



Opportunities to encourage the secondary use of health data amongst Western Balkan countries

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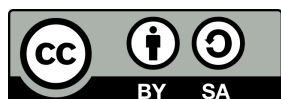
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About

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1.

The health data policy context

Understanding health data, data governance and the health data ecosystem

Increased use of **health data** can make a fundamental difference to society.

Health data can:

- Improve population health outcomes¹
- Identify and reduce health inequalities²
- Increase efficiencies and reduce costs of healthcare service delivery and administration³
- Speed up the response to emerging threats like pandemics and heatwaves⁴
- Promote the role of the patient as a collaborative partner with their healthcare providers⁵
- Foster innovation and improve opportunities for researchers and innovators⁶ and
- Fundamentally shift health services towards personalised healthcare: the ability to fine-tune and adapt generic treatments and therapies to the specific needs of each individual patient.⁷

¹ NHS England (n.d.), [‘The benefits of using data in population health management’](#), NHS Confederation (2022), [‘Improving population health outcomes with integrated data sets’](#), Siddiqui, MK., Hall C., Cunningham, SG., McCrimmon, R., Morris, A., Leese, GP., Pearson, ER., Diabetes Care (2022), [‘Using Data to Improve the Management of Diabetes: The Tayside Experience’](#), Alotaibi, YK, Federico, F., Saudi Medical Journal (2017), [‘The impact of health information technology on patient safety’](#).

² Health Data Governance Summit (2021), [‘Pre-read: Health Data as a Global Public Good’](#), AHA (2021), [‘Leveraging Data for Health Care Innovation’](#), NHS England (n.d.), [‘How one Yorkshire Trust eliminated the elective care backlog for people with a learning disability’](#).

³ AHA (2021), [‘Leveraging Data for Health Care Innovation’](#), NYEC (n.d.), [‘Statewide Health Information Network for New York \(SHIN-NY\)’](#). <https://downloads.healthcatalyst.com/wp-content/uploads/2017/11/Data-Driven-Approach-Ide ntifies-Nearly-33-Million-of-Savings-Annually.pdf>

⁴ Health Data Governance Summit (2021), [‘Pre-read: Health Data as a Global Public Good’](#).

⁵ ODI (2020), [‘Sharing eye health data: Putting patients at the heart of decision-making’](#), Denniston, A., Kale, AU., Lee, WH., Mollan, SP., Keane, PA., Current Opinion in Ophthalmology (2022), [‘Building trust in real-world data: lessons from INSIGHT, the UK’s health data research hub for eye health and oculomics’](#).

⁶ NL Times (2021), [‘New cancer medicine more quickly available to Dutch patients’](#).

⁷ Tudur Smith, C., Nevitt, S., Appelbe, D. et al. (2017), [‘Resource implications of preparing individual participant data from a clinical trial to share with external researchers’](#), Tuominen, S., Uusi-Rauva, K., Blom, T., Jyrkkö, S., Tuppurainen, K., Alanne, E., Future Oncol (2022), [‘Real-world data on diffuse large B-cell lymphoma in 2010-2019: usability of large data sets of Finnish hospital data lakes’](#).

But health data can also be used negatively. There are cases where health data has been used to:

- Deny or de-prioritise healthcare and insurance to specific patients based on data in their healthcare records, their personal choices, or their existing medical conditions⁸
- Discriminate, provide poorer care delivery, or increase the level of negative attitudes from healthcare professionals or administrators⁹
- Share beyond the health system to prevent access to, or increase discrimination in, other settings.¹⁰

Health data has also been used *at scale* detrimentally, in erroneous and biased algorithms,¹¹ or other systems that calculate and prioritise care for certain populations. This has widened health inequalities and introduced new barriers to receiving appropriate healthcare for patients, particularly non-white and migrant patients. Often, those impacted are unaware that bias has occurred, have no clear mechanism to appeal the decision, or are worried about reduced healthcare access in the future if they complain.

The value – including incomes – generated from the use of health data has also been disproportionately distributed: those that willingly or unknowingly share their data have received fewer benefits from doing so,¹² while those collecting and making use of the data have generated new income, created new patents and medical inventions, increased their professional prestige and role, or otherwise benefited from the use of health data sourced from others.¹³ Some researchers have also blocked data sharing in order to limit or reduce

⁸ Sun, M., Oliwa, T., Peek, ME., Tung, EL., Health Affairs (2022), '[Negative Patient Descriptors: Documenting Racial Bias In The Electronic Health Record](#)', Hugueta, N., Angier, H., Hoopes, MJ., Marino, M., Heintzman, J., Schmidt, T., DeVoe, JE. (2019), '[Prevalence of Pre-existing Conditions Among Community Health Center Patients Before and After the Affordable Care Act](#)', Boyd, A (n.d.), '[Could your fitbit data be used to deny you health insurance?](#)', Rogin, A., Young, K., Fuisz, J., PBS News Weekend (2023), '[How algorithms are being used to deny health insurance claims in bulk](#)'.

⁹ Richwine, C., Johnson, C., Patel, V., JAMIA (2023), '[Disparities in patient portal access and the role of providers in encouraging access and use](#)', Fox, A., Healthcare IT News (2023), '[Report confirms racial disparities in patient access to their health data](#)', Vyas, DA., Eisenstein, LG., Jones, DS., The New England Journal of Medicine (2020), '[Hidden in plain sight – reconsidering the use of race correction in clinical algorithms](#)', Eneanya, ND., Yang, W., Reese, PP., JAMA Network (2019), '[Reconsidering the consequences of using race to estimate kidney function](#)'.

¹⁰ Possible use of health data to restrict employment in the US is discussed in: Privacyrights.org (2012), '[Employment and your medical history](#)'.

¹¹ Vyas, DA., Eisenstein, LG., Jones, DS., The New England Journal of Medicine (2020), '[Hidden in plain sight – reconsidering the use of race correction in clinical algorithms](#)'.

¹² For example, in Madrid, socioeconomic and health data was used to create stricter lockdown conditions in low income neighbourhoods: Gullón, P., Cuesta-Lozano, D., Cuevas-Castillo, C., Fontán-Vela, M., Franco, M., Health & Place (2022), '[Temporal trends in within-city inequities in Covid-19 incidence rate by area-level deprivation in Madrid, Spain](#)'.

¹³ Moodley, K., Cenzig, N., Domingo, A., et al, The Lancet Global Health (2022), '[Ethics and governance challenges related to genomic data sharing in southern Africa: the case of SARS-CoV-2](#)', Health Data Governance Summit (2021), '[Pre-read: Health Data as a Global Public Good](#)', Campbell, EG., Clarridge, BR., Gokhale, M., JAMA Network (2022), '[Data Withholding in Academic Genetics](#)'.

the potential of innovation in a competitive environment.¹⁴ At a country level, this has even resulted in countries being ostracised in some ways while their data is used to advance treatments in other countries.¹⁵

Health data is considered one of the most valuable types of data in the digital era, enabling a vast new range of improvements and opportunities. But health data is also recognised as one of the most sensitive and personal types of data available. Health data must be treated ethically, responsibly, securely, and with respect to the individuals to whom the data relates.

Health data is generated and reused within the wider healthcare system. As health systems become increasingly digitised, more opportunities to generate and make use of health data become available. **Data governance** encompasses the policies and systems that enable data generated within the healthcare system to be managed across the data journey: from collection and storage to normalisation and standardisation, to use and analysis, and for reuse and sharing in combination with other datasets.

Health data and the data governance systems in place represent the **health data ecosystem**. An overall model of the health data ecosystem has been conceptualised by the Open Data Institute (ODI) in recent work conducted for the World Health Organization (WHO).¹⁶

Diagram label	Ecosystem component	Description
A	Datasets	Health data is about people, organisations, society and the environment. Data is stored/collected both within and outside the health sector.
B	Stakeholders	Health data is used to generate value by a range of stakeholders that draw on data collected and managed by data stewards. Data stewards work with data processors along the data journey – from collection, through validation, storage, to use and analysis, and sharing.
C	Data governance processes	Underpinning the way data stewards and data processors handle data are data governance principles and processes. Data governance helps ensure that the management and use of health data is handled responsibly and fosters trust.
D	Value generation	Health data, when used by stakeholders, generates a number of personal, commercial, societal and environmental benefits.

Table 1: Key components of the health data ecosystem

¹⁴ Campbell, EG., Weissman, JS., Causino, N., Blumenthal, D., Research Policy (2000), '[Data withholding in academic medicine: characteristics of faculty denied access to research results and biomaterials](#)'.

¹⁵ Moodley, K., Cenzig, N., Domingo, A., et al, The Lancet Global Health (2022), '[Ethics and governance challenges related to genomic data sharing in southern Africa: the case of SARS-CoV-2](#)', Health Data Governance Summit (2021), Joi, P., Gavi Vaccines Work (2022), '[Data-sharing in a pandemic: even though scientists shared more than ever, it still wasn't enough](#)', Harding, A., BBC News (2021), '[New Covid variant: South Africa's pride and punishment](#)'.

¹⁶ Health Data Governance Summit (2021), '[Pre-read: The health data landscape](#)'.

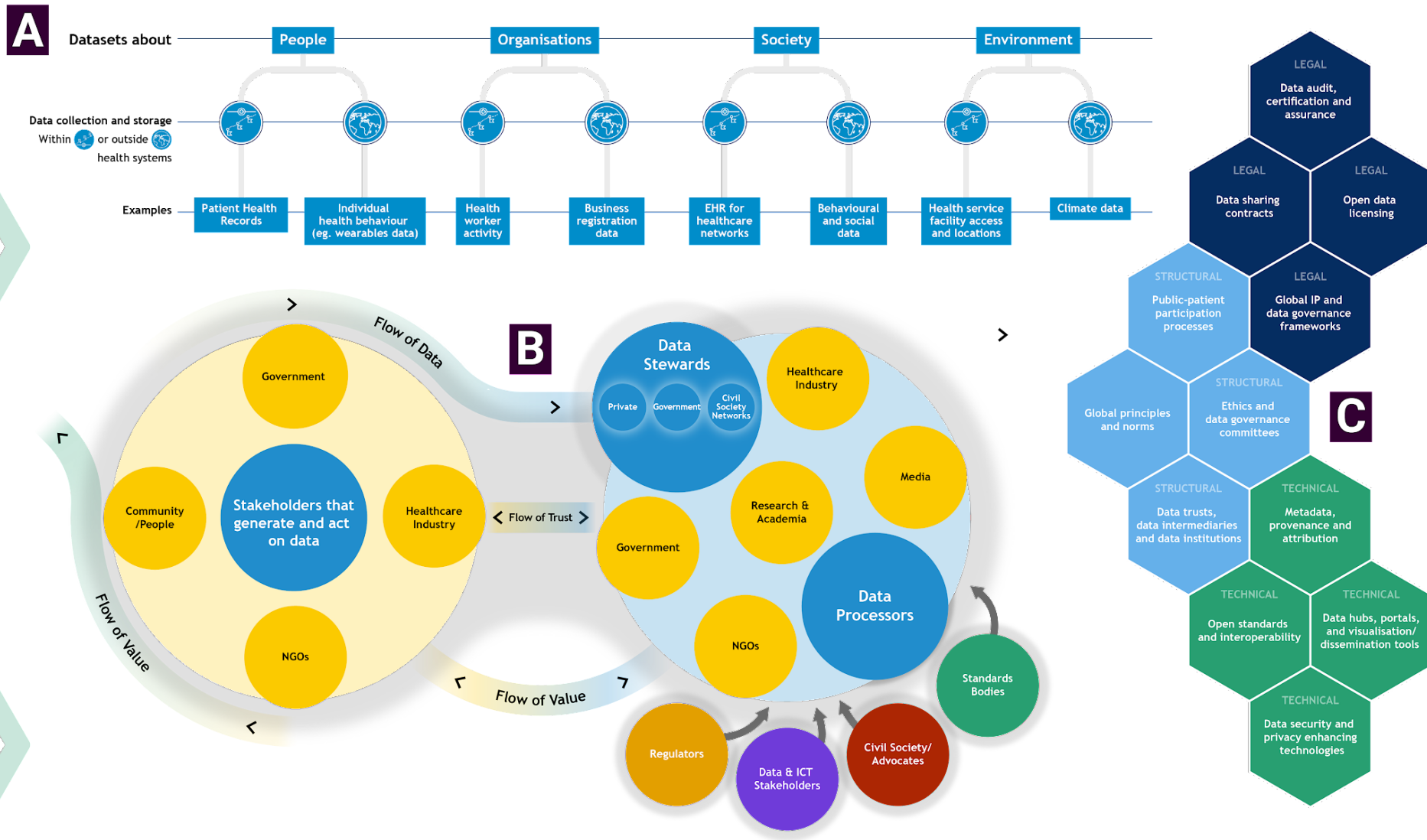


Figure 1. Key elements of a health data ecosystem and how value flows between stakeholders
 Source: 'Pre-read: The health data landscape')

Primary and secondary use of health data discussions in e-health and digital health strategies

Primary use of health data refers to the collection and use of health data to treat an individual's health and wellbeing. It is usually collected during an interaction with a healthcare professional. Prior to digitisation, these health records were hand-written or typed, and stored as paper copies in a patient file. Each healthcare professional or healthcare provider organisation would have their own system for managing paper client files.

In many parts of the world, including in some parts of Europe, paper-based health records are still in use. Countries, regions and the health industry sector have all worked -at times independently, at times collaboratively, and sometimes in a more structured, coordinated fashion – to ensure the digitisation of the health sector. That is, major investments have been made around the world to digitise paper-based systems and move them to electronic-based systems. Initially, this led to a policy momentum in which countries and regions created e-health strategies that were focused on shifting health record systems to be stored in electronic form for primary use -that is, to create electronic health records that were used for patient treatment. E-health strategies and implementation plans often include investment in digital systems and encourage, or mandate, some standardisation in data models and metadata so that every patient's electronic health record (EHR) is in a templated, standardised form that can be shared across healthcare providers, sectors, and borders if needed. Work is ongoing to create interoperable digitised EHR systems.

In recent years, the value of the secondary use of health data has become more apparent. **Secondary use of health data** refers to the use of health data from EHRs, genomic data, health-insurance claims data, health registry data – or burden of disease registries – clinical trials and other research, wearable technologies and personal health and wellbeing apps, and drug consumption data to improve personal healthcare, health services planning and delivery, medicines development, safety monitoring, health industry research, and policymaking. To avoid identifying individuals, health data is at times anonymised and aggregated for any secondary uses – for example, when using health records data or health insurance claims data to calculate the burden of disease in a population and the health outcomes in a country or population over a given time period. These are published as burden of disease registries, usually by country statistics offices or institutes of public health, and are used in areas such as health services planning. The systems that collect and store these types of health data are often referred to as 'real world data infrastructures'.

But at times, secondary use of health data still needs to be identifiable, or at least tracked in a way that ensures the individual patient's outcomes throughout a treatment journey are collected, alongside demographic characteristics like age, gender, race/ethnicity, and bio-social characteristics such as height, weight, employment status, and wellbeing scores. This information can be used as aggregate data to help design treatment plans for others with similar profiles, or to conduct algorithmic and machine learning (ML) analysis of datasets in early stages of drug and medical device research, or to test hypotheses and so on. Such use of secondary health data is often referred to as 'real world evidence', and the systems that enable this evidence to be stored and accessed are real world evidence systems or infrastructures.

Countries and regions are understanding the potential of secondary use of health data to help create open health ecosystems in which data can help improve personalised healthcare, spur new innovation, reduce inefficiencies, and automate elements of healthcare system delivery. Strategies and plans to leverage e-health systems towards these goals are sometimes referred to as 'digital health strategies', while others still incorporate them into their e-health strategies.

Defining a policy framework to measure country and regional action towards enabling secondary use of health data

During previous research and policy analysis on secondary use of health data policy approaches across governments, a research team, lead by Dr Milly Zimeta and including Mark Boyd as lead author alongside Jeni Tennison and Mahad Alassow, developed a policy framework model aligned with the ODI's six manifesto points for open and trustworthy data ecosystems.¹⁷ In 2023, the ODI updated its manifesto by building the points into a set of six principles as part of its new Five Year Strategy.¹⁸ As a result, the secondary use of health data policy framework was similarly updated to reflect these new principles.

As the principles aligned with the previous manifesto attributes, this task was fairly straightforward, as shown in Table 2 below.

¹⁷ ODI (n.d.), '[How well is your country doing on policy for secondary use of health data?](#)'.

¹⁸ ODI (2023), '[ODI Strategy 2023–2028](#)'.

Principle	Alignment with previous ODI manifesto attribute
Principle 1: We believe that a strong data infrastructure is the foundation for building an open, trustworthy data ecosystem on a global scale and that this can help address our most pressing challenges.	Infrastructure
Principle 2: Strong data infrastructure includes data across the spectrum, from open to shared to closed. But the best possible foundation is open data, supported and sustained as data infrastructure. Only with this foundation will people, businesses and governments be able to realise the potential of data infrastructure across society and the economy.	Innovation
Principle 3: For data to work for everyone, it needs to work across borders – geographic, organisational, economic, cultural and political. For this to happen ethically and sustainably, there needs to be trust – trust in data and trust in those who share it.	Ethics
Principle 4: There is greater need than ever for trusted, independent organisations to help people across all sectors, economies and societies benefit from better data infrastructure.	Engagement
Principle 5: For data to work for everyone, those collecting and using it need to be highly alert to inequalities, biases and power asymmetries. All organisations working in data must take proactive steps to ensure that they contribute fully and consciously to creating a diverse, equitable and inclusive data ecosystem.	Equity
Principle 6: The world needs a new cohort of data leaders – individuals who have data knowledge and skills and are equipped to understand the value, limitations and opportunities offered by data, data practices and data sharing.	Capacity

Table 2: ODI Principles and their alignment with the ODI's previous manifesto attributes model

Overall, the policy framework, which comprises 22 indicators that demonstrate a country's capacity to manage secondary use of health data responsibly and for the benefit of all, is unchanged from the previous research conducted.¹⁹

¹⁹ ODI (2021), '[Secondary use of health data in Europe](#)'.

Policy framework component	Alignment with ODI principles	Success indicator
Burden of disease registries	Principle 1 (Infrastructure)	National illness and disease registries have been established with >75% of relevant patient population data recorded
Biobank and genomic data centralisation	Principle 1 (Infrastructure)	Established biobank and genomics databases centralise all structured diagnostic results
Patient health records	Principle 1 (Infrastructure)	Interoperable formats and standards for electronic health records are adopted, and records can be shared securely across borders
Medicine/pharmaceutical registers	Principle 1 (Infrastructure)	National registers are maintained, including adverse drug-reaction registers
Patient-reported outcomes data	Principle 1 (Infrastructure)	Interoperable formats and standards are created for patient-reported outcomes
Science/clinical data	Principle 1 (Infrastructure)	Data from scientific studies, observational studies and clinical trials are available, and can be shared
Insurance-claims data	Principle 1 (Infrastructure)	National registers on social health-insurance claims are maintained and published regularly
Employment sickness and social-security data	Principle 1 (Infrastructure)	National registers on illness and sickness, including social-security financing and costs of illness on workplace participation, are maintained and published regularly
Personal and health-technologies data	Principle 1 (Infrastructure)	National systems for standardising, collecting and reusing personal-health data from wearables, fitness trackers, remote patient monitoring and software as a medical service are described, with people participating
Real-world data infrastructure	Principle 1 (Infrastructure)	All real-world data is captured in consistent standardised formats with advanced data-curation systems that enable exploration, cleaning and enrichment
Real-world evidence decision-making	Principle 1 (Infrastructure)	Health-technology assessment (HTA) bodies, regulators and policymakers have established a clear framework for using real-world evidence in decision-making
Adoption of open standards	Principle 1 (Infrastructure)	Health-data policies confirm the importance of using open standards for health datasets, and ministries of health are committed to adopting them
Legal framework for sharing secondary use of data	Principle 1 (Infrastructure)	A legal framework is articulated that protects personal data so de-identified data can benefit society
Evaluation framework for health technologies	Principle 6 (Capability)	A strong, ethical, and community-inclusive health-technology assessment process is adopted across Europe and in each member state

Investment in EHR systems	Principle 2 (Innovation)	Training is resourced and incentives are available to healthcare institutions and data ecosystem stakeholders to encourage adoption of standard and data sharing, including use of EHRs
Secondary use of health data policy is a national priority	Principle 2 (Innovation)	Specific policy is developed that recognises the value of secondary use of health data and all stakeholders are encouraged to participate in ecosystem networks, with strategic investment available to foster best practices
Equity considerations addressed	Principle 5 (Equity)	Policies recognise the uneven distribution of health resources and want secondary use of health data to address this
Privacy regulation	Principle 5 (Equity)	There is rigorous privacy regulation that allows appropriate industry access and use of high-quality healthcare data within agreed privacy constraints
High level of trust in data-informed healthcare	Principle 3 (Ethics)	There is a high degree of willingness by the public to consent to reuse of their health data for research and personalised healthcare goals
Ethical/accountability framework for secondary use of health data	Principle 3 (Ethics)	Clear reporting, methods of redress and consequences are defined and resourced
Sustainable and trustworthy data institutions	Principle 4 (Engagement)	Strategic investment in data institutions that can oversee data infrastructure and report on implementation and capabilities
Public/patient participation	Principle 4 (Engagement)	Investment to support participation of citizens and healthcare communities in decision-making

Table 3: Policy framework for secondary use of health data: what does good look like?

For each component, we identified current policy work, institutional support and strategic initiatives. We then evaluated these activities using two measures:

- **What is the quality of policy activity for this indicator?** The scoring range for these quality evaluations is: having only limited aspects of the success indicator (low/0); aligned intent, but missing key aspects (medium/2); or fully comprehensive (high/ 4).
- **What progress is being made on implementation of policy for this indicator?** The scoring range for policy implementation stages is: not started (0); defined (1); planned (2); pilot initiatives (3); scaled-up implementations (4).

For this study, the policy framework was applied to five countries in the Western Balkan region – Bosnia and Herzegovina, Kosovo, Serbia, Montenegro and North Macedonia – alongside a review of the European Commission policy context as a benchmark for regional activities.

2.

Health data strategies and action in the Western Balkan region

Digitisation in the Western Balkan region

Across the Western Balkan region of Europe, countries including Serbia, Bosnia and Herzegovina, North Macedonia and Montenegro (amongst others) are recognised as European member state candidate countries, while Kosovo is recognised as a potential candidate.

Following war and upheavals, Western Balkan countries began building economic and political systems in the early 2000s. This was disrupted by the Global Financial Crisis of 2007-2008, which impacted heavily on the region and reduced the expenditure available for the reorientation and rebuilding of core societal infrastructures. While local economies slowly built up again in the following years, the impact of Covid-19 – in 2019 and 2020 – and the nearby Russian attack on Ukraine in 2022 – including its impact on energy resources – have created shockwaves that have caused new, and ongoing, instability and nationwide challenges to prioritise.²⁰

Despite these geopolitical challenges, the Western Balkan countries are recognised for their ‘remarkable resilience despite significant economic headwinds’.²¹ Work has begun on the continuing modernisation of the societal infrastructure of Western Balkan countries, and the digitisation of each country’s systems score. With funding from the [European Union](#), the [Organization for Security and Co-operation in Europe](#), the [Regional Cooperation Council](#), Open Government Partnerships and other stakeholders, Western Balkan countries have developed digitisation strategies. These are being implemented at pace, although some areas still need help to modernise infrastructure and enable new economic activities to flourish.²²

²⁰ Jaćimović, D., Deichmann, JI., Tianpin, K., Trans European Policy Studies Association (2022), ‘[Challenges of Enlargement in the Western Balkans](#)’.

²¹ The World Bank (2023), ‘[Western Balkans Show Resilience Despite Slowing Growth and Continued Price Rises](#)’.

²² OEGFE (2023), ‘[The role of digitalisation in transforming Western Balkan societies](#)’.

Particular areas in need of focus include the slow move towards regional coordination, the uptake of best practices in digitalisation, disparities between rural and urban access to digital services, the need for citizen digital literacy, and cybersecurity infrastructure.²³

E-health and digital health strategies in the Western Balkan region

The modernisation of health infrastructure is occurring in these regions within this context of overall digitalisation. For now, the e-health strategies adopted by most of the countries studied prioritise digitising electronic health records and creating e-government and e-health service infrastructure that allows digital appointments and online consent for patients to approve sharing of their medical records amongst their healthcare providers, in cases where it is necessary for a patient to be referred to a specialist.

As a result, the bulk of the focus in the region is on primary use of health data; that is, making health data available digitally for the delivery of healthcare services to the patient.

At a European-wide level, efforts are focused on the creation of a European health data space that aims to clarify the use of health data for a range of activities, including secondary use of health data. This aims to build appropriate regional data governance and promote in-country data governance processes that adequately enable data to be used for research, innovation and personalised healthcare purposes, while protecting individual privacy of health data.

As Western Balkan countries seek to pursue a faster European enlargement and membership agenda in the coming years, they will need to show they can integrate with existing infrastructure and work programmes across Europe. Advancing their e-health strategies, and creating digital health strategies that describe how they plan to harness and manage broader health data opportunities, could help Western Balkan countries to better align with European Health Data Space infrastructure and demonstrate readiness to participate in these regional activities.

²³ OEGFE (2023), '[The role of digitalisation in transforming Western Balkan societies](#)'.

Assessing the Western Balkan region against the ‘Secondary Use of Health Data Policy Framework’

In **Bosnia and Herzegovina**, solid data infrastructure is in place: burden of disease registries collect and publish data, and investment in digitisation of electronic health records has increased coverage for most of the population and is in place at most healthcare provider organisations. Digital health strategy goals are listed in the work plan for the country.²⁴ However, at this stage, implementation appears to have stalled. Nevertheless, Bosnia and Herzegovina is in a solid place to take action towards leveraging secondary use of health data, given that infrastructure, including legislation, patient organisation participation, and clear goals to address health inequalities, are in place.

Kosovo faces significant challenges. At present, it still needs a focus on its basic e-health infrastructure. There appear to be mixed messages on the progress it has made towards establishing electronic health records infrastructure: some report that, thanks to investment, its system now covers the leading healthcare providers, yet others say there is still significant work to do. The European Commission's 2022 report on Kosovo progress recommended investment and focus on e-health infrastructure and a focus on ensuring data systems support addressing health inequalities faced by Roma and Ashkali communities.²⁵

Montenegro advanced significantly during the Covid-19 pandemic by investing in e-health infrastructure that now covers EHR, appointment scheduling, e-prescription services and patient data access.²⁶ This digitisation is now expected to centre the patient as the owner of their health data, enabling them to decide how to share it, and with whom. It is unclear if new legislation is being developed to support this shift in data rights at present, but government policies do indicate that it is now intending to shift towards a digital health model in which this infrastructure, with patients' data consent, could enable a digital tech ecosystem to grow.

²⁴ BOSNA I HERCEGOVINA (2020), '[Strategija Razvoja Federacije Bosne I Hercegovine 2021–2027](#)'.

²⁵ European Commission (2022), '[Kosovo* 2022 Report](#)'.

²⁶ Kara, PA., Ognjanovic, I., Maindorfer, I., et al. ENG (2023), '[The Present and Future of a Digital Montenegro: Analysis of C-ITS, Agriculture, and Healthcare](#)'.

North Macedonia has established a strong base for future digital health activities, which includes the national Moj Termin EHR data infrastructure being expanded to cover most of the population. In addition, health strategy goals explicitly define the value of making wider use of health data and the use of health data systems to reduce inequalities. This has led to new projects being implemented. However, some 'early wins' are not yet in place; for example, the burden of disease register data is not easily available.

Serbia has one of the most exciting digital health agendas, not only for the region, but perhaps for all of Europe. Recent work to document its potential is comprehensive when measured against the policy framework for secondary use of health data:

- health data portals are available for citizens to manage their health data, make appointments, and access prescription data
- open standards and open data models have been defined for use amongst the healthcare ecosystem to ensure interoperability
- patient organisations were consulted during e-health strategy development,
- legal frameworks have been prioritised for development, and
- real world evidence infrastructure is being piloted.

However, Serbia is just at the start of implementing its strategy and is still in the process of establishing many of the data governance structures that will help guide strategy implementation. It is therefore unclear whether Serbia's vision, which recognises the potential of using health data for secondary uses, will materialise.

3.

A way forward: how Western Balkan nations can best act to advance their country-level health data ecosystems

There are four key areas that Western Balkan nations can focus on to advance towards fostering digital health ecosystems that can enable secondary use of health data.

1. Consider digital health policy goals while implementing e-health strategies, particularly when reviewing data protection regulations

The Western Balkan nations face significant challenges in moving towards a stage where they are making greater use of health data for a wider range of uses beyond primary healthcare. It is understandable, in the broader context of increasing digitisation for the region, that the current focus is on e-health infrastructure. In particular, the shift towards EHR for entire populations, and at each healthcare provider setting, is a necessary priority, as this is fundamental in greater use of data in the future.

As countries consider the implications of digitised health records, and how patients can manage their health data – and provide consent for sharing it – across their healthcare professional providers, it is useful to have a wider view of digitisation, one that encompasses the potential for making use of health data for other purposes beyond primary care. Recognising this potential future avenue can help countries avoid duplication when updating data protection legislation for e-health outcomes and revisiting these legislative frameworks in the near future as moves towards digital health ecosystem development emerge.

2. Increase regional cooperation and knowledge sharing, especially in the adoption of open standards and open data models

There appear to be few structures in place that would allow countries in the region to share knowledge and progress on their e-health strategy development and implementation. For example, several of the e-health strategies do not mention which standards or data models are being adopted,

while others note that new data governance structures are being established to make decisions on the adoption of standards. This work is ideal for collaboration across the region to support future cross-border healthcare delivery, but also to help the region cluster population health data into a larger dataset that could be used for artificial intelligence (AI) initiatives, where a single country's population may not be large enough to aid ML models. The use of open data standards and data models can also help improve the quality of collected data, which is an area of concern in some datasets across the region.

3. Seek to partner with European countries participating in the emergent European health data space

Western Balkan countries face two key challenges in the current digital health environment. Firstly, several countries are still digitising their health records infrastructure, although this work is now nearing completion in several of the countries we reviewed – of which Serbia and North Macedonia are the most advanced. Secondly, other countries across Europe that have already completed this digitisation are now moving to capitalise on health data as an opportunity for improving population health outcomes, reducing healthcare costs, and encouraging new industry and research investments in their country. To avoid ‘falling behind’ as European member states prepare for an expansion in their use of health data, governed by the European health data space,²⁷ it may be beneficial for Western Balkan countries to identify a potential member state to partner with and engage in talks to understand implementation and data strategy preparedness. This does not necessarily need to be the more regularly consulted countries like Finland, the Netherlands or France. Slovenia,²⁸ Germany,²⁹ and several other countries in Western Europe have made significant progress towards implementing digital health strategies in the past several years.

4. Ensure that the digitisation and secondary use of health data initiatives does not further widen health inequalities

Some assessments have already noted³⁰ that the implementation of digital infrastructure and the digitisation of health systems is being unevenly applied in the region. For example, the disparity in digital access between rural and urban citizens has been noted in some assessments of the digitisation of the region. Roma populations’ lack of electronic health records is also highlighted. Other inequalities may emerge, based on gender, ethnicity,

²⁷ European Commission (n.d.), ‘[European Health Data Space](#)’.

²⁸ Ministry of Health, Office of the Government of the Republic of Slovenia for Digital Transformation (2023), ‘[Digitalisation is the key step to a modern health system](#)’.

²⁹ Artur Olesch, ICT & Health (2023), ‘[Germany unveils a new strategy to “bring healthcare into the 21st century”](#)’.

³⁰ OEGFE (2023), ‘[The role of digitalisation in transforming Western Balkan societies](#)’.

disability, or socio-economic status. Ensuring data collection can be disaggregated by population characteristics that measure potential unequal healthcare service delivery and outcomes is essential to ensuring that digitisation and digital health efforts do not inadvertently widen inequalities. Specific strategies may also be required to ensure digital health benefits are generated for these populations. There are some examples in the region where population-wide initiatives are coupled with targeted strategies that address the sub-populations that are facing greater inequality. A project to ensure data infrastructure reached vulnerable populations between North Macedonia and Greece is one example of a targeted implementation that occurred alongside population-wide e-health strategy implementations.³¹

³¹ European Commission (2020), '[Boosting health services for the most vulnerable across the Greece-North Macedonia border](#)'.

Conclusion: the secondary use of health data landscape in the Western Balkan region

Significant work to digitise and modernise health systems across the Western Balkan region is continuing at pace. While there are pockets where action has stalled, or where further detail is needed on implementation progress, the region is committed to establishing digital infrastructure that will allow for the greater use of health data in future.

While this work continues, the region needs to ensure that core goals of enabling greater data collection and use for primary care are extended, to recognise the value of secondary use of health data. The ODI's previous study on secondary use of health data policy across Europe and with collaborative countries outlines the benefits and potential of making use of health data for secondary purposes.³²

This study reviewed the current activities of Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia and Serbia against a secondary use of health data policy framework. Activities to ensure greater health data collection are principally focused on primary use cases, which could result in the region lagging behind the rest of Europe, where member states are advancing to consider how to attract new investment and research and to improve local population health outcomes by establishing the policy and legislative environments that enable secondary use of health data.

The Western Balkan region's ability to act quickly, and to implement digitisation, remains undisputed. The region is recognised for its resilience and actions: Serbia's creation of a comprehensive e-health strategy and Montenegro's modernisation of its health infrastructure during the Covid-19 pandemic each demonstrate the capacity to take action and build robust health data infrastructure. The coming two years will require this pace to continue. It is hoped the findings of this study can help contribute to a wider understanding of the work that needs to be done in each country and provide the inspiration to work collaboratively across the region.

³² ODI (2021), '[Secondary use of health data in Europe](#)'.