hope
European Hospital and Healthcare Federation

Newsletter

Newsletter N°223 - September 2024

The monthly HOPE Newsletter is designed first of all for HOPE Liaison officers. It covers the wide range of issues related mostly to EU institutions that are relevant to hospitals and healthcare services. It is up to Liaison officers to redistribute articles to their colleagues and members.

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HOPE Agora report 2024

The HOPE Exchange Programme that started in 1981 today consists of a 4-week training period that culminates at the HOPE Agora (organised since 1992). This year, it took place in Brussels from 7 to 9 June.

The HOPE Exchange Programme is intended for managers and other professionals with managerial responsibilities. Participants must work in hospitals and healthcare facilities and be proficient in the language(s) required by the host country. For the 2024 edition almost 200 applications were submitted out of which 120 candidates from 20 countries were selected.

An important part of the HOPE Exchange Programme is to facilitate the exchange of knowledge and expertise between healthcare professionals in a European context. This is why the closing conference is considered an integral part of the programme. In line with the 2024 HOPE Agora theme, 'Keeping our health workforce!', participants were asked to observe how hospitals and health care services are working to meet challenges in retaining health and social care staff. They identified good practices, shortlisted three examples, and presented them at the closing conference.

This **document summarises the event proceedings**. If you would like to learn more about next year's programme, **click here**.

KEEPCARING is a new 4-year Horizon Europe project in the area of "Resilience and Mental Wellbeing of the Health and Care workforce", funded by the European Commission and coordinated by Amsterdam UMC.

The project aims to (re-)build wellbeing and resilience of the healthcare workforce in EU hospitals in the surgical pathways, to promote onboarding as well as staying in the workplace by systematically researching factors and signals of job stress and novel mitigating solutions and by co-creating a multi-faceted non-digital, digital and AI-supported solution package to prevent burnout among (aspirant) healthcare professionals on the individual, team, and organizational level.

Why? Stress, on an individual, team and organizational level is the biggest factor attributing to burnout among hospital healthcare workers.

The project kicked off with a first consortium call in July 2024. It is comprised of 20 partners from academic and non-academic areas across 11 European countries, bringing together leading experts to improve the resilience and well-being of healthcare professionals and students, including the European Union of Medical Specialists (UEMS) and European Federation of Nurses Associations (EFN).

For up-to-date information, check the KEEPCARING **website** and LinkedIn!

InnoFacilitator aims to create a community to promote innovative procurement in the field of health through business support, tailor-made training courses, coaching for buyers and solution providers, and the creation of collaborative tools. The overall objective is to raise awareness, increase the skills and knowledge of stakeholders on innovative procurement, and collaborate to co-designate the Public Procurement of Innovative solutions (PPI). InnoFacilitator is funded by Horizon Europe Programme 2021-2022 European Innovation Ecosystems (EIE).

Join the **Health InnoFacilitator community** and follow its activity on its **website** and on **LinkedIn**.

DIOPTRA is a Horizon Europe project, aiming to revolutionise Colorectal Cancer (CRC) screening via a holistic, personalised and accessible method for early detection. Its mission is to use new technologies for CRC risk assessment, screening, and progression while incorporating lifestyle and environmental factors to develop a unified holistic protocol for primary CRC screening using network modelling and Artificial Intelligence-based Decision Support System.

You can now follow DIOPTRA's latest development by **subscribing to its newsletter**! Visit **DIOPTRA website** and follow DIOPTRA on **Twitter** and **LinkedIn**.

SAFEST (Improving quality and patient **SAFE**ty in surgical care through **ST**andardisation and harmonisation of perioperative care in Europe) is a four-year project funded under the EU's framework for research and innovation, Horizon Europe.

Be sure to follow the project on **Twitter** and **LinkedIn**, or **check our website for interesting blog posts, in-depth project information, and news**!

Update

The European Commission encourages all projects funded under the topic "**Enhancing quality of care and patient safety"** to

participate in networking and joint activities, including workshops and exchanging knowledge.

To mark World Patient Safety Day 2024, the SAFEST, DeliverEU, SafePolyMed, and BE-SAFE consortia hosted an open online session to jointly reflect on the theme adopted by the World Health Organization: ‘Improving diagnosis for patient safety’.

The primary purpose is to encourage other researchers, clinicians and policymakers to use and promote effective strategies for the correct and timely diagnosis in the areas covered by the participating projects (perioperative care, prescription of benzodiazepines, polymedication and oral care).

Following the recommendations provided by the WHO, each project shared their contexts, perspectives, knowledge, and recommendations guided by the following questions:

- What is the importance of diagnosis errors in the area covered by the project?
- What are the crucial steps to understand the diagnostic process?
- What type of solutions, interventions and recommendations are available to promote a safe diagnosis?
- How can the different stakeholders contribute to reduce diagnosis errors?

RE-SAMPLE (REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision making for Long-term Pulmonary care Ecosystems) is a project funded by Horizon 2020.

Discover more: **register for our newsletter** and follow us on **X (Twitter)** and **LinkedIn**.

Update

This month the RE-SAMPLE project released its 10th newsletter! **You can read it here**.

Additionally, the project was highly represented at the European Respiratory Society Congress in Vienna with 3 presentations!

FLASH, funded by Horizon Europe, undertakes a comprehensive analysis of health care financing mechanisms in Europe and, by employing a wide range of methodological approaches, it provides evidence on the ability of existing financing mechanisms and contracts to address such challenges and study new solutions to achieve more effective, efficient, and equitable health care systems.

Read more and discover **FLASH new website** and follow FLASH on Twitter **@EUFlashproject** and **LinkedIn**!

LUCIA (LUng Cancer-related risk factors and their Impact Assessment) is a project funded by Horizon Europe.

The project focuses on the risks associated with developing Lung Cancer and its subtypes, as well as the methods best suited for prompt diagnoses.

You can follow the project activities on **LinkedIn**, **Twitter** and **Instagram** or by subscribing to **LUCIA newsletter**!

The XpanDH project is a 2-year (2023-2024) Coordination and Support Action financed by the Horizon Europe Framework Programme and led by ISCTE Knowledge and Innovation Centre (Portugal), aims to prepare, support and empower individuals and organisations to be ready to adopt the European Electronic Health Record Exchange Format (EEHRxF). This will be achieved by exploiting a “network of networks” approach and developing a vibrant ecosystem.

Follow XpanDH project activities on **LinkedIn** and **Twitter**! For further information, you may also wish to subscribe to the **project newsletter**, peruse the **project flyer** or listen to the XpanDH **podcast** series.

Update

An interactive workshop of the “Community of Doers” established in April took place on 23 September 2024. Using a multi-stakeholder co-creation methodology, the main objective was to explore and deliver recommendations for formalising the evolution of existing ePrescription/eDispensation services into new adoption domains or approaches to existing data categories (including ePatient Information) in the context of the EHDS.

Commissioners-designate

On 17 September 2024, the European Commission President Ursula von der Leyen presented a **list of Commissioners-designate and their portfolios**, reflecting the ambitions set out in the **Political Guidelines for the next European Commission 2024-2029**.

On 18 July 2024, she was elected for a second mandate and presented those political guidelines to the European Parliament. Commissioners-designate received from the President a mission letter based on those Guidelines.

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes several elements of the previous legislation but also new ones. Among the new pieces there is in the first 100 days a non-legislative European action plan on the cybersecurity of hospitals and healthcare providers (to which the Commissioner-designate for Technological Sovereignty, Security and Democracy will contribute). The other new elements are a proposal for a Critical Medicines Act as well as a new European Biotech Act.

The Health Emergency Response Authority is mentioned in the letter but also in the letter for the Commissioner-designate for Preparedness and Crisis Management, Hadja Lahbib (who will have the possibility to draw on HERA).

Commissioners-designate will appear in public hearings at the European Parliament during the autumn. After that, the Commission as a whole is approved in a single vote of consent by the Parliament. Finally, the European Council, acting by qualified majority, will formally appoint the Commission's new leadership most probably in December.

His appointment is far from a foregone conclusion, so much has he been criticised for breaking with the Commission's official line and pursuing an agenda dictated by Viktor Orbán. In 2019, Hungary's first choice, László Trócsányi, was rejected by MEPs , leading to the appointment of his replacement, Mr Várhelyi. At the time, Mr Orbán's *Fidesz* party belonged to the *European People's Party* (EPP). Today, it is associated with the far-right *Patriots for Europe* party, around which the centrist parties have in principle established a "cordon sanitaire."

Mr. Várhelyi's term of office has been marred by a series of controversies, which are set to resurface at his hearing before MEPs. In January 2023, the Parliament called for an independent and impartial investigation to determine whether Mr Várhelyi had breached the Commission's code of conduct. MEPs accused the senior official of playing down the decline in the rule of law in Serbia and supporting Milorad Dodik's separatist actions in Bosnia-Herzegovina. Mr Várhelyi denied this. A month later, during a Parliament on the Western Balkans, Mr Várhelyi was caught on the microphone asking "How many idiots are left?," which provoked a fierce reaction from MEPs, who demanded his resignation. Mr. Várhelyi apologised.

In October 2023, in the wake of Hamas' terrorist acts against Israel, Mr. Várhelyi announced that "all payments" to the Palestinian authorities would be "immediately suspended." This statement caused a stir within the EU. In response to questions, the Commission stated that Mr. Várhelyi had acted without Ms. von der Leyen's consent. In May 2024, Mr. Várhelyi travelled to Israel and met Prime Minister Benjamin Netanyahu and Defence Minister Yoav Gallant, a few days after the Chief Prosecutor of the International Criminal Court (ICC) announced that he was seeking arrest warrants for both of them on war crimes charges.

An article on the reaction in Hungary: **EU nomination shows up Hungary's struggling health service.**

Draghi report on EU competitiveness

The Draghi report aimed at reinvigorating Europe's economy as a whole, outlines his proposals to help the pharmaceutical sector revive its competitive edge.

On Monday, 9 September, former President of the European Central Bank and former Italian Prime Minister Mario Draghi, who saved the euro, finally set out his **analysis and plan** to save the European economy from "a slow agony." In summary, Draghi identifies four broad areas for improving productivity in the pharma sector.

He wants faster and fitter authorisation processes for medicines and medical devices, ways to improve joint purchasing to support more advanced treatments, a lot more funding to help more cutting-edge research, as well as support for SMEs, and special attention paid to how data and AI, can ensure Europe keep pace with the US and Chinese markets.

The analysis and proposals have received a warm welcome from the sector.

"If pharmaceutical companies are to catch up and compete on a level playing field, these recommendations should be actioned swiftly alongside a coherent and comprehensive life science strategy with dedicated oversight by the European Commission," said Nathalie Moll, director general of EFPIA.

The EU still enjoys a €45 billion trade balance advantage over the US in this sector, but Draghi's team found that Europe is falling behind in the most dynamic market segments.

"While the EU's pharma sector still leads globally in trade measured by value, it is falling behind in the most dynamic market segments and losing market share to US-based companies," reads Draghi's report.

"The Draghi report identifies ATMPs (advanced therapy medicinal product) as a vital sector for innovation and correctly notes that the EU is falling behind in this area of medicine," said Paolo Morgese, Alliance for Regenerative Medicine, vice president of public affairs, Europe.

The report calls for implementing current legislation and the measures for faster medicine authorisation included in the **contested** Pharma Package. AI and data mobilisation are central themes of the report and is particularly important to healthcare.

“The report rightly calls out the need to capitalise on the potential for artificial intelligence to supercharge innovation in our industry,” said a spokesperson from Bristol Myers Squibb. “The report’s emphasis on strengthening the European Health Data Space (EHDS), promoting multi-country clinical trials, and enhancing the use of artificial intelligence in healthcare presents a real opportunity to accelerate the development of orphan medicines,” said Virginie Bros-Facer, chief executive of Rare Diseases Europe (EURORDIS).

“We are pleased to see the report highlight joint procurement and the need to step up cross-country initiatives for joint pricing and reimbursement negotiations for specific medicines.”

The main question is where the money will come from to realise these ambitions. The EU could help the private sector step up, but ultimately public funding will play a crucial role. Draghi’s world-class innovation hubs in life sciences and ATMP will need funds commensurate with their ambition.

Draghi leaves EU leaders with a stark choice, accept decline, or find a way to fill the gap with their main competitors. He concludes that this requires joint European debt.

- **The future of European competitiveness: A competitiveness strategy for Europe**
- **The future of European competitiveness: In-depth analysis and recommendations**

Bruegel memo for the new Commissioner for health

The think-tank Bruegel published on 4 September 2024 a **memo** for the new commissioner for health.

On health security, Bruegel suggests that HERA should be merged into ECDC (European Centre for Disease Prevention and Control) as this might help in supporting large-scale investment in R&D for counter-medical measures, though the memo also points to the more prosaic explanation, “but it would need an adequate budget.” The ‘One Health’ plans could be enhanced with better member state coordination and stronger mandates for the European Food Safety and Environmental agencies, with more involvement in global discussions.

Bruegel sees the fundamental problem in pharma as a structural failure to address the sectors loss in competitiveness. The memo calls for an ARPA (Advanced Research Projects Agency) for medical research in top-down priorities and high-risk projects.

The memo calls for a review of the legislation on Advanced Therapies and Medicinal Products (ATMP) and a new protocol on clinical trials to be managed by the European Medicines Agency.

It is acknowledged that innovative medicines often come at a price, so a few suggestions are made on new pricing and reimbursement models including joint procurement, pay-for-performance, and annuity models.

Given ECDC's existing links with national health authorities and the growing numbers of calls for action plans in different areas of non-communicable disease, from cardiovascular to neurodegenerative diseases, Bruegel touts for ECDC to extend its mandate to cover non-communicable disease.

EPP and S&D clash over future health committee

The European Parliament's sub-committee on Public Health (SANT) discussed on 9 September 2024 whether a new full committee dedicated to health should be created, raising tensions between MEPs over its future competencies.

Hungarian Presidency debriefs European Parliament committees on priorities

Hungarian ministers have been holding a series of meetings in parliamentary committees to present the priorities of the Hungarian Presidency of the Council.

On 23 September 2024, Péter Takács, Secretary of State for Health, highlighted to the Environment, Public Health and Food Safety Committee, as priorities, adopting Council conclusions on cardiovascular diseases and renewing EU cooperation on organ donation and transplants. The Presidency also intends to adopt the updated Council recommendation on smoke-free environments and advance on the pharmaceutical package. MEPs quizzed the Presidency on measures foreseen on rare diseases, equal access to medicines, shortages in the healthcare workforce, the competitiveness of the EU's pharmaceutical industry as well as mRNA vaccines.

Medical Devices

Mission letter for the Commissioner-designate for Health

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare mentions that he will ensure the availability and competitiveness of medicals devices,

including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes.

Targeted evaluation

HOPE attended on 12 September 2024 the Medical Device Coordination Group (MDCG) information session on the targeted evaluation of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR).

The Commission presented the current state of play of the targeted evaluation of the MDR and IVDR. It was noted that as the Regulations are still in the process of being implemented, only those aspects that have been implemented can be evaluated at this stage. In line with the Better Regulation guidelines and toolbox of the European Commission the following five criteria will be assessed: effectiveness, efficiency, relevance, coherence, and EU added value.

The Commission presented the already well progressed work on the foundations of the targeted evaluation (evaluation questions, reconstructed logic of intervention). It was noted that the Commission is continuing to progress its work related to the data mapping/consultation strategy and call for evidence/public consultation. The call for evidence and public consultation are expected to be published simultaneously in Q4 2024. For more information on the current state of play of the targeted evaluation and the steps to come, please refer to the presentation.

Stakeholders welcomed this information session on the targeted evaluation of the MDR and IVDR and reiterated their support to this exercise providing the necessary data. It was highlighted that the specificities of medical devices and *in vitro* diagnostic medical devices need to be differentiated, also for the purpose of this targeted evaluation. As such, separate questionnaires for MDR and IVDR should be included in the upcoming public consultation. The Commission reassured that the data already being collected as part of other ongoing studies will be taken into account for this targeted evaluation. It was however also noted that, where possible, cross-verification by using various sources (triangulation) is needed to validate different types of evidence.

The Commission will continue to keep the MDCG members and stakeholders informed on the progress of the targeted evaluation of the MDR and IVDR.

Health Technology Assessment

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes several elements of the previous legislation mentions that he will lead the work on a new European Biotech Act, focusing on the need for a regulatory environment conducive of innovation in areas of HTA, clinical trials and others.

Member State Coordination Group on HTA

The tenth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 19 September 2024 in Brussels.

After the presentation of the Chair of the subgroup for methodological and procedural guidance, the HTACG adopted the guidance document by consensus. It will be published on the Commission's HTA website on the Europa portal.

The Commission presented key elements of the future procedures for joint clinical assessments (JCA) and for joint scientific consultations (JSC) for medical devices and *in vitro* diagnostic medical devices (IVDs). Members agreed that the same overall approach for JCA and JSC for medical devices and IVDs as for the JCA and JSC for medicinal products be followed, with necessary adaptations.

The HTACG Co-Chair presented options for the selection process of medical devices subject to JCA. Members considered which subgroup should lead this selection and make recommendations to the HTACG. The discussion will be continued at the next meeting of the HTACG. The HTACG Co-chair and the Commission presented an information point on identification and selection criteria that apply to medical devices and *in vitro* diagnostic medical devices.

The HTACG reviewed the different selection criteria for JCAs, JSCs and emerging health technologies, listed in the HTA Regulation. They discussed possible harmonisation of definition/interpretation of similar criteria, the use of already existing definitions in other EU legislation and EC guidance documents to ensure a coherent EU legislative framework and also the needs for guidance documents.

The Chairs of the JCA and JSC subgroups gave an update about the ongoing work in the subgroups on identifying capacities for the joint work. The Chair of the JCA subgroup informed

that further capacities had been identified. Members highlighted the importance of proper advance planning to efficiently prepare resources.

The Commission explained its procedure to receive early information from HTDs on upcoming products which may fall in scope of the HTA Regulation (HTAR). With this voluntary procedure, the HTDs have the possibility to share with the HTA Secretariat their Letters of Intent sent to the European Medicines Agency. This is useful for planning purposes. The EHT subgroup can play a role in adding more granularity to the information submitted by HTDs as the HTACG has at its disposal other sources of information about products in the regulatory pipeline.

The HTACG Chair presented the draft Work Programme 2025. It was agreed that this draft Work Programme will be shared with the HTA Stakeholder Network for consultation. The Commission will update and publish the HTAR implementation rolling plan on the HTA webpage in-line with planned and ongoing work. The Work Programme 2025 will be adopted by the HTACG at its next meeting in November in line with the HTAR.

The next meeting of the HTACG is planned for 28 November 2024 in Brussels in hybrid format. The next joint meeting of the HTACG and the HTA Stakeholder Network is planned for 29 November 2024 in Brussels in physical only format.

New guidance on validity of clinical studies

The Commission has published a **guidance** document on the validity of clinical studies for joint clinical assessments under the EU Health Technology Assessment Regulation, adopted by the Member State Coordination Group.

This guidance helps to define, classify, and assess the certainty of clinical study results in an objective, reproducible and transparent way. It covers the analysis of data from different types of single clinical studies.

This guidance complements the guidance documents previously adopted by the Member State Coordination Group on outcomes for joint clinical assessments, on quantitative evidence synthesis for direct and indirect comparisons and on reporting requirements for multiplicity issues and subgroup, sensitivity, and post hoc analyses in joint clinical assessments.

The Member State Coordination Group on Health Technology Assessment adopted the new guidance document at its 10th meeting on 19 September 2024.

Pharmaceuticals

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes several elements of the previous legislation mentions that Europe needs a strong, competitive, and innovative pharmaceutical sector and that he will lead efforts to support the European Parliament and the Council to conclude work on the pharmaceuticals reform and follow up on its implementation.

EDQM study on anticancer medicines & storage times

The European Directorate for the Quality of Medicines and Health Care (EDQM, depending of the Council of Europe) launched on 23 September 2024 a survey to assess storage times to reconstituted anticancer medicines.

A study from national monitoring activities revealed that some hospital pharmacies assign longer in-use storage times to reconstituted anticancer medicines than those specified in the marketing authorisation and summary of product characteristics (SmPC).

This practice, often unsupported by stability data, poses potential risks to patient safety and should be discouraged. Additionally, the use of open single-dose vials, which is not approved by the SmPC, raises further concerns for patient health.

Hospital pharmacies are generally expected to adhere to SmPC guidelines when reconstituting medicines, with any deviations well-documented and supported by data. Such deviations should be treated as exceptions.

A group of experts has developed a survey to assess how common these practices are across Europe, to identify the sources used to justify extended storage times, and to understand the rationale behind them. The goal is to map current practices and evaluate the potential need for guidance to ensure the safe use of reconstituted medicines.

All responses to the **survey** will remain confidential, and the deadline for submission is 8 November 2024.

Cross-border threats

The mission letters for the Commissioner-designates

The letter to Commissioner-designate for Health states that the Health Emergency Response Authority (HERA) will support him and the letter to Commissioner-designate for Preparedness and Crisis Management states that she will be able to draw on the HERA.

Indeed, among her tasks she should develop a new strategy to support medical countermeasures against public health threats, to harness tools such as joint procurements, stockpiling or using innovative financial instruments to support the development of medical countermeasures from research to manufacturing. She will support this by developing a wider EU stockpiling strategy.

Court of Auditors releases report on Covid-19

On 4 September 2024, the EU Court of Auditors found that, within the limits of their respective competences and capacities, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) "generally managed their response to the Covid-19 crisis well. However, there is still room for improvement in specific areas," reads the conclusions of the Court's report on the EU's response to the pandemic.

The Commission and the agencies are currently implementing the lessons learned from the pandemic, but it is too early to say whether this will be sufficient to prepare them properly for future public health emergencies, according to the auditors.

The Court of Auditors found that both the ECDC and the EMA had developed detailed public health contingency plans, but that under the applicable legal and financial framework, these did not address the issue of capacity building in the event of a severe and prolonged pandemic.

In the weeks following China's report of the first cases of the new coronavirus, "ECDC underestimated the seriousness of the situation," according to the report. Based on newly available evidence, the Centre subsequently revised its assessment. The guidance and assistance provided to Member States was not always timely.

The ECDC did begin collecting data on the pandemic, but the number of infections reported depended heavily on the screening strategies of the different Member States. This was also the case for the attribution or non-attribution of deaths to Covid-19. According to the Court's auditors, more reliable techniques, such as the analysis of virus concentrations in wastewater, could have been used to a greater extent.

With the support of the Commission, the EMA has taken advantage of regulatory flexibility to speed up the assessment procedure for Covid-19 vaccines and treatments. The EMA has also stepped up its surveillance of Covid-19 medicines and acted swiftly when major potential side effects were discovered. “However, its efforts to proactively promote larger clinical trials at EU level have been less successful,” the auditors said.

The Commission has adopted a series of decisions which have filled certain gaps in the EU’s capacity to respond to health emergencies. The creation of a new Commission Directorate-General (the Health Emergency Response and Preparedness Authority, HERA), whose responsibilities partly overlap with those of the ECDC and the EMA, requires greater coordination.

Preparedness 2.0: Mobile laboratories simulation exercises

HOPE was invited to attend on 23 September 2024 74th Session of the WHO Regional Committee for Europe Virtual Side Event on “Preparedness 2.0: Mobile laboratories simulation exercises.”

Rapid Response Mobile Laboratories (RRMLs) are indispensable assets within the global health emergency infrastructure. They play a pivotal role in enhancing diagnostic capacities during infectious disease outbreaks, migrant and refugee crises, and natural disasters, while also strengthening national public health systems. These efforts are integral to the implementation of the WHO's Preparedness 2.0 strategy. Designed for deployment at both national and international levels, RRMLs effectively address diagnostic gaps across all phases of emergency management by providing targeted surge capacities. With adaptable diagnostic modules tailored to specific missions, RRMLs deliver high-quality, scalable responses that are precisely adjusted to meet the unique needs of affected communities.

Following the 35th GOARN Steering Committee meeting in May 2024, the RRML Initiative, led by the WHO Regional Office for Europe, transitioned into the globally focused GOARN Strategic Group for Diagnostic Surge Capacities (GOARN DiSC). This transition marks the establishment of the first strategic group within the GOARN Strategy 2022-2026.

The Health Emergencies Programme at the WHO Regional Office for Europe, in collaboration with GOARN partner institutions, is advancing the diagnostic surge capacities of RRMLs through the implementation of the Interregional Field Simulation Exercise for RRMLs. This simulation exercise has laid the groundwork for the establishment of minimum operational standards for RRMLs, while also fostering their interoperability and coordination within the broader context of emergency response.

Promotion, prevention and care

➢ Antimicrobial resistance (AMR)

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare mentions that he will continue the work on AMR as one of the major threats of health, working with Member states to reach the 2030 targets. The Commissioner's formal title also reflects a continued strong focus on building on the One Health approach, as well as his task to modernise animal welfare rules and standards aiming for improved sustainability and ethics.

UNGA high-level meeting toughens AMR goals

Long-awaited by the AMR stakeholder community and following a multi-stakeholder hearing organised in May, the **second high-level meeting on AMR** took place on 26 September 2024 as part of the 79th session of the United Nations General Assembly (UNGA) in New York City.

Pressure was high on global leaders to deliver a strong and visionary political declaration that would lead to stronger commitments than the text agreed upon in 2016 at the first high-level meeting. Already during the preparatory phase of the meeting, countries were pushing to establish a global governing group to oversee national efforts to prevent the growth of AMR, as well as stronger financing of these measures. The issue of setting bold targets to reduce the amount of antibiotics used in the global agri-food system, and to eliminate the use in animals of antimicrobials essential for fighting human infections was hotly debated. Overuse of antibiotics in farm animals is a key driver of superbugs.

In the end, the final version of the **political declaration adopted** by global leaders contains the following key points:

Reducing the estimated 4.95 million human deaths associated with bacterial antimicrobial resistance (AMR) annually by 10% by 2030.

- Sustainable national financing and US$100 million in catalytic funding, to help achieve a target of at least 60% of countries having funded national action plans on AMR by 2030. This goal is to be reached through, for example, diversifying funding sources and securing more contributors to the Antimicrobial Resistance Multi-Partner Trust Fund.
- On human health, a more ambitious target was set so that at least 70% of antibiotics used for human health globally should belong to the WHO Access group antibiotics with relatively minimal side effects and lower potential to cause AMR.

- It also includes targets around infection prevention and control (IPC), such as 100% of countries having basic water, sanitation, hygiene and waste management services in all healthcare facilities and 90% of countries meeting all WHO's minimum requirements for IPC programmes by 2030. There are also commitments on investments to facilitate equitable access to and appropriate use of antimicrobials, as well as on reporting surveillance data on antimicrobial use and AMR across sectors.
- On agriculture and animal health, the declaration has commitments to, by 2030, meaningfully reduce the quantity of antimicrobials used globally in the agri-food systems by prioritizing and funding the implementation of measures to prevent and control infections and ensuring prudent, responsible and evidence-based use of antimicrobials in animal health. This is to be achieved in the context of the WOAH list of priority diseases and FAO's RENOFARM initiative, as well as preventive strategies, including animal vaccination strategies, good husbandry practices, biosecurity, and water, sanitation and hygiene (WASH).
- On the environment, the declaration underscores the need to prevent and address the discharge of antimicrobials into the environment. It also calls for increased research and knowledge on the environmental dimensions of AMR and for catalysing actions to address key sources of antimicrobial pollution.

The Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH), known as the Quadripartite, applauded countries for recognising the need for global, regional and national efforts to address AMR through a One Health approach, which recognizes that the health of people, animals, plants and the wider environment, including ecosystems, are closely linked and interdependent. The declaration formalises the standing Quadripartite Joint Secretariat on AMR as the central coordinating mechanism to support the global response to AMR. It also requests the Quadripartite organisations, together with countries, to update the Global Action Plan (GAP) on Antimicrobial Resistance by 2026 to ensure a robust and inclusive multisectoral response, through a One Health approach. It also gives the Quadripartite the mandate to follow up and report back on implementation of the GAP and political declaration outcomes.

It also acknowledges the critical contributions of global AMR governance mechanisms, including the Global Leaders Group and the AMR Multi-Stakeholder Partnership Platform, committing to strengthening the latter, among others, to facilitate the multisectoral exchange of experiences, best practices, and the assessment of Member States' progress in implementing multisectoral national action plans on AMR.

The declaration emphasizes key aspects, including the importance of access to medicines, treatments and diagnostics, while calling for incentives and financing mechanisms to drive multisectoral health research, innovation and development in addressing AMR. A stronger, transparent partnership between the public and private sectors, as well as academia is critical.

The declaration also encourages countries to report quality surveillance data on AMR and antimicrobial use by 2030, utilising existing global systems such as the Global Antimicrobial Resistance and Use Surveillance System (GLASS), the Global Database for Antimicrobial Use in Animals (ANIMUSE) of WOAH, and the International FAO Antimicrobial Resistance Monitoring (InFARM). It further calls for 95% of countries to annually report on the implementation of their AMR national action plans through the Tracking AMR Country Self-assessment Survey (TrACSS).

➢ Mental health

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare, mentions mental health twice. He is asked to draw on the work of the European Beating Cancer Plan to design a common approach in other areas looking in particular at mental health. The second time is when he is asked to focus on the impact of social media and excessive screen time of people, especially young populations, on their wellbeing and mental health to begin an evidence-based debate on this issue.

Digital transformation for better mental health

HOPE was invited to the pre-RC74 side event "**Harnessing the power of digital transformation for better mental health**" on 30 September 2024.

According to WHO, digital health technologies have emerged as possible allies in the fight against mental health challenges. Tools such as telepsychiatry, mental health mobile applications (mApps), and digital therapeutics are showing great promise. Telepsychiatry, which leverages information and communication technology to provide mental health services, became particularly prominent during and after the pandemic. Today, it is established in 1 out of 3 of the Member States in the WHO European Region. Additionally, some WHO Europe Member States (12%) are actively evaluating and approving mApps designed to support mindfulness and manage mental health conditions.

This session explored evidence-based digital mental health solutions including speakers providing country examples from Ireland, Scotland (where experience with digital mental health already dates back 20 years), France, Kazakhstan and Denmark, complemented with contributions by representatives of Mental Health Europe (MHE) and the World Psychiatric Association (WPA). Together, they underlined several important points applicable to the meaningful introduction of digital mental health solutions including the importance of political will, government support and funding (including for research), the value of co-creation and empowering patients and healthcare professionals using the technologies, as well as the need for quality standards and formal evaluation mechanisms. MHE director Claudia Marinetti

stressed that digital solutions by themselves were neither good nor bad; rather, their successful deployment in mental health depended on applying psychosocial and human rights approaches to ensure their safety, quality, and equity of use, while also ensuring accountability. Important social and economic determinants were equally applicable in this area.

WHO / Europe representatives highlighted the key applicable documents in this area and actions supporting the organisation's European Programme of Work, including synergies created between the **European Framework for Action on Mental Health 2021-2025**, the regional **Digital Health Action Plan 2023-2030**, as well as the activities of the **pan-European Mental Health Coalition** established in 2022 and discussions for moving towards a roadmap for the digitalisation of mental health systems.

➢ Cancer

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare mentions as part of the work on preventative health that he will have to ensure the implementation of the European Beating Cancer Plan.

Comprehensive Cancer Infrastructure

The CCI4EU project, a Horizon Europe Coordination and Support Action funded under the EU Cancer Mission, was organising its virtual Stakeholder Forum on 30 September 2024.

This project, which is coordinated by the Organisation of European Cancer Institutes (OECI), aims to help cancer centres across EU Member States and Associated Countries develop comprehensive cancer infrastructures (CCIs) through targeted capacity building interventions. As such, it strives to reduce existing inequalities in access to cancer-related innovation and quality care across Europe. You can read more about CCI4EU on **the project website**.

In this webinar, the leaders of the project's work packages explained the scope of their activities and present the progress that has been made so far by the CCI4EU consortium.

Cancer and Precision Medicine

The first meeting of the Thematic Network on Advancing Precision Medicine for Europe's Cancer Patients with AI-powered Imaging led by the European Society of Radiology took place on 11 September 2024.

The overall aim of this Thematic Network is to discuss with health stakeholders how AI-powered cancer care can improve personalised treatment strategies and reduce the burden of cancer.

This first webinar presented and discussed the envisaged key elements of the proposed joint statement, sought stakeholder input and presented next steps and engagement opportunities.

It works in close partnership with EUCAIM – Cancer Image Europe which will deliver an atlas of >60 million annotated cancer images and >100,000 patients. It will be a continuously growing infrastructure based on observational studies at hospitals, from >21 clinical sites at >12 countries (DWH and Screening programs). An AI-platform will develop reproducible image-based decision support models in oncology. It will have impact on Clinical Pathways in Radiology and Oncology by growing evidence-based use of imaging biomarkers and imaging panels identifying the right treatment to the right patients, in many different oncologic situations. It is aligned with policy makers on the role of European Health Data Space (EHDS); AI Legislation; Ethical, Legal, and Social Implications (ELSI); and Sustainability initiatives such as EDIC.

The thematic network wants the adoption of a Call for action with a long list of wishes: Advance precision medicine for Europe's cancer patients, Review and validate existing literature into AI powered promising predictive biomarkers, Consider AI-powered imaging in in-vivo clinical cancer trials, Improve the results of cancer screening programmes by AI-powered imaging, Ensure interdisciplinary stakeholder engagement in the development and implementation of strategies, Develop a comprehensive strategy for research on innovative AI solutions, Enhance data quality and infrastructure in healthcare and research institutions, Improve the coordination and accessibility of research data in Europe, Ensure seamless integration of AI-generated results into clinical workflows, Establish clear guidelines and frameworks for data access and usage in clinical care, Build trust and transparency to enable integration of AI technology in healthcare.

Final meeting of JA JANE

On 25 September 2024, HOPE attended the final meeting of the EU Joint Action on Networks of Expertise on Cancer (JA JANE), hosted by newly elected MEP Vlad Voiculescu at the European Parliament in Brussels.

The key aims of JA JANE have been to prepare for actions, lay the groundwork for the next phase (follow-up EU-funded networks with increased financing), and perform the conceptual work. The next focus of the Cancer networks will focus greatly on stepping up prevention.

With a background in public health in Romania, MEP Voiculescu's will be working closely with matters of health policy among other things, particularly as coordinator of the Sub-committee on Health. He is part of the **Renew Europe** party. In addition to his coordinating role, he is part of a working group on pharmaceuticals that aims to find ways to incentivise cancer medications development. This is in line with his position on national v. supranational competences with

regards to health, namely, that there are things that can be done well at the supranational level, and research and development is a clear example.

Paolo G. Casali, Coordinator of the JA JANE, shared the output of this preliminary phase, which includes a **Green Paper released on the same day**. The paper centers on 13 open questions deemed crucial to address to move forward. They include questions on the value of the networks, their sustainability, as well as questions about subsidiarity, politics at EU and national levels, integrating research and the GDPR challenge, etc.

Finally, coordinators also summarized and presented the key aims and potential outputs of each of the seven networks, as well as the synergies these networks had with JA European Network of Comprehensive Cancer Centres (EUnetCCC) and the Reference Network on Rare Adult Solid Cancers (EURACAN):

- Complex and poor prognosis cancers. Key aims have included promoting early detection, improving care and quality of life. To work towards these aims, the network relies on the multidisciplinarity of its members and patient involvement. One of the key challenges has been how to address inequalities across regions in the EU.
- Palliative care. While evidence shows that palliative care works well for patients, such measures are not well integrated across Europe or even the entirety of the cancer journey itself. One of the central aims is to encourage national engagement to mobilize resources and education in this area, as well as addressing the physical and psychological dimensions of entering palliative care.
- Survivorship. This network also focuses on the psychological and physiological dimensions of survivorship as fear and treatment side effects are big obstacles in patient care. Network members hope to involve Member States further to train and educate professionals further who are involved with cancer survivors and their reintegration into society.
- Personalised primary and secondary cancer prevention. The network identified that the Baltic and Eastern European countries need the most support in this area, making access of care in these regions a central feature of the group. Next steps include tailoring care to reduce the burden of chronic diseases (not just cancer) and encouraging multidisciplinary contributions.
- Omics technologies. Using the large-scale collection of data on molecules, this network has sought to improve prevention, diagnosis, and care of cancer. This can be achieved by gaining a better understanding of the different types of cancer and the biomarkers used to identify them. One of the hoped for outcomes includes providing recommendations for systematic data collections on molecules and designing a clinical trial to test biomarker identification for detection, prevention, care, etc.
- Hi-tech medical resources. Similarly to other networks, access inequalities and variations across different regions in Europe constitutes one of the biggest challenges in this network. Members have explored options to address such gaps; one option

includes sharing medical infrastructure. Furthermore, the network has also worked to improve adaptability to rapid changes in care delivery and treatments.

- Adolescents and young adults with cancer. The major obstacle this network has faced involves significant differences in survivorship from cancer to cancer, as well as geographic disparities. Therefore, members have been working to identify specific characteristics of different cancers, address the unique psychological and physiological issues that arise in adolescence and impact treatments, outcomes, care, etc. of young patients, bring together pediatric oncologists and other types of oncologists to develop specific programmes, and improve survivorship and quality of life care.
- Synergies with EUnetCCC and EURACAN. The seven networks formed synergies with these two networks belonging to other Joint Actions. With regard to EUnetCCC, they aim to create 100 CCCs, build capacity in each one, implement pilot programmes, and ensure their sustainability. The aim is that 90% of patients in Europe can access quality care by 2030. To this end, the network focuses on education to develop specific skills and research collaboration, as well as the development of quality improvement standards, prevention measures, and improvement of diagnostic methods. With regard to EURACAN, the key aims are to ensure quality of care, expand research, and improve diagnostics and collaborative efforts. Preliminary findings shared during the presentation seem to indicate that survivorship is better in reference networks. However, there are still some rare cancers that are not well researched and therefore their diagnoses and treatments have not advanced significantly.

➢ Other non-communicable diseases

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare asks him to draw on the work of the European Beating Cancer Plan to design a common approach in other areas looking in particular at cardiovascular diseases, degenerative illnesses and other non-communicable diseases.

Social policy

Discrimination

A **report** published in September 2024 from the Migration Policy Group and funded by the Robert Bosch Foundation tries to reckon with structural racism in eight EU countries.

Healthcare, education, and housing are the sectors where structural racism hits hardest. Roma, Black people, and Muslims are most affected, per the report. In 2018, **a scandal around the Netherlands' childcare benefits** revealed a biased algorithm that wrongly accused many low-income parents — especially those from ethnic minorities — of fraud; some 70 percent of victims were from migrant families. To this day, the Dutch government hasn't taken meaningful action to address this issue, said Carmine Conte, the think tank's legal policy expert.

Anti-Asian racism is a growing problem since the Covid-19 pandemic, but it's especially hard to track. "Some Asian groups tend to minimize microaggressions and do not like to assume the role of victims," said Conte. Antisemitic discrimination also tends to be underreported.

But there are bright spots. Romania is taking steps to level the playing field for Roma students by implementing **initiatives** that give them a shot at reserved spots in high schools and universities. Greece is setting aside 0.5 percent of university slots specifically for Muslim minority students and working on **programmes** to help them integrate into society while honouring their cultural backgrounds.

Equal Treatment Project

The final dissemination event of the Equal Treatment Project is planned for 26 November 2024 at the European Economic and Social Committee, Brussels. The **project developed policy recommendations** for inclusive healthcare for people with intellectual disabilities.

This event to foster a discussion and raise awareness of the disparities in access to healthcare for people with intellectual disabilities. The aim is to bring together healthcare professionals, policymakers, academics, and individuals with lived experiences to explore the challenges and opportunities in creating a more inclusive healthcare system to identify barriers, share innovative solutions, and commit to actions that promote dignity, respect, and equal treatment within healthcare services for people with intellectual disabilities. The draft programme for the event can be found **here**.

Roundtable on Monitoring Access to Healthcare

HOPE joined the European Network of Equality Bodies (Equinet)-European Public Health Alliance (EPHA)-United National Human Rights Regional Office Europe (OHCHR) roundtable on "Monitoring effective access to quality healthcare" on 25 September 2024.

This event focused on discussing the gaps between the expanding anti-discrimination EU legislation (including the Racial Equality Directive, EU Action Plan Against Racism, and EU Roma Strategic Framework for equality, inclusion and participation 2020-2030) and the reality in the Member States, which continue to make it difficult for migrants, racialised minorities and Roma populations to access quality healthcare due to individual and institutionalised forms of

discrimination.

The event focus was on monitoring and reporting on racialised communities' access to healthcare and the role of Equality Bodies in ensuring that existing rights can be exercised. The OHCHR General Recommendation on racial discrimination and the right to health includes concrete guidance for countries on collecting data across many relevant areas, and many indicators are available that should be applied. Nonetheless, the speakers deplored that Member States are using many excuses related to national data protection cultures or technical obstacles as to why much-needed aggregated data on the heath of ethnic minorities in Europe are not being collected. As a consequence, this makes it very difficult to provide them with targeted prevention and treatment strategies.

Stronger synergies could be created between the different EU initiatives mentioned above, which might also stimulate better data collection and greater awareness at national level, where the problem of structural exclusion is strongest as individuals experienced healthcare access problems on a daily basis, despite this being illegal (depending on national specificities regulating access). For example, Danut Cae of Cairde in Ireland mentioned that service denials for Roma living in the country were frequent and unpredictable, often targeting individuals who appeared to be economically inactive and/or based on gender discrimination.

Human resources

➢ Health workforce

Court of Auditors releases report on recognition of professional qualifications

On 1 July 2024, the European Court of Auditors published a **special report** 10/2024: "The recognition of professional qualifications in the EU: An essential mechanism, but used sparsely and inconsistently."

The report states that the recognition of professional qualifications in the EU is an essential mechanism but used sparsely and inconsistently for exercising the right to pursue a profession in another member state. The application of the directive still has shortcomings, and the information provided to citizens is not always reliable.

The Court asks in particular the Commission to clarify, such as by means of proposing changes in the legislation or issuing Commission recommendations the concept of public health and safety implications, to avoid a restrictive interpretation of the rules by authorities that would

hinder an effective procedure on the recognition of professional qualifications. It also suggests that the Commission monitor the effectiveness of the whole system and take timely and effective remedial action if weaknesses are identified, particularly focusing on obtaining harmonised data from member states in line with their reporting obligations and ensuring deadlines established in the Directive are respected for each of the different recognition procedures.

➢ Safety at work

Exposure to carcinogens, mutagens, and reprotoxic substances

Eleven Member States are failing to fully transpose EU rules regarding the exposure to carcinogens, mutagens, and reprotoxic substances at work.

The European Commission sent a letter of formal notice to eleven Member States that have yet to fully transpose Directive (EU) 2022/431 into national law and notify their measures to the Commission. The Directive aims to broaden the protection of workers, including health care workers exposed to carcinogens, mutagens and reprotoxic substances contained in certain hazardous medicinal products.

Use of hazardous substances in electrical and electronic equipment

Three Member States are failing to transpose EU rules regarding the use of hazardous substances in electrical and electronic equipment.

The European Commission sent a letter of formal notice to Belgium, Malta, and Slovakia for failing to transpose Directives (EU) 2023/1526 and (EU) 2023/1437 into their national legislation. The two directives set out exceptions allowing the use of lead in in vitro diagnostic medical devices and of mercury in rheometers respectively.

Digital

➢ Cybersecurity

European action plan on cybersecurity of hospitals and healthcare providers

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes a European action plan on the cybersecurity of hospitals and healthcare providers to which the Commissioner-designate for Technological Sovereignty, Security and Democracy will contribute**.**

The idea was already mentioned by President Von Der Leyen in her 18 July speech to the European Parliament: "We must also do more to protect the security of our health systems, which are increasingly the target of cyber and ransomware attacks. To improve threat detection, preparedness and crisis response, I will propose a European action plan on the cybersecurity of hospitals and healthcare providers in the first 100 days of the mandate."

An "action plan" means that there will not be legislation but a proposal calling on Member states to put in place immediate measures against ransomware and other cyber-attacks. The aim may be to quickly boost cybersecurity in hospitals while longer-term work based on the NIS2 Directive (EU-wide legislation on cybersecurity) gets going.

Cash-strapped hospitals are unlikely to have the necessary resources to get their systems in order and may complain about overlapping requirements and initiatives.

In this task, the future Commissioner for Health and Animal Welfare will be supported by the future Executive Vice-President for Tech Sovereignty, Security and Democracy, whose own **mission letter** also mentions improving the adoption process of European cybersecurity certification schemes and making the European Commission more resilient to cyber threats.

Inputs into the proposed action plan will be sought from health stakeholders at a dedicated eHealth Stakeholder Workshop on 11 October 2024, which HOPE will attend.

NIS2 implementation deadline likely to be missed

Although the contents of the **NIS2 cybersecurity directive** already came into force in early 2023, several EU member states appear to be lagging regarding the requirement to transpose it into respective national legislation by 17 October 2024. A number of countries will not have the relevant implementing legislation in place by this deadline, let alone the wider frameworks of guidance that would provide impacted organisations with the tools to work towards compliance.

While little has been officially confirmed yet, both the larger Member States (including Germany, France, Spain) and some of the smaller digital leaders (including the Netherlands and Ireland) are still reviewing important legal aspects and undertaking consultation processes to allow them to draw up national implementing laws. In some cases, there are legal uncertainties over whether national preferences could still comply with EU law.

The stricter NIS2 rules will, inter alia, be applicable to “essential entities” in sectors such as energy, financial services, transport and health, as well as businesses that have not previously been subject to NIS regulation – including providers of electronic communication networks or services; pharmaceutical companies; operators of hydrogen production, storage and transmission; and potentially businesses designated as ‘very large online platforms’ under the EU’s Digital Services Act. They must undertake cybersecurity risk management by adopting appropriate and proportionate technical, operational and organisational measures to secure their networks and information systems used for their operations or service provision, and by preventing or minimising the impact of incidents on recipients of their services and on other services.

The precise cybersecurity measures will depend on factors such as organisational size, exposure to risk, the likelihood of occurrence of incidents and their severity, and the availability and cost of implementing technology or international standards. Cybersecurity measures endorsed in the legislation include policies on risk analysis and information system security, incident handling, access control policies and the use of multi-factor authentication or continuous authentication solutions.

Supply chain security must also be considered, including the vulnerabilities “specific to each direct supplier and service provider” as well as “the overall quality of products and cybersecurity practices of their suppliers and service providers, including their secure development procedures”. Senior managers could be held personally responsible if their organisations are found to be non-compliant with the NIS2 legal obligations.

Cyber Resilience Act Expert Group

The Commission is looking for cybersecurity experts to join the Cyber Resilience Act Expert Group through a continuously open call for applications.

The call aims to set up an **expert group on cybersecurity** of products with digital elements (CRA Expert Group), which will assist and advise the Commission on issues relevant to the implementation of the Cyber Resilience Act (CRA).

The Expert Group will represent a valuable forum for the Commission to gather input from relevant stakeholders contributing to the successful implementation of the Cyber Resilience Act, designed to benefit business users and consumers by enhancing the transparency of the security properties and promoting trust in products with digital elements.

It will be chaired by a representative of Commission's Directorate General for Communications Networks, Content and Technology (DG CONNECT) and will be composed of up to 60 members (Member States' authorities, the European Agency for Cybersecurity - ENISA, and individuals / organisations with relevant expertise), providing for diverse representation of the relevant stakeholders. Experts will assist with the preparation of delegated acts and development of guidance documents.

To be considered for the first round of evaluations, experts **must send their applications** by **17 October 2024**.

ENISA certification support for EU Digital Identity Wallet

The European Commission has requested ENISA, the EU Agency for Cybersecurity, to provide support for the certification of **European Digital Identity Wallets**.

These wallets will allow everyone in Europe to securely identify themselves when accessing public and private services as well as store and display digital documents like mobile driving licenses and education credentials — all from their mobile phones. They will also enhance privacy by only sharing the exact information agreed to.

In line with the **Digital Identity Regulation,** which entered into force in May 2024, the European Commission has requested ENISA to provide support for the certification of European Digital Identity Wallets, including the development of a candidate European cybersecurity certification scheme in accordance with the **Cybersecurity Act**.

ENISA will support the establishment of national certification schemes of EU Member States by providing harmonised certification requirements, and it will kick off the work for the preparation of a candidate European cybersecurity certification scheme.

The wallets will be available as from 2026 to any EU citizen, resident or business in the EU intending to use them.

➢ Artificial Intelligence (AI)

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes several elements of the previous legislation. It mentions that he should promote the uptake of artificial intelligence, notably through clear and timely guidance on its use in the lifecycle of medicines.

More broadly but also carrying implications for the health sector, the **mission letter** addressed to Henna Virkkunen, the Executive Vice-President-designate for Tech Sovereignty, Security and Democracy asks her to boost AI innovation, making it safer and more trustworthy. In the first 100 days, the AI Factories Initiative is to give AI start-ups and industry access to tailored supercomputing capacity. An Apply AI Strategy is to boost new industrial uses for AI and improve delivery of public services. A European AI Research Council will also be set up. Other important mentions include developing a proposal for a new EU Cloud and AI Development Act to increase computational capacity, a Digital Networks Act to boost secure high-speed broadband, and enforcement actions of the Digital Services Act and Digital Markets Act.

Inaugural meeting of AI Act Board

The first meeting of the **European Artificial Intelligence (AI) Board** took place on 10 September 2024, following the entry into force of the AI Act on 1 August.

As a key advisory body, the AI Board – the secretariat of which is hosted by the new EU AI Office - is comprised of high-level representatives from the European Commission and all EU Member States. It is tasked with discussing how to enhance the development and uptake of AI in the EU and the next steps in the implementation of the AI Act. The European Data Protection Supervisor (EDPS) and EEA/EFTA representatives from Norway, Liechtenstein, and Iceland are also participating as observers.

The inaugural meeting focused on the establishment of the AI Board's organisation and the adoption of its rules of procedure; a strategic discussion on EU AI policy, including the GenAI4EU initiative and international AI activities; a discussion on the first deliverables of the Commission related to the AI Act's implementation; and an exchange of best practices for national approaches to AI governance and AI Act implementation.

The Commission and Member States aim to ensure a robust and timely setup of the AI governance framework, facilitating effective participation of Member States and implementation of the AI Act.

AI Pact obtains 100+ signatures

On 25 September 2024, the European Commission announced that over a hundred companies had signed up to the **EU AI Pact**. The signatories include multinational corporations and European SMEs from diverse sectors, including IT, telecoms, healthcare, banking, automotive, and aeronautics. The Pact supports industry's voluntary commitments to start applying the principles of the AI Act ahead of its entry into application and enhances engagement between the EU AI Office and all relevant stakeholders, including industry, civil society and academia.

The Pact's voluntary pledges call on participating companies to commit to at least three core actions:

- AI governance strategy to foster the uptake of AI in the organisation and work towards future compliance with the AI Act.
- High-risk AI systems mapping: Identifying AI systems likely to be categorised as high-risk under the AI Act
- Promoting AI literacy and awareness among staff, ensuring ethical and responsible AI development.

More than half of the signatories also committed to additional pledges, including ensuring human oversight, mitigating risks, and transparently labelling certain types of AI-generated content, such as deepfakes.

Alongside the Pact, the **AI Factories** initiative of 10 September 2024 will provide start-ups and industry with a one-stop-shop to innovate and develop AI, including data, talent and computing power. They are meant to propel the development and validation of AI industrial and scientific applications in key European sectors including healthcare.

Council of Europe Framework Convention signed by EU

On 5 September 2024, the European Commission signed the **Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and Rule of Law** on behalf of the EU. The Convention, adopted by the Council in May, is the first legally binding international agreement on AI and in line with the **EU AI Act**, the first comprehensive AI regulation in the world.

It provides for a common approach to ensure that AI systems are compatible with human rights, democracy and the rule of law, while enabling innovation and trust. It includes key concepts from the AI Act, such as the adoption of a risk-based approach, transparency along the value chain of AI systems and AI-generated content, detailed documentation obligations high-risk systems, and risk management obligations with the possibility to introduce bans for AI systems considered a clear threat to fundamental rights. Digital literacy and skills and non-discrimination are also included among the articles.

That being said, the Framework Convention has also been criticised for the exclusion of the private sector and for its use of vague language, allowing for loopholes and exceptions rather than outlining prescriptive rights and obligations.

The signature took place at the informal conference of Council of Europe Ministers of Justice in Vilnius, Lithuania. Negotiating parties included the EU, other Council of Europe Member States, the Holy See, the USA, Canada, Mexico, Japan, Israel, Australia, Argentina, Peru, Uruguay, and Costa Rica. Input from 68 international representatives from civil society,

academia, industry and other international organisations were also considered. The Convention is part of the EU's broader efforts in AI at the international level, which include discussions at the G7, the OECD, the G20 and the United Nations.

In the EU it will be implemented through the AI Act, which provides harmonised rules for the placing on the market, deployment, and use of AI systems, along with other relevant EU legislations where needed.

The signature expresses the EU's intention to become a Party to the Convention. The European Commission will now prepare a proposal for a Council decision to conclude the Convention, with additional consent to be given by the European Parliament.

Poland: An Analysis of the Growth of the Top Disruptors in Healthcare Startups

The AI in Health Coalition, the Polish Hospital Federation and the expert team wZdrowiu published the fifth anniversary edition of the Top Disruptors in Healthcare Report, which for the past five years has been an integral part of the medical innovation landscape in Poland and the CEE region, showcasing the latest startups and inspiring solutions that are changing the face of healthcare. PZU Health is a partner of this year's Report.

The survey shows that in the technology sector, AI and machine learning play a key role, chosen by 64% of healthcare startups (108 respondents). The rapid increase in interest in these technologies, from 30% in the first edition of the report to 64% in the fifth, reflects their growing importance in the digitization of healthcare.

The biggest challenge for Polish medical startups is finding an investor or obtaining financing, as indicated by 50% of respondents. Expanding abroad and promoting and selling solutions are also significant barriers, indicated by 40% and 37% of startups, respectively. Collaboration with the public remains a challenge for 31% of startups, highlighting the need for better integration of innovations into the public healthcare system. Less of a problem are issues related to acquiring competent employees and creating business models, indicated by 7% of startups.

The most common target users are doctors and other medical professionals (66%) and healthcare providers (65%). Patients make up 59% of target users, highlighting the importance of direct health solutions available to patients. Medical entities are also the most important ultimate paying customer for medical startups (62%), suggesting that medical facilities remain a reliable source of revenue for innovative companies. The share of patients as paying customers, although declining, is still an important group of ultimate customers (40%).

The data shows that medical startups most often establish partnerships with medical institutions (2nd edition - 70%, 3rd edition - 63%, 4th edition - 62%, 5th edition - 73%). The

increase in collaboration in the fifth edition after previous declines underscores the growing importance of direct involvement of clinics and hospitals in the development of innovative solutions. Such close collaboration is indispensable for testing, implementing and scaling new technologies in medicine.

As the review "AI is not Sci-Fi," published by the Polish Hospital Federation in collaboration with the AI in Health Coalition and the expert team wZdrowiu, points out, medical innovations, including solutions developed by startups, are already being implemented in some hospitals and benefiting practice. The current increase in collaboration suggests that more and more medical facilities are seeing the positives of using innovation in the health sector. However, a very unfavorable is the significant decrease in cooperation with investors (2nd edition - 52%, 3rd edition - 42%, 4th edition - 32%, 5th edition - 20%).

Indicating the development stages of Polish startups, 14% are at the Proof of Concept (PoC) stage, the lowest percentage in the five-year history of the market survey. This decline suggests that more companies have already moved to more advanced stages. The Minimum Viable Product (MVP) stage has been selected by 25%, and the commercialization stage is at 31%, an increase from previous editions, indicating a maturing market and greater readiness to generate revenue. Stability at the growth stage has remained at 30% in the last two editions, showing that many startups are focusing on scaling operations and expanding into new markets.

Most medical startups (51%) were founded by mixed teams, reflecting diversity and openness to different perspectives. However, only 4% of startups were founded exclusively by women, while 44% were founded exclusively by men. This shows that there are still some gender inequalities, which can be reduced by supporting and promoting female entrepreneurship.

Pointing to the financing of Polish medical startups, it is worth noting that the share of the founder's own funds remains high, it is also the most frequently chosen answer by startups (58%). The second most popular source of funding is private investors (36%), A clear decrease can be observed in the case of funding from domestic VCs (4th edition - 34%, 5th edition - 24%), which may indicate difficulties in accessing domestic funds. On the other hand, if we indicate the current level of funding, the majority of startups declare it at the level of less than EUR 200 thousand (37%).

Top Disruptors in Healthcare report.

➢ European Health Data Space

Mission letter for the Commissioner-designate

The **mission letter** for Oliver Várhelyi, the Commissioner-designate for Health and Animal Welfare includes several elements of the previous legislation. It mentions that he should work to complete the EHDS.

HELT Talk on secondary use of health data

HOPE attended the first of a new Health, Law and Technology talks series organised by Vrije Universiteit Brussel (VUB) on 26 September 2024.

The inaugural session focused on the secondary use of health data in the context of nascent national data spaces and the EHDS, with speakers Prof. Thomas Berlage (U of Aachen, Germany) and Prof. Peter-Bram t'Hoen (Radboud University, Nijmegen, Netherlands). The two presentations revealed that national efforts to design data spaces do not perfectly match the proposed EHDS architecture for various reasons, including the different format of data used for coding, different data volumes, as well as different systems for recording data in the first place (e.g. invoicing purposes vs. research). Much of the available data is currently hidden away in silos: this is largely a result of differing health system organisation at national and/or regional levels. Different motivations for collecting data can also make the available pool of data hard to compare and unreliable, especially in a cross-border context where comparability is key. As most health systems across the EU are quite behind when it comes to developing effective data-sharing cultures – and data holders currently have no real incentive to actually share their data – it could still take many years before the EHDS will be fully operational internationally. The lack of available people to process data presents another acute challenge.

However, good health data governance can help to overcome most of the obstacles; EU Reference Networks, the larger patient registries, and big EU-funded and national projects in disease-specific (e.g., rare diseases, cancer) and other important areas (genomics, clinical trials) stimulating data sharing can be helpful in this regard as they require all participants to collect quality and interoperable data meeting the same standards.

The EURO-NMD Registry Hub linked to the respective EU Reference Network makes it possible to collect data based on FAIR principles and avoiding duplication of recoding data in different registries; this will benefit, inter alia, the modelling of disease progression in the neuromuscular domain. Nonetheless, there are significant technical and administrative obstacles, and large upfront investments were required to get it going.

The German data space under construction foresees introducing a "broad consent" for sharing personal electronic health data for research purposes, and similar models across Europe could

increase the data pool for secondary uses, although the majority of data is expected to be recorded by healthcare providers serving primary uses.

➢ Digital health

EHFG takes stock of digital progress across Europe

The 2024 edition of the European Health Forum Gastein (EHFG), which took place during the week of 23 September, devoted several sessions to the digital transformation of health and care in Europe. This included discussions about how to enhance care delivery through new digital innovation, realising the European Health Data Space ambition, digitalising palliative cancer care, AI as a potential gamechanger, the role of digital in pandemic preparedness, and what it means to be 'growing up digital'.

The EHDS sessions were particularly interesting as they underlined the need for effective stakeholder collaboration and steady political will to make it a reality. For example, experienced Finnish special advisor on digital health, Tapani Piha, mentioned the importance of avoiding "bad PR" since one negative data scandal could erode public trust in sharing personal electronic health data for healthcare and research purposes. The needs of health systems and patients had to be met, and positive messaging could contribute to building up confidence. A win-win relationship needed to be built for data holders to want to generate and share data so that the EHDS could be enriched, especially regarding the secondary use purposes.

Piha also hinted at the likelihood that not all hospitals as important data holders would be ready yet to participate in certain parts of the EHDS due to the fragmented nature of digitalisation across Europe and lack of infrastructure and health data expertise; however, the larger university hospitals already had ample experience with health data sharing through projects and collaborations with industry. Importantly, the EHDS should not create a burden for healthcare professionals who needed support. Piha expressed confidence that the new Commissioners would be able to bring the EHDS project to fruitful completion.

Marco Marsella of DG SANTE, European Commission, stated he expected formal adoption of the EHDS agreement at the end of 2024 or in early 2025. He explained that, following important work focusing on technical implementation and guidelines, the EHDS would then be fully operational in 2028. There would be funding opportunities under EU4Health to map what is needed for effective implementation at Member State level, but also to create awareness, boost patient engagement and create twinning schemes between more digitally advanced and less advanced participants in the EHDS.

Barbara Prainsack, Chair of the European Group on Ethics in Science and New Technologies based in Vienna, Austria, also mentioned the importance of moving to a global model that places more emphasis on the public value of data sharing, not only focusing on individual but

on societal health. She stated it was no longer sufficient to say to patients that sharing health data would improve healthcare.

Lack of compliance with EU Data Governance Act

The European Commission sent a letter of formal notice to 18 Member States, including Belgium, which have not designated the authorities responsible for implementing Regulation (EU) 2022/868, or which have failed to prove that the latter are empowered to perform the tasks required by the Regulation.

These authorities oversee the registration of data altruism organisations, and of monitoring the compliance of data intermediation service providers. Data altruism allows citizens to give their consent to use their data for the common good, for example for medical research projects.

Link.

New Data Governance Act practical guide

To mark the one-year anniversary of the Data Governance Act (DGA) entering into application, the European Commission released a new **DGA practical guide** to help stakeholders implement its provisions.

The guidance document is an in-depth guide to help stakeholders understand the provisions and reap the benefits of the DGA. It is neither legally binding nor does it represent the formal position of the Commission; instead, it is intended to help industry and Member States, and any other interested stakeholders, to better understand the various measures established.

The guide is subject to periodic updates, notably to take on board lessons learnt as experience in implementing the DGA builds up over time.

Environment and climate

Professional Dishwashers

The European Commission DG Environment has launched the ESPR Preparatory Study and Impact Assessment support study for Professional Dishwashers.

This preparatory study aims to provide a basis on which the Commission can consider the introduction of eco-design requirements, potentially green public procurement criteria, label criteria and/or a Digital Product Passport for professional dishwashers under the Ecodesign

for Sustainable Products Regulation (ESPR). The study is managed by Oeko-Institut e.V. together with the partners VITO, Trinomics, Fraunhofer ISI, Fraunhofer IZM, and Ecomatters.

Link.

After an initial consultation with regard to the scope, definitions, standards and legislation (MEErP Task 1), the study team has now launched a second consultation on markets, users, and technologies of professional dishwashers (MEErP Tasks 2, 3, and 4). To be involved and contribute to the consultation:

- **For registered stakeholder**.
- **For others**.
- The deadline for this consultation is 15 October 2024.

Financing

Late payments

Greece and Romania are failing to correctly apply EU rules on late payments in the health sector.

The European Commission sent a letter of formal notice to Romania and referred Greece to the Court of Justice of the EU for not correctly applying Directive 2011/7/EU. In the case of Romania, the public health authorities are found to be paying independent pharmacies with an excessive delay for medicines dispensed to patients through the national health insurance system. In Greece, the Commission wishes to address the incorrect payment practices of public hospitals towards their suppliers.

Public procurement

Three Member States are failing to comply with the public procurement legislation.

The European Commission sent a letter of formal notice to Bulgaria, Romania, and Spain for failing to comply with EU rules covering public contracts and concession contracts. In the case of Bulgaria, the letter notably addresses the exclusion of private hospitals from EU public procurement rules, even when these hospitals are partly financed through public funds.

EU Programmes

European Parliament: EU4Health Annual Work Programme

The new Chair of the Environment, Public Health and Food Safety Committee (ENVI), Antonio Decaro MEP (Italy, S&D), issued harsh criticism of the cuts to EU health funding agreed by the European Council in February 2024.

In a **letter** to the Chair of the Parliament's Budget Committee, Johan Van Overtveldt MEP (Belgium, ECR), concerning the general EU budget for 2025, Decaro "deplored" the cuts made by the European Council to health and environmental programmes.

Decaro writes that the committee "strongly regrets" the €1 billion cut to the EU4Health programme for the 2025-2027 period, which would amount to €189 million in 2025. The Parliament suggests that the EU's **Flexibility Instrument**, which amounts to €9.2 billion for the entire 2021-2027 period, could be mobilised to cover the gap in funding.

The Parliament is also calling for a reversal in cuts to the **Horizon Health Cluster**, which MEPs say was severely overstretched by the pandemic. The health cluster budget supports research into developing capabilities to tackle emerging, re-emerging, neglected and rare diseases.

The MEPs propose that the **Single Margin Instrument**, which uses the difference between actual payment commitments and the EU's budgetary ceilings, could cover these funding gaps.

The main **amendments** concerning health funding were supported by most of the EU lawmakers from the European People's Party (EPP), the Social Democrats (S&D), Renew and the Greens/European Free Alliance (Greens/EFA).

"We shared the rapporteur's concerns about the significant cuts," said Alexandr Vondra MEP (Czechia, ECR), the coordinator of the European Conservatives and Reformists (ECR) group. "However, the cuts are the result of difficult decisions made by the European Council, which relocated more than 10 billion to support Ukraine."

Call for proposals under the EU4Health Annual Work Programme

HaDEA has published on 17 September 2024 **a call for proposals** on cancer, mental health, health promotion and disease prevention and the use of AI in health, under the EU4Health Annual Work Programme 2024.

Interested parties are invited to send in their application by 22 January 2025.

World Health Organization

Framework for Action on the Health and Care Workforce

The first meeting on engagement with civil society in implementing the Framework for Action on the Health and Care Workforce in the WHO European Region took place on 6 September 2024.

The Framework for Action on the Health and Care Workforce in the WHO European Region 2023–2030 was approved by the WHO Euro Regional Committee in September 2023, with contributions from Non-State Actors. To advance this goal, WHO Euro is convening non-state actors such as health worker unions and associations, civil society networks and academic institutions to support countries in implementing the framework.

WHO Euro is already collaborating with many different partners across the Region to support countries in designing and implementing health workforce policies, to ensure effective approaches to addressing health workforce challenges. This collaboration includes joint policy work, developing technical guidance documents and publications, organizing knowledge-sharing platforms, and providing direct support to the ministries of health. In taking this work forward, WHO/Euro proposes to organize a series of round-table discussions bringing together partner organizations working on health workforce, including health worker unions and associations, civil society networks, youth network and academic institutions. These include organisations who may not be in a formal relationship with WHO as a non-state actor but are accredited by WHO Regional Committee for Europe. This initiative will be aligned with existing structures within WHO for engagement with civil society and will contribute to that work. This initiative hopes to contribute to more impactful implementation of the framework for action in the region.

Roundtable discussions will take place as webinars/meetings on specific topics to share experiences and identify best practices and challenges in addressing the pillars of the Framework on:

- Retention and recruitment of the health workforce in rural and underserved areas (medical deserts),
- Policies to improve working conditions of health workers,
- Integrating gender and intersectionality in strengthening the health workforce,
- Migration of the health workforce: experiences of countries providing and receiving health workers.

New Child and Adolescent Health and Wellbeing Strategy

The first pre-RC74 side event – "A New Child and Adolescent Health and Wellbeing Strategy in the WHO European Region - a co-creation exercise"– took place virtually on 2 September 2024.

Children and adolescents across Europe face unprecedented challenges that demand immediate action. Hard-earned reductions in child mortality and morbidity are reversing or stagnating. Inequities continue to widen. Investments in children and adolescents today will not only enhance their development and future opportunities but also contribute to a healthier aging population and more prosperous societies.

This virtual session provided an opportunity to consult on the development of a new child and adolescent health and well-being strategy for the WHO European Region to be approved at RC75 in October 2025.

The event saw the participation of key stakeholders and partners and was spearheaded by the WHO Regional Director for Europe, Dr Hans Henri P. Kluge and the UNICEF Regional Director for Europe and Central Asia, Regina De Dominicis.

Participants were able to hear updates on key facts concerning children and adolescent health in the WHO European region and children and adolescents will share some of their stories and reflections on how they see health challenges in the Region and how to best address them.

The Child and Adolescent Health and Wellbeing Strategy outline a high-level vision, clear key objectives, and a monitoring framework for implementation. The new strategy will be a crucial tool for developing national child and adolescent health and wellbeing strategies across the 53 member states, ensuring that all children and adolescents in the WHO European Region realize their rights to physical, social, and mental health and wellbeing addressing health inequities.

WHO, UNICEF and stakeholders including children and adolescents are embarking on a co-creation exercise for the development of the new strategy. This event marks the first step and will be followed by a series of consultations with all stakeholders, including a series of member states technical consultations with the final strategy to be submitted for next year's RC for approval.

Data on non-communicable diseases

The European Union-funded projects JA-PreventNCD (Joint Action Prevent Non-Communicable Diseases) and JACARDI (Joint action cardiovascular diseases and diabetes), along with WHO/Europe, are collaborating to identify the characteristics of countries that effectively address NCD threats and strengthen their monitoring systems. On 10 September

2024, the organizations held a joint event "Strengthening NCD monitoring systems in the EU: A collaborative approach" that presented new data on countries' progress in achieving regional and global targets to tackle NCDs.

Denmark, Estonia, Norway and Sweden are among the countries of the Region that succeeded in reducing premature mortality from NCDs. WHO/Europe is currently undertaking an in-depth analysis of characteristics or patterns associated with those reductions.

Some recommendations to reduce NCDs burden across the European region include:

- increasing taxes and pricing on tobacco products, alcohol, and unhealthy foods (high in transfats, salt and sugar); and
- banning the advertising and sponsorship (on all platforms including social media) of tobacco products, alcohol, and unhealthy foods (high in transfats, salt and sugar).

Such policy levers can help countries reduce the burden NCDs and create living environments that foster healthy choices over unhealthy ones.

- **NCDs dashboard**
- **Guidance document: Roadmap released 2022**

Comparative assessment on patient safety culture performance

The OCDE published on 12 July 2024 a working paper on Findings based on the Hospital Survey on Patient Safety Culture.

Safety is a core dimension of health care quality. Measurement of patient safety culture in OECD countries has been increasingly conducted as part of efforts to monitor patient safety and to contribute to health system performance assessment.

Building on four years of work, a second OECD data collection on patient safety culture was conducted in 2022-2023, with the support of the members of OECD Expert Group on Patient Safety Culture. Data from almost 650,000 health care workers, from over 3,000 different sites/hospitals, across 14 countries was added in this round of data collection. This report documents the state-of-the-art of patient safety measurement using the Hospital Survey of Patient Safety Culture (HSPSC) and is the first report to document international comparisions using the HSPSC v2, which has been recently adopted by ten countries who submitted data.

Despite many commonalities between countries in the implementation of PSC measurements, there remains differences in the scope of implementation and survey response rates. Moreover, survey findings show general deficits in staff perceptions of safe staffing and workpace levels and response to errors among hospital workers, areas that could be targeted for policy action to improve patient safety.

Download PDF.

Alternative Payment Models and Quality of Chronic Care

Payment reforms are frequently implemented alongside service delivery reforms, thus rendering it difficult to disentangle their impact. The article “Disentangling the Impact of Alternative Payment Models and Associated Service Delivery Models on Quality of Chronic Care: A Scoping Review” was recently published in Health Policy.

Link.

This scoping review aims to link alternative payment arrangements within their context of service delivery, to assess their impact on quality of chronic care, and to disentangle, where possible, the impact of payment reforms from changes to service delivery. A search of literature published between 2013 and 2022 resulted in 34 relevant articles across five types of payment models: capitation/ global budget (n = 13), pay-for-coordination (n = 10), shared savings/shared risk (n = 6), blended capitation (n = 3), and bundled payments (n = 1). The

certainty of evidence was generally low due to biases associated with voluntary participation in reforms.

This scoping review finds that population-based payment reforms are better suited for collaborative, person-centred approaches of service delivery spanning settings and providers, but also highlights the need for a wider evidence base of studies disentangling the impact of financing from service delivery reforms. Limited evidence disentangling the two suggests that transforming service delivery to a team-based model of care alongside a purchasing reform shifting to blended capitation was more impactful in improving quality of chronic care, than the individual components of payment and service delivery.

Further comparative studies employing causal inference methods, accounting for biases and quantifying aspects of service delivery, are needed to better disentangle the mechanisms impacting quality of care.

Tackling Medicine Shortages During and After the COVID-19 Pandemic

In response to increasing shortages of medicines, governments have implemented legislative and non-legislative policy measures.

An article “Tackling Medicine Shortages During and After the COVID-19 Pandemic: Compilation of Governmental Policy Measures and Developments in 38 Countries” was recently published on that topic in Health Policy.

Link.

This study aimed to map policies across high-income countries in Europe and beyond as of 2023 and to analyse developments in governmental approaches since the beginning of the pandemic. Information was collated from 38 countries (33 European countries, Australia, Brazil, Canada, Israel and Saudi Arabia) based on a survey conducted with public authorities involved in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network in 2023. 34 countries requested pharmaceutical companies to notify national registers of upcoming shortages and 20 countries obliged manufacturers and/or wholesalers to stock supply reserves of critically needed medicines. Further common measures included export bans for defined medicines (18 countries), regulatory measures to facilitate import and use of alternative medicines (35 countries) and multi-stakeholder coordination (28 countries). While the legislation of 26 countries allows imposing sanctions, particularly for non-compliance to reporting requirements, fines were rather rarely imposed. Since 2022, at least 18 countries provided financial incentives, usually in the form of price increases of some off-patent medicines. Overall, several policies to address medicine shortages were taken in recent years, in some countries as part of a comprehensive package (e.g., Australia, Germany). Further

initiatives to secure medicine supply in a sustainable manner were being prepared or discussed.

Activity-Based Funding Based on Diagnosis-Related Groups

Across the member countries of the Organisation for Economic Co-Operation and Development, policy makers are searching for new ways to pay hospitals for inpatient care to move from volume to value.

An article “The End of an Era? Activity-Based Funding Based on Diagnosis-Related Groups: A Review of Payment Reforms in the Inpatient Sector in 10 High-Income Countries” was published in Health Policy 141.

Link.

This paper offers an overview of the latest reforms and their evidence to date. Methods We reviewed reforms to DRG payment systems in 10 high-income countries: Australia, Austria, Canada (Ontario), Denmark, France, Germany, Norway, Poland, the United Kingdom (England), and the United States.

The authors identified four reform trends among the observed countries, them being (1) reductions in the overall share of inpatient payments based on DRGs, (2) add-on payments for rural hospitals or their exclusion from the DRG system, (3) episode-based payments, which use one joint price to pay providers for all services delivered along a patient pathway, and (4) financial incentives to shift the delivery of care to less costly settings. Some countries have combined some or all of these measures with financial adjustments for quality of care.

These reforms demonstrate a shift away from activity and efficiency towards a diversified set of targets, and mirror efforts to slow the rise in health expenditures while improving quality of care. Where evaluations are available, the evidence indicates mixed success in improving quality of care and reducing costs and expenditures.

Financial incentives for integrated care

In response to the increasing prevalence of people with chronic conditions, healthcare systems restructure to integrate care across providers. As many systems fail to achieve the desired outcomes, one likely explanation is lack of financial incentives for integrating care.

An article “Financial Incentives for Integrated Care: A Scoping Review and Lessons For Evidence-Based Design” was published on this topic in Health Policy 141: **Link**.

The authors aimed to identify financial incentives used to promote integrated care across different types of providers for patients with common chronic conditions and assess the

evidence on (cost-)effectiveness and the facilitators/barriers to their implementation. Methods This scoping review identifies studies published before December 2021 and includes 33 studies from the United States and the Netherlands. They identified four types of financial incentives: shared savings, bundled payments, pay for performance, and pay for coordination. Substantial heterogeneity in the (cost-)effectiveness of these incentives exists.

Key implementation barriers are a lack of infrastructure (e.g., electronic medical records, communication channels, and clinical guidelines). To facilitate integration, financial incentives should be easy to communicate and implement, and require additional financial support, IT support, training, and guidelines. Conclusions All four types of financial incentives may promote integrated care but not in all contexts. Shared savings appears to be the most promising incentive type for promoting (cost-) effective care integration with the largest number of favourable studies allowing causal interpretations. The limited evidence pool makes it hard to draw firm conclusions that are transferable across contexts.

The Effect of Health-Care Privatisation on the Quality of Care

Over the past 40 years, many health-care systems that were once publicly owned or financed have moved towards privatising their services, primarily through outsourcing to the private sector.

An article “The Effect of Health-Care Privatisation on the Quality of Care,” was recently published in The Lancet Public Health 9(3): **Link**.

What has the impact been of privatisation on the quality of care? A key aim of this transition is to improve quality of care through increased market competition along with the benefits of a more flexible and patient-centred private sector. However, concerns have been raised that these reforms could result in worse care, in part because it is easier to reduce costs than increase quality of health care. Many of these reforms took place decades ago and there have been numerous studies that have examined their effects on the quality of care received by patients.

The authors reviewed this literature, focusing on the effects of outsourcing health-care services in high-income countries. They found that hospitals converting from public to private ownership status tended to make higher profits than public hospitals that do not convert, primarily through the selective intake of patients and reductions to staff numbers. They also found that aggregate increases in privatisation frequently corresponded with worse health outcomes for patients. Very few studies evaluated this important reform and there are many gaps in the literature. However, based on the evidence available, the Review provides evidence that challenges the justifications for health-care privatisation and concludes that the scientific support for further privatisation of health care services is weak.

Health system review: Spain

On 16 September 2024, the European Observatory on Health Systems and Policies released the Health System Review for Spain, a Health Systems in Transition (HiTs) document. Such summaries will be updated every two years.

You can find a link to the discussions on release day **here**, and a link to the document **here**.

30th International Conference on Health Promoting Hospitals and Health Services

Registration is now open for the **30th International Conference on Health Promoting Hospitals and Health Services** (HPH), which will take place from 6 to 8 November 2024 in Hiroshima, Japan. The conference theme is **"**The contribution of Health Promoting Hospitals and Health Services to health equity**."** The early bird discount applies until 14 July 2024**.**

Register Here.

Health & Tech Summit

The 2024 edition of the Health & Tech Summit in Paris will take place at PariSanté Campus from 17 to 19 December 2024, with the ambition of bringing together leaders in health, data, and AI around the theme: "Drive the Change".

Today, solutions are emerging and evolving at lightning speed. However, they will only have a positive impact if we use them as strategic levers to enhance the quality of organizations, professionals, and patients. Without this, necessary investments will not be made, professionals and organizations will not receive the support they need, and research and evaluation will suffer.

Link.

International Conference on Integrated Care

The 25th International Conference on Integrated Care (ICIC25) will take place in the CCB Lisbon on 14-16 May 2025.

With the overarching theme 'Synergising Health and Care: Leveraging Integrated Care for a Sustainable Future' the conference will bring together leaders, researchers, clinicians, managers, community representatives, patients and caregivers from around the world who are engaged in the design and delivery of integrated health and care.

The International Scientific Committee (ICS), Chaired by Dr Adelaide Belo, President of the Portuguese Association for Integrated Care (PAfIC), is now seeking abstracts of good practice in research, policy, practice and education from around the world. This is expected to be a

competitive process, so presenters are asked to take time in understanding the guidelines and to follow the process carefully. We are particularly keen to hear from our colleagues in Portugal and to celebrate the great achievements that have been made in progressing people-centred integrated care across the region.

The **International Scientific Committee** for this conference has been established from a broad range of international experts who are leading in the field of Integrated Care. They are accepting paper submissions on research, policy, practice or education and specifically related to the Conference Themes and the 9 Pillars of Integrated Care until 31 October 2024. All accepted abstracts will be published in the International Journal of Integrated Care (IJIC) and recordings of presentations and posters will be made available to IFIC's global network after the conference. All presenters must register and pay to attend the conference.

- **Submit an abstract**.
- **Learn more** about the event.

HOPE Agora 2025

SAVE THE DATE: The HOPE Agora 2025 will take place from **13 to 15 June 2025 in Vienna, Austria**, and will focus on the topic 'Together for Quality!'. More information regarding the venue and programme will be provided closer to the date.