EPF European Patients Forum

PEST ANALYSIS 2020

Contents

1. POLITICAL

The political environment is shaped by an important change in the European institutions that took place at the end of last year: a new European Commission and a new European Parliament for the term 2019–2024. The new Commission's priorities are undoubtedly influenced by a growing Euroscepticism and the rise of populist political movements across the Union, but also global concern about climate change, and the ongoing process of Brexit. It should be noted that the European political environment on health is shaped by wider political issues and global developments. The COVID-19 pandemic will have an impact on the Commission's work and political priorities not only this year but also beyond.

I. THE POLITICAL IMPACT OF THE COVID-19 PANDEMIC

The pandemic may become a catalyst for a fundamental rethink of how societies and economies (should) work, an urgent need and also an opportunity to readjust the balance of private and public interests.[1] Economist Marianna Mazzucato, referring to the "triple crisis" of health, economy and climate, argues that rescue measures should come with conditions in order to secure more inclusive and sustainable future economies: "We desperately need entrepreneurial states that will invest more in innovation—from artificial intelligence to public health to renewables. But as this crisis reminds us, we also need states that know how to negotiate, so that the benefits of public investment return to the public."[2] Historian Yuval Noah Harari said in an interview he was concerned about short-term choices focusing on isolationism and narrow national interests. "What we choose in the next month or two will change the world for years or even decades … but I hope that … by the end of this crisis, we will come out with stronger international organisations and a strengthening of global solidarity" that would lead to greater resilience against future threats.[3]

In Europe, attention has been on the tensions between Member States' own actions and those taken collectively at European level. The pandemic is testing the European Union's capacity to cope with an unprecedented economic crisis, but also its core values of solidarity, democracy and the rule of law. Early signs of nationalist political response, such as the closing of borders and issuing of export bans on medical equipment, were not reassuring. In addition, some countries have seen a roll-back of their democracy. Countries "where illiberal populists have already started to translate the 2020 health emergency as the victory of the nation-state over a helpless EU, and the liberal rules-based multilateral order" include Hungary, where Viktor Orbán's rule by decree during the state of emergency without any clear time limit

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[1] https://www.weforum.org/agenda/2020/04/coronavirus-covid19-business-economics-society-economics-change

[2] https://www.socialeurope.eu/capitalisms-triple-crisis

[3] https://www.euractiv.com/section/global-europe/interview/harari-we-will-have-to-choose-between-uniting-humanity-or-selfishness-and-nationalisms/

has raised alarm. In Poland, “the government changed the electoral law overnight to make sure the 10 May presidential elections go ahead, hoping that the only candidate able to organise a campaign is the current president”. Criticism of the government or the performance of the health system is being suppressed.[4] The Polish government has also put forward regressive draft laws on abortion, transgender people’s rights and sex education, in a move some commentators believe is taking advantage of circumstances where public protest is constrained.[5] The European Parliament in a resolution called for the Commission to revive its Article 7 sanctions procedure against the two countries and to link EU funding to upholding the rule of law.[6]

II. BREXIT

Following “Brexit day” on 31 January 2020, the EU and UK managed only one round of talks before the coronavirus pandemic led to a halt. A timetable for negotiations published in mid-April indicated that further rounds of talks would take place during the last week of April, mid-May and beginning of June. Agendas were expected to cover the 11 key topics of post-Brexit talks, including trade, security and fisheries.[7] The UK has so far not sought an extension to the transition period which ends on 31 December 2020. Such an extension would need to be agreed before July, and would need to include a deal on payments into the EU’s budget.

Brexit presents a number of difficulties for the EU as a whole and for the internal market’s “four freedoms” of movement – of goods, capital, services, and labour. Several issues are still unclear as there are questions on whether, and in what form, a deal may emerge. Unresolved issues include healthcare coverage for EU nationals residing in the UK and British nationals in various EU countries and the work and residency status of many healthcare professionals in the UK’s NHS.[8] Participation of UK institutes in research under EU funding mechanisms such as Horizon Europe and the European Social Fund+, and participation in future digital health infrastructures and sharing of data. It is also uncertain whether the UK will gradually move away from regulatory alignment on pharmaceuticals and medical technologies. A no-deal Brexit, or a deal that does not adequately take into account patients’ needs and rights will have adverse effects for people on both sides. Access to medicines and medical technologies for both UK and EU patients and safeguarding the highest standards of patient safety will be critical priorities as negotiations unfold.[9]

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[4] https://www.theguardian.com/world/commentisfree/2020/apr/01/coronavirus-contaminating-europe-democracy-viktor-orban-seize-more-power

[5] https://www.euractiv.com/section/justice-home-affairs/news/hungary-seeks-to-clamp-down-on-transgender-rights-sparking-eu-protests/

[6] https://www.europarl.europa.eu/doceo/document/B-9-2020-0032_EN.html

[7] https://www.theguardian.com/politics/2020/mar/01/brexit-what-are-the-key-flashpoints-as-eu-uk-trade-talks-begin

[8] King’s Fund (Oct. 2019), Brexit: the implications for health and social care, https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care

[9] https://www.eu-patient.eu/globalassets/library/publications/brexit--prioritising-patients---final.pdf

III. NEW EU INSTITUTIONS: 2019–2024

The second half of 2019 saw the creation of the 9th legislature of the European Parliament, in place from July 2019 to May 2024. This was accompanied with the establishment of a new European Commission from 1 December 2019. The European Council has a new President in Charles Michel, former Belgian prime minister, who took over from Donald Tusk on 1 December 2019.

The 2019 European Elections were marked by the rise of populist political forces in many EU Member States, as well as anti-EU sentiment from certain parts. This was set a wider context of distrust in governments, in science and in expert opinion, as exemplified by the anti-vaccination phenomenon, fed by increasing amounts of misinformation and disinformation that multiplies quickly through social media and networks. The EU institutions tried to counter the distrust by making promises of bringing the Union closer to the people, including a focus on implementing the European Pillar of Social Rights and a commitment to holding a "people's conference on Europe"; however, it remains to be seen whether this sentiment will be reflected in health policy, which is traditionally closely guarded by the Member States.

Article 168 of The Treaty on the Functioning of the European Union (TFEU) remains the legal basis for the EU's health policy. While it obliges the Union to ensure "a high level of human health protection" in all its activities, it also sets clear limits to EU competence in health. That health is accorded low priority in the Treaty while being very high on the citizens' priorities has in past years created a gap in terms of expectations that is not properly reflected on the EU policy agenda. Citizens continue to prioritise health as their top concern and around 70% want the EU to do more on health.[10] Health is, of course, spread over a number of EU policy areas with different Treaty basis: public health, internal market, and fiscal governance.[11]

The EU's response to COVID-19 highlights its limitations in dealing with systems issues such as cross-border health threats. It has particularly revealed the limited role and resourcing of the European Centre for Disease Control and Prevention (ECDC).. One of the key EU's responses to the crisis is the new proposal for a standalone 9.4 Billion EUR health programme ''EU4Health''.[12] The new proposal radically shifts budget and framework initially planned for the 2021-2027 Health Programme (412 Million EUR under the ESF+ Programme) and it is developed around three main objectives:

- protecting people in the EU from serious cross-border health threats and improving crisis management capacity;
- making medicines, medical devices and other crisis relevant products, available and affordable and supporting innovation;

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[10] https://www.europarl.europa.eu/infographic/eurobarometer/2017/index_en.html#health

[11] See Palm et al. (2019) Everything you always wanted to know about EU health policy but were afraid to ask.

[12] The funding will partly come from the EU budget (€1.7 billion) and partly via external assigned revenues, stemming from the borrowing operations of the Union as set out in the EU Recovery Instrument Regulation (€7.7 billion). European Commission, https://ec.europa.eu/health/funding/eu4health_en.

- strengthen health systems and the health care workforce, including by investing in public health, for instance through health promotion and disease prevention programmes and improving access to healthcare. [13]

The EU4Health Programme, following discussion at European Parliament's level between June and October 2020[14] and its final approval, should be implemented starting January 2021.

Despite an increased budget dedicated to health, this is not expected to change the fundamental balance of competencies of the EU in health, at least not in the short term. Yet, it is noteworthy to mention that representatives from several political groups in the European Parliament[15] addressed the need for more health cooperation at European level in a series of calls, letters and statement published between May and July 2020. These initiatives led to a Joint Motion for Resolution on Public Health in the European Union voted on 10 July 2020 by the European Parliament's Plenary[16] . In the Motion's text, MEPs underline the need to draw the right lessons from the COVID-19 crisis and engage in far stronger cooperation in the area of health to create a European Health Union[17]. Such cooperation would include, among other things, common minimum standards for quality healthcare, a European Health Response Mechanism, more systematic use of joint EU procurement and a call for affordable access to vaccines, essential medicines and treatments, strengthening of health agencies (ECDC and EMA) and better joint research, including through the new EU4Health Programme.

The new European Commission

The new European Commission's overall political priorities[18] are divided into six areas: A European Green Deal; An economy that works for people; A Europe fit for the digital age; Promoting our European way of life; A stronger Europe in the world; and A new push for European democracy[19] In the Commission's political guidelines there is language on the importance of economic policy going hand in hand with social rights. Notably, a commitment to "refocus the European Semester into an instrument that integrates the

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[13] See 1.2. for more details on the specific objectives or the EU4Health factsheet: https://ec.europa.eu/health/sites/health/files/funding/docs/eu4health_factsheet_en.pdf

[14] European Parliament, Draft Report on the proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme") (2020/0102(COD), June 2020, https://www.europarl.europa.eu/doceo/document/ENVI-PR-653803_EN.pdf

[15] For example, Socialist and Democrats call for a European Health Union (May 2020), https://www.politico.eu/wp-content/uploads/2020/05/European-Health-Union-SD-Position-FINAL1.pdf;

[16] European Parliament (P. Liese, EPP; J. Guteland, S&D; P. de Sutter, Greens; K. Konečná, GUE/NGL), Joint Motion for a Resolution on the EU's public health strategy post COVID-19 (2020/2691(RSP)), https://www.europarl.europa.eu/doceo/document/RC-9-2020-0216_EN.html

[17] European Parliament Press Room, Parliament wants a European Health Union, https://www.europarl.europa.eu/news/en/press-room/20200710IPR83101/parliament-wants-a-european-health-union

[18] Ursula von der Leyen, A Union that strives for more: my agenda for Europe (Jul. 2019), https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

[19] https://ec.europa.eu/info/priorities_en#relatedlinks

United Nations Sustainable Development Goals" and to "an action plan to fully implement the European Pillar of Social Rights."[20]

The College of Commissioners[21] comprises 27 commissioners led by President Ursula von der Leyen. The nomination of eight vice-presidents, of whom three are "executive vice presidents" is new. The three are Frans Timmermans (Netherlands); Margrethe Vestager (Denmark) and Valdis Dombrovsksis (Lithuania). They will support one of the Commission's priorities in addition to their own commissioner responsibilities. Mr Timmermans is responsible for the European Green Deal and climate policy; Ms Vestager oversees all activities relating to digitalisation as well as competition policy; Mr Dombrovskis is responsible for the Economy at the service of the people as well as the financial services portfolio. The other vice presidents are Josep Borrel from Spain, Vera Jourova from the Czech Republic, Margaritis Schinas from Greece, Maroš Šefcovic from Slovakia, and Dubravka Šuica from Croatia. The Health Commissioner, Stella Kyriakides of Cyprus, will work with Mr Schinas, who is responsible for "promoting our European way of life" on public health matters, and with Mr Timmermans on issues related to food safety.

DG Sante is also going through staff changes for some of its key positions: following the nomination of Sandra Gallina[22] as new DG SANTE Deputy Director General, and in July 2020, DG Sante Director General Anne Bucher announced that she will retire in September 2020.

- **The new European Parliament**

The 9th legislature of the European Parliament brought important changes to the institution, not least due to the removal of UK MEPs a result of Brexit. A record-breaking number of Members elected were under the age of 40.[23] Voter turnout exceeded 50% for the first time in 25 years. About 60% of the MEPs are new to their role. The new President of the European Parliament is David Sassoli (IT, S&D).

Many key MEPs who worked on health issues are no longer in the Parliament – a significant loss of expertise and long experience they brought to EU health policy. On the other hand, the presence of new MEPs is an opportunity for advocacy and developing good working relations.

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[20] A Union that Strives for More. Political guidelines for the next European Commission 2019-2024.

[21] https://ec.europa.eu/commission/commissioners/2019-2024_en

[22] Sandra Gallina, formerly number two at DG TRADE, replaced Martin Seychell as DG Sante Deputy Director General. Gallina has a reputation as a strong negotiator — a key asset as DG SANTE works on negotiating deals with pharma companies for coronavirus vaccine candidates, https://pro.politico.eu/news/dg-sante-head-to-step-down-in-september.

[23] European Parliament, Eurobarometer (Jul. 2019), The 2019 Elections: A pro-European – and young – electorate with clear expectations: First results of the European Parliament post -electoral survey, https://www.europarl.europa.eu/at-your-service/en/be-heard/eurobarometer/post-election-survey-2019-first-results

The balance of political power in the Parliament has changed. The two major political groups – the European People's Party and the Socialist and Democrats – no longer hold a combined majority. The onslaught of far-right nationalists Eurosceptics feared by some did not materialise in the end; pro-Europe centrists still prevail overall though the number of far-right MEPs increased. However, the relative growth of smaller groups main mean that in order to get anything through MEPs – and stakeholders – will need to work cross-politically. One interesting development is an increase in Green party MEPs by at least 15 more seats. This could mean stronger links between public health and environmental issues, as well as more critical stance towards industry.

IV. THE NEW EU HEALTH AGENDA

In 2019, the Commission put forward a proposal for the EU's budget (called the Multiannual Financial Framework, MFF) for the period 2021–2027. Agreement on the budget was not reached in Council in 2019. Legislation on new framework programmes was passed in 2019, including the European Social Funds (ESF+) that comprises health and social policy, and the 9th research and innovation programme titled "Horizon Europe". At the time of writing the Commission has not yet released its revised proposal for the MFF and its work programme 2020. Some items on the work programme are almost certain to be delayed. It also remains uncertain how the pandemic will impact the work of the upcoming EU Presidencies. (Germany in the second half of 2020, followed by Portugal and Slovenia in 2021).

It is notable that Commission President Ursula von der Leyen said the Commission would adopt the **UN Sustainable Development Goals (SDGs)** as its framework to measure impact and gauge success of policies – from the Green Deal to digital transformation. Goal 3 is focused on ensuring healthy lives and promoting wellbeing for all at all ages and includes universal health coverage – a key principle of the European Pillar of Social Rights.

Looking at the mission letter of the Commissioner for Health and Food Safety – Stella Kyriakides, a Cypriot and a clinical psychologist by training – her health mandate is strikingly ambitious compared to that of her predecessor in the Juncker Commission, Dr Vytenis Andriukaitis. [24] Thus the fears of an abolition of EU health policy did not materialise. The priorities set out in Ms Kyriakides's mission letter include "supporting Member States in constantly improving the quality and sustainability of their health systems" through finding ways to improve information, expertise and exchange of best practices. Six specific policy priorities are listed:

- ensure a supply of affordable medicines that meet Europe's needs, while also supporting the European pharmaceutical industry
- effective implementation of the new regulatory framework on medical devices
- work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes" and for citizens to have control over their data
- implementation of the European One Health Action Plan against antimicrobial resistance

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[24] https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

- communication on vaccination, “explaining the benefits and combating the myths, misconceptions and scepticism that surround the issue”
- put forward “Europe’s Beating Cancer Plan to support Member States to improve cancer prevention and care” across prevention, diagnosis, treatment, survivorship and palliative care and in close link with the Horizon Europe programme.

In addition to the critical decision to create a standalone EU4Health Programme, health is also recognised as a key area under the research framework programme, **Horizon Europe**, which will apply from 2021.[25] The Commission has also proposed a Council Regulation for a **European Partnership on Innovative Health** under Horizon Europe. This successor to the previous Innovative Medicines Initiative programmes, IMI and IMI2, will aim to create a space for pre-competitive research and innovation where small and big companies can join forces with researchers, patients, healthcare professionals and regulators; the proposal is scheduled to be published in the first quarter of 2020.[26]

Below, we elaborate on some of these areas listed above.

ACCESS TO AND AFFORDABILITY OF MEDICINES

The Commissioner’s broad mandate includes looking at access to new medicines and their affordability, but also to continue efforts to reach a deal on EU-wide HTA and to take action on medicines shortages. Indeed, DG Sante announced that its pharmaceutical strategy would be published as a communication in the last quarter of 2020, which was confirmed by the revised EC’s work programme published in May 2020..[27] In June 2020, the European Commission opened its public consultation process on the Pharmaceutical Strategy and its preliminary roadmap.[28]

The final version of the strategy is likely to include a review of the EU’s pharmaceutical legislation, including the basic 2001 legislation and the regulations on orphan and paediatric medicines. It may also look at the fee structure of the European Medicines Agency and its role. Non-legislative actions will include a plan on shortages, examining the environmental impact of medicines, and – timely in view of the pandemic – looking into reducing Europe’s growing dependence on imports of medicines and active pharmaceutical ingredients.

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[25] As concerns Horizon Europe, on top of the regular calls for projects and initiatives, it is noteworthy to mention the new plans for Horizon Europe’s ‘partnerships’, in particular the European partnership on Health and Care Systems Transformation, https://ec.europa.eu/info/files/european-partnership-health-and-care-systems-transformation_en

[26] European Commission (Sep. 2019), European Partnership for innovative health (Horizon Europe programme), https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11906-European-Partnership-for-innovative-health

[27] https://eur-lex.europa.eu/resource.html?uri=cellar%3Af1ebd6bf-a0d3-11ea-9d2d-01aa75ed71a1.0006.02/DOC_2&format=PDF

[28] The Consultation process launched by the European Commission will allow interested stakeholders to share their views on the Pharma Strategy Roadmap (by 7 July 2020) and on the Pharma Strategy key concepts (by 15 September 2020), https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines.

Discussions on the European Commission's January 2018 proposal for a Regulation on Health Technology Assessments remain blocked as there is no agreement between Member States in Council.[29] Member States opposing the proposal include the Czech Republic, France, Germany, Spain and Poland; many draw the line at mandatory joint assessments. While the German Presidency has said it will try to find an acceptable compromise during its Presidency of the Council in the second half of 2020, it remains to be seen how the work is affected by the pandemic. In the meantime, in response to the COVID-19 crisis, the negotiation team of the European Parliament on the regulation on health technology assessment (HTA)[30] has published a letter to urge Commissioner Kyriakides and Vice President Schinas to further push to advance on the HTA Regulation and include it within the new Pharmaceutical Strategy.[31]

Between May and July 2020, the issue of medicine shortages has been addressed by the European Parliament in a Draft Report led by MEP Nathalie Colin-Oesterlé.[32]. The report focused on some key elements of the shortages issue, namely better coordination at European level between Member States, the role of EMA, securing supplies in the interests of the patients and restoring 'sovereignty' at European level addressing the issue of active ingredients dependency on import from third world countries.[33]

DIGITAL TRANSFORMATION OF HEALTH

One of the headline priorities of the new European Commission as set out in the political guidelines of Commission President Ursula von der Leyen, is "A Europe fit for the digital age". From this overall priority flow several areas of action, including the request to the Health Commissioner to work towards the creation of a **European Health Data Space** in compliance with the EU data protection rules and supported by the establishment of a dedicated Code of Conduct for processing of personal data in health sector.[34] On 19 February 2020 the Commission published several documents that build on previously publications to take forward its strategy on digital health:

- A communication titled "Shaping Europe's digital future,"[35] which sets out priority actions under three headings: technology that works for people; a fair and competitive economy; and an open, democratic and sustainable society – all of which relate to health in some way

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[29] Council (Jun. 2019), Employment, Social Policy, Health and Consumer Affairs Council – information on the state of play – Proposal for the Regulation on health technology assessment, https://data.consilium.europa.eu/doc/document/ST-9770-2019-INIT/en/pdf

30 The negotiation team members are: Tiemo Wölken, Rapporteur, Socialists and Democrats, Nathalie Colin-Oesterlé, Shadow Rapporteur, European People's Party, Véronique Trillet-Lenoir, Shadow Rapporteur, Renew Europe, Michèle Rivasi, Shadow Rapporteur, Greens/EFA, Kateřina Konečná, Shadow Rapporteur, GUE/NGL

31https://www.politico.eu/wp-content/uploads/2020/06/CLEAN_20200616_Letter-on-the-Regulation-on-HTA.pdf?utm_source=POLITICO.EU&utm_campaign=057c65e0ed-EMAIL_CAMPAIGN_2020_06_17_05_13&utm_medium=email&utm_term=0_10959edeb5-057c65e0ed-190571555

32 European Parliament, Draft Report on the Shortage of medicines – how to deal with an emerging problem (2020/2071(INI)), https://www.europarl.europa.eu/doceo/document/ENVI-PR-650394_EN.pdf

33 Ibid.

34 The Code of Conduct establishment (in accordance with Article 40 of the GDPR) , is mentioned as a key element of the EHDS as per the European Commission's Data Strategy, https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

35https://ec.europa.eu/info/sites/info/files/communication-shaping-europes-digital-future-feb2020_en_4.pdf

- A communication titled a European strategy for data[36]
- A white paper "Artificial Intelligence – a European approach to excellence and trust"[37]

In April 2018, the Commission had presented its **Communication on the digital transformation of health and care in the digital single market** (COM(2018) 233 final),[38] which set out its plan on digital health for the coming years. The communication includes measures to enable people to access and share their health data safely; to pool data across Europe to boost research and spur the development of personalised medicine; and for scaling up of digitally-enabled person-centred care models. This communication led to the adoption of the Recommendation on Electronic Health Record Exchange format, which will allow interoperability of Member states' electronic health record systems.[39]

To incentivise the use of digital tools, the Commission will promote common principles for validating and certifying health technology, support the exchange of innovative and best practices, capacity building and technical assistance for health and care authorities for using open standards and interoperable digital solutions to promote health, prevent and manage chronic conditions, empower people and centre care on the person; and raise awareness about innovative procurement and investment possibilities for digital transformation in public health and healthcare.[40] The EU is also rolling out its overall digital strategy, which covers high-performance computer facilities, cloud services, high-speed networks, open data, data analytics, blockchain, machine learning and artificial intelligence – all either directly or indirectly pertinent to healthcare.[41] Questions have been raised on whether the GDPR needs to be adjusted in view of technological developments such as AI. However, in its planned review,[42] the European Commission has highlighted that 'the GDPR has met most of its objectives, in particular by offering citizens a strong set of enforceable rights and by creating a new European system of governance and enforcement', yet calling for continuous monitoring on adoption and harmonisation across Member States to tackle fragmentation. Alongside the GDPR the Commission also continues to work on a Code of Conduct for health apps used on mobile devices to safeguard privacy.[43]

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[36] https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

[37] https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

[38] https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

[39] European Commission (Feb. 2019), Recommendation on a European Electronic Health Record exchange format, https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[40] European Commission (Apr. 2018), https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

[41] European Commission (Nov. 2018), European Commission Digital Strategy, https://ec.europa.eu/info/publications/EC-Digital-Strategy_en

[42] European Commission (Jan. 2020), Commission Work Programme 2020, https://eur-lex.europa.eu/resource.html?uri=cellar:7ae642ea-4340-11ea-b81b-01aa75ed71a1.0002.02/DOC_2&format=PDF. The review was published on 24 June 2020, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1163

[43] European Commission (Dec. 2018), https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps

The Commission aims to establish a new public-private partnership in artificial intelligence (AI) and robotics to strengthen and connect AI research excellence centres – possibly along the lines of the ERN concept.[44] The European Investment Fund will contribute financing to AI projects, and EU-wide public procurement measures will be used to encourage better uptake in public institutions such as hospitals. Under AI for Citizens, the Commission aims to develop a regulatory framework that will help the EU to be a leader in safe AI use.[45] The approach includes further legislation beyond the GDPR.

The European Commission will seek to incentivise data sharing whilst securing personal data protection, consumer protection and competition rules, and to upskill citizens' digital abilities to ensure people have better control over "machine-generated data".[46] Its February 2020 "Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics" highlights that a future regulatory framework on AI should include safeguards against the mental health of persons, in particular vulnerable populations such as the old.[47] On the horizon is the Commission's proposal for a Digital Services Act, updating the 2000 eCommerce legislation, will look to address the sale of online goods, in particular, harmful, unsafe, illegal, fake, counterfeit, and misleading products which may impact consumers, including medical goods.[48] As a future consequence of a legislative proposal on AI, the Commission may also seek to adjust the legal framework surrounding the issue, such as the 2001 General Product Safety Directive.[49] The Commission is currently looking at legal implications around AI systems that provide medical information to physicians, those providing medical information directly to patients, and those directly performing medical tasks on patients.[50] Furthermore, the European Commission has opened a public consultation on its Digital Education Action Plan,[51] which aim is to increase digital literacy and help EU countries work together to adapt their education & training systems to the digital age. in concert with digital policy documents released in 2020 by the European Commission mentioned earlier, the Plan will serve as support to enhance citizens' levels of digital literacy also in view of the future initiatives at digital health level such as the European Health Data Space.

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[44] European Commission, Excellence and trust in artificial intelligence, https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/excellence-trust-artificial-intelligence_en

[45] European Commission (Feb. 2020), https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en

[46] European Commission (Feb. 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_273

[47] European Commission (Feb. 2020), https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[48] European Commission (Feb. 2020), https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en

[49] European Commission (Feb. 2020), https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

[50] European Commission (Feb. 2020), https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

[51] European Commission, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12453-Digital-Education-Action-Plan

ANTIMICROBIAL RESISTANCE

If projections on AMR deaths are realised, they threaten to return the world to the "dark ages" of medicine where common infections, routine surgeries and many cancer treatment become life-threatening. Some 33,000 patients die annually in the EU as a result of infections caused by resistant bacteria. They account for €1.5 billion per year in healthcare costs and productivity losses.[52] The Health Commissioner's mandate prioritises implementation of the Commission's 2017 One Health Action Plan on AMR. The new European Parliament, likewise, sees AMR as a priority and established a new MEP Interest Group on Antimicrobial Resistance in January 2020, coordinated by EPHA. On a global level, WHO issued a warning in early 2020 of a serious lack of investment and innovation by the pharmaceutical industry in developing new antibiotics. Dr Tedros Adhanom Ghebreyesus, Director-General of WHO said: "Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines."[53]

VACCINATION

Vaccination is seen as a high priority globally, especially at the time the COVID-19 pandemic when the hopes of decision-makers, epidemiologists and ordinary people alike centre on the rapid development of an effective vaccine.

Low vaccination uptake remains a major issue in the EU/EEA region. Repeated outbreaks of measles have been seen in countries such as France, Greece, Italy and Romania, as well as a concerning increase in the incidence of other vaccine-preventable diseases.[54] In September 2019, the European Commission in partnership with the WHO organised a Global Vaccination Summit, which called for actions to improve the accessibility, availability, quality and convenience of vaccination services as well as tackle vaccine hesitancy.[55] Public confidence in vaccination varies in countries, but a recent Eurobarometer survey showed an average of 48% of the EU public believe (erroneously) that vaccines can often produce serious side effects, 38% think they can cause the diseases against which they protect, and 31% are convinced that they can weaken the immune system.[56]

The EU's Roadmap on the implementation of actions on vaccination in 2019–2022 includes creation of a common vaccination card/passport for EU citizens, guidance to address vaccine hesitancy, EU public awareness initiative on vaccination during the annual European Immunisation Week, a particular focus on

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[52] European Commission (2020), EU Action on Antimicrobial Resistance webpage, https://ec.europa.eu/health/amr/antimicrobial-resistance_en

[53] WHO (Jan. 2020), Lack of new antibiotics threatens global efforts to contain drug-resistant infections, https://www.who.int/news-room/detail/17-01-2020-lack-of-new-antibiotics-threatens-global-efforts-to-contain-drug-resistant-infections

[54] European Commission, State of the Health in the EU: Companion Report 2019, https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf

[55] European Commission (Sep. 2019), Press Release: Vaccination: European Commission and World Health Organization join forces to promote the benefits of vaccines, https://ec.europa.eu/commission/presscorner/detail/en/IP_19_5536

[56] European Commission (Apr. 2019), Special Eurobarometer 488, https://ec.europa.eu/health/vaccination/ev_20190912_en

looking at uptake by the socially disadvantages, country reports and e-learning platforms; the Roadmap also includes measures which seeker greater coordination between Member States when it comes to research and innovation, access, stockpiling, manufacturing and continuity of supply, forecasting demand, dealing with pandemics, outbreaks and other health threats.[57] Moreover, there are plans to create a European data warehouse on vaccine needs and creating a system for voluntary exchange by 2022.[58]

In response to the COVID-19 pandemic, the Commission has invested into vaccine development and urged countries not to hoard, stockpile or limit pharmaceuticals and medical devices within national borders. Working with the industry, the Commission has mobilised up to €140 million in public and private funding to support urgently needed research.[59] However, in the broader sense, future actions need to address complacency amongst the public, issues of convenience, and confidence in vaccines – clearly linked to greater health literacy and awareness[60] – linking back to the Health Commissioner's priorities.

- **HEALTH SYSTEMS STRENGTHENING**

The organisation of healthcare systems and delivery of healthcare remains a carefully guarded national competence. Nevertheless, the Commission has in recent years orientated itself increasingly towards providing support, including technical support and information, to Member States on health systems issues. Tools include the European Semester which was originally conceived purely for the purpose of encouraging budgetary discipline and fiscal sustainability. The State of Health in the EU policy cycle (a collaboration between European Commission and the OECD) is in its second iteration and closely linked to the Semester. The Commission also established the Expert Panel on Effective Ways of Investing in Health, and the High-Level Group on Promotion and Prevention at Member State level.

During the COVID-19 pandemic, the EU has developed rapid response systems, bodies and networks to outbreaks, but ultimately it is still a national competency to act and take measures when responding to a cross-border health threat. It may be that health systems strengthening will acquire a new urgency in the aftermath of the pandemic.

This should be seen in a wider context of a shift in health systems towards a focus on disease prevention and health promotion rather than care and cure, and from a hospital-centric model to healthcare based in the community. There is a recognition that chronic disease requires a different model of care than acute disease – centred around a person and their family, and comprising self-management support and

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[57] European Commission (last updated 2019), Roadmap For The Implementation Of Actions On Strengthening Cooperation Against Vaccine Preventable Diseases, https://ec.europa.eu/health/sites/health/files/vaccination/docs/2019-2022_roadmap_en.pdf

[58] European Commission (last updated 2019), Roadmap For The Implementation Of Actions On Strengthening Cooperation Against Vaccine Preventable Diseases, https://ec.europa.eu/health/sites/health/files/vaccination/docs/2019-2022_roadmap_en.pdf

[59] European Commission (Mat. 2020), Coronavirus: Commission offers financing to innovative vaccines company CureVac, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_474

[60] European Commission, State of the Health in the EU: Companion Report 2019, https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf

interdisciplinary team work. Similarly, the idea of health promoting health systems recognises that many key determinants of health are subject to factors outside of the heath system and therefore, a whole-of-society approach (or Health in All Policies) is needed to tackle poverty, social exclusion, unemployment, the availability of healthy food, air quality, urban planning and green spaces, and others factors that have a bearing on people's health. The COVID-19 crisis has brought this into stark relief: those who suffer most are those in precarious employment, the homeless, marginalised and discriminated communities.

Key to the realisation of a health system that delivers both prevention and treatment equitably and inclusively and meets the needs of its people, is measuring the health outcomes in a way that matters to people (patients) in order to capture the "value" of the services provided. The importance of the OECD "PaRIS" project on patient-reported outcome and experience measures lies in the fact that eventually the internationally comparable survey questions will be included in the EU's health statistics framework, will be reported as part of the State of Health cycle and will thus be used to inform policy. It is thus critically important that the survey is informed by the patient perspective in all its stages of development and implementation. This should be echoed in the EU4Health Programme and Horizon Europe.

2. ECONOMIC

The economic trajectory for Europe affects patients, especially as most countries' healthcare systems continue to face pressures from decreasing budgets and increasing costs. Currently, the situation is even more precarious and unpredictable. The global economic downturn as a result of the **COVID-19 pandemic** is estimated to be "much worse" than the 2008-09 financial crisis and the worst since the Great Depression of the 1930s.[61] It should be borne in mind, however, that so far the crisis has really manifested in wealthy countries; much is still unknown about what exactly is happening in other parts of the globe where the consequences of the pandemic on already fragile health systems and economies would be more destructive.

The International Monetary Fund in World Economic Outlook in April 2020 projected global growth in 2020 to fall to -3 percent, down 6.3 percentage points from the outlook in January 2020. If the pandemic fades in the second half of the year and containment measures can be lifted, the global economy is projected to grow by 5.8% in 2021; however, the risk of more severe outcomes is substantial. Many countries are facing several crises at the same time: a health crisis and a financial crisis, as well as a collapse in commodity prices, all of which interact in complex ways and make the fall-out difficult to predict. [62]Measures of national governments have focused on tax deferrals for businesses, wage subsidies for workers affected, and late payments allowed on social charges.[63] Countries are, however, evolving their plans fast, as they absorb the various repercussions of the pandemic.

The societal impact of COVID-19 is difficult to gauge at the moment, though it has undoubtedly exposed cracks it national health systems, exposing healthcare systems as often under-funded, under-equipped and ill prepared for crisis. Moreover, the crisis is highlighting inequalities, with people in vulnerable, precarious and marginalised situations suffering most both from the direct impact of the pandemic as well as its indirect social and economic impacts.[64]

i. European Union response to the COVID-19 pandemic

The European response to the pandemic comprises actions in several fields, from the technical to health systems to economic measures. The European Commission has said it will develop a recovery plan that will be based on a **revised proposal for the next EU budget** – the Multiannual Financial Framework – and will include an **updated Work Programme for 2020**.

The political impact of the COVID-19 pandemic will be closely linked to how the economic fall-out of the crisis is managed, not only by the Member States themselves but how it is managed at European level.

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[61] https://www.imf.org/en/Publications/WEO/Issues/2020/04/14/weo-april-2020

[62] https://blogs.imf.org/2020/04/14/the-great-lockdown-worst-economic-downturn-since-the-great-depression/

[63] Financial Times (Mar. 2020), How European economies are trying to mitigate the coronavirus shock, https://www.ft.com/content/26af5520-6793-11ea-800d-da70cff6e4d3

[64] Eurohealthnet,

The crisis has wreaked havoc on countries' economies.[65] The Eurogroup – finance ministers of Member States with the euro as their currency – agreed on 9 April to a total of €540 billion in support measures: the temporary SURE instrument that will channel up to €100 billion to enable countries to subsidise wages for unemployed workers; an initiative by the European Investment Bank that aims to guarantee €200 billion of loans focusing on small and medium businesses; and the Pandemic Crisis Support that amounts to around €240 billion to address the costs of the pandemic. [66]

However, according to comments by the head of the European Stability Mechanism, another €500 bn will be needed to cushion the economic blow "For the second phase [of post-pandemic bailouts] we need at least another €500bn from the European institutions, but it could be more".[67]

Countries also agreed to work on a temporary Recovery Fund to help in the aftermath of the crisis. However, the discussions have not been smooth. President Macron of France proposed the issuing of bonds – a joint debt instrument – an idea welcomed by several countries including Italy and Spain – but rejected by some others, such as the Netherlands and Germany. This in turn prompted accusations of lack of solidarity. The European Commission is working on a revision of its budget for 2021–2027, which will incorporate the Recovery Fund, while discussions about the instruments to be included are ongoing among Member States. The current proposal for a major EU recovery plan was put forward by the Commission in May 2020. To ensure the recovery is sustainable, even, inclusive and fair for all Member States, the European Commission is proposing to create a new recovery instrument, Next Generation EU,[68] embedded within a powerful, modern and revamped long-term EU budget. The Commission has also unveiled its adjusted Work Programme for 2020, which will prioritise the actions needed to propel Europe's recovery and resilience.[69]

Writing in *The Guardian*, ex-Greek finance minister Yannis Varoufakis was scathing on the measures taken by the Eurogroup, calling their failure to agree on debt-sharing "macroeconomically insignificant … politically irresponsible and a fantastic boon for Eurosceptics."[70] The OECD Secretary-General Angel Gurría, too, said issuing joint debt would be important for solidarity, "not only to support those who need it most (…), but it would also be a step forward for European integration" and would benefit everyone.[71]

The overall impact of all these measures on the **EU's health budget** is yet to be seen. However, the decision to propose the new revise EU4Health Programme shows the European Commission's intention

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[65] https://www.brusselstimes.com/brussels-2/106602/coronavirus-has-cost-brussels-economy-five-billion-says-trade-federation-hotels-tourism-citytax

[66] For an overview on the EU/EA EU/EA measures to mitigate the economic, financial and social effects of coronavirus, it is possible to consult the State of Play document prepared by the European Parliament's Think Tank, accessible here: https://www.europarl.europa.eu/RegData/etudes/IDAN/2020/645723/IPOL_IDA(2020)645723_EN.pdf

[67] https://www.euractiv.com/section/economy-jobs/news/esm-chief-europe-needs-at-least-e500-billion-from-eu-institutions-for-recovery/

[68] https://ec.europa.eu/info/files/eu-budget-powering-recovery-plan-europe_en

[69] European Commission, Europe's moment: Repair and prepare for the next generation,

[70] https://www.theguardian.com/world/commentisfree/2020/apr/11/eu-coronavirus-relief-deal-enemies-debt-eurozone

[71] https://www.euractiv.com/section/global-europe/interview/gurria-calls-for-further-european-integration-debt-mutualisation-in-eurozone/

to respond to the COVID-19 crisis with a revamped and stronger common action towards strengthen and more resilient health systems.

- **Support to health systems**

The European Commission has committed to spending €3 billion from the EU budget, matched with the same amount by the Member States, to **directly support national healthcare systems**. This will include funding for the Emergency Support Instrument and the RescEU medical equipment stockpiling programme. "The first priority would be managing the public health crisis and securing vital equipment and supplies, from ventilators to personal protective gear, from mobile medical teams to medical assistance for the most vulnerable, including those in refugee camps … [the] second area of focus would be on enabling the scaling up of testing efforts. The proposal would also enable the Commission to procure directly on behalf of the Member States."[72] The Emergency Support Instrument will enable the Commission to procure equipment and supplies directly, and finance and coordinate transport of equipment and of patients in cross-border regions. At a later stage, it will also contribute to testing.

The Commission has also coordinated **medical and scientific advice**, having set up a scientific advisory panel in March. The panel, and the European Centre for Disease Prevention and Control, provide advice on pandemic response, clinical management of patients, prioritisation and civil protection as well as other policy measures. The Commission has published guidelines (as at 19 April) on social distancing; securing adequate supply and availability of medicines; antitrust guidance for critical medicines.; testing methodologies; and guidance on how to develop tracing mobile apps in compliance with EU data protection rules, once confinement measures are gradually lifted.[73]

The Commission has also published a **Roadmap towards lifting coronavirus containment measures**.[74] This was originally requested by the European Council in March; however several Member States nevertheless went ahead with their own plans ahead of the publication of the Commission's roadmap.[75]

- **Economic measures**

On 2 April the Commission launched a new initiative called SURE – Support mitigating Unemployment Risks in Emergency. SURE will provide financial assistance of up to €100 billion in the form of loans granted on favourable enable to help Member States subsidise salaries of people made unemployed. The Commission also proposed to redirect all available structural funds to pandemic response. An EU Solidarity for Health Initiative worth €3billion will cater for the needs of Member States' health systems. The EU State Aid rules have been revised to increase Member States' ability to manoeuvre, and the Commission

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[72] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_582

[73] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response_en

[74] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/european-roadmap-lifting-coronavirus-containment-measures_en

[75] https://www.politico.eu/article/eu-left-behind-as-capitals-plan-coronavirus-exit-strategies/?utm_source=POLITICO.EU&utm_campaign=a7346126b1-EMAIL_CAMPAIGN_2020_04_15_04_53&utm_medium=email&utm_term=0_10959edeb5-a7346126b1-189085093

has set up a €37 billion Coronavirus Response Investment Initiative to provide liquidity to small businesses and the health care sector.[76] Please see also section on Political factors.

ii. Health systems: expenditure, financing and coverage

Please note this section is drafted whilst the various systemic impacts of the COVID-19 pandemic are only beginning to be assessed. Figures and statistics, as always at international level, are available at a time lag of at least a couple of years; the figures presented below are the latest available at the time of writing.

EU countries have a variety of arrangements for financing healthcare; in simplified terms they range from government funding through taxes and social insurance contributions (such as Sweden and Denmark) to insurance-based models (such as in Germany, France and The Netherlands). The share of health in total public spending is around 17% in the EU; it is near 20% in Germany and Sweden but just over 10% in Hungary and Poland. [77] Across the EU, the existence of complementary private insurance is not common, but in five countries (France, Netherlands, Slovenia, Belgium and Croatia), half or more of the people have private coverage.[78]

Concerns around the **financial sustainability** of health systems are not new[79], and they will no doubt persist also in the coming years. Health (and long-term care) expenditure is showing a growing trend again following the post-2008 dip. Since most of it is financed from public resources, this means a potentially significant impact on national budgets compounded by ageing populations, which lead to increased need but also a smaller working-age population to finance these costs. The OECD-EU 2018 report Health at a Glance presents, in simple terms, a scenario where public spending on health increases by 0.9 percentage points of GDP in total for EU-28 by 2070. The rise is forecasted at only 0.3 percentage points in Bulgaria and Estonia and more than 2 in Portugal and Malta. The share of long-term care is expected to increase. Different policy and institutional factors, such as financing mechanisms, decentralisation, organisation of healthcare provision, can have a substantial impact on this growth.[80]

Countries' **spending on health** varies widely. It can be examined as spending per person (per capita) or as percentage of GDP. The EU as a whole spent €2.773 per capita on health in 2017, with Luxembourg the highest spender at €4,713 followed by Germany, Sweden and Austria, while Romania (at €983) and Bulgaria (€ 1.234) spent least. Overall, health spending increased around 1.9% each year between 2013 and 2017, picking up again after a slowdown or even decline in some countries in the years following the 2008 financial crisis.[81] The other way of looking at health spending is in relation to the size of the economy

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[76] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/economy_en

[77] Ibid., p. 142

[78] Ibid., p. 174

[79] Addressing financial sustainability in health systems. Policy summary prepared for the Czech European Union Presidency Ministerial Conference on the Financial Sustainability of Health Systems in Europe. World Health Organization, 2009.

[80] Ibid., p. 204

[81] OECD/European Union (2018) Health at a Glance, p.132. Figures are adjusted for countries' purchasing power.

as a whole. Health spending for the EU overall accounted for 9.6% in 2017, being broadly in line with overall economic growth. Again, this figure conceals large differences: seven EU Member States spend 10% or more, with France and Germany the highest (11.5% and 11.3% respectively), while the lowest share for health was in Romania (5.2%), Luxembourg (6.1%), Latvia and Lithuania (both 6.3%). The proportion declined somewhat following the 2008 financial crisis (though in some countries it grew) but has since stabilised. [82]

Pharmaceutical spending represents the third largest item after inpatient and outpatient care and accounts for one sixth of health spending. This spending increased around 5% between 2010 and 2016. Many factors affect the differences in pharmaceutical spending across countries. Germany spent most on medicines per person, with Ireland and Belgium also spending more than average. Lowest spenders were Denmark, Romania, Estonia and Poland. Government or compulsory insurance cover around 64% of (retail) pharmaceutical spending and out of pocket payments 34%. The most generous coverage was in Germany and Luxembourg and the least generous in Bulgaria and Cyprus. [83] Following the financial crisis, several countries introduced measures to curb pharmaceutical budgets, but a trend towards new expensive medicines has again spurred growth in medicines spending. (OECD, 2017)

It should be noted that the official figures on pharmaceutical spending do not include medicines used in hospitals. Such medicines typically include the most expensive, new and specialty medicines. It is estimated that such spending can add another 20% to the pharmaceutical "bill". Data also suggest that spending in hospital settings is increasing more quickly than retail pharmaceuticals.[84]

Health coverage can be looked at over three dimensions: who in the population is covered (breadth), what is included in the "benefits basket" (depth), and what proportion of costs is covered (height). Population coverage is not a comprehensive indicator of financial protection. Core services covered in the EU usually include medical consultations, test and examinations, and hospital care; but this is not universal. Three EU Member States (Cyprus, Bulgaria and Romania) still have at least 10% of the population not covered. Often, the services included in the benefits package are not fully covered.[85] Across the EU, 93% of all inpatient hospital costs are covered by government or compulsory insurance schemes, with access to acute hospital carefree in many countries. More than three quarters of outpatient care is covered, though user charges may apply. Coverage of medicines is less comprehensive, with around 64% of all pharmaceutical costs covered across the EU (but less than 20% in Cyprus and Bulgaria). Therapeutic appliances and medical devices, including eyeglasses and hearing aids, are covered to a lesser extent than other health services.[86]

All health systems include some proportion of **out-of-pocket payments** by the users of healthcare.[87] Across the EU, some 20% of health spending is borne directly by households, ranging from 10% in France,

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[82] Ibid., p. 134.
[83] Ibid., p. 140
[84] Ibid.
[85] Ibid., p. 174
[86] Ibid., p. 176
[87] Expenses borne directly by patients.

Luxembourg or the Netherlands to over 40% in Bulgaria, Latvia and Cyprus. Financial hardship can be found in all countries regardless of the percentage of out-of-pocket expenditure on health.[88] Between 2% and 8% of households across the EU face *catastrophic health spending*[89], with the poorest household likely to experience it despite the existence of financial protection policies in many countries. Out-of-pocket payments have been shown to contribute to financial hardship when there is inadequate financial protection in place, leading to reduced access to healthcare, worsening of health status, deepening poverty, and increased inequalities. Recent research shows choices of coverage policy have a significant impact, especially reduction of co-payments, fixed rather than percentage co-payments, caps and exemptions.[90]

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[88] Ibid., p. 172

[89] Defined as out-of-pocket payments that exceed a predefined percentage or threshold of a household's ability to pay for healthcare

[90] WHO Regional Office for Europe (2018), "Can people afford to pay for health care?" www.euro.who.int/en/health-topics/Health-systems/health- systems-financing/universal-health-coverage-financial- protection

3. SOCIETAL

The first part of this section looks at societal trends, including population, health and disease, and aspects of the health systems such as workforce. The second part examines the changing roles of patients and patient organisations. Social, technological and political factors are closely intertwined both with each other and with economic factors in a broader European and global context.

I. DEMOGRAPHIC TRENDS

A long-term projection of **population growth** by Eurostat estimates that the European Union's population will increase to a peak of 525 million by 2044, after which it will progressively decrease by almost 4%, or 20 million people by 2100.[91] Meanwhile, the population of the entire world population is projected to pass 10 billion in 2057 and almost 11 billion people by 2100. The EU's proportion of the world's population therefore decreases from 6.9 % today (down from 13.5 % in 1960) to just 4.1 % by the end of the century.[92]

The **population is ageing**. In the EU, the share of working-age people is projected to shrink from 65% in 2018 to 55% in 2100. The share of peple aged 65+ is projected to increase from 20% at the start of 2018 to 31% by 2100. The very old, those aged 80+, will more than double by 2050 and almost triple by 2100, from 6% to 15%.[93] "In 2006, there were four people of working age (15 to 64) for each person aged 65 or over; by 2050, the ratio is projected to be just two people. This outlook is essentially set in the shorter term, at least, meaning the focus is on smoothing the transition to an older population and adapting to its needs."[94]

Life expectancy at birth reached 81 years across EU-28 in 2016, though it remains at around 75 in Bulgaria, Latvia, Lithuania and Romania. Life expectancy had risen steadily for several decades, but since 2011 this growth has slowed.[95] Causes of this **slow-down in life expectancy** are multifaceted and need further research, but among them are increases in obesity and diabetes – linked to deaths from heart disease and stroke – and more deaths from influenza and pneumonia, especially among older people. Smoking and alcohol use are also linked to many chronic conditions, leading to ill health, premature deaths and bad quality of life. Main causes of death EU countries are circulatory diseases and cancers, followed by respiratory diseases.

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[91] Eurostat, as below.

[92] Demographic outlook for the European Union 2020. European Parliament Research Service, March 2020.

[93] https://ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20190710-1 and Demographic outlook for the European Union 2020.

[94] Demographic outlook for the European Union 2020.

[95] OECD and EU (2018), Health at a Glance: Europe 2018 report, p. 82.

- ## GROWING BURDEN OF CHRONIC DISEASES

Living longer does not always mean people live in good health. **A third of adults live with two or more chronic conditions**. About half experience **mental health problems** during their lifetime.[96] Other chronic diseases with a major disease burden on people and societies include **dementia**, expected to become more common as the population ages, with the number of people expected to reach 14.3 million by 2040; **diabetes**, which is increasing rapidly and is linked to several modifiable risk factors**;** several types of **cancer** with half of all cancers affecting breast, prostate, colon and lungs; and **communicable diseases**, notably HIV, tuberculosis and some vaccine-preventable diseases.[97]

Cancer survival is used as a key measure of health systems' effectiveness in managing cancer, reflecting early detection and effectiveness of treatment. As an example, cervical cancer (age-standardised five-year net) survival ranged from 70% in Denmark to 54% in Latvia with average EU survival increasing from 61% to 63% over the last 10 years. Variation among countries is decreasing. Mortality rates declined across the EU, but in many CEE countries are still high, suggesting a need for better prevention, diagnosis and treatment.[98]

Healthcare-associated infections increase the burden on patients and health systems. An estimated 3.8 million people acquire such an infection each year in acute care hospitals; an estimated 90,000 people die each year due to six most common infections, which include pneumonia, urinary, bloodstream and surgical site infections. At least one in five healthcare-associated infections could be avoided through better infection prevention and control measures.[99] **Antimicrobial resistance** further compounds the problem.[100]

The growing burden of chronic diseases, demographic changes, changing healthcare needs and constrained health budgets have sparked interest in reorienting European health systems to focus more on **disease prevention and health promotion**. Health promotion is seen as the precondition for effective and resilient health systems. Data shows that €1 spent on a validated public health intervention can generate savings of more than €14.[101] However, only around 3% of health spending is devoted to prevention across the EU.[102]

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[96] Health at a Glance 2019: OECD indicators. https://www.oecd-ilibrary.org/sites/e88a7402-en/index.html?itemId=/content/component/e88a7402-en

[97] Ibid., p. 100-108.

[98] Ibid., p. 158. The report also includes data on breast and colorectal cancers.

[99] Ibid., p.166

[100] https://www.ecdc.europa.eu/en/publications-data/surveillance-antimicrobial-resistance-europe-2018

[101] European Commission, Management Plan 2019 DG Health and Food Safety, https://ec.europa.eu/info/sites/info/files/management-plan-sante-2019_en.pdf

[102] European Commission, State of the Health in the EU: Companion Report 2019, https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf

According to the OECD report Health at a Glance 2018, better prevention and healthcare could have prevented 3 million premature deaths.[103] Main causes of **preventable mortality** were heart disease, lung cancer, accidents, alcohol-related deaths, colorectal cancer and suicides, which combined account for over two-thirds of all preventable deaths. Furthermore, heart and cerebrovascular diseases accounted for nearly half of all amenable deaths (i.e. those linked to effective and timely healthcare). Deaths from colorectal and breast cancer could also be reduced through earlier detection and more timely, effective treatments. The three countries with the highest amenable mortality – Lithuania, Latvia and Romania – also spend least on health across the EU. Overall, amenable mortality has declined across the EU.[104] The "health is wealth" argument is now increasingly accepted.[105] Health spending has excellent return on investment: one Euro invested is estimated to return €14 for the economy.[106] Policies that lead to higher life expectancy also bring macroeconomic benefits: every additional average year of life expectancy increases GDP by up to 4%.[107] The economic impact of chronic diseases is huge: they account for €700 billion in healthcare spending annually in the EU[108] and premature deaths are linked to a 0.8% loss in EU GDP per year.[109] The WHO estimates that up to 80% of all heart disease, stroke and type-2 diabetes and 40% of cancers could be prevented.[110]

- ## HEALTH INEQUALITIES AND ACCESS TO HEALTHCARE

Large inequalities in health and in life expectancy persist across Europe. People with a low level of education can expect to live six years less than the highly educated.[111] Health inequalities remain one of the most intractable challenges to achieving the Sustainable Development Goals including Goal 3 on health and wellbeing. "Health inequities are both the consequence of, and a key contributor to, social and economic inequities … they limit people's potential and the risk of poor health is consistently shown to be greatest for those who are deprived and marginalised and at the bottom of the socio-economic gradient."[112]

EU statistics ask about **self-reported health** as a measure of burden of disease. Latest (2016) data show that two thirds of adults report being in good health, but disparities are found in gender and across socio-

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[103] Health at a Glance 2019: OECD indicators. https://www.oecd-ilibrary.org/sites/e88a7402-en/index.html?itemId=/content/component/e88a7402-en

[104] Ibid., p. 146

[105] World Health Organisation. Sustainable Development Goals (SDGs). http://www.who.int/sdg/en/

[106] Asters et al. (2017) Return on investment of public health interventions: a systematic review. http://jech.bmj.com/content/early/2017/03/07/jech-2016-208141

[107] Berkley et al. (2013) A healthy perspective; the post-2015 development agenda. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60722-9/fulltext

[108] European Commission (2014) Chronic Diseases. The health challenge of our times. http://ec.europa.eu/chafea/documents/health/lealet/2014_chronic_diseases_informationsheet_en.pdf

[109] OECD and European Commission (2016) Health at a Glance: Europe 2016. https://ec.europa.eu/health/state/glance_ en

[110] World Health Organisation. Overview - Preventing chronic diseases: a vital investment. http://www.who.int/chp/chronic_disease_report/part1/en/index11.html

[111] OECD/European Union (2018), Health at a Glance: Europe 2018, State Of Health In The EU Cycle, https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf

[112] EXPH (2019) opinion on Benchmarking access to healthcare.

economic groups with almost 80% of people with highest incomes reporting good health compared to 60% for those with lowest income. One in three adults reports having a chronic disease or health problem; one in four says their normal activities are limited by this. Of people aged 75 and older, 60% say they are limited by their health condition.[113] Again the statistics show a **socio-economic gradient in chronic illness** and its impact. Importantly, the report states: “It is likely that there is also a reverse causal link between health and income inequalities, with poor health status leading to lower employment and lower income,” meaning that this has not been studied.

Access to healthcare can be limited by different factors, including cost, distance or waiting times. The EU indicators for measuring access include waiting times for elective (i.e. non-emergency) surgery. Examples measured are to high-volume procedures, namely cataract and hip replacement surgery. Waiting times matter to patients not only because waiting results in lower quality of life (such as living with pain) but also because the benefits of treatment are postponed. The average waiting time for cataract surgery in 2916 ranged from a month (Netherlands) to 3-4 months (Finland, Spain and Portugal) to over a year (Poland). For hip replacement, waits ranged from 1-2 months (Netherlands, Denmark) to over a year (Poland). Long waits in Poland were explained at least partly by low numbers of surgeons and lack of equipment as well as uneven geographical distribution. In Sweden, 12% of patients were on a waiting list for over three months, but in Estonia and Poland, 85%. Ireland was mentioned as a country where waits over three months increased between 2010 and 2016. Waiting time “guarantees” have become common in many countries, but the OECD-EU report notes they are only effective if they are enforced. Some countries set a standard for waiting times, while others give patients a choice of alternative providers if a certain waiting time is exceeded.[114] These indicators do not capture issues that are regularly raised by patients with chronic conditions, according to EPF: delays in accessing diagnosis (timeliness and accuracy), and delays in being referred to or being able to consult a medical specialist.[115]

The only timely and comparable source of information available across all Member States[116] is the EU-SILC questionnaire on self-reported unmet needs, but this is not sensitive to picking up access gaps in a granular way. Consistently, however, the poorest people are five times more likely to report unmet medical needs than the richest.[117] Financial barriers and waiting times are the main reason for unmet medical needs in Europe.[118]

A milestone study by the World Health Organization European region in 2018 captured and made visible **important gaps in universal health coverage**, combining for the first time an analysis of indicators of

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[113] Ibid., p. 98

[114] Ibid., p. 188

[115] EPF (2017) Report “Patients’ Perceptions of Quality in Healthcare”, https://www.eu-patient.eu/globalassets/policy/quality-of-care/quality-survey-report.pdf

[116] EXPH, 2018 cited in OECD-EU, 2018

[117] Ibid., p. 170

[118] European Commission (2019) Companion report, State of Health in the EU. Chapter 3.

unmet need with financial protection indicators.[119] Subsequently, the European Commission acknowledged, for the first time in an official Commission document, that despite the rhetoric, no EU country has truly achieved universal health coverage. Some countries exclude parts of the population from coverage; some have coverage gaps according to age; some countries disadvantage patients in specific disease-areas, such as rare disease, mental health, or in provision of non-medical care for cancer patients. "[S]tandard data that are routinely used across the EU are not granular enough to capture the multi-dimensional character of the challenge. They do not reveal how differences in covered services and medical goods relate to socioeconomic characteristics or clinical needs. Nor do they capture the huge variation within and across Member States."

Patient organisations such as EPF have, of course, known about those access gaps and lack of appropriate indicators to capture these for many years. EPF has collected patient evidence to shed light on patients' experiences, with a recent example being the 2016 survey which led to the development of its position paper on access to healthcare (2017). The report highlighted that:

- 20% of respondents had experienced delay in accessing medicines
- 24% in accessing treatment
- 17% in accessing a medical device
- 37% accessing a diagnostic test
- 24% in consulting primary care doctor
- 50% in getting a specialist appointment.

In addition, significant numbers of patients said they weren't informed about all available treatment options; informed about the safety of the treatment; or involved in shared decision-making. Patients' feedback about the quality of care was not routinely captured.[120] Similar results were obtained in EPF's survey on patients' perceptions of quality in healthcare, which highlighted access gaps and accessibility without financial hardship as a key aspect of quality.[121]

HEALTH WORKFORCE TRENDS

The health workforce is affected by demographic trends and changes in the incidence and prevalence of diseases that result in different demands for care. Ageing population also means ageing workforce, coupled with problems in recruitment and retention of health workers. New technologies on the other hand will require new and different skills and shifting roles. "From the perspective of the health system, there is a need for improved health workforce planning and forecasting, finding innovative solutions through new technologies and organisational changes."[122]

The **availability of health professionals** varies widely across the EU, with lowest numbers of **doctors** in Poland and Romania and the highest in Greece, Austria, Sweden and Portugal.[123] Across the EU, the

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[119] WHO European Region (2018) Can people afford to pay for healthcare?
[120] EPF (2016) Access survey
[121] EPF (2016) Report of a survey on patients' perceptions of quality in healthcare.
[122] European Commission (2019) Companion report State of Health in the EU. Chapter 4.
[123] The numbers for Greece and Portugal are thought to be an overestimation, however. Ibid., p. 178

average number of doctors per capita has increased in all but three EU Member States, from 2.9 in 2000 to 3.6 in 2016. Many countries have increased education to ensure enough new doctors will replace those who retire. Shortage of general practitioners and uneven distribution particularly affecting rural and remote areas, is a concern; they make up 25% of all doctors and the percentage has declined. Many countries provide incentives to address shortages of doctors in underserved areas. Most countries many more **nurses** than doctors, reflecting the role of nurses in providing care not only in hospitals – where most nurses work – and in primary care, but also in long-term and home care settings. The number of nurses has also risen from 6.7 in 2000 to 8.4 in 2016, with most nurses per capita found in Denmark and Finland and fewest in Greece (though the way nurses are counted differs). Demand for nurses is predicted to rise along with population ageing, and shortages are a concern. Some countries have introduced advanced roles for nurses to address the shortage of primary care doctors and to improve access.[124]

Task shifting is increasingly seen as a way to improve the accessibility, effectiveness and efficiency of healthcare, ultimately aiming to "future-proof" the health workforce and improve the resilience of the health system. "Fiscal sustainability may be strengthened if the task shifting improves efficiency, while quality of care may improve if newly redistributed roles lead to better population health and patient satisfaction." Well-known examples of task shifting are prescribing by nurses and enhanced roles for pharmacists. Task shifting can be understood in terms of "enhancement" – increasing the depth of a job by extending roles or skills. Secondly, "delegation" – shifting tasks from one to another type of health worker, such as from doctors to nurses or from nurses to informal carers. Third, "innovation" – a new job or role is created for a new type of health worker.[125]

The breaking and extending of professional boundaries, with a greater focus on team work and integrated, person-centred care models implies a need for more inter-disciplinary training of healthcare professionals.

The health workforce can also be said to include **informal carers**. A very substantial part of patient and long-term care is provided by informal (or family) carers supporting patients at home. In Europe, informal carers provide 80% of long-term care. Estimates of the economic value of informal care, which is unpaid, ranges from 50 to 90%. According to the European association of informal carers, "[t]he projected budgetary impact of a progressive shift from informal to formal care by 2070 would imply an increase of the share of GDP devoted to Long-Term Care by 130% on average for the EU." The value of this is not only a matter of finances but also the quality of care and the human connection between the carer and the cared-for.[126] Informal carers will become more important as the population ages.

II. EVOLVING ROLES OF PATIENTS AND PATIENT ORGANISATIONS

This section looks at the changing role of patients both at individual level in terms of the patient's changing role healthcare, and collectively in terms of the evolution of patient communities and organisations.

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[124] Ibid., p. 178

[125] For examples and discussion see EXPH 2019 opinion on task shifting

[126] Eurocarers, https://eurocarers.org/about-carers/

Patient-centeredness is recognised as one of the "common operating principles" of European health systems. However, in practice its application varies across the EU. Indeed, patient-centred care is often approached superficially, still too often focusing on consumer "choice" and "satisfaction", with user feedback as a tick-box exercise. An important barrier to the actual implementation of patient-centred healthcare is the lack of a common understanding of what this really means and how to implement it.

- **THE INDIVIDUAL PATIENT IN HEALTHCARE**

An emerging policy focus at EU and international level[127] on delivering patient-centred care (also sometimes referred to as "person-centred care" in particular as an element of a "people-centred health system"[128]) reflects the recognition that health systems need to deliver for and meet the needs of the people that use them. The term "patient-centred" is starting to give way to other terms, particularly "person-centred"[129] and concepts of partnership and collaborative care[130], especially as countries move towards more integrated health and social welfare systems and the patient is increasingly seen as part of the care team. This subtle shift in objective brings with it challenges of how to translate a philosophy into clinical practice; shared decision-making is still not ubiquitous even in health services that term themselves patient-centred, and paternalistic attitudes are still pervasive.

As health systems recognise the need to reorient themselves towards prevention and health promotion, the role of the patient as a citizen and political actor is increasingly emphasised. Indeed the definition of health promotion – "the process of enabling people to increase control over, and improve, their health"[131] – bears a close relationship to the definition of (collective patient) empowerment, and harks back to the 1978 Alma Ata declaration that proclaimed the people's "right and duty to participate individually and collectively in the planning and implementation of their health care."

Moreover, a shift to person-centred, integrated care provided along a continuum spanning health promotion and prevention, diagnosis, treatment, and rehabilitation/support services, often mediated by digital tools, puts a spotlight on individual responsibility for self-management and self-care. In this context patient is implicitly also as a consumer – despite the fact that in European health systems the patient has not traditionally been seen as a consumer. Borrowing from consumer rhetoric can have certain advantages, for example when patients increasingly insist on their right to choose from different treatment options; and when healthcare providers recognise the patient's right to access and exercise control their own health data. Some patient rights are, in fact, largely conceptualised as consumer rights.[132]

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[127] OECD PaRIS initiative – ministerial statement. The PaRIS initiative is co-funded by the European Union.

[128] WHO famework for people-centred health systems

[129] Reflecting the belief that every patient should be seen in a holistic way as a person, rather than "only" a patient or a diagnosis.

[130] As the concept of patient-centredness still allows health professionals and services to exclude the patient from being a partner in their own care, so long as they "place the patient in the centre".

[131] Ottawa Charter for Health Promotion (1986)

[132] Townend et al., "Patients' Rights in the European Union. Mapping Exercise". Final report. European Union, 2016. https://op.europa.eu/en/publication-detail/-/publication/8f187ea5-024b-11e8-b8f5-01aa75ed71a1/language-en

Health literacy is a core part of self-care and person-centred care, comprising the "knowledge, motivation and competence to access, understand, appraise and apply information to make decisions in terms of healthcare, disease prevention and health promotion."[133] Health literacy is an aspect of patient empowerment that is necessary to support self-management and shared decision-making.[134] There is potential in health literacy for reducing the burden of chronic disease[135] as well as empowering patients; however, health literacy remains a challenge across Europe and the concept is still sometimes poorly understood as relating to individual responsibility. In reality, health literacy is a determinant of health and a relational concept that manifests itself in the *interactions* between individuals and other individuals, organisations, or systems. It is thus a formidable *health system* challenge. Promoting health literacy is recognised as a key action to reduce health inequalities.[136]

As access to the **Internet** is rising and smartphones becoming ubiquitous, people are increasingly accessing health information online and interacting with providers of different services. (See also "technology" chapter.) Half of Europeans sought health information on line in 2017: almost double compared to 2008. This was most common in The Netherlands and Finland (about 70%) and in Cyprus (almost 60%). Much fewer people are using the Internet to make healthcare appointments: this figure increased from 8% in 2012 to 13% in 2016 though in some countries, such as Denmark, Finland and Spain, it is much higher (almost half of all Danes and around a third in the other two).[137]Disparities by age and socioeconomic group exist in using the Internet for health-related purposes.[138] While online medical information can be life-saving, its quality is highly variable, mis- and disinformation is common, and regulation of information online impossible, and many people are not confident that they can trust information found online.[139]

Social media platforms are gateways for Internet communications; YouTube, Facebook, WhatsApp, Instagram, Tik Tok, Snapchat, Twitter, Pinterest, Tumblr and LinkedIn as well as private and corporate blogs are some of the social media technologies commonly used in the EU, including by patients and patient organisations.

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[133] Gianluca Quaglio, Kristine Sørensen, Paul Rübig, Luigi Bertinato,Helmut Brand, Theodoros Karapiperis, Irina Dinca, Terje Peetso, Karin Kadenbach, and Claudio Dario (Apr. 2016), Health Promotion International: Accelerating the health literacy agenda in Europe, https://ec.europa.eu/digital-single-market/en/news/accelerating-health-literacy-agenda-europe

[134] European Patients' Forum (2017) Toolkit on Patient Empowerment

[135] WHO Europe (Jan. 2019), Health literacy as a lever to prevent and control NCDs – workshop in Portugal, http://www.euro.who.int/en/media-centre/events/events/2019/01/health-literacy-as-a-lever-to-prevent-and-control-ncds-workshop-in-portugal

[136] Options to foster health promoting health systems. Report of the Expert Panel on effective ways of investing in Health, 2019, p 76.

[137] Health at a Glance: Europe 2018.

[138] Ibid., 194. See also recent sources e.g. Eurobarometer, HLS-EU…

[139] Eurobarometer on digital health literacy, 2014.

Health literacy is equally essential for the development of patient-driven digital health solutions. The digital transformation raises the need to address digital health literacy and media literacy, especially in the context of increasingly rapid circulation of mis- and disinformation online and through social media. Six out of 10 Europeans looked for information online according to a 2014 Eurobarometer – though that figure has likely increased. Most people though they could tell good information from bad, but 17% said they could cannot.[140]

THE PATIENT COMMUNITY

Beyond the individual, there is a slow but sure trend towards patient engagement in different parts of the health system, a recognition that partnering with patients is a necessity to develop and implement truly person-centred healthcare. The patient's knowledge and experience can, for example, help improve health systems and governance.[141] At European level, patients are now well-established as a legitimate and valued stakeholder group, and EPF is recognised as the prime representative organisation across chronic diseases. The European Commission is increasingly consulting citizens on new policies, and requests for input are received on an increasing number of diverse policy areas – touching on health either directly or indirectly.

Traditionally, the **research and regulatory** environments have been the natural habitat of many patient organisations, and this engagement is also the most developed. Still, recent years have seen an increasing interest from research and regulatory institutions nationally and in different regions of the globe to actively engage with patients and patient organisations. The European Medicines Agency has been leading the way in Europe (and globally, together with the FDA and some other countries such as Canada), and countries such as Japan are taking its first steps in this direction. Bringing the patient perspective into the evaluation of medicines' safety and effectiveness and ensuring the data collected from clinical trials reflect patients' priorities is also a feature of the EMA's new strategy "Regulatory Science to 2025", though its operationalisation will depend on many factors, including investment and institutional support.

With the emergence of **new technologies**, patient organisations are playing a crucial role in facilitating participation in clinical research and providing education resources for patients to understanding clinical research, pharmaceutical research and development, ethics, and other technical topics. Initiatives such as EUPATI have contributed to the capacity of patients to participate.

Patient involvement in **health technology assesment** is evolving, though slowly, inter alia through leadership from international collaborations such as HTAi and EUNetHTA, whereas at national level the landscape is still patchy. Decision-making on pricing and reimbursement of new therapies is also a national prerogative, and patient involvement is still under-developed for the most part.

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[140] Flash Eurobarometer 404 "European Citizens' Digital Health Literacy", European Union, 2014.

[141] David Gilbert (Nov. 2019), Future Patient – musings on patient-led healthcare: From Job-Job to Rock n'Roll-Role – The Sussex Model of Patient Partnership, https://futurepatientblog.com/2019/11/23/from-job-job-to-rock-nroll-role-the-sussex-model-of-patient-partnership/

Some international organisations have taken steps to involve patient organisations more, such as the OECD with its PaRIS project and its working group on healthcare quality, developing **more meaningful indicators** to include in health systems performance assessment.[142] The International Consortium for Health Outcomes Measurement (ICHOM) regularly involves patient representatives in its work developing “core outcome sets” for measuring outcomes in different disease-areas. These efforts are welcome, but much more remains to be done and processes are not yet working perfectly.

One emerging area is patients’ involvement in **professional education**.[143] Some **journals**, spearheaded by The BMJ, have initiated Patient and Public Partnership programmes to increase the quality and relevance of their content and the research they publish.[144] **Medical conferences** are slowly moving towards greater involvement of patients, along the lines of the #PatientsIncluded criteria.[145] However, engagement in conferences is still too often tokenistic or predicated on voluntary contribution, and in some countries legislation poses a barrier. Moreover, patient representative are not included in health *policy* conferences as readily as in medical ones.

Increasing **demand for patient input** can mean that there are not enough patient advocates to go round. Those patient advocates and organisations that are well known can find themselves overwhelmed with requests, and lack of proper compensation forms a barrier to meaningful patient involvement. In addition, some forms of advanced engagement require training – ideally on both sides – in order to level the ground and enable a genuine partnership. Establishing new ways of working in partnership and changing cultural norms remains a challenge in health systems.[146]

The **international patient community has diversified** in recent years. “Traditional” membership-based patient organisations are being complemented, and occasionally challenged, by the emergence of a new community of patient advocates comprising virtual communities and individual patients. Individual advocates network with each other, inter alia through online platforms, but are not necessarily formally affiliated with any traditional patient organisation.[147]

At the same time, the role of patient advocates and organisations is still not fully understood by all stakeholders; some express reservations about the “professionalisation” and the representativeness of patients organisations. Patient organisations have, in turn, pointed out that such concerns are not normally expressed about elected representatives of other health stakeholders.[148] Some patient organisations are increasingly engaging in wider social and civic issues than just healthcare, such as social

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[142] https://www.oecd.org/health/paris.htm

[143] https://www.eu-patient.eu/globalassets/events/epfcongressreport.pdf

[144] https://www.bmj.com/campaign/patient-partnership

[145] https://patientsincluded.org

[146] Tessa Richards (Nov. 2019), Should patient advocates adopt guerilla tactics?, https://blogs.bmj.com/bmj/2019/11/26/should-patient-advocates-adopt-guerilla-tactics/

[147] Interesting examples include Sara Riggare http://www.riggare.se, Tim Omer aka the “Diabetic hacker” http://www.hypodiabetic.co.uk, Dave DeBronkart (e-patient Dave) http://www.epatientdave.com and Paul Buchanan http://www.bmj.com/about-bmj/advisory- panels/patient-panel-members/paul-buchanan).

[148] The Added Value of Patient Organisations. EPF, 2017.

determinants of health, public health, trade, environmental issues and social justice; they see their role as part of the wider civil society.

Communication technology has been a major driver of patient empowerment and networking. Patients can access more and more information and communicate rapidly with each other and with health professionals. At the forefront are some individual patient advocates, particularly from the younger generation of "digital natives", who are using technology to "radically empower" themselves vis a vis the healthcare system. The "e-patients"[149] phenomenon from the US and Canada is spreading to Europe, albeit more slowly than could have been expected a few years ago. E-Patients – empowered, informed patients – advocate for a participatory medicine[150] model where patients become responsible drivers of their health, and in which healthcare providers encourage and value them as full partners. For example, many patients with diabetes type 1 self-monitor their blood glucose levels, heart rate and other vital signs, self-dose their medication, and even "hack" their own medical devices.[151] In some cases this has led to patients contributing to the development of new technologies themselves, raising questions of "career" and "profit".

Social media has also contributed to the transformation of the patient advocacy space. Given the relatively free or low cost of online platforms, their appeal to younger people, and the possibility of instant connection and global visibility, social media can create spaces for patients to link up and exercise their advocacy muscle. Digital technologies and online communities have potential for enhancing health literacy and supporting patients in their self-management, as long as patients feel the advice can be trusted. Health professionals as well as trained peers were most trusted facilitators in one recent study. [152]

The concept of "patient-centricity" has become one of the key concepts in the discourse of **pharmaceutical companies**, with some companies already actively engaging patient perspectives throughout the company's value chain, from early discovery over clinical trial design and patient reported outcomes to market access discussions. Even if this is still a new territory for many companies, the direction has been set.

Traditional patient organisations' **relationships with the pharmaceutical industry** continue to be sensitive. Organisations receiving funding from pharmaceutical companies continue to be often regarded with suspicion; in the last years much work has been done to address transparency and ethical collaboration between different actors, including healthcare professionals but also patient organisations

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[149] Term originally coined by Dave deBronkart, known as e-Patient Dave https://www.epatientdave.com

[150] Society for Participatory Medicine https://participatorymedicine.org

[151] https://expmag.com/2019/11/the-diabetes-patients-who-hacked-a-pancreas/

[152] Melanie Louise Plinsinga, PhD; Manuela Besomi, BSc, MSc; Liam Maclachlan, PhD; Luciano Melo, PhD; Sarah Robbins, PhD; Belinda J Lawford, PhD; Pek Ling Teo, BPT, MHS; Kathryn Mills, PhD; Jenny Setchell, PhD; Thorlene Egerton, PhD; Jillian Eyles, PhD; Leanne Hall, PhD; Rebecca Mellor, PhD; David J Hunter, MBBS, PhD, FRACP; Paul Hodges, PhD; Bill Vicenzino, PhD; Kim Bennell, PhD (Dec. 2019), Journal Of Medical Internet Research: Exploring the Characteristics and Preferences for Online Support Groups: Mixed Method Study, https://www.jmir.org/2019/12/e15987/pdf

and industry. Nevertheless, scrutiny of patient organisations and perceptions of conflicts of interest are likely to persist or even intensify in the future, in a context of a global push for transparency, growing concerns over the prices of medicines, and wider concerns about commercial influences in healthcare, from research to the development of clinical guidelines and health policies.[153]

Social media is complicating this picture. Social networks are popular with businesses, with 51% of enterprises in the EU using them for creating information profiles, sharing experiences, expressing views, exchanging information and creating "communities" around topics and brans.[154] One emerging phenomenon relating to social media is so-called "**patient influencers**". Companies – including pharmaceutical companies – are using social media influencers to convey marketing messages to their target audiences. Some companies, like ClinicalScore and WEGO Health have developed a business model around offering "the right patients" to pharmaceutical companies to support their drug development – and their marketing. Advantages include "targeted audience for product announcements, including trial results, approvals and brand names" and "articulate brand ambassadors and advisory board members".[155]

Logically, while such initiatives are not explicitly focused on a specific product, brand loyalty and trust in the company is a benefit companies expect to gain by working with patient advocates to whom other patients look for information and guidance.[156] Such interactions and relationships between individual patient advocates and companies can be opaque and fraught with ethical problems.[157] To date, the phenomenon seems unique to the US, where "disease awareness" promotion without naming a specific product "isn't regulated as advertising, so companies historically haven't had to reveal their involvement or funding." WEGO rules even forbid this.[158] In the EU restrictions on direct-to-consumer marketing of prescription medicines may prevent such practice; however, the global nature of social media and the Internet, possible future developments are hard to predict.[159]

4. TECHNOLOGICAL

Technological advancements are rapidly changing the EU healthcare landscape. These include the digital transformation and advanced therapies, such as gene and cell therapies, targeted therapies and personalised medicine, as well as the increasing use of Big Data and Artificial Intelligence. These

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[153] McCoy MS, Carniol M, Chockley K, Urwin JW, Emanuel EJ, Schmidt H. Conflicts of interest for patient-advocacy organizations. N Engl J Med 2017 11 N Engl J Med 2017; Industry links with patient organisations - BMJ 2017;356 : j1251

[154] European Commission (Jan. 2020), Social media - statistics on the use by enterprises, https://ec.europa.eu/eurostat/statistics-explained/pdfscache/49114.pdf

[155] https://clinicalscore.com/real-patient-voices/

[156] Chief Strategy Officer of WEGO Health, quoted in Pharmavoice. https://www.pharmavoice.com/article/2019-11-patient-influencers/

[157] "Patient Influencers Paid By Pharmaceutical Companies Should Be Required To Disclose Industry Ties". Health Affairs blog, https://www.healthaffairs.org/do/10.1377/hblog20200109.985594/full/

[158] Ibid.

[159] https://www.statnews.com/2018/11/13/patient-influencers-get-a-voice-and-pharma-is-ready-to-pay-up/

technologies present enormous promise for treatment and prevention of diseases, but also challenges both in terms of ensuring that the regulatory framework is fit for purpose, and in terms of ensuring equitable access. The need for effective digital tools has been made urgent by the **COVID-19 pandemic**.[160] Creative solutions are emerging to safeguard patients' continuity of care.[161] This crisis might as a result spur faster digitalisation of health systems – and the patient voice will need to be at the centre of policy and practice.

The emerging COVID-19 pandemic has led to a rush to implement eHealth services including telemedicine consultations in countries such as China, the US, Canada and the UK, at a scale and pace that is "unprecedented". Other countries have seen an explosion in demand but run up against limited infrastructure and technical resources as well as staff, as has happened in many Italian hospitals. Some commentators welcome this as something that should have happened a long time ago; others have cautioned against eroding the quality of care: "It's inexpensive and expedient, but it'll never be the same as a physical examination with all of its human qualities of judgment and communication. But with COVID, this is a trade-off we have to accept."[162] . In the COVID-19 aftermath, it will be necessary to ensure a thorough evaluation of digital health best practices (e.g. telemedicine) adopted during the crisis. This should enable an assessment of what should be considered as adoptable at a larger scale to drive systematic, and not ad-hoc, innovation in our health systems. Furthermore, the rather limited positive impacts and adoption of tracing apps, [163] also in spite of EU coordination efforts,[164] raise questions on both levels of confidence and trust of EU citizens but also on Member States' capacity to adopt and implement large scale digital health solutions.

I. PHARMACEUTICALS AND MEDICAL TECHNOLOGIES

The **global gene therapy market** is expected to reach US$6.6 billion [around €6 billion] by 2027, with the development of **CAR-T cell therapies**, driving market growth.[165] Although cancer is one of the key areas of focus, gene therapy is also expanding in some rare diseases beyond cancer, such as beta-thalassemia. Given the complexity of the research and manufacturing of gene therapy molecules and the need for specialised manufacturing facilities and highly skilled technical personnel, this area presents high risks, but also potentially high profits: recently approved medicines in this category are among the world's most

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[160] https://www.politico.eu/article/coronavirus-bundles-greece-into-the-digital-era/?utm_source=POLITICO.EU&utm_campaign=a1f43744b0-EMAIL_CAMPAIGN_2020_04_06_05_10&utm_medium=email&utm_term=0_10959edeb5-a1f43744b0-189085093

[161] A French company is offering free online consultation tools: https://www.safesante.fr/search . A Spanish company Eurecat is providing 3D-printed medical devices, such as protective screens, to fight coronavirus. https://eurecat.org/actualitat/

[162] Prof. Eric Topol quoted in The Lancet, "Virtual health care in the era of COVID-19". Vol 395 April 11, 2020.

[163] https://www.technologyreview.com/2020/06/19/1004190/uk-covid-contact-tracing-app-fiasco/

[164] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1043

[165] "Gene Therapy Market Size, Share & Trends Analysis Report By Indication, By Vector Type, By Region And Segment Forecasts, 2020 - 2027"

expensive.[166] At the same time, questions remain about the long-term safety and effectiveness of some of these new therapies.

The development of **personalised medicine[167]** (also called “precision medicine”) is closely linked to the development of information technology. Basic research supported by the collection of real-world data at an unprecedented scale (big data) is identifying the biochemical and genetic processes that cause diseases, creating an understanding that the way diseases are categorised may need to change. Personalised medicine promises a paradigm shift in medicine, from a focus on specific organs to a focus on cells, molecules and genes. Insights from genomics and other -omics will lead to a more individualised approach to treatment; precision diagnostics will make it possible to detect and treat diseases at an early stage with higher effectiveness, better tolerability and fewer side effects; and personalised prevention based on an individual’s risk profile will enable targeted prevention, so that ultimately many may never become “patients” at all.

Personalised medicine is considered as the future of medicine. However, the paradigm shift from curative to pre-emptive and individualised is slow to materialise. Progress in translating personalised medicine into standard patient care is slow and patchy.[168] Moreover, the benefits of personalised medicine have been questioned for example by a recent study stating that from 2006 to 2018, the number of patients with metastatic cancer eligible for genome-targeted therapy rose from modestly 5.09% to 8.33%, with those estimated to have actually benefited going from 1.3% to 6.62%.[169] It is hoped that so-called “basket” clinical trials will increase the number of patients by identifying medicines that can work for many cancers. In basket studies patients are classified by mutation rather than by cancer type, and treated with a therapy targets their specific mutation. Another challenge in realising personalised medicine is that most diseases are caused by a complex interplay of multiple genetic and environmental factors, rather than a single mutation. It may be that over-optimism is “distorting clinical consultations, resource allocation and research funding prioritisation” and that the promise by personalised medicine should be tempered by realism.[170]

While much of the attention is focusing on innovation, changes in the pharmaceutical sector and the expiry of the exclusivity periods of many “blockbuster” medicines are contributing to wider availability of generics, which is known to lower costs and increase access. the worldwide market for **biologic and**

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[166] https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever?t=1586115200303

[167] “A medical model using characterisation of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.” Council Conclusions on personalised medicine for patients (2015/C 421/03).

[168] https://scienceblog.cancerresearchuk.org/2019/06/19/nhs-to-fast-track-new-personalised-cancer-medicines-but-its-not-ready-quite-yet/

[169] “Estimation of the Percentage of US Patients With Cancer Who Benefit From Genome-Driven Oncology”, Marquart J, Chen E, Prasad V. JAMA Oncol. 2018;4(8):1093-1098 https://jamanetwork.com/journals/jamaoncology/fullarticle/2678901

[170] The promise and the hype of ”personalised medicine”. Tim Maughan, *The New Bioethics*, Vol. 23 No. 1, 2017, 13–20. https://www.researchgate.net/publication/317083364_The_Promise_and_the_Hype_of_'Personalised_Medicine'

biosimilar medicines is also expected to increase[171] with manufacturers of biosimilars being more widespread globally and many in developing countries. These products are currently emerging in many disease-areas, including diabetes, cardiovascular disease, autoimmune diseases, haemophilia and some cancers.[172]

Technology advances coupled with the availability of big data can also enable **repurposing of existing medicines.** Pharmaceutical companies working with academic research institutes have managed to successfully repurpose several products in recent years for common and rare diseases. Advantages of repurposing include reduced likelihood of failure, as the produce has already proved safe in preclinical studies and early-stage trials; faster time-frame for development, and smaller financial investment.[173] Many new therapies are also coming in the form of **"borderline" products** (straddling the limit between pharmaceutical and medical device) or combinations of pharmaceutical and device, or pharmaceutical and diagnostic test. They may thus require different regulatory approaches.[174]

II. DIGITAL TRANSFORMATION OF HEALTHCARE

The **digital transformation** of healthcare is already happening, though at varying speeds across Europe and globally. This is linked to the increasing availability of technology and infrastructure; in 2018, the share of EU households with Internet access had risen to 89%, from 60% in 2008. Broadband internet access

- *Patients Know Best* is a UK social enterprise and technology platform that developed the world's first online patient portal with an inbuilt consent engine. Patients can invite their doctors and caregivers to view their medical records while adjusting privacy levels for different categories of data. For example, a patient can choose to share general health information but to restrict access to data on their mental health to select groups of people.
- *OpenNotes* is an international movement originating in the United States based on the conviction that shared medical notes can improve the processes and outcomes of care. By 2019 it had facilitated more than 40 million patients in the US to have access to their medical notes.

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[171] 360 Research Reports (Nov. 2019), Biologics and Biosimilars Market 2019 Research, https://www.marketwatch.com/press-release/biologics-and-biosimilars-market-2019-with-top-countries-data-industry-trends-share-size-top-key-players-analysis-and-forecast-research-2019-11-05

[172] 360 Research Reports (Nov. 2019), Biologics and Biosimilars Market 2019 Research, https://www.marketwatch.com/press-release/biologics-and-biosimilars-market-2019-with-top-countries-data-industry-trends-share-size-top-key-players-analysis-and-forecast-research-2019-11-05

[173] Nature (Oct. 2018), Drug repurposing: progress, challenges and recommendations, https://www.nature.com/articles/nrd.2018.168

[174] Overview by the European Medicines Agency: https://www.ema.europa.eu/en/documents/presentation/presentation-interface-between-medicinal-product-medical-devices-development-update-ema_en.pdf

was used by 86 % of the households in the EU28 in 2018, compared to 48% in 2008.[175]

Digitalisation has profound implications not only for research, but also for the practice of healthcare, the ways in which patients interact with healthcare and patients' active role in their own care – with implications for the future "roles" of health professionals and patients.

Health care that is safe, effective, timely, efficient and patient-centred relies on the right information reaching the right person (or organisation) at the right time. A digitalised information infrastructure that ensures timely and reliable sharing of clinical and other information can improve health outcomes and efficiency, and also create a repository of valuable data for researchers and system managers (OECD, 2017). Enabling people to access, and interact with, their electronic medical record is an important feature that can help people become more involved in their health and their care.

Digital technology offers opportunities for individual patients, patient organisations and healthcare professionals to connect, share different perspectives on topics such as quality of care, optimal care pathways, self-management support and patient feedback[176] and develop new ways of communication and engagement – including telemedicine, remote access to health records, and so on. Tools such as electronic health records, telemedicine and mHealth can help in better coordination of care from diagnosis to treatment and rehabilitation; better communication between patients and healthcare professionals or providers; and the timeliness of information flows to patients (for example on updates to medicines information) that can make healthcare safer.

Shared, ideally portable **electronic health records** controlled by the patient, and technologies such as personalised remote monitoring devices and novel communication solutions have the potential to empower patients to take greater control of their own healthcare and play a more active role in the patient - health professional relationship.

Many countries are implementing EHRs across healthcare settings, including primary care. In 2016, the proportion of primary care practices using an EHR was about 80% on average across 15 EU countries studied, although there are wide variations. In most of those countries, patients were able to view the information (exceptions being Croatia, the Czech Republic and Ireland). In Denmark, Estonia, France, Greece, Latvia, Luxembourg, Spain and Sweden patients were also able to add or amend information.[177]

When it comes to prescribing, most countries are transitioning from paper-based to **ePrescribing**, but implementation varies greatly across the EU. In 2018, over 90% of prescriptions were transmitted to community pharmacies electronically in Finland, Estonia, Sweden, Denmark, Portugal and Spain. However, systems do not yet exist in many other EU Member States including Bulgaria, Cyprus, France, Germany, Ireland and Poland though they plan to introduce them.[178]

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[175] European Commission (Nov. 2019), Digital economy and society statistics - households and individuals, https://ec.europa.eu/eurostat/statistics-explained/index.php/Digital_economy_and_society_statistics_-_households_and_individuals#Internet_access

[176] Sometimes through online portals such as www.careopinion.org.uk in the UK.

[177] OECD (2018) State of Health in the EU report.

[178] Ibid., p. 192

III. BIG DATA AND ARTIFICIAL INTELLIGENCE

Big data refers, simply, to very large collections of data that are too large to be analysed by traditional means. In healthcare Big data usually refers to large healthcare databases, such as electronic health record systems, or networks of interconnected healthcare databases. These might typically contain information on a million or more patients, perhaps reflecting the population of a health region, country, or all of the people with a particular condition across Europe.[179]

Big data can be used for improving disease prevention as well as treatment and care. Examples include new understanding of disease mechanisms or associations; discovery or validation of new biomarkers for patient stratification for targeted therapies ("personalised medicine"); new markers for identifying people with a disease who were formerly undiagnosed; and medicines safety monitoring and studies.

Examples of studies using Big data:

- In Taiwan a study of >782 million outpatient visits in the National Health Insurance database was used to identify previously unmapped cancer–disease associations across ages and genders. The tool developed is able to detect cancer comorbidities earlier than would be possible by manual inspection, and identify potential effect modifiers or new risk factors.
- Analysis of 25 million patient records of the US Veterans Administration discovered that patients with periodontal disease were more likely to have rheumatoid arthritis.
- A study of 27 million patient records that accurately determined individual risk factors post knee arthroplasty
- Algorithm-enabled rapid searching of an EHR database of 2.5 million people to accurately identify systemic lupus erythematosus – potential for application to other autoimmune disorders
- Claims-based surveillance of over 17 million vaccinations did not indicate a statistically significant rise in Guillain–Barré syndrome following seasonal influenza vaccination.
- Nine million clinical notes for over 1 million patients detected statistically significant safety signals. (Singh et al (2018))

In pharmaceutical regulation, Big data can be used in assessing the benefit-risk of medicines across their lifecycle. Sources of such data include **real-world data** (e.g. from electronic health records and registries), genomics, clinical trials, spontaneous adverse drug reaction reports, social media and wearable devices. The European Medicines Agency and Heads of national Medicines Agencies set up a joint task force on Big Data in 2017 which looked at the challenges and opportunities and made recommendations for strengthening regulation in support of public health.[180]

Real-world data promises to **improve healthcare through better monitoring of real-life outcomes**, leading to the ability of healthcare providers and policymakers to evaluate the effectiveness of healthcare

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[179] https://datasaveslives.eu/big-data

[180] https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/Big_Data/Final_-_Priority_Recommendations_of_the_HMA-EMA_joint_Big_Data_Task_Force.pdf

and identify best practices. We can also expect to see medical advances achieved through big data analysis, including speedier development of new medicines, devices and smart applications to support both healthcare professionals and patients.

This is conditional on having the right infrastructure in place as well as the right indicators that **capture the outcomes that matter** to patients (especially quality of life). Patients' expertise, is based on experiential knowledge, is starting to be recognised as valid and important for complementing scientific knowledge. Patient input into research and development is an opportunity to develop new treatments and technologies that better meet patients' needs and are also cost-effective. This will require a culture change and re-assessment of priorities, and the patients' voice is of critical importance.[181]

To protect people's privacy, data is usually aggregated and **anonymised** or **pseudonymised**[182] to remove explicit identifiers. Nevertheless, analytical techniques applied to big data make it technically possible to re-identify a person. This leads to concerns about its potential use for surveillance, inappropriate disclosure of personal information, or discriminatory profiling.

Artificial Intelligence (AI), sometimes called *augmented intelligence*, is one of the leading drivers in the digital healthcare revolution. The primary aim of health-related AI applications is to analyse relationships between prevention or treatment techniques and patient outcomes.[183]

Examples of AI already in use include devices used for image analysis, deep learning algorithms are currently used in mammography for breast cancer detection[184], CT for colon cancer diagnosis, chest radiographs for the detection of pulmonary nodules, MRI for brain tumour segmentation, and for the diagnosis of neurologic disorders, such as Alzheimer's disease. Algorithms can help dermatologists make better diagnoses, for example detecting 95% of skin cancers by learning from large sets of medical images.[185] Speech recognition can assist in diagnosis if the patient talks or writes to an artificial doctor to give their medical information and history.[186] In nephrology, the artificial kidney has the potential to revolutionise treatment for kidney patients, but a warning system which is not fully transparent and regulated by AI or machine-learning may pose a threat to the patient undergoing dialysis.[187] Some countries, like Sweden, are starting to look at AI for decision-making (organ donation etc). Linking organ donors to patients required doctors to analyse blood types and tissue variations in patients' and potential donors' charts, which is very time-consuming. AI can now perform they analyses and make these

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[181] See also European Patients' Forum (2020) policy briefing for patient organisations: Trends in Digital Health: Focus on Big Data, Artificial Intelligence and Real-World Evidence.

[182] *Anonymised* data are data that cannot be at all linked back to the person behind the data. In practice it is sometimes impossible for researchers to work with truly anonymised data, which is why pseudonymization is used to ensure confidentiality. *Pseudonymisation* is done through key-coding the data so it is almost impossible to identify who the data is about without the key.

[183] Coiera, E. (1997). *Guide to medical informatics, the Internet and telemedicine*. Chapman & Hall, Ltd..

[184] https://www.nature.com/articles/s41571-020-0329-7

[185] Denis Horgan, Mario Romao Servaas A. Morré, Dipak Kalra (Dec. 2019), Artificial Intelligence: Power for Civilisation – and for Better Healthcare, https://www.karger.com/Article/FullText/504785

[186] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6779111/

[187] Vellido (Sep. 2018), Societal Issues Concerning the Application of Artificial Intelligence in Medicine, https://www.karger.com/Article/Pdf/492428

complicated matches.[188] In the COVID-19 pandemic, robots have been used to minimise risks to healthcare workers treating patients, and artificial intelligence has played a role in diagnosis and modelling the spread of new cases.[189]

One of the potential benefits of AI would be to save the time of medical professionals for other things – such as interacting with patients. AI-supported tools can also result in reduced costs, and support patients take control of their health. But as with any new technology, there may be unrealistic expectations, and cautions are in order. Sometimes traditional analytical methods outperform machine learning, or the addition of AI does not improve results.[190] As with any scientific endeavour, correct use of AI hinges on whether the correct scientific question is being asked, and whether one has the right high-quality data to answer that question. As machine learning is based on patterns in big data, the system is only as good as the data that is fed to it. Biases in data collection can affect the type of patterns AI will identify. This is an issue since, for example, women and ethnic minorities are often under-represented clinical trials and patient registry populations. Bias in the data will have an effect on the algorithm that is developed, replicating the bias. Patients with multiple or rare diseases may also be affected by this.[191]

Another concern is that artificial intelligence might be so good at picking up “anomalies”, for example in medical imaging such as x-rays and MRI scans, that it will end up increasing overdiagnosis and overtreatment. As people age, most develop some anomalies that do not cause any symptoms and do not need treating; furthermore, some cancerous growths never become malignant. Overdiagnosis by AI can increase the number of unnecessary medical interventions and – as any medical intervention carries potential risks – actually increase harm to patients.[192]

IV. CONNECTED MEDICAL DEVICES, WEARABLE TECHNOLOGY AND MHEALTH

Another category of technological advancement is **wearable technology** and **implantable devices** that feed a patient’s **data** directly into an app or database. Connected devices also enable patients to track their own health. Moreover, use of **robotics**, sometimes using artificial intelligence, and **3-D printing** of medical devices is becoming a reality in some instances. The US is currently a front runner on 3D-printed devices[193] whereas Europe struggles with bottlenecks, such as lack of uptake by end-users.[194] More assessments are needed into the efficacy, effectiveness and safety of 3D-printed devices before they can be widely used in clinical settings.[195] However, urgent need as a result of the COVID-19 pandemic has

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[188] https://qz.com/1383083/how-ai-changed-organ-donation-in-the-us/

[189] McCall B. COVID-19 and artificial intelligence: protecting health-care workers and curbing the spread. Lancet Digital Health2020

[190] https://www.ncbi.nlm.nih.gov/pubmed/20304609

[191] https://medium.com/datadriveninvestor/sidewalk-toronto-and-why-smarter-is-not-better-b233058d01c8

[192] https://www.theverge.com/2020/1/27/21080253/ai-cancer-diagnosis-dangers-mammography-google-paper-accuracy

[193] https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices

[194] European Commission, KETs Observatory Phase II, 3d-Printed Medical Devices, https://ec.europa.eu/growth/tools-databases/kets-tools/sites/default/files/documents/analytical_report_nr6_3d_printed_medical_devices_final.pdf

[195] BMJ Open, Laura E Diment, Mark S Thompson, Jeroen H M Bergmann (2017), Clinical efficacy and effectiveness of 3D printing: a systematic review, https://bmjopen.bmj.com/content/bmjopen/7/12/e016891.full.pdf

spurred the manufacture of 3D-printed medical devices also in Europe, including personal protective equipment for health professionals and even emergency ventilators.[196]

Mobile smartphone technology holds significant promise, not only to connect patients to their own health data and to healthcare, but to support access to healthcare in low-resource settings. Mobile phones are now ubiquitous (which is not the case for personal computers) and "technological barriers to the adoption of virtual health care are easily surmountable, even in the most resource-scarce settings … 'Whether I'm deep in Malawi or deep in the Amazon, all I need is a mobile phone and a connection that allows me to talk to a clinician. That's all it takes for a clinical encounter … The regulatory barriers that have held virtual health care back for all these decades were never justifiable' " and have in fact been easily circumvented in the circumstances of the COVID-19 pandemic when there was a clear and sudden need.[197] It will remain to be seen whether this trend continues after the immediate pandemic situation is over. In public health, so-called **contact tracing apps** are being developed in several countries to enable better control and prevention of coronavirus infections during the COVID-19 pandemic. Please see "policy" section on the EU policy response to this.

Smart wearables are "body-borne computational and sensory devices which can sense the person who wears them and/or their environment."[198] Wearables have been on the market for some years, but the number of users will increase and their possibilities for patients will grow. Most wearables originate in the so-called wellness industry, including fitness trackers, wristbands, smart watches; applications in medicine include wearable electrocardiogram (ECG) monitors, wearable blood pressure monitors and biosensors.[199] The devices are linked to apps that collect, store and process the user's data. Mobile health data can, for example, enable real-time monitoring of adverse effects or the effectiveness of a treatment, and there are potential uses for the development of new therapies. However, the quality of the data needs to be improved.[200]

In a recent study it was found that **metrics tracked by wearables**, such as resting heart-rate, temperature, blood pressure, pulse oximetry, electrocardiogram, or even cough recognition could help increase quick detection of influenza-like illness. In future, such information could help deploy "non-pharmaceutical intervention (e.g., staying home when sick or handwashing) and pharmaceutical interventions (deploying antivirals and vaccines) that can help to prevent further spread and infection in the most susceptible populations."[201] The patient perspective is vital to ensure wearables are fit for purpose, effective and

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[196] https://www.3dnatives.com/en/3d-printed-medical-equipment-covid-19-240320205/

[197] Paul Webster, "Virtual health care in the era of COVID-19", *The Lancet* , 11 April 2020.

[198] European Commission (Dec. 2017), 'Smart Wearables Reflection and Orientation Paper', https://ec.europa.eu/digital-single-market/en/news/european-commission-seeks-input-reflection-and-orientation-paper-smart-wearables

[199] Business Insider (Jan. 2020), Latest trends in medical monitoring devices and wearable health technology, https://www.businessinsider.com/wearable-technology-healthcare-medical-devices?r=US&IR=T

[200] European Commission (Dec. 2017), 'Smart Wearables Reflection and Orientation Paper', https://ec.europa.eu/digital-single-market/en/news/european-commission-seeks-input-reflection-and-orientation-paper-smart-wearables

[201] The Lancet Digital Health, (Feb. 2020), Jennifer M Radin, PhD, Nathan E Wineinger, PhD, Prof Eric J Topol, MD, Steven R Steinhubl, MD, Harnessing wearable device data to improve state-level real-time surveillance of influenza-like illness in the USA: a population-based study, https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30222-5/fulltext

respect patients' rights. Issues such as (lack of) human control, data privacy, and risk of hacking can play a role in uptake.[202]

V. DIGITALISATION LEADING TO LOSS OF PRIVACY?

Use of digital technology and big data in healthcare raises legal and ethical issues, including guarding patients' **privacy and confidentiality**, meaningful informed consent, the use and re-use of individual patients' data for research, access to their data by third parties such as insurers and related concerns around discrimination based on health status or genetic risk profile.

Issues that need to be resolved when policies and practices for digitalisation and the collection and use of patients' data are developed include how to ensure patients' privacy is respected; how to prevent inappropriate use of patients' sensitive data; ethical concerns around ensuring that human rights are respected; anonymity and identification – e.g., is the person behind the data identifiable? Can the data be anonymised? Can the process be reversed? Are there other ways of identifying the person?

Privacy issues are brought to the fore by mobile apps and wearable technology that tracks users' behaviour – but also websites. A recent report found that 52% of public-sector websites with health information had ad trackers. These can potentially gather data about the visitor's health condition and life situation; the data can be assimilated, processed and resold to companies that then create targeted ads and can potentially have an impact on a patient's medical or life insurance premium. The report claims that "EU governments and public sectors are thereby – unintentionally – serving as platforms for online commercial surveillance" and recommends a stronger ePrivacy Regulation with no "legitimate interest" exception and with mandatory, explicit and meaningful consent, alongside the General Data Protection Regulation.[203]

VI. THE PATIENT'S ROLE IN POLICY AND RESEARCH

Patient organisations and patient advocates are playing an increasing role in influencing research priorities, clinical trials design and conduct, ethics guidance, and related policies. Patient involvement ranges from pharmaceutical industry-led medicines research to participation in ethics committees, involvement with regulatory authorities and in health technology assessments.[204] Education and training for all parties are imperative in the journey of patient advocacy. A careful balance of diverse and representative voices is needed.[205]

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[202] Nature, Viet-Thi Tran, Carolina Riveros & Philippe Ravaud (Jun. 2019), 'Patients' views of wearable devices and AI in healthcare: findings from the ComPaRe e-cohort', https://www.nature.com/articles/s41746-019-0132-y

[203] Cookiebot (2019), Ad Tech Surveillance on the Public Sector Web: A special report on pervasive tracking of EU citizens on government and health service websites. https://www.cookiebot.com/media/1121/cookiebot-report-2019-medium-size.pdf

[204] See for example Paul Wicks et al., "Patients' roles and rights in research", BMJ 2018;362:k3193. https://www.bmj.com/content/362/bmj.k3193; EUPATI (2016), "Guidance for patient involvement in ethical review of clinical trials", https://www.eupati.eu/clinical-development-and-trials/guidance-for-patient-involvement-in-ethical-review-of-clinical-trials/

[205] Tessa Richards (Nov. 2019), Should patient advocates adopt guerilla tactics?, https://blogs.bmj.com/bmj/2019/11/26/should-patient-advocates-adopt-guerilla-tactics/

An obvious role for patients is in the collection and **sharing of medical data** for research and for improving healthcare. There is increasing recognition that medical and health data needs to be more widely shared. According to a recent Eurobarometer survey, 42% of the people polled would be willing to share some of their personal information securely to improve medical research and care.[206] Patients, however, tend to be even more willing than the general public to share their data.[207]

Patients need however to be more represented in **debates and policymaking processes** on emerging technologies and use of their data. This presents a challenge, as the tech sector has not traditionally involved patients and lacks awareness and experience of good practice. Patients' rights must remain at the forefront, and any future regulatory framework also needs to ensure that people's specific needs are catered for, such as appropriate training and support for using online tools, and a wider public understanding of the implications of new technologies as they become more integrated into healthcare provision.

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[206] European Commission (Mar. 2020), "Impact of Digitalisation on Our Daily Lives" https://ec.europa.eu/digital-single-market/en/news/eurobarometer-survey-shows-support-sustainability-and-data-sharing

[207] EPF survey on Electronic Healthcare Records (2020), https://www.eu-patient.eu/globalassets/policy/ehr-survey-2020_summary_final.pdf, EURORDIS survey – Share and protect our health data (2019), https://www.eurordis.org/publication/share-and-protect-our-health-data