Recommendation of the Council on Health Data Governance

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Background Information

The Recommendation on Health Data Governance was adopted by the OECD Council on 13 December 2016 on a proposal of the Health Committee (HC) and Digital Economy Committee (DPC), and was welcomed by OECD Health Ministers at their meeting in Paris on 17 January 2017.

The Recommendation aims to guide Adherents in setting the framework conditions for enabling the availability and use of personal health data to unlock its potential. In so doing, it also provides a roadmap toward more harmonised approaches to health data governance across Adherents. The health sector remains significantly behind other economic sectors such as transportation, travel, banking and finance, in the interoperability of data. It was designed to be technology neutral and robust to the evolution of health data and health data technologies.

The Recommendation has provided important guidance to governments during the global COVID-19 pandemic. The pandemic shone a spotlight on the capacity of each countries' health information systems to provide critical information for the public welfare; as well as on aspects of data governance that created obstacles to responding to the pandemic in a timely way.

The need for an international standard on health data governance

Health data are necessary to improve the quality, safety and patient-centeredness of healthcare services, to support scientific innovation, the discovery and evaluation of new treatments and to redesign and evaluate new models of health service delivery. The volume of personal health data in electronic form is already very large and is growing with technological progress including electronic health and administrative records; behavioural and environmental monitoring devices and apps; and bio-banking and genomic technologies. The scale, capabilities and methodologies of health data gathering, aggregation, and analysis are also radically evolving.

When personal health data are linked and analysed, an exponential gain in information value can be attained to serve the health related public interest, such as improving diagnosis, particularly for rare diseases; identifying optimal responders to treatment and personalising care for better patient outcomes; detecting unsafe health care practices and treatments; rewarding high quality and efficient health care practices; detecting fraud and waste in the health care system; assessing the long-term effects of medical treatments; and discovering and evaluating new health care treatments and practices. Emerging technologies including Big Data analytics, for example, can utilise enhanced computing power to process broad ranges of data in real time, that when applied to health can improve patient-care and further the discovery of disease markers and disease-specific solutions.

However, often the data are held in silos by the organisations collecting them and there are uncertainties on how the potential benefits of the new analytic techniques can be achieved while ensuring the implementation of existing data protection standards and procedures. A 2013 OECD study showed that many OECD Members lack a co-ordinated public policy framework to guide health data use and sharing practices, so as to protect privacy, enable efficiencies, promote quality and foster innovative research.

There are benefits and risks from health data processing at both the individual and societal levels. The maintenance of a confidential health care system is fundamental to effective individual care and treatment, and to public health. Appropriate reconciliation of these risks and benefits is necessary to best serve the interests of both individuals and societies. In addition, international collaboration is essential to enable countries to safely benefit from health data and to support the production of multi-country statistics, research and other health-related uses of those data that serve the public interest.

It is against this backdrop that in 2014, the HC and the DPC agreed to jointly develop an OECD standard to tackle those issues. The work of the OECD to support strengthening health data infrastructure and governance and to protect privacy and data security culminated in the OECD Recommendation on Health Data Governance.

Process for developing the Recommendation

The Recommendation is the product of a multi-stakeholder effort. It was jointly developed by the DPC and the HC through their respective relevant subsidiary bodies, the former Working Party on Security and Privacy in the Digital Economy (renamed since 2019 as the Working Party on Data Governance and Privacy) and the former Health Care Quality Indicators Expert Group.

The development of the Recommendation involved the advice of experts in privacy, law, ethics, health, government policy, research, statistics and Information Technology and extensive consultations with civil society (the Civil Society Advisory Committee) and business and industry (Business and Industry Advisory Committee).

Scope of the Recommendation

The Recommendation applies to the access to, and the processing of, personal health data for health-related public interest purposes, such as improving health care quality, safety and responsiveness; reducing public health risks; discovering and evaluating new diagnostic tools and treatments to improve health outcomes; managing health care resources efficiently; contributing to the progress of science and medicine; improving public policy planning and evaluation; and improving patients' participation in and experiences of health care.

The Recommendation recommends that Adherents establish and implement a national health data governance framework to encourage the availability and use of personal health data to serve health-related public interest purposes while promoting the protection of privacy, personal health data and data security. Twelve principles set the parameters to encourage greater cross-country harmonisation among the health data governance frameworks of Adherents so that more countries can use health data for research, statistics and health care quality improvement.

The Recommendation also recommends that Adherents support trans-border cooperation in the processing of health data for purposes that serve the public interest. It further recommends that Adherents engage with relevant experts and organisations to develop mechanisms that enable the efficient exchange and interoperability of health data.

Finally, it encourages non-governmental organisations to follow the Recommendation when processing personal health data for health-related purposes that serve the public interest and invites non-Adherents to take account and to adhere to the Recommendation

For further information please consult: www.oecd.org/els/health-systems/health-data-governance.htm; www.oecd.org/health/digital-health.htm, www.oecd.org/digital/.
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Implementation

Upcoming work

Over the next five years, the Health Committee and the Committee on Digital Economy Policy will continue developing tools to support the implementation and dissemination of the Recommendation.

In line with the 2022 Report, work could focus on three areas that pose challenges for Adherents in implementing the Recommendation: 1) increasing the interoperability of health data and data analytics; 2) achieving greater harmonisation of health data governance frameworks for cross-country collaboration involving the sharing and use of health data; and 3) enhancing the sharing of experiences and best practices in health data security in response to the increasing occurrence of malicious attacks on health data.

2022 Report to Council

The 2022 Report to Council presents progress made by Adherents in implementing the Recommendation and conclusions on its dissemination and continued relevance. It was prepared using three surveys (the 2019/20 Survey of Health Data Use and Governance, the 2021 Survey of Electronic Health Record Systems Development, Use and Governance, and the 2021 Survey of Health data and Governance Changes during the COVID-19 pandemic) as well as the results of several workshops including one on Health Innovation through Fair Information Processing Practices in 2021.

The 2022 Report confirms the continued relevance of the Recommendation, which has proven to be particularly important to address the COVID-19 pandemic (see section above). Overall results indicate that there are many Adherents that are still working toward implementation of the Recommendation.

Among Adherents with lower scores for dataset availability, maturity and use, the challenge lies in making data available for research and statistical purposes. In these countries, there is work to be done to develop collaborative policies and practices among government authorities in custody of key health data. Considerable work and investments are required in such Adherents to improve data quality, linkability and sharing with researchers, so that data can serve health-related public interests. Among Adherents with lower scores for data governance, there are gaps to address in data privacy and security protections for key health datasets such as having a data protection officer and providing staff training, access controls, managing re-identification risks, and protecting data when they are linked and accessed.

The 2022 Report also concludes that the Recommendation has been widely disseminated to various stakeholders through various avenues, in particular through policy workshops, reports, scientific articles, newsletters and blogs and presentations to meetings and conferences. More work can be done and Adherents are encouraged to disseminate the Recommendation further at all level of governments and to non-governmental organisations.

The next reporting to Council is scheduled to take place in 2027.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data [C(80)58/FINAL as amended by C(2013)79], the Recommendation of the Council on Human Biobanks and Genetic Research Databases [C(2009)119] and the Recommendation of the Council on Digital Security Risk Management for Economic and Social Prosperity [C(2015)115];

NOTING the OECD report *Health Data Governance: Privacy, Monitoring and Research* (OECD, 2015);

RECOGNISING that access to, and the processing of, personal health data can serve health-related public interests and bring significant benefits to individuals and society;

RECOGNISING that health systems are increasingly affected by a growing volume of personal health data in electronic form, including electronic health and administrative records; that such data are often held in silos by the organisations that have collected them and by governmental authorities, such as health ministries and statistical agencies; and that when the secure transfer, linkage and analysis of health data occurs, then the value of the data to serve health-related public interest purposes increases significantly.

RECOGNISING that public trust and confidence in the protection of personal health data must be maintained if the benefits achievable through its processing are to be realised; and that governments have a role in fostering compliance with privacy laws and policies.

RECOGNISING that personal health data, being sensitive in nature and subject to ethical standards and the principle of medical confidentiality, require a particularly high level of protection and that technological developments can both enable the privacy protective use of personal health data and also introduce new risks to privacy and data security;

RECOGNISING that achieving these benefits requires the careful development and application of robust, context appropriate, privacy protective health data governance frameworks that require the identification and management of privacy and security risks;

RECOGNISING that although Members and non-Members adhering to this Recommendation (hereafter the “Adherents”) are investing in health data infrastructure and that considerable progress is being made to achieve co-ordinated health data governance frameworks, the many differences in the availability of, access to and use of personal health data both within and across national borders must be addressed; and

CONSIDERING that, while there are differences in their domestic laws, effectively safeguarding the public interest is an important function of governments; that health data governance is not only the domain of central governments but that it encompasses all levels of government, where different mandates apply in different countries; and that this Recommendation is accordingly relevant to all levels of government.

On the proposal of the Health Committee and the Committee on Digital Economy Policy:

I. **AGREES** that this Recommendation applies to the access to, and the processing of, personal health data for health-related public interest purposes, such as improving health care quality, safety and responsiveness; reducing public health risks; discovering and evaluating new diagnostic tools and treatments to improve health outcomes; managing health care resources efficiently; contributing to the progress of science and medicine; improving public policy planning and evaluation; and improving patients’ participation in and experiences of health care.

II. **AGREES** that for the purpose of this Recommendation the following technical terms require a brief description to support a common understanding:

- "Personal health data" means any information relating to an identified or identifiable individual that concerns their health, and includes any other associated personal data.
- "Processing personal health data" means all data-related operations involving personal health data such as data collection, use, disclosure, storage, recording, editing, retrieval, transfer, sharing, linkage or combining, analysis, and erasure.
- "De-identification" means a process by which a set of personal health data is altered, so that the resulting information cannot be readily associated with particular individuals. De-identified data are not anonymous data. "Re-identification" means a process by which information is attributed to de-identified data in order to identify the individual to whom the de-identified data relate.

III. RECOMMENDS that governments establish and implement a national health data governance framework to encourage the availability and use of personal health data to serve health-related public interest purposes while promoting the protection of privacy, personal health data and data security. Such a health data governance framework should provide for:

1. **Engagement and participation**, notably through public consultation, of a wide range of stakeholders with a view to ensuring that the processing of personal health data under the framework serves the public interest and is consistent with societal values and the reasonable expectations of individuals for both the protection of their data and the use of their data for health system management, research, statistics or other health-related purposes that serve the public interest.
2. **Co-ordination within government and promotion of cooperation among organisations processing personal health data, whether in the public or private sectors**. This cooperation should:

    i. Encourage common data elements and formats; quality assurance; and data interoperability standards; and

    ii. Encourage common policies and procedures that minimise barriers to sharing data for health system management, statistics, research and other health-related purposes that serve the public interest while protecting privacy and data security.

3. **Review of the capacity of public sector health data systems used to process personal health data to serve and protect the public interest.** Such review should include:

    i. Data availability, quality, fitness for use, accessibility, as well as privacy and data security protections.

    ii. Elements of data processing that are permitted for health system management, research, statistics or other health-related public interest purposes, subject to appropriate safeguards, particularly dataset transfers and the linkage of dataset records.

4. **Clear provision of information to individuals.** Such provision should ensure that:

    i. Where personal health data are collected from individuals, information about the processing of their personal health data, including possible lawful access by third parties, the underlying objectives behind the processing, the benefits of the processing, and its legal basis is disclosed in clear, accurate, easily understandable and conspicuous terms.

    ii. Individuals are notified in a timely manner of any significant data breach or other misuse of their personal health data. Where individual notification is not practicable then notification may be made by effective public communication.

5. **Informed consent and appropriate alternatives.**

    i. Consent mechanisms should provide:

a. Clarity on whether individual consent to the processing of their personal health data is required, and, if so, the criteria used to make this determination; what constitutes valid consent and how consent can be withdrawn; and lawful alternatives and exemptions to requiring consent, including in circumstances where obtaining consent is impossible, impracticable or incompatible with the achievement of the health-related public interest purpose, and the processing is subject to safeguards consistent with this Recommendation.

b. That, where the processing of personal health data is based on consent, such consent should only be valid if it is informed and freely given, and if individuals are provided with clear, conspicuous and easy to use mechanisms to provide or withdraw consent for the future use of the data.

ii. Where the processing of personal health data is not based on consent, to the extent practicable, mechanisms should provide that:

a. Individuals should be able to express preferences regarding the processing of their personal health data, including not only the ability to object to processing under certain circumstances but also the ability to actively request that their personal health data be shared for research or other health-related public interest purposes.

b. If data processing objections or requests cannot be honoured, then individuals should be provided with the reasons why this is the case including the relevant legal basis.

6. **Review and approval procedures, as appropriate, for the use of personal health data for research and other health-related public interest purposes**. Such review and approval procedures should:

i. Involve an evidence-based assessment of whether the proposed use is in the public interest;

ii. Be robust, objective and fair;

iii. Operate in a manner that is timely and promotes consistency of outcomes;

iv. Operate transparently whilst protecting legitimate interests; and

v. Be supported by an independent multi-disciplinary review conducted by those with the expertise necessary to evaluate the benefits and risks for individuals and society of the processing, and risk mitigation.

7. **Transparency, through public information mechanisms which do not compromise health data privacy and security protections or organisations' commercial or other legitimate interests.** Public information should include the following elements:

i. The purposes for the processing of personal health data, and the health-related public interest purposes that it serves, as well as its legal basis.

ii. The procedure and criteria used to approve the processing of personal health data, and a summary of the approval decisions taken, including a list of the categories of approved data recipients.

iii. Information about the implementation of the health data governance framework and how effective it has been.

8. **Maximising the potential and promoting the development of technology** as a means of enabling the availability, re-use and analysis of personal health data while, at the same time, protecting privacy and security and facilitating individuals' control of the uses of their own data.

9. **Monitoring and evaluation mechanisms.** Such mechanisms should:

i. Assess whether the uses of personal health data have met the intended health-related public interest purposes and brought the benefits expected from such uses and whether any negative consequences of such uses have occurred, including failures to comply with national requirements for the protection of privacy, personal health data and data security; data breaches and data misuses; and feed the results of such assessment into a process of continuous improvement, including through:

a. Periodic review of developments in personal health data availability, the needs of health research and related activities, and public policy needs; and

b. Periodic assessment and updating of policies and practices to manage privacy, protection of personal health data and security risks relating to personal health data governance.

ii. Encourage those processing personal health data to periodically review and assess the capabilities, reliability and vulnerabilities of the technologies they use.

10. Establishment of appropriate training and skills development in privacy and security measures for those processing personal health data, that are in line with prevailing standards and data processing techniques.

11. Implementation of controls and safeguards. These should:

i. Provide clear and robust lines of accountability for personal health data processing, accompanied by appropriate mechanisms for audit.

ii. Establish requirements that personal health data can only be processed by, or be the responsibility of, organisations with appropriate data privacy and security training for all staff members, commensurate with their roles and responsibilities in relation to processing personal health data and consistent with any applicable professional codes of conduct.

iii. Encourage organisations processing personal health data to designate an employee or employees to coordinate and be accountable for the organisation's information security programme, including informing the organisation and its employees of their legal obligations to protect privacy and data security.

iv. Include formal risk management processes, updated periodically that assess and treat risks, including unwanted data erasure, re-identification, breaches or other misuses, in particular when establishing new programmes or introducing novel practices.

v. Include technological, physical and organisational measures designed to protect privacy and security while maintaining, as far as practicable, the utility of personal health data for health-related public interest purposes. Such measures should include:

a. Mechanisms that limit the identification of individuals, including through the de-identification of their personal health data, and take into account the proposed use of the data, while also allowing re-identification where approved. Re-identification may be approved to conduct future data analysis for health system management, research, statistics, or for other health-related public interest purposes; or to inform an individual of a specific condition or research outcome, where appropriate.

b. Agreements, when sharing personal health data with third parties for processing that help to maximise the benefits and manage the risks while maintaining the utility of personal health data. Such agreements should specify arrangements for the secure transfer of data and include appropriate means to effectively sanction non-compliance.

c. Where practicable and appropriate, considering alternatives to data transfer to third parties, such as secure data access centres and remote data access facilities.

d. Robust identity verification and authentication of individuals accessing personal health data.

12. Require organisations processing personal health data to demonstrate that they meet national expectations for health data governance. This may include establishment of certification or accreditation of organisations processing personal health data, in so far as these certifications or accreditations help to implement standards for the processing of personal health data or demonstrate capacity to meet recognised governance standards.

IV. **RECOMMENDS** that governments support transborder co-operation in the processing of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest subject to safeguards consistent with this Recommendation. To that effect, governments should:

i. Identify and remove barriers to effective cross-border cooperation in the processing of personal health data for health-related public interest purposes in a manner consistent with protecting privacy and data security, in light of all the circumstances.

ii. Facilitate the compatibility or interoperability of health data governance frameworks.

iii. Promote continuous improvement through the sharing of outcomes and best practices in the availability and use of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest.

V. **RECOMMENDS** that governments engage with relevant experts and organisations to develop mechanisms consistent with the principles of this Recommendation that enable the efficient exchange and interoperability of health data whilst protecting privacy, including, where appropriate, codes, standards and the standardisation of health data terminology.

VI. **ENCOURAGES** non-governmental organisations to follow this Recommendation when processing personal health data for health-related purposes that serve the public interest.

VII. **INVITES** the Secretary-General to disseminate this Recommendation.

VIII. **INVITES** Adherents to disseminate this Recommendation at all levels of government.

IX. **INVITES** non-Adherents to take account and to adhere to this Recommendation.

X. **INSTRUCTS** the Health Committee, in co-operation with the Committee on Digital Economy Policy, to:

a) Serve as a forum to exchange information on progress and experiences with respect to the implementation of this Recommendation, and;

b) Monitor the implementation of this Recommendation and report to the Council within five years of its adoption and thereafter as appropriate.

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