



GLOBAL
SELF-CARE
FEDERATION

GSCF HEALTH DATA
**FUTURE VISION
AND POLICY
PRIORITIES**

POLICY POSITION

Self-care and the data it generates offer numerous benefits that extend from the individual to the whole community. Self-care health data⁷ has the potential to improve health outcomes, contributing to improved public health for the entire population. Examples of recent innovations are at-home diagnostic kits, telemedicine, and portable diagnostic devices. However, there are still a number of barriers preventing self-care health data from being used as efficiently as possible to generate the most value for consumers and society.

Health data was used in a variety of ways during COVID-19, ranging from **basic online symptom reporting** to **complex connected tele-health and contact tracing solutions**, which leveraged digital technology. In addition, the pandemic has made consumers aware of the importance of taking care of their health while adapting new behavioral patterns, such as social distancing and mask-wearing. The acceleration in digitalization due to the COVID-19 pandemic has accelerated the development of self-care options, while also increasing the number of digital tools available and their usage. Generally, people became more aware of the possibilities of digital solutions that exist to take more ownership of their health. These positive trends need to be further nurtured by joint action to realize their full benefits.

The current legal, policy and regulatory environment is not conducive to harnessing the full potential of self-care health data: legal and regulatory frameworks are lagging behind innovation while existing self-care health data is fragmented and of varying quality. Expanding and diversifying the sources of data (e.g., capturing data on interactions between individuals and pharmacists), as well as harmonizing data standards, could further unlock insights to the benefit of individuals and health systems.

⁷GSCF understand as Self-Care Health Data any data about an individual related to their health and wellbeing, including medical and non-medical data, generate through both online and offline activities.

GSCF and its members fully support the further development of the policy environment for self-care health data to one that enables individuals and society to harness all its benefits. In particular, GSCF calls for action in the following areas:

1. ADOPTING FIT-FOR-PURPOSE LEGAL AND REGULATORY FRAMEWORKS FOR SELF-CARE HEALTH DATA

Regulatory frameworks are currently not suitable for present challenges, providing opportunities to improve existing and future frameworks to enable the full use and benefits of self-care health data.

- Today, the regulatory landscape of self-care health data is governed by the same framework as overall health data. As a result, the differences between self-care health data and clinical health data are not recognized. Whereas they do not have the same purposes, they should not have the same constraints. In an area like self-care health data, where innovation occurs very quickly, **there is the need for regulators and regulatory frameworks that can readily adapt to new technologies** or that is “technology neutral”.⁸ **Self-care health data requires a more flexible regulatory framework** that improves on long lead times to allow innovative products and services to reach consumers faster.

- **Regulatory frameworks on data standards, collection and use of self-care health data are fragmented globally.** This is a problem both for the acquisition of the data and for its use. Harmonized frameworks based on internationally recognized best practices for privacy, security and ethics are needed to enable broader opportunities for data collection and to enhance the trust of consumers and patients. All frameworks should be based on FAIR (Findable, Accessible, Interoperable and Re-usable) data.⁹ Regulation and harmonization need to take place in a collaborative manner between regulators, the private sector, academia, and other stakeholders, including ones from developed and developing countries.¹⁰

A regulatory approach tailored to self-care will help pave the way for more, better, and faster health solutions.

To facilitate an environment in which the potential of self-care health data is unlocked, GSCF advocates for supportive and fit-for-purpose policy and regulatory frameworks that enable innovation and the appropriate use of self-care health data. We believe that regulations based on internationally recognized best practices¹¹ are needed to maximize the potential in self-care health data. These should include facilitating the exchange of best practices and expertise between developed and developing countries, and between multi-sectoral stakeholders (e.g., industry, academia, NGOs etc.).

⁸ OECD, [Regulatory effectiveness in the era of digitalisation](#), 2019.

⁹ The [FAIR principles](#) are widely accepted and adopted by scientists and policy makers (e.g. [G20](#) and [EU](#)).

¹⁰ On how co-operation is central to effectiveness and efficiency in digital regulatory policy: OECD, [Regulatory effectiveness in the era of digitalisation](#), 2019.

¹¹ Some examples of innovative and conducive proposals & practices include: (i) use of real world data and real world evidence for regulatory decisions such as new product authorization or product line extension by [EMA, FDA](#); (ii) South Africa Protection of Personal Information Act ([POPIA](#)) 2013, (iii) the common [European Health Data Space](#), and (iv) use of digital tools to satisfy labelling requirements for prescription to OTC switch ([proposal](#)).

2. STANDARDIZING SELF-CARE HEALTH DATA

To get the full potential out of self-care health data, we need common standards, which can facilitate a connected health data ecosystem and help to overcome data fragmentation.¹²

- There is a **need for data quality standards**. The quality of insights depends on the availability of a sufficient volume of high-quality data in data science. The implementation of global data quality standards would therefore enable cross-country collaboration based on high-quality data and ensure the best possible outcomes.
- The health data ecosystem would benefit from a **federated network approach**¹³, which can benefit from the use of individual, private sector and public healthcare data based on the FAIR-ification of data (Findable, Accessible, Interoperable, Re-Usable).¹⁴
- The use of **open application programming interfaces (APIs) should be encouraged to facilitate data sharing and interoperability** for more effective linkages between individuals accessing self-care within the health system.¹⁵ By standardizing information flows across health systems it will also be possible to provide data transparency between patients and healthcare professionals working across health care systems.
- It is also important to work on a common **understanding of terminology** across the industry.¹⁶ This will further promote standardization and consequently generate more high-quality self-care health data.
- The ecosystem would also benefit from introducing harmonized minimum privacy safeguards, requirements and principles for the processing of self-care health data in the context of the activities outlined above.

Taking into account the numerous advantages that are linked to standardization, GSCF advocates for standardization to ensure data quality and allow for FAIR (Findable, Accessible, Interoperable and Re-usable) data, while safeguarding privacy and security.

¹² The WHO "[Global strategy on digital health 2020-2025](#)" also recognizes as a strategic objective promoting standards for safety, security, privacy, interoperability, and the ethical use of data within and outside the health sector.

¹³ See as an example of application of federated network by [EHDEN](#).

¹⁴ See note 9 above.

¹⁵ On the importance of interoperability for digital health, see WHO "[Global strategy on digital health 2020-2025](#)" and WHA Resolution [71.7](#). On the importance of APIs for interoperability, see USA Office of the National Coordinator for Health Information Technology (ONC), [Understanding Emerging API-Based Standards](#).

¹⁶ Expanding for instance on the terminology coined by the [WHO Classification of Digital Health Interventions v 1.0](#).



3. BUILDING AN INCLUSIVE & TRUSTWORTHY DIGITAL SELF-CARE ENVIRONMENT

People are more engaged in their own health, and the role digital technologies can play in supporting it, than ever before. This is a trend that will only increase in the future. However, it is important that no one is left behind.

- **Health and digital literacy are essential** to ensure that everyone can benefit from the advantages that self-care health data brings.¹⁷ **Industry, regulators, healthcare professionals and consumer organizations should make sure that self-care health data is understandable and accessible in a fully anonymized and aggregated format to everyone with a “need to know basis” to access it.** It is an opportunity to enable better use of medicines and treatments. In addition, it would also help to generate more high-quality and standardized self-care health data.
- It is important that regulation supports patient and consumer **access to services and solutions** that would allow them to better manage their health. The fragmentation stemming from data protection practices could be countered by rules on minimum safeguards, permitted data access and sharing and use on a “need to know basis”, which would instill patients’ and consumers’ trust while protecting their privacy.¹⁸ It is also important to foster opportunities for individuals to access remote (telemedicine) solutions and equip healthcare professionals with sufficient data sets for best appropriate treatment solutions and recommendations.

¹⁷ The WHO “[Global strategy on digital health 2020-2025](#)” also recognized the importance of digital health literacy and data ownership to achieve the strategic objective of pursuing a people-centred health system enabled with digital health.

¹⁸ This should apply to all three levels/types of self-care health data: (i) data provided by the individual for their own use (e.g. receive care); (ii) data provided by individuals to be used for “public interest” (depersonalized data used to benefit the community of consumers / patients); (iii) data provided by individuals for uses (i) or (ii) which is anonymized to serve on a larger scale purposes (e.g. research).

- Data collection needs to always rely on a valid legal basis which must have been explicit for data collected and each purpose data is used for. Moreover, policies regarding the use of data must always seek to preserve individual autonomy and empowerment. Individuals should always be aware of their rights and choices regarding their data and have the possibility to correct/remove their data at any point.¹⁹ They must also be able to trust that their data will be handled responsibly and securely. Clear user guidelines for the entire self-care sector would enable individuals to generate and manage their data in an informed manner and understand how choosing to make their anonymized data available for public health objectives is contributing to improving their own health, self-care products and overall public health.
- **Infrastructure investment into digital connectivity**²⁰ by public actors will play an important role in ensuring that the benefits of self-care health (data) reach everyone. This will also help bridge the digital divide by providing people with remote access to data-driven solutions, and in turn, it will feed their own results into data pools to make them more representative.
- To enhance trust in the industry handling self-care health data, **GSCF members commit to taking steps to ensure privacy, prevent bias and discrimination occurring through the use of self-care health data.**

Taking into account the importance of an inclusive and trustworthy environment, GSCF members commit to following the GSCF Principles on Safe and Appropriate Use of Self-care Health Data, and advocate for: the promotion of data literacy; clear rules on data access, sharing in an anonymized way and use to enhance patient and consumer trust; and public infrastructure investment into healthcare connectivity.

¹⁹ To the extent technically possible, as anonymized data can no longer be edited or removed.

²⁰ Including wireless and wired connectivity, both in terms of coverage (e.g. rural areas) and bandwidth (e.g. 5G). For instance: UNDP, [The catalytic role of digital connectivity](#).