in the next five years?

Alessandro: Omnipresent. Artificial intelligence will support even more human intelligence without replacing it but will continue to improve our efficiency and efficacy in the reporting activity.

Stéphane: The key for us is to ensure we are absolutely aligned. We can see how AI supports radiologists – we have seen the best and most accurate AI solutions support approximately 90% of their clinical questions.

So, I think this would benefit our radiology community's future. ■



Central Role of Nuclear Medicine in Personalised Medicine

Molecular radionuclide imaging and therapies have a central role in the management of some oncological diseases, in particular they find a central application in neuroendocrine tumours (NETs). Peptide receptor imaging is a fundamental part of the tumour staging, preoperative imaging, therapy selection and restaging. Using the same drug, labelled with a different radionuclide, it's possible to offer a therapeutic option that is specific to the characteristics of the patient and his/her neoplasm. This is a model of personalised medicine is spreading more and more, due to the reduction of side effects and the promising results on the prognosis of patients.



VALERIA GAUDIERI

Researcher,
Department of Advanced Biomedical Sciences,
University of Naples Federico II,
Naples, Italy

key points

- Precision medicine is a medical model that proposes the personalisation of healthcare, with medical decisions and practices tailored to the patient. In this context theragnostic is based on diagnostic molecular imaging, followed by an individually personalised treatment plans.
- Well-differentiated neuroendocrine tumours are characterised by the presence of a peculiar receptor that can be used as a “target” for diagnosis and selection of therapy.
- Peptide receptor radionuclide therapy has achieved such encouraging results in patients with neuroendocrine tumours that the scientific research suggests that the number of cancer patients with the characteristics to benefit from radionuclide therapies could significantly increase in the near future, including prostate cancer, breast, lung and pancreatic cancer.

Alberto Cuocolo | Full professor | Diagnostic Imaging and Radiotherapy | Director |
Department of Advanced Biomedical Sciences | University of Naples Federico II | Naples, Italy

Theragnostic in Neuroendocrine Tumours

Theragnostic is the best example of the tailored medicine today, because it brings together the two pillars of this science namely Therapy and Diagnosis, combined into one weapon with a single target: to preserve patients' health.

Tailored medicine focused on more specific algorithms for different kinds of pathology contributes to developing several advances in surgery, medicine, and radiotherapy with excellent perspectives for the future, mainly in the oncological field.

In this scenario, the approach to cancer disease is changing thanks to an ever-increasing understanding of how malignant and healthy cells differ and how they interact with the surrounding micro-environment.

Drugs against specific “targets” are able to detect and to act directly on the diseased cells, reducing damage to healthy cells and consequently decrease side effects.

Based on this knowledge, cancer diagnostics and therapy are developing in an integrated way, going hand in hand rather than separately. In this era of precision medicine, which aims to find more accurate, safer, and personalised pathways, the concept of theragnostic has found its niche in the field of nuclear medicine, an imaging field that uses radioisotopes for molecular imaging and therapeutic purposes, with the possibility of labelling the same ligand with radionuclides with different characteristics, so as to allow staging, risk stratification, therapy selection and interventions, and response monitoring.



The first and the most promising example of a theragnostic application uses peptide receptor imaging and peptide receptor radionuclide therapy (PRRT) for neuroendocrine tumours (NET).

Neuroendocrine neoplasms (NEN) represent a heterogeneous group of tumours deriving from endocrine cells with the capacity to produce bioactive molecules. Even if NENs can occur in almost every tissue or district of the body, most of them originate from the digestive system, in particular from the gastroenteropancreatic (GEP) tract.

The classification of these neoplasms is based on proliferation index and cells' morphology, accordingly, the prognosis and behaviour are generally favourable in well-differentiated NETs (G1, G2 and G3) depending on grading, whereas low-differentiated tumours and neuroendocrine carcinomas (NEC) have an adverse outcome. Often NETs are non-secreting and late diagnosis is frequent, due their asymptomatic presentation, and therefore most of them present with advanced disease (Hallet J et al. 2015). NETs can differ in clinical symptoms and biology; however, they have specific markers of neuroendocrine cells and more than 80% of them over-express somatostatin receptors (SSTR) on cell surface (Kulaksiz H et al. 2002).

This discovery of the over-expression of SSTRs in NETs has led to the development of radiolabelled somatostatin analogues for diagnostic imaging at first. Thanks to technological advances, the current imaging methodologies have a high diagnostic performance and high accuracy. Today, the clinical scenarios in which peptide receptor imaging has definite value are the initial staging of well-differentiated NETs, identification of the primary tumour in patients who have neuroendocrine metastases of unknown origin and defining eligibility of patients for PRRT (Pavel M et al. 2020).

The introduction of PRRT is more recent than its imaging counterpart and requires that the diagnostic radionuclide is replaced with a therapeutic radionuclide, which has a different kind of radioactive emission, in the radiolabelled somatostatin analogues (Strosberg J et al. 2017). Once administered to a patient, the therapeutic radiopeptide binds to the neuroendocrine tumour cells that express SSTRs, then the constituted

radiopeptide-receptor complex is internalised by the diseased cell, entrapping the radionuclide that acts locally and kills the tumour cell.

This innovative therapeutic option is most successful in patients with well-differentiated NETs that are low or intermediate grade and have over-expression of SSTRs as depicted on peptide receptor imaging.

The management of patients with NENs generally takes place in a multidisciplinary setting and it is in this context that the decision is made whether to treat an eligible patient with PRRT, considering several factors: therapy is usually prescribed in patients with inoperable tumours or with metastases at numerous sites and disease progression despite standard treatment. Unlike other treatment choices, PRRT has been shown to be effective in increasing overall survival, moreover, it has been demonstrated that it has positive effects also on progression-free survival and quality of life of patients, reducing the production of hormones with improvement of symptoms (Werner RA et al. 2015). Among other advantages, PRRT has few adverse side effects that are generally easily managed and has a favourable toxicity profile even in patients with disseminated disease.

The excellent results of the theragnostic approach in the management of neuroendocrine tumours, which for decades have had no valid therapeutic options to improve the prognosis, have paved the way for the search for new molecular targets for the treatment and diagnosis of other types of tumours.

Conclusion

Peptide receptor imaging and PRRT are a new frontier in personalised medicine because they allow for tailoring treatment plans to the unique features of the patient and the molecular characteristics of the tumour.

Many lessons have been learned from the progress in this field, and they may be the basis for developing new technologies. Probably theragnostic is more than an innovative approach because it will be able to change the course of many lives bringing hope even for diseases currently without an effective cure.

Conflict of Interest

None. ■

references

Hallet J et al (2015) Exploring the rising incidence of neuroendocrine tumors: a population-based analysis of epidemiology, metastatic presentation, and outcomes. *Cancer*. 121(4):589-97.

Kulaksiz H et al (2002) Identification of somatostatin receptor subtypes 1, 2A, 3, and 5 in neuroendocrine tumours with subtype specific antibodies. *Gut*. 50(1):52-60.

Pavel M et al (2020) ESMO Guidelines Committee. Gastroenteropancreatic neuroendocrine neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann*

Oncol.31(7):844-860.

Strosberg J et al (2017) NETTER-1 Trial Investigators. Phase 3 Trial of 177Lu- Dotatate for Midgut Neuroendocrine Tumors. *N Engl J Med*. 376(2):125-135.

Werner RA et al (2015). 68Gallium-and 90Yttrium-/ 177Lutetium: "theranostic twins" for diagnosis and treatment of NETs. *Ann Nucl Med*. 29(1):1-7.



Governance and Leadership



Business Continuity Management in Medical Technology: Ensuring Uninterrupted Healthcare Services

The article emphasises the importance of Business Continuity Management (BCM) in medical technology to ensure uninterrupted healthcare services. It discusses the need for BCM, challenges in implementation, benefits, and best practices. The focus is on identifying potential disruptions, developing response plans, and maintaining effective communication.



THOMAS
JÄSCHKE

Medical Informatician, Entrepreneur, Professor,
FOM University of Applied Sciences for Economics
and Management, Germany

key points

- **BCM in Medical Technology:** The article highlights the critical role of medical technology in healthcare delivery and the risks associated with disruptions. BCM helps hospitals identify and mitigate potential disruptions to ensure the availability and reliability of medical devices, enhancing patient safety and care quality.
- **Challenges and Benefits:** Implementing BCM in medical technology faces challenges such as technological complexity, limited resources, and lack of awareness. However, the benefits include improved 'patient' safety, regulatory compliance, reduced downtime and costs, and increased organisational resilience.
- **Best Practices:** The article outlines key practices for effective BCM implementation, including thorough risk assessments, comprehensive BCM plans, regular testing and updates, investment in redundant systems, staff training and awareness, and collaboration with external stakeholders.

Introduction

The healthcare industry relies heavily on medical technology to provide efficient and effective patient care. However, medical technology is susceptible to a variety of risks, including power outages, natural disasters, cyber-attacks, and equipment malfunctions. These risks can cause significant disruptions to hospital operations, jeopardising patient safety and care quality. This is where Business Continuity Management (BCM) comes into play. BCM is a holistic approach to risk management that aims to identify potential disruptions and develop strategies to ensure the continuity of critical operations in the event of an incident such as enumerated above. This article discusses the importance of BCM in medical technology and how it can help healthcare organisations avoid costly downtime and ensure uninterrupted healthcare services.

The Need for BCM in Medical Technology

Medical technology is critical to delivering quality healthcare services. Hospitals rely on a range of medical devices, such as CT scanners, MRI machines and, for example, ventilators, to diagnose and treat patients. Any disruption in the operating of these devices can have serious consequences for patient safety and care quality. For example, a power outage that shuts down an MRI machine could delay critical diagnoses and result in cancelled appointments, which can cause significant inconvenience for patients and their families. Also, hospitals must comply with regulatory requirements and standards that mandate the availability and reliability of medical technology. Failure to meet these requirements can result in penalties, legal liabilities, and damage to an organisation's reputation.

BCM helps hospitals identify potential disruptions to medical technology and develop strategies to



mitigate them. For example, hospitals can implement redundant power systems, such as backup generators or uninterruptible power supplies, to ensure that medical devices have a continuous source of power.

Hospitals can also establish emergency response plans that outline procedures for addressing power outages or other disruptions to medical technology. These plans can include procedures for quickly repairing or replacing faulty equipment, ensuring that critical patient data is available, and communicating with patients and staff.

include:

1. Enhanced patient safety and care quality: BCM can help hospitals ensure the availability and reliability of critical medical devices, reducing the risk of disruptions that could harm patients.
2. Improved regulatory compliance: BCM can help hospitals comply with regulatory requirements and standards related to the availability and reliability of medical technology.
3. Reduced downtime and costs: BCM can help

BCM helps hospitals ensure the availability and reliability of critical medical devices, reducing the risk of disruptions that could harm patients

Challenges to Implementing BCM in Medical Technology

Implementing BCM in medical technology can be challenging due to a variety of factors. One of the main challenges is the complexity of medical technology. Medical devices are often interconnected and require specialised expertise to maintain and repair. This can make it difficult to identify potential disruptions and develop effective response plans. In addition, medical technology is constantly evolving, requiring hospitals to stay up-to-date on the latest equipment and software.

Another challenge is the limited financial resources in many hospitals. Often, hospitals lack the personnel and financial resources to implement comprehensive BCM strategies. This can lead to a reactive approach to risk management, where hospitals only address risks after they have occurred. Reactive risk management can result in costly downtime, legal liabilities, and damage to a hospital's reputation.

Finally, there is a lack of awareness among healthcare organisations about the importance of BCM in medical technology. Many hospitals view BCM as a cost center rather than a strategic investment with a measurable ROI. This can result in inadequate funding for BCM initiatives and a lack of commitment from senior leadership.

Benefits of BCM in Medical Technology

Despite the above described challenges, implementing BCM in medical technology can provide significant benefits for healthcare organisations. These benefits

hospitals avoid costly downtime by identifying potential disruptions and developing effective response plans.

4. Increased organisational resilience: BCM can help hospitals build resilience and adaptability, enabling them to quickly recover from incidents and maintain critical operations.

Best Practices for Implementing BCM in Medical Technology

To effectively implement BCM in medical technology, healthcare organisations should follow these best practices:

1. Conduct a thorough risk assessment: Identify potential hazards, vulnerabilities, and risks that may disrupt medical technology operations. Prioritise the identified risks based on their impact and likelihood of occurrence.
2. Develop a comprehensive BCM plan: Based on the risk assessment, develop a detailed BCM plan that outlines the actions to be taken before, during, and after a crisis. This should include contingencies for staffing, communication, and alternative facilities.
3. Test and update the BCM plan regularly: Testing the plan ensures that it is effective and up to date. Regular testing also identifies gaps and areas for improvement. BCM plans should be reviewed and updated at least annually or whenever significant changes occur in the organisation.
4. Invest in redundant medical technology systems: Redundant systems and backup power supplies can prevent downtime and ensure continuous medical



technology operations. Organisations should invest in backup systems for critical medical technology equipment, such as imaging machines, ventilators, and dialysis machines.

5. Provide staff training and awareness: All employees involved in medical technology operations should be trained and aware of their roles and responsibilities during a crisis. Regular training ensures that staff is prepared to respond to an emergency and can effectively execute the BCM plan.
6. Establish effective communication channels: Effective communication is critical during a crisis to ensure timely and accurate information sharing. Establish communication protocols and ensure all staff knows how to use them. Communication channels should be tested regularly to ensure they are effective.
7. Collaborate with external stakeholders: External stakeholders, such as medical technology vendors and emergency responders, can provide valuable assistance during a crisis. Establish relationships with these stakeholders and ensure they are included in BCM planning and testing.

By following these best practices, healthcare organisations can effectively manage risks and ensure that medical technology operations are maintained during a crisis.

One such example of a healthcare organisation implementing BCM in medical technology is the case of Children’s Hospital Los Angeles (CHLA). In 2008, CHLA experienced a power outage that affected several areas of the hospital, including the neonatal intensive care unit (NICU) and the paediatric intensive care unit (PICU). As a result of this power outage, CHLA activated its BCM plan, which included backup generators and procedures for ensuring that critical medical devices, such as ventilators and monitors, were functional. Thanks to their BCM plan, CHLA was able to ensure continuous patient care throughout the power outage.

Another key aspect of BCM in medical technology is maintaining effective communication during a crisis. In order to ensure that everyone is aware of the situation and can take appropriate action, healthcare organisations should establish clear communication

channels and protocols. This includes having a designated spokesperson who can communicate with the media and the public, as well as establishing backup communication systems in case of failure.

In addition to the best practices mentioned above, healthcare organisations can also benefit from leveraging technology to enhance their BCM efforts. For example, digital tools such as automated alerts and notifications can help organisations quickly identify and respond to potential threats, while data analytics can provide valuable insights into the effectiveness of BCM plans and identify areas for improvement.

Ultimately, the success of BCM in medical technology depends on the commitment and dedication of healthcare organisations to ensure the safety and well-being of their patients, staff, and community. By investing in BCM and following best practices, healthcare organisations can minimise the impact of crises and ensure that critical medical technology operations are maintained during even the most challenging circumstances.

Conclusion

In conclusion, the importance of BCM in medical technology cannot be overstated. With the increasing reliance on medical technology to deliver critical care to patients, healthcare organisations must be prepared to manage risks and ensure that operations can continue in the face of a crisis.

By implementing best practices such as conducting risk assessments, developing and testing BCM plans, and maintaining effective communication, healthcare organisations can minimise the impact of crises and ensure the safety and well-being of their patients and staff.

As the healthcare industry continues to evolve, it is critical that organisations prioritise BCM in medical technology to ensure the continued delivery of safe and effective patient care.

Conflict of Interest

None. ■

Effective Management in Times of Health Crisis

The COVID-19 pandemic and the rapid evolution of events on a national and international scale required the adoption of immediate and effective measures to deal with these events.

In this article we would like to share our experience as a public procurement department that faced the pandemic by taking innovative actions to respond to this world-wide health crisis.

SUSANA ÁLVAREZ
GÓMEZ



Deputy Director General,
Public Procurement, Madrid Health Service,
Madrid, Spain

key points

- The rapid responsiveness of Public Procurement Units to the pandemic.
- The need for public-private partnerships is illustrated.
- The importance of collaboration between different public administrations is key.

Introduction

The COVID-19 pandemic has illustrated the need to change the ways in which health care tasks have been carried out, generating expectations and opportunities, which must be reflected in the day-to-day work of the Public Procurement Units, with an eye towards consequences for the organisation as a whole.

The immediacy of the pandemic and its high incidence has forced us to undertake a transformation in the public procurement model, including tasking professionals to perform actions without previous experience, and establishing new systems with clearly differentiated actions and responsibilities. This was done in order to optimise the response to the increased demand for contracts in order to cover the increasing procurement needs to which the healthcare centres were subjected.

As soon as the declaration of the state of emergency in Spain, all activities of a contractual nature ceased in accordance with the provisions of the Fourth Additional Provision of the Suspension of the Limitation and Expiry Periods of Royal Decree 463/2020 of 14 March.

Exceptions were those activities derived from the monitoring and payment of agreements, concerts, contracts and other agreements with external funds, including hospitals under concession, given the serious

damage that the cessation of these activities would have entailed.

It should also be remembered that the legislation in force in Spain is Law 9/2017 of 8 November on Public Sector Contracts, which absorbs into Spanish law the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (Hereinafter PSCL).

Our Experience

One of the first responses to the pandemic was the reorganisation of the staff of the Subdirectorate General of Public Procurement (hereinafter SGPP), creating two working teams to draw up the different types of contracts.

The first team was dedicated to the formalisation of those procurement files for services and/or equipment, in which it had more experience and prior knowledge.

The second team was dedicated to the procurement of medical supplies and personal protective equipment (PPE) in response to an unprecedented demand for products, which also involved the management of suppliers and the development adjustments of the logistics of these supplies and medical devices, tasks that had not been carried out before the pandemic by the SGPP.



The second initiative was to develop a network of suppliers in order to guarantee the supply of medical equipment and PPE.

As we were asked to collaborate in the provision of the IFEMA COVID-19 Field Hospital, which had to be able to treat patients within 48 hours, we decided to contact the Spanish Federation of Healthcare Technology Companies (FENIN), in order to facilitate contact with associated suppliers. The response was immediate, and that weekend in March we were able to start contracting the much-needed supplies.

Emergency Service.

Aware that we could only respond to PPE acquired from the SGPP and not to other PPE received in the warehouse from different sources, we formalised a procedure called: “Management of enquiries regarding personal protective equipment”.

The aim of this procedure was to standardise the methodology to be followed for the management of enquiries made by healthcare centres of the Madrid Health Service (hereinafter SERMAS) (hospitals, primary care centers and Summa 112) regarding

The high responsiveness of Public Procurement Units to the pandemic

This relationship, still active, has enabled us to provide the healthcare centres such as the IFEMA COVID-19 Field Hospital and later the Enfermera Isabel Zandal Emergency Hospital, with appropriate supplies, medical devices and PPE within the regulatory framework.

With centralised public procurement in place as well as the start-up of the IFEMA COVID-19 Field Hospital, the next step was a central warehouse.

The already smooth communication with the personnel stationed there led to the creation of a single e-mail address for the management of any incidents that might arise in the warehouse with any of the deliveries of goods to ensure a prompt solution, as well as the monitoring of stocks to help us identify the specific needs for material, especially PPE.

The next initiative involved guaranteeing the traceability of the material. The formalising of the public procurement process necessitates tracing the process of ordering, billing and payment of the corresponding invoice. To safeguard that entire chain of events we decided to implement the SAP “NEXUS LOGISTICO” environment application for PPE material contracts.

We were aware that this system involves a large number of administrative transactions, but it allows us to have total control of the entire purchasing, logistics and payment process, from the formalisation of the contract, request to the supplier, receipt of the product, and finally billing and payment.

In time, and with the increasing number of patients affected by the COVID-19 disease, we began to receive requests for information regarding the suitability of the PPE distributed from the central warehouse to the hospitals, Primary Care centres, and the “SUMMA 112”

compliance with the regulations required of the PPE supplied to them during the pandemic.

In order to respond to queries on PPE not acquired by us, we contacted the National Centre for Means of Protection (hereafter CNMP), through the National Institute for Safety and Health at Work of the Ministry of Labour and Social Economy, in its capacity as the authorised centre for carrying out the tests considered critical to verify whether the self-filtering masks type FFP2 and FFP3 submitted offer protection against the penetration of particles, with a view to allowing their use during the COVID-19 pandemic.

Along the same lines, we got requests for gloves not acquired by us. It was agreed to validate those gloves through tests considered critical to verify whether the gloves submitted offer some protection against contact with micro-organisms, with a view to their use during the COVID-19 pandemic.

All the information resulting from these validations was sent to the health centres and is also available in the common electronic folder created for this purpose.

This procedure received special recognition by the International Hospital Federation (hereinafter IHF) under the “Beyond the call of duty for COVID-19” programme.

We presented the above described under the title “Beyond Health Public Procurement: How We Manage To Improve The Protection Of Health Professionals Against COVID-19” and were recognised among the 15 best projects for “having shown initiative, agility and an incredible ability to innovate under extraordinary circumstances”.

A PPE advisory group was also formed with technical staff and doctors from SERMAS who voluntarily



accepted to form part of the project, and who have contributed to the drafting of the technical prescriptions that will be used for the centralised acquisition of PPE.

We also had an important collaboration with the General Directorate of Industry, Energy and Mines of

actions can respond to the needs that may arise from a resurgence of the pandemic caused by COVID-19, or any other similar situation. All of them remain active.

None of us expected the events that took place, neither the 14 weeks of state of alarm that we experienced nor

The need for public-private partnerships is illustrated

the Regional Ministry of Economy, Employment and Competitiveness on the technical requirements of PPE.

Finally, we are aware that the implementation of a single catalogue of health products for all SERMAS health centres means facilitating centralised purchasing and its subsequent distribution to health centres. In this sense, work has expanded on the implementation of the single catalogue, and since the beginning of the pandemic, 9 health centres have been included in this single catalogue. We believe that this is the only way to have a centralised logistics platform.

Finally, it is worth noting that from the very first moment the pandemic was declared by the World Health Organisation, an information system was set up at the SGPP to monitor the pandemic, using various Spanish and international data sources. These sources reported on the pandemic situation in real time.

This exhaustive monitoring gave rise to our own information system, which allowed us to acquire what we needed before the appearance of the second pandemic wave, and this dynamic was maintained in successive waves. This working dynamic allowed us to guarantee material to the health centres by acquiring it before other public procurement departments, without any stock-outs. It also allowed us to introduce diagnostic tests for COVID-19 ahead of the decisions of other public procurement departments.

At least in Spain, we were the first to go to the market for these tests.

Conclusion

In a very short time we have taken practical and immediate measures to meet the strong demand for care caused by the pandemic, trying to guarantee the health care demanded by citizens and to guarantee the protection of healthcare professionals. As a result, these

the weeks that followed. But it is not all behind us, we are still in a state of health crisis and we are aware that new pandemics may occur. This makes us vigilant and alert, but we are convinced that in future situations we will be able to cope with what we have learned so far.

Our experience shows us the importance of maintaining and intensifying coordinated and collaborative work between different areas (procurement, logistics-warehouse, hospitals, SUMMA 112, Primary Healthcare, suppliers...), both in our own organisation and in other organisations, whether public or private. Multidisciplinary work, such as that formed with prevention technicians, also guarantees new synergies. For this reason, we are working on forming groups of experts even for the technical design of new public contracts.

Telemedicine has proven to be useful especially in risk situations for health care workers.

But it has also proved useful in streamlining processes, and it is a tool that has been a boost to the motivation and dedication of public procurement professionals. We must not forget that people are the real driving force of any organisation. That is why their motivation is so important, and this requires training and professionalisation, which is why we provide training tools and work towards staff recognition.

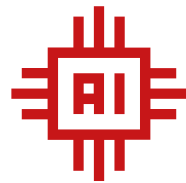
I am sure that all these activities will continue to grow, as they are lines of action that have a positive impact on improving the public procurement of goods and services that are so important and have such an impact on the entire organisation. We dedicate every day to this objective.

Conflict of Interest

None. ■

references

For full references, please email edito@healthmanagement.org or visit <https://iii.hm/1jxw>



AI: Opportunities Capabilities and Limits

How Imaging Generative AI Will Transform the Medical Radiological Practice

Generative AI imaging has emerged as a powerful tool in radiology, allowing for the creation of highly detailed bio-models that can assist in diagnosis and treatment planning. Generative AI algorithms can generate 3D models of organs, tissues, and other structures with unprecedented accuracy and speed.

This technology thus has the potential to revolutionise the field of radiology, enabling more accurate and personalised medical care, including synthetic data for training or creating specific understandable bio-models, and clinical information to patients, enhancing health literacy and automating the generation of anamnesis and clinical notes. However, it also raises many ethical, regulatory, legal and philosophical questions that need to be solved before being ready for wide adoption in healthcare.



**JOSEP
MUNUERA DEL CERRO**

Director of Radiology Department,
Hospital de la Santa Creu,
Sant Pau,
Barcelona, Spain

key points

- Generative AI will have a role in radiology departments at different levels: professional-patient communications, quality and processes, as well as in the generation of medical imaging.
- Generative AI Imaging can have multiple uses, an example of which synthetic imaging generation for diagnosis. On the one hand, enhancing or accelerating the radiological images, but also as an aid to augment AI training databanks for rare or data-poor diseases.
- Medical imaging biomodels currently have multiple applications: surgical planning, student training, and improved communication with patients. Generative AI imaging tools will facilitate accessibility and speed of implementation in these scenarios.
- However, there are still many technical, usability, regulatory and ethical limitations to the implementation of these solutions. We must begin to collate experiences, research, and test the applicability in order to extend its use in an appropriate manner.

Arnau Valls Esteve | Head of Innovation Area | Technical Manager of 3D4H Department |
Hospital de Sant Joan de Déu | Barcelona, Spain

What Is a Generative Image AI? And, How Can It Be Applied and What Effect Will It Have in Imaging?

Deep learning has revolutionised the field of artificial intelligence (AI) by enabling machines to learn from

large amounts of data and perform complex tasks based on them. One of the most exciting applications of deep learning is in the field of generative models. Generative models are deep learning models that can generate realistic images, videos and audio. These models have

a wide range of applications in healthcare, including imaging.

Generative Image AI is a type of artificial intelligence that can generate images that are similar to real-world images or those used to train the algorithm. These models use deep learning algorithms to analyse and understand the patterns and features of real-world images, and then use that knowledge to generate new images that are similar in appearance.

There are several types of generative image AI models, including Generative Adversarial Networks (GANs), Variational Autoencoders (VAEs), and Autoencoders.

GANs are a popular type of generative image AI model that consists of two neural networks: a generator network and a discriminator network. The generator network generates synthetic images, while the discriminator network attempts to distinguish between the synthetic and real images. The two networks are trained together in an adversarial manner, where the generator tries to fool the discriminator and the discriminator tries to correctly classify the synthetic and real images. GANs have a wide range of applications in radiology, including image segmentation, image synthesis and image de-noising. Image segmentation is the process of dividing an image into multiple regions or segments. GANs can be used to segment medical images such as MRI scans, CT scans and X-rays. GANs can also be useful for synthesising medical images that are difficult to acquire, such as rare diseases or anatomical variations. GANs can also be

the models. This can also help reduce the time and cost involved in acquiring labeled data.

VAEs are another type of generative image AI model that uses an encoder-decoder architecture to generate images. The encoder network maps the input image to a low-dimensional latent space representation, while the decoder network maps the latent space representation back to the input image. The VAE is trained to learn the distribution of the input data in the latent space representation, and to generate new samples from that distribution.

Autoencoders are a simpler type of generative image AI model that use a single neural network to learn a compressed representation of the input image. The compressed representation can then be used to generate new images that are similar to the original image. The goal of the VAE is to learn a latent space representation that captures the underlying distribution of the input data. This latent space representation can be used for a variety of tasks, such as image generation, data augmentation, and classification.

One application of VAEs in medical imaging is image segmentation. Image segmentation is the process of dividing an image into different regions or segments, each of which corresponds to a different anatomical structure. VAEs can be used to learn a low-dimensional representation of the imaging data that captures the underlying distribution of the anatomical structures in the image. This low-dimensional representation can then be used to perform image segmentation.



Figure 2A. Example from the AI Dall-E.2. In this example, from a real MRI image of the circle of Willis in TOF the algorithm was asked to generate variants of the image. This type of approach, as MONAI and NVIDIA are already working on, will make it possible to generate a synthetic image from a few real cases, so it can be of great value in those rare diseases or situations in which there are very few cases of some types of findings. Also for the generation of large datasets to train new AI models.

used to de-noise medical images, which can improve the accuracy of diagnosis and treatment planning. One of the major challenges in radiology is the scarcity of labeled data. Labeled data is data that has been manually labeled by a radiologist or a medical expert. GANs can be used to generate synthetic data that can augment the labeled data and improve the accuracy of

Generative Imaging Algorithms Will Help in the Creation of Synthetic Radiological Images but also to Design New Bio-Models

A quick history about Generative AI:

Generative AI has become a trend since its first launch on November 22nd 2022, creating high expectations about a long-awaited potential of AI real use. ChatGPT



Figure 2Ba

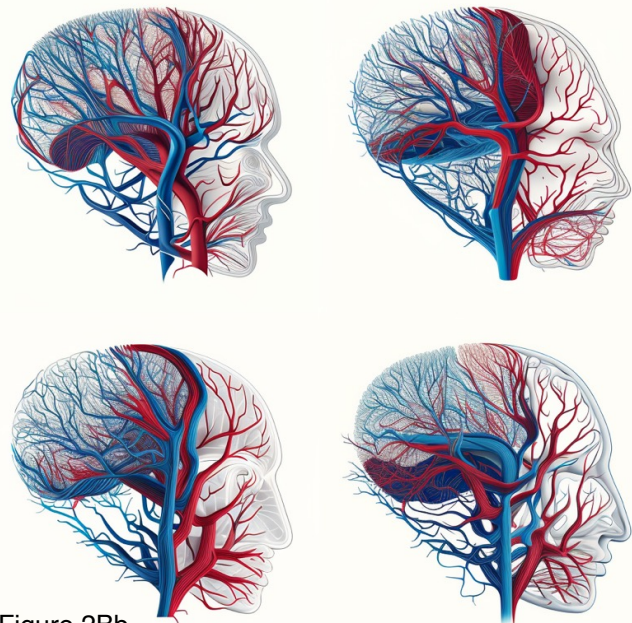


Figure 2Bb

Figure. 2B a and b: In this example, the algorithm was asked to create variations of the brain vasculature. These models, although insufficient and poorly accurate, are a sample of how image generation can evolve.

gained one million users in its first week after launch and reached the milestone of 100 million users in the 2 months, surpassing all known digital solutions so far.

The use of Generative Artificial Intelligence (AI) in healthcare has the potential to revolutionise the management of health and help on diagnosis and treatment. One area where this technology has already shown promise is in the creation of synthetic imaging such as 3D bio-models and radiological images.

By improving accuracy, reducing costs, and streamlining processes, this technology can help healthcare providers deliver better care to their patients. Its earlier adopters are already reporting first evidence of the potential impact. For instance, Dr. Isaac Kohane, a computer scientist at Harvard and a physician in his book, "The AI Revolution in Medicine" (Lee et al. 2023) applied Chat GPT-4 to a US medical licensing exam, which the algorithm passed, being able to diagnose a real-life case of a congenital adrenal hyperplasia based on data from the physical exam, as well as some information from an ultrasound and hormone levels. This is a rare disease affecting 1 in 100,000 newborns.

In another example, researchers from the Massachusetts General Hospital (MGH) and AnsibleHealth, published in a recent study (Kung et al. 2023) that Chat GPT-4 can pass the United States Medical Licensing Exam (USMLE) without clinician input with a score of 60% accuracy, exceeding the passing score on USMLE by over 20 points. These results are in line with similar research done by Nori et al (2023) and

Freedman et al (2023).

However, there are also challenges associated with the use of generative AI in healthcare. Privacy concerns and the potential for bias are just two examples. As with any new technology, it is important to approach generative AI with caution and to address these issues as they arise.

Nonetheless, generative AI represents a significant opportunity for healthcare providers to improve patient outcomes and advance the field of medicine.

What Is the Potential Role of Generative AI in the Medical Imaging Departments?

This potential to transform the practice of radiology may occur in several ways in general workplace management, exam reporting and last but not least, enhancing the imaging itself.

Here are some actual practice examples:

- **Automating Repetitive Tasks:** Radiologists spend a significant amount of time performing routine tasks such as locating and measuring abnormalities in medical images. Generative AI can automate these tasks, reducing the time and effort required by radiologists and enabling them to focus on more complex cases.
- **Facilitating Remote Consultations:** Generative AI can enable radiologists to provide remote consultations and second opinions in routine cases, automating the process to give a first answer even when they are not physically present with the patient. This can be particularly

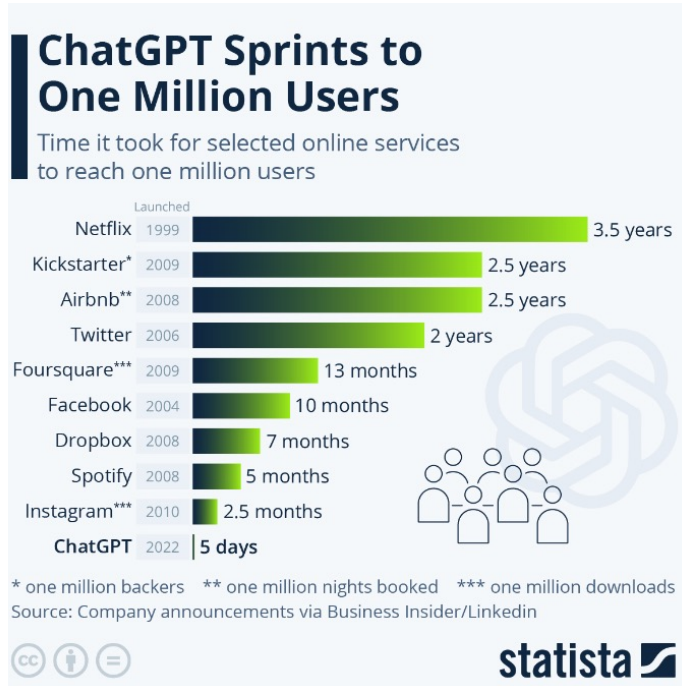


Figure 1. Time to reach 1 million users of main digital innovations since 1999. Source: Statista

useful in situations where there is a shortage of radiologists or when patients are located in remote or underserved areas.

- **Extracting structured information from unstructured radiology reports** for research or secondary use of data.
- **Translating radiology reports into a layman version** so that patients better understand them.

Focusing on **Imaging Generative AI**, the main potential roles are:

- **Improving Diagnostic Accuracy:** Generative AI can improve the accuracy of radiological diagnoses by providing radiologists with additional information and insights. For example, AI algorithms can analyse large datasets of medical images to identify patterns and trends that may not be immediately apparent to imager's eyes.
- **Enhancing Image Analysis:** Generative AI, combined with other image processing and AI techniques, can be used to enhance the analysis of medical images, enabling radiologists to identify subtle changes that may be difficult to detect with the naked eye. For example, AI algorithms can be trained to identify the early signs of disease processes, such as (malignant) tumors or degenerative conditions. Generative AI models can be used to 'clean up' medical images by removing noise or artifacts. For example, generative models

can be trained to remove noise from medical images such as MRI or CT scans, making them easier to interpret and analyse.

- **Medical imaging synthesis** with generative AI algorithms and other artificial intelligence techniques could generate synthetic medical images that are visually realistic and clinically relevant and that can resemble real patients images in different acquisition techniques such as US, MRI, and CT scans. The capacity of generating infinite newly created data can enable the training and validation of AI algorithms, reducing the need for live patient data, and enabling the generation of diverse and customizable medical images for specific research or educational needs.
- **Automated Diagnosis:** Generative AI models can be trained to analyse medical images and provide automated diagnosis. For example, generative models can be trained to detect abnormalities in any and all medical images, and provide a diagnosis based on the type and severity of the abnormality.
- **Image Segmentation:** Generative AI models can be trained to segment medical images into different regions based on the structures and tissues present. This can be useful in identifying and analysing specific structures or tissues in medical images such as the brain or lungs.
- **Personalising Treatment Plans:** Generative AI can help radiologists develop personalised treatment plans based on a patient's individual characteristics and medical history. For example, AI algorithms can analyse medical images to identify the most effective treatment options for a particular patient based on factors such as age, gender, and medical history. Generative AI models can be also used to simulate the effects of different treatment options on medical images. For example, generative models can be trained to simulate the effects of radiation therapy on a patient's medical images, allowing imagers to optimise treatment plans.

Various Generative AI algorithms are today available that could be of potential use in the field of radiology. **Table 1** shows the Radiology Generative AI Applications Landscape:

In summary, the use of generative AI in radiology has the potential to improve diagnostic accuracy, increase efficiency, and enhance patient care. However, it is important to note that AI should not replace the expertise of radiologists but rather complement and support their work becoming a useful tool.



Research	Image Generation	Image Segmentation	Text Generation	Diagnosis or Clinical plan generation based on symptoms	Medical summarisation	Personal Medical Assistant	3D shape generation
Elicit	Dall -E (OpenAI)	CLIPSeg	Chat GPT (OpenAI)	Glass AI	Curai	Nabla	SP-GAN
Semantic Scholar	Midjourney	Segment Anything (Meta)	Med-PaLM (Google)				Magic3D (NVIDIA)
Scholarcy	GauGAN2 (NVIDIA)		Bard (Google)				Imagine 3D (LumaAI)
Scite.ai	Stable Difussion (Stability.ai)		BioGPT (Microsoft)				Point-E (Open-AI)
Bearly							
Compose.ai							
Grammarly							
Lucia.ai							

Table 1. The Radiology Generative AI Applications Landscape

The Importance of Human Imaging Bio-Models in Healthcare

The transition from hand-drawn anatomical models to digital models and eventually to AI-generated models has been a gradual process driven by advancements in technology. Before delving into the role of AI-synthesised image, we must explain the healthcare value of imaging bio-models.

Hand-drawn anatomical models have been used for centuries to teach anatomy and physiology. With the advent of digital technology, these models were digitised and rendered in 3D, allowing for more interactive and realistic visualisations. However, creating accurate and detailed 3D models can be a time-consuming and expensive process. With the development of AI, generative models can now be trained on large datasets of medical images to generate highly detailed and realistic anatomical models. These models can be generated much faster and with greater accuracy than traditional methods, and can be used for a variety of applications in healthcare, including diagnosis, treatment planning, and medical education.

A. What Are the Main Applications of Bio-Models and Medical Imaging Design?

These bio-models, whether inspired by reality, created through traditional design methods, or specially extracted from radiological (medical) images, allow for improvements in the field of medicine. Furthermore, recently, thanks to 3D imaging technologies (whether through automatic projections and renderings or

through 3D models for visualisation in augmented or virtual reality), the value of bio-models has been further demonstrated.

- **Improved Diagnostic Accuracy:** Medical image design can help healthcare professionals visualise and understand complex medical conditions, resulting in improved diagnostic accuracy. Accurate diagnosis is essential for effective treatment planning and can lead to better patient outcomes.
- **Disease Image Pattern Study:** Finally, 3D imaging can be used to study the patterns of disease in patients. By analysing 3D images of organs and tissues, medical professionals can identify patterns of disease progression and develop new treatment strategies. For example, 3D imaging can be used to study the growth patterns of tumors, identify areas of ischemia in the heart, or detect early signs of Alzheimer disease in the brain.
- **Treatment Planning:** Medical image design can be used to simulate the effects of different treatments, allowing healthcare professionals to develop customised treatment plans for individual patients. This can help ensure that patients receive the most appropriate and effective treatments.
- **Education:** Medical image design can be used to create educational materials for healthcare professionals and patients. For example, medical animations can help explain complex medical concepts and procedures, while medical illustrations can help visualise the structures and functions of the human body. 3D images provide an excellent

tool for teaching complex anatomical structures and help students to understand the spatial relationships between different anatomical regions. Furthermore, 3D imaging can be used to simulate surgical procedures, which can provide students with valuable experience before performing actual surgeries. By providing a realistic and immersive experience, 3D imaging can help to improve the quality of medical education.

- **Reduced Risk:** Medical image design can be used to simulate medical procedures, allowing healthcare professionals to identify potential risks and develop strategies for mitigating those risks. This can help reduce the likelihood of complications and improve patient safety. **Geometric Understanding of Complex Anatomy:** 3D imaging also provides a more accurate and detailed view of complex anatomical structures. By creating 3D models of structures such as the brain, heart, and spine, medical professionals can gain a better understanding of their shape, size, and orientation. This information can be used to plan surgeries and treatments more effectively, leading to improved patient outcomes. Additionally, 3D imaging can also be used to create custom prosthetics and implants that are tailored to the patient's unique anatomy.
- **Improved Patient Communication:** Medical image design can help improve communication between

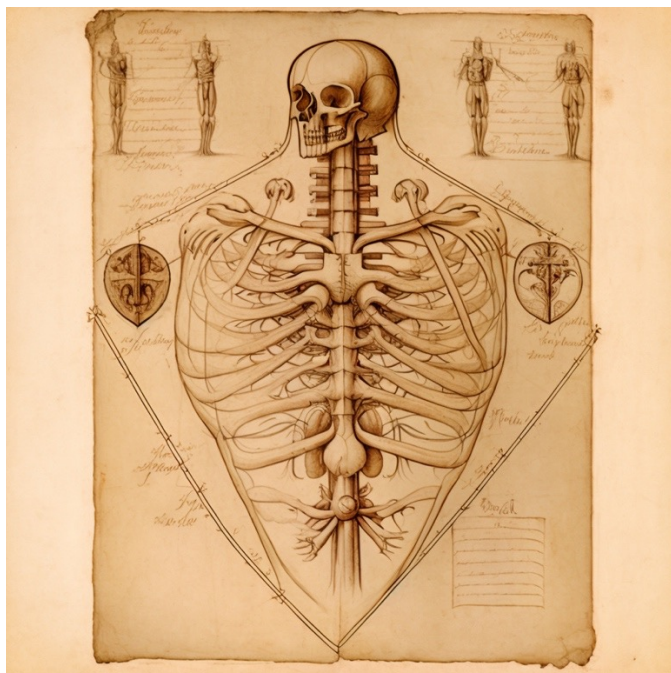


Figure 3A. Example of a synthetic image of a thorax simulating a drawing from an old medical book (Da Vinci style). This type of AI also allows the creation of new types of images that can help communicate with patients or facilitate anatomical understanding as they are interpretable images.

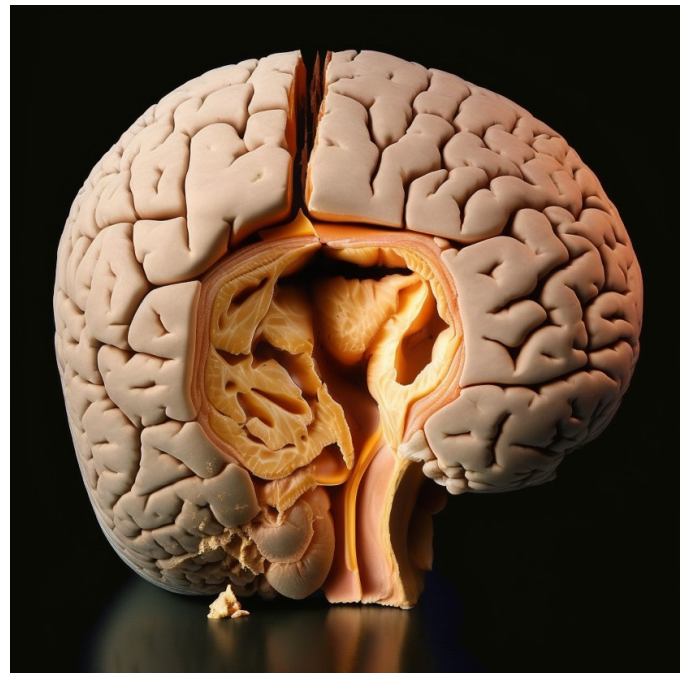


Figure 3B. In this example, it was requested to show a brain after a resection of a meningioma. A "cavity" can be seen in the brain tissue. This type of images could be helpful for communication with the patient.



Figure 3C. Synthetic image created with Midjourney to explain what are the main consequences of an acute ischemic stroke [ischemic tissue and penumbra of perfusion] in case of a brain arterial occlusion.

healthcare professionals and patients. Visual aids such as medical animations and illustrations can help patients better understand their medical conditions and treatment options, resulting in more informed decision-making and better patient outcomes. One of the main advantages of 3D



imaging in medicine is the ability to improve patient education. 3D images provide patients with a more accurate and comprehensive view of their anatomy and medical condition. Patients can easily visualise their condition and understand the nature of their disease or injury, which can lead to better patient compliance and satisfaction. Furthermore, 3D imaging can also help patients to understand the surgical procedure, and this can reduce anxiety and improve outcomes.

B. How Can Imaging Generative AI Enhance the Imaging Bio-models?

Here are some of the possibilities of using synthetic medical imaging created with generative AI:

- **Augmenting Real Medical Images:** Synthetic medical images generated by generative AI can be used to augment real medical images. For example, synthetic images can be used to enhance the resolution of real images, to create additional images of organs or structures that are difficult to visualise with current imaging techniques, or to simulate the effects of different treatment options on medical images.
- **Data Augmentation:** Synthetic medical images can be used to augment datasets for machine learning models. This is particularly useful when the amount of real medical image data is limited or when the available data is imbalanced.
- **Medical Image Analysis:** Synthetic medical images can be used to train and test algorithms used for

medical image analysis. Generative AI can be used to create synthetic images that are similar to real images, but with known characteristics such as specific abnormalities or tissue types. This can help in the development and testing of algorithms used for medical image analysis.

- **Research:** Synthetic medical images can be used in medical research to simulate disease progression or treatment effects. For example, generative AI can be used to simulate the progression of Alzheimer disease or the effects of chemotherapy on tumors.
- **Education:** Synthetic medical images can be used in medical education to provide students with additional images for study and practice. Generative AI can be used to create synthetic images that are similar to real images, but with known characteristics such as specific abnormalities or tissue types. These images can be used to teach students about specific diseases or conditions.

Overall, the possibilities of using synthetic medical imaging created with generative AI are vast and have the potential to greatly enhance medical research, diagnosis, and treatment planning. However, it is important to note that these images must be thoroughly validated and tested before they can be used in clinical settings.

Generative AI also Has Several Limitations:

While ChatGPT and other generative AI systems create great expectations for the long-awaited democratisation of AI in many sectors, including healthcare, they also raise many ethical, regulatory, legal and philosophical issues that need to be resolved before widespread adoption. In fact, some of the earliest adopters of the technology since the launch of ChatGPT in November 2022, already started to report first issues. As an example, according to The Economist Korea (2023), on March 20th, the Samsung's Korea-based semiconductor business reported 3 data leakage accidents occurred within Engineers of the semiconductor plants: The developers sent confidential lines of code to ChatGPT on three separate occasions, which the AI chatbot leveraged as training data for future public responses. This act, automatically supposed a leaking corporate secret that could be included in the chatbot's future responses as it is stated by the OpenAI user guide warning users: "We are not able to delete specific prompts from your history. Please don't share any sensitive information in your conversations." The system uses all questions and text submitted to it as training data. Moreover, on 31st May 2023, Italy's data protection agency announced the blockage use of ChatGPT within the country while studying the potential violation

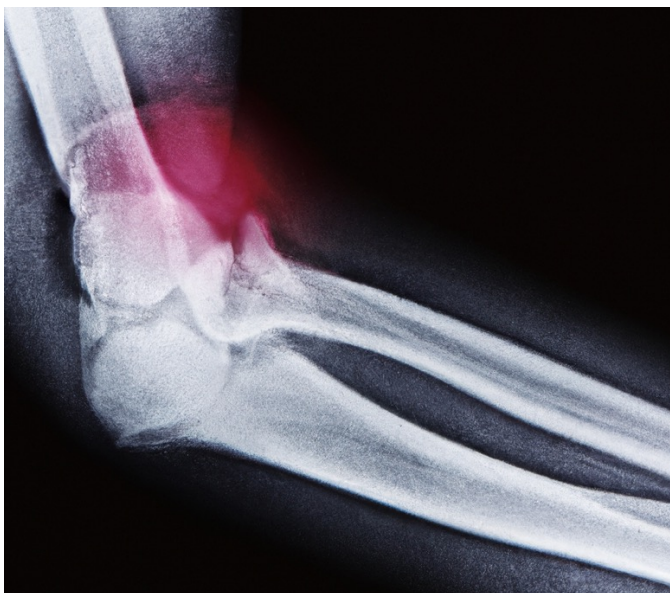


Figure 4. Example of a synthetic image of a fracture of the head of the radius and humerus. This type of synthetic data will allow increasing the cases, for training new diagnostic algorithms, as well as serving as training for readers.



of GDPR compliance (The Italian Data Protection Authority 2023).

Above mentioned examples, poses a need for regulation and reflection on the potential uses of these new technologies, and this is also the case for the use of biomodels. Today, as can be seen in the following examples, photo-realistic images generated by generative AI still have a moderate intrinsic error that makes the results unrealistic, needing to be validated

However, ongoing studies focus on improving the computational efficiency, which opens the door that in a few years it will not be unusual to have customised and private generative AI algorithms trained for specific tasks.

3. Data Bias: Generative AI models can be biased if the training data is biased. For example, if the training dataset contains mostly images of a specific demographic group, the generated images may not

Possibilities of using synthetic medical imaging created with generative AI are vast and have the potential to greatly enhance medical research, diagnosis, and treatment planning

by an expert. This highlights the importance of quality control. However, considering the main nature of continuous learning of generative AI algorithms, we will soon be able to have re-trained and improved algorithms focused on medical imaging capable of having highly accurate image results.

In addition to those “model” generated problems, there are other limitations of image generative AI:

1. Limited Information: Generative AI models are trained on specific datasets and may not generalise well to new, unseen data. This means that the generated images may not accurately represent real-world images and may contain artifacts or distortions. Actual generative AI models may lack anatomical precision because they are trained on large publicly available datasets, rather than on specific datasets of medical images with a quality control with a deep understanding of human anatomy. For example, a generative AI model that generates images of people may be trained on a large dataset of photographs, but it may not have a comprehensive understanding of the underlying structure of the human body. Additionally, generative AI models are typically designed to generate output quickly and efficiently, which can lead to simplifications and inaccuracies.

2. Computational Requirements: Generative AI models require significant computational resources to train and generate images. This can make it challenging to apply these models in real-time or in resource-constrained environments.

be representative of the general population. This leads to potential gender, ethnic, racial and intrinsic imbalances due to the entry training data. As with any AI algorithm, quality control and preparation of the input data is important.

4. Limited Control: Generative AI models are often difficult to control, meaning that the generated images may not align with specific requirements or desired features. This can be particularly challenging in medical applications where specific features or abnormalities need to be highlighted.

5. Ethical Considerations: Generative AI models can be used to create realistic images of people or objects that do not exist in the real world or that resemble publicly known individuals. This raises ethical concerns around the potential misuse of these images, such as the creation of deepfakes or other forms of digital manipulation.

Prompts are crucial in generative AI because they provide a starting point for the model to generate new content. A prompt is a piece of text or input that the generative AI model uses to generate new output, such as a story, a poem, a piece of music, or even an image. Without prompts, the generative AI model would not know where to start or what kind of output to generate. Prompts help to guide the model and give it context and direction. By providing a prompt, the user can influence the output of the model and steer it in a particular direction. Prompts can also be used to fine-tune generative AI models for specific tasks. But, when prompts are not used correctly with generative

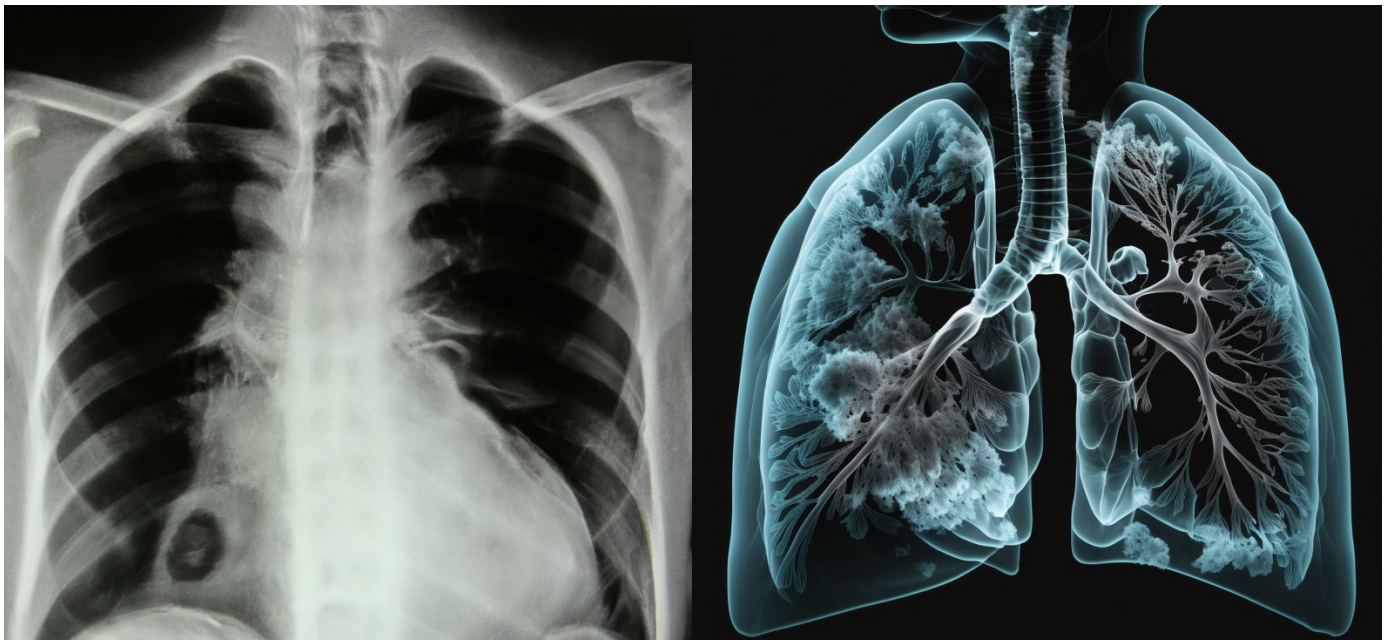


Figure 5. Two different examples of synthetic image generated from the Dall.e.2 algorithm and Midjourney. In this case, the prompt used was: chest x-ray of pneumonia. In addition to seeing the differences that correspond to the datasets. Therefore, the limitations of prompts and data bias are currently one of the main limiting factors for the generation of realistic synthetic images.

AI, several problems can arise. Without clear and appropriate prompts, the model may generate irrelevant or nonsensical output, or it may simply repeat the same output repeatedly. In some cases, the output may be offensive or harmful, particularly if the model has been trained on biased or inappropriate data. Additionally, without careful monitoring and selection of prompts, the model may become overfit to a specific set of prompts, limiting its ability to generate diverse and novel output.

In response to the accelerated adoption of these new tools, the European Parliament issued on 23 March 2023 a communication on Generative AI and ChatGPT stating that: “The recent launches of artificial intelligence (AI) tools (...), and the development of general-purpose AI technologies, are expected to revolutionise the application of AI in society and the economy.(...) However, many scientists and politicians are calling for the establishment of a legal and ethical framework to avoid potentially detrimental impacts from the use of such technologies” (European Parliament 2023). In 2021, the European Commission proposed the AI Act to regulate this area (European Union 2021), but that regulation is still being debated (European Parliament 2023) and is expected to come into force in 2024. The EU Commission proposes in the AI Act that member states must appoint or establish at least one supervisory authority that will be responsible for ensuring that the “necessary procedures are followed” to ensure ethical and secure AI. According to European Parliament recommendations from May 2022, “AI has huge potential

to boost capital and labour productivity, innovation, growth and job creation. However, its development could also pave the way for potential mass surveillance and other detrimental impacts on fundamental rights and values”.

Overall, image generative AI has several limitations that need to be addressed before it can be widely used in medical imaging and other applications. It is important to carefully evaluate the performance of these models and to develop methods for controlling and addressing their limitations.

In this article we have seen the possibilities that generative image AI can contribute to radiology and biomodels (some already possible and others future). We have also shown some of the current limitations. But all this leads us to a broader reflection at the present time. General generative AI in radiology is still under development, raising two questions for the future: how will it affect the management of imaging departments? And what will be the impact on professionals?

What Will Be the Main Impact in Healthcare System Management of Generative AI in Radiology?

The impact of generative AI in radiology is expected to be significant in the healthcare system business. Here are some potential effects:

- **Improved Accuracy:** Generative AI in radiology can help to improve the accuracy of diagnoses. By leveraging large datasets and advanced algorithms, generative AI can identify subtle patterns and



anomalies in medical images that may be difficult for human radiologists to detect. This can lead to earlier and more accurate diagnoses, which can improve patient outcomes and reduce costs.

- **Increased Efficiency:** Imaging departments often face backlogs of images that need to be reviewed by imagers, which can lead to delays in diagnosis and treatment. Generative AI can help to alleviate this bottleneck by automatically triaging images, flagging urgent cases for immediate review, and routing less urgent cases to imagers for review at a later time. This can help to reduce wait times for patients and improve overall efficiency.
- **Cost Savings:** By improving accuracy and efficiency, generative AI in imaging can help to reduce healthcare costs. Earlier and more accurate diagnoses can lead to faster and more effective treatments, which can reduce the need for costly interventions such as surgeries or extended hospital stays. Additionally, by automating routine tasks such as image triage and annotation, generative AI can free up imagers to focus on more complex cases, which can improve overall productivity and reduce costs.
- **Better Resource Allocation:** Generative AI can help healthcare systems to better allocate resources by identifying urgent cases that require immediate attention and prioritising them accordingly. This can help to ensure that resources such as imaging equipment and staff time are used most efficiently.
- **Data-Driven Decision-Making:** Generative AI can help to provide healthcare managers with valuable insights into patient outcomes, resource utilisation, and other key performance indicators. This can help to inform data-driven decision-making and optimise healthcare system performance.
- **New Opportunities for Innovation:** As generative AI becomes more widely adopted in radiology, it is likely to open up new opportunities for innovation in the healthcare industry. For example, it may be possible to use generative AI to develop new imaging modalities or to identify new biomarkers for diseases. This could lead to the development of new diagnostic tools and therapies that could improve patient outcomes and reduce costs.

Overall, the impact of generative AI in radiology is expected to be significant, with potential benefits for patients, healthcare providers, and the healthcare

industry as a whole. The speed and capacity of adoption and its impact will depend on the ability to integrate this new technology into healthcare systems and hospitals and its professionals, and this depends on the business models, regulation, ethical considerations and incentives. The speed of emergence and growth of this technology has meant that these questions have yet to be defined and we will see how they develop in the coming months and years. Probably, in a near future, we will see the expansion of proprietary Generative AI applications developed to solve specific complex tasks based on proprietary data.

How Will all This Affect the Future Imaging Job Situation? Training, Description, Content and Numbers

While generative AI in imaging has the potential to improve efficiency and accuracy, it is unlikely to completely replace the need for human professionals in the field. Rather, it is likely to transform the role of radiologists and other healthcare professionals involved in imaging.

Generative AI can help automate routine tasks such as image triage and annotation, freeing up radiologists to focus on more complex cases and to spend more time with patients. This can improve productivity and enable radiologists to provide more personalised care.

At the same time, generative AI may also create new job opportunities for healthcare professionals with expertise in data science and machine learning. These professionals may be needed to help develop and implement generative AI algorithms, as well as to analyse and interpret the results generated.

In summary, while the adoption of generative AI in radiology may change the role of imagers and other healthcare professionals involved in imaging, it is unlikely to completely replace the need for these professionals. Rather, it is likely to transform the nature of their work and create new opportunities for professionals with expertise in data science and machine learning. Thus, it is of most importance to introduce new skills and knowledge to the actual curricula of radiological and imaging specialties studies.

Conflict of Interest:

“All the images and part of the written content was created using a Generative AI” ■

references

For full references, please email edito@healthmanagement.org or visit <https://jii.hm/1knb>

Upcoming Issue Cover Story: (non) Profitability in Healthcare

Artificial Intelligence has the potential to transform healthcare. It can help provide more efficient care and solve issues of access and quality. However, assessing the safety of medical devices with AI is equally important. What measures are needed for improved regulation of medical devices and healthcare tools that use AI? What are some ongoing regulatory reforms, and what can be expected in the future?



Submit your abstract to
edito@healthmanagement.org

SAFE AND SOUND

Always effective. Never compromised.

Ever wonder why Aquasonic® continues to be the worldwide ultrasound leader? It's because **patient safety is our priority**. It starts with stringent water treatment and raw materials testing, followed by an industry-unique manufacturing and packaging process. You'll get the same *can't-be-matched* quality from every tube, bottle or packette.

Aquasonic® 100 Ultrasound Transmission Gel
Aquasonic CLEAR® Ultrasound Gel



Precision Flow Packettes™ are specially designed to allow pinpoint application while reducing the risk of cross-contamination.

AQUASONIC. DELIVERING THE PARKER PROMISE FOR QUALITY-ASSURED MANUFACTURING.

MADE IN USA

ISO 13485:2016



Parker Laboratories, Inc.

The sound choice in patient care.™

973.276.9500

parkerlabs.com



HealthManagement

Promoting Management and Leadership