



**Transform
Health**

Health for all in the digital age

Protecting data privacy while ensuring health data benefits all

Recommendations for building a global
data governance framework

foundation
BOTNAR

PATH
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Suggested citation: Bennett, A., Deelstra, J., & Goertz, H. *Protecting data privacy while ensuring health data benefits all: Recommendations for building a global data governance framework*. Basel, Switzerland: Fondation Botnar; 2020

Published August 2020



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Acknowledgments

Fondation Botnar, PATH, and Transform Health thank many individuals across different organizations for their contributions. This document was authored by Ashley Bennett, Jacqueline Deelstra, and Hallie Goertz of PATH.

The following individuals participated in key informant interviews that informed this landscape (in alphabetical order): Arundih Burman (Carnegie Endowment for International Peace-India), Lynsey Chediak (World Economic Forum), Francesca Colombo (Organisation for Economic Co-operation and Development), Tiago Cravo Oliveira Hashiguchi (Organisation for Economic Co-operation and Development), Jillian Oderkirk (Organisation for Economic Co-operation and Development), Gabriella Ramos (Organisation for Economic Co-operation and Development), 'Gbenga Sesan (Paradigm Initiative).

The following individuals reviewed and provided feedback on this landscape (in alphabetical order): Darcy Allen (Women Deliver), Marwa Azelmat (Young Experts: Tech 4 Health), Richard Dzikunu (Young Experts: Tech 4 Health), Mathilde Forslund (Transform Health), Louise Holly (The Lancet & Financial Times Commission on Governing Health Futures 2030), Ulla Jasper (Fondation Botnar), Rigveda Kadam (FIND), Kiara Jade Marvuglio (Fondation Botnar), Micaela Neumann (The Lancet & Financial Times Commission on Governing Health Futures 2030), Kate Pundyk (Young Experts: Tech 4 Health), Neema Ringo (PATH), Matt Robinson (PATH), Mijail Santos (The Partnership For Maternal, Newborn & Child Health), Dykki Settle (PATH), Parminder Jeet Singh (IT for Change), Frank Smith (Transform Health), Martin Leschhorn Strebel (Network Medicus Mundi Switzerland), Erica Troncoso (Jhpiego), Akarsh Venkatasubramanian (International Digital Health and Artificial Intelligence Research Collaborative)

This work was funded by Fondation Botnar.

Abbreviations

AFRO	World Health Organization Regional Office for Africa
AI	artificial intelligence
EU	European Union
G7	Group of Seven (international forum for economic cooperation)
G20	Group of Twenty (international forum for economic cooperation)
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
ITU	International Telecommunication Union
LMIC	low- and middle-income country
OECD	Organisation for Economic Co-operation and Development
UHC	universal health coverage
UN	United Nations
WHO	World Health Organization

Foreword

Health in the digital age

Digital health technologies, combined with high-quality data, have the power to accelerate health equity by making health systems stronger, more effective, and more responsive to the needs of the populations they serve. As innovation accelerates, the volume of data that enables digital technologies and powers health decisions is growing exponentially. Data are key to improving health, whether through successfully combating health emergencies or providing ongoing essential health services and primary health care. The way the world governs health data and data for health has never been more pivotal than it is in this digital age.

Health data are any data that relate to the physical or mental health of an individual, or to the provision of health services to the individual. Any personal data that reveal information about an individual's health status, such as immunization status, blood pressure readings and diagnostic results.

Data for health are data that do not specifically describe the health status of individuals, but are used to support health decisions, such as demographic data, telecommunications data, and weather data.

Transform Health

Transform Health was set up to respond to health sector access and delivery challenges by bringing together local, regional, and global stakeholders from multiple sectors dedicated to achieving universal health coverage (UHC) in the digital age. Transform Health is building a global movement that brings together organizations and institutions across different sectors who are committed to achieving UHC within the next ten years by expanding the use of digital technology and increasing access to data. Transform Health campaigns for and collaborates with individuals—particularly women and young people—and communities who would benefit most from the digital transformation of health systems, as well as the governments, organizations, and institutions who recognize and support the fundamental role of digital technologies and data for improved health.

Transform Health commissioned a review of the landscape of data governance regulations and approaches to help determine the role Transform Health can play in harnessing digital transformation to promote UHC. Below are recommendations drawn from that landscape that Transform Health can take to improve global health data governance. Once prioritized and adopted, the individual recommendations can be developed into a comprehensive work plan, with additional input from Transform Health members and other key stakeholders.

Recommendations for Transform Health action

Advocate for greater formal global alignment in health data governance and data privacy

Many policies have been created and launched to govern data at national, regional, and global levels, but these efforts often conflict and overlap, resulting in a global data governance landscape that can be simultaneously ineffective and overly complicated. Through this landscape review, we identified four global approaches to data governance and data privacy, each with powerful regional and national champions.

- **Stringent, individually centered.** Best illustrated by the General Data Protection Regulation (GDPR) and championed by European Union (EU) members, as well as South Africa, India, and subnational regions such as the state of California in the United States.
- **Relaxed, commercially centered.** Used by the United States. Promotes few regulations on the collection or use of data, and privacy guidelines are more relaxed than the GDPR.
- **Stringent, government/state centered.** Embodied by China's current data sovereignty laws. Some components can also be found in other countries, such as Tanzania and India.
- **Relaxed, innovation centered.** Highlighted by Japan at the recent G20 meetings, a 'middle road' approach to data privacy that promotes building trust in technology.

Data privacy is the ability of a citizen to make their own decisions about how their personal data are collected and used. Data privacy is recognized as a key component of the larger body of individual data rights. Individual data rights give people the rights needed to stipulate how their data are used. Beyond data privacy, data rights are seen to include aspects such as the right of people to be secure against unreasonable surveillance and the right to not be unfairly discriminated against on the basis of data.ⁱⁱⁱ

Technology and health care do not follow borders, and many important user populations are not defined by regional or state boundaries. To create an environment where all people, communities, stakeholders, partners, and institutions can share, use, and benefit from data, a collaboratively developed global framework to build connections between these approaches is needed.

Transform Health can use its position to advocate for the development and adoption of a global framework—engaging health experts and technologists in multilateral organizations, government agencies, civil society, the for-profit sector, payer organizations such as insurance schemes, and end users such as women and youth—to help overcome the existing challenges posed by having conflicting and overlapping policies and regulations. This framework does not

have to be one-size-fits-all, but rather can offer a variety of components that can be adopted and adapted to meet specific national and regional needs.

Specifically, Transform Health should align its efforts with the Lancet & Financial Times Commission and explore a deeper engagement with the International Telecommunication Union (ITU) and World Health Organization (WHO).

Champion an equitable, human-centered design approach to data governance regulation

The digital health technology development community often describes its ideal development process as ‘designing with the user’.ⁱⁱⁱ The same approach should be used to design and implement the guidelines, policies, and regulations needed to govern health data and protect privacy. Human-centered design is a creative approach to problem solving that focuses on listening to and co-designing with users so that a solution can be developed that is tailored to their needs. A regulatory framework that is designed without human-centered approaches may mandate actions that are challenging to implement or enforce, making the regulation ineffective. Getting feedback from various stakeholders and iterating on the regulation with their support will lead to regulation that is more likely to be accepted by all parties, leading to better compliance and overall outcomes.

Transform Health can adopt participatory design processes as a core value of its work and ensure that this approach is integrated in all activities and frameworks. Participatory design aligns with the human rights-based approach to global development, which seeks to analyze inequalities that lie at the heart of development problems and redress discriminatory practices and unjust distributions of power that impede development progress.^{iv} Transform Health can work to address the unequal voice that has historically been given to local communities in the development process by using design approaches that value local knowledge and allow for deeply engaging with and listening to end users.^v Specific focus should be placed on ensuring that applications of artificial intelligence are designed with considerations for human rights, ethics, and social good.^{vi}

Lead the community to define a foundation of data governance principles

Starting with principles that communicate the value of an equitable and just approach to data governance provides a baseline of commitment for national governments, global partners, and stakeholders from across all sectors. Although localization and adaptation will always be needed, global alignment on the basics will promote a common understanding of what data governance should accomplish. For example, potential principles may be centered around ethical responsibility, transparent governance, accountability, and equity, and should build on the existing body of literature on data ethics and management.

Transform Health should consider partnerships with the Digital Impact Alliance, the WHO Health Data Collaborative, and other national and regional organizations and entities that are undertaking similar efforts to define common ground for data governance practices. These principles can be modeled on the Principles for Digital Development,² the Principles of Donor Alignment for Digital Health,^{vii} and the Organisation for Economic Co-operation and Development (OECD) Recommendation on Health Data Governance.^{viii}

Develop and promote a health data governance regulation framework

Transform Health should develop a set of health data governance regulations on a foundation of common principles^{ix} that can be refined and adapted to national contexts, health systems, and priorities. This proposed framework is a key component to improving universal data governance and data privacy. The current uneven and inconsistent state of data governance policies is confusing to stakeholders and ineffective for health workers and users at many health system levels. Further, ensuring that data governance regulations are shared across regional and national borders creates transparency and trust not just within a health system but between health systems, removing or reducing barriers to information and data access and sharing. Once developed, normative bodies like WHO, G7/G20, and ITU could promote and provide oversight. See Annex II for more information on policy tools leveraged by various normative bodies.

This health data governance framework should:

- **Bridge the analog and digital worlds, as well as the digital and data worlds.** Although we are moving toward a digital future, currently some health data are collected using only paper-based tools or a combination of paper-based and online tools. Any global framework must ensure that data privacy is protected and health equity is prioritized, regardless of collection modality.
- **Draw attention to health data governance structures as well as policy.** Policies and guidelines can be ineffective when they stand alone without consideration for the people and structures for and in which they are developed and implemented. Political will combined with the sustainability of enacted policy are the pillars of strong governance. This is particularly relevant and necessary for data governance at the national level, though additional support and focus are needed in ensuring that health workers and users at all levels have the access and ability to implement data governance practices.
- **Reduce bias and promote equity.** As innovation in digital technology—and especially automated decision systems—advances, the global health community must ensure that its governance mechanisms do not translate existing systemic biases to the digital world^x or bring in new biases enabled by the biases designed into some digital and data technologies. Further, new and improved data governance mechanisms should promote equity and decolonize^{xi} the way that health data are collected, accessed,

shared, and used. Underrepresented stakeholders may include racial, ethnic, or religious minorities; lesbian/gay/bisexual/trans/queer (LGBTQ) people; disabled people; refugees and migrants; women; or youth and elderly.

- **Include lessons from COVID-19.** The current pandemic has raised both the profile and the urgency of health data governance—as well as the importance of data analytics and data science in using non-health data in pursuit of health objectives. It is critical that the global community not waste this opportunity to enact the policy changes needed to learn from the technological advances made and knowledge gained during the pandemic response, and also to address the dangers to data privacy and to other rights of data subjects that have been exacerbated and uncovered throughout the response.

Transform Health can act in concert with the diverse and inclusive group of stakeholders it mobilizes to develop a global data governance regulation framework. Transform Health should also use its member organizations and Youth Council to promote and connect with stakeholders and communities who have historically been left out of these discussions, ensuring that those leading and designing its advocacy and policy objectives reflect the global citizens, communities, and stakeholders that Transform Health seeks to serve.

This work may also benefit future research needed to articulate and solve how data governance in public health emergencies can inform longer-term progress in the provision of ongoing health services. Further, as the development of this framework progresses, Transform Health can also provide guidance to countries, organizations, and other stakeholders for how to use emergent approaches, in conjunction with WHO, UNICEF, the OECD, and other global bodies and experts.

Beyond data, we know that digital technologies can be an accelerator of equity if applied in the right way. To this end, Transform Health is well placed to advocate for specific improvements in data governance to reduce or eliminate technological bias and other harms (such as targeting and exploitation due to poorly secured health data, identity theft, etc.) by contributing to the efforts to audit guidelines for the data sets used to train algorithms. The OECD guidance on artificial intelligence (AI) principles^{xiii} may provide a useful foundation for this effort.

Engage outside of the formal policymaking process

Health data governance is not keeping up with the speed of digital innovation. Current normative structures, such as the International Health Regulations (IHR) coordinated by WHO, can take almost a decade to be ratified and are often developed through non-inclusive processes that don't engage those who are most impacted by the resulting policies.

Transform Health's position in the global health and development field provides it with governance- and policy-related privileges that official member state governments and the private sector may not have. Transform Health can host and convene a wide range of

stakeholders outside of formal policy negotiations in a way that global multilateral normative bodies have not or cannot.

Transform Health can also support a more agile process to develop a data governance framework that can better respond to today's rapidly changing and often disparate technology landscape. Transform Health can use its platform to propose and advocate for bold changes to global health data governance policy, such as the right to have personal data deleted or not processed, nudging global policymakers to move beyond incremental change to protect data rights and ensuring that all stakeholders benefit equally from health data. Transform Health should also engage new stakeholders and innovators, prioritizing private sector and civil society groups, governments in low- and- middle-income countries (LMICs), and typically underrepresented groups such as young people, women, and racial and ethnic groups.

The connections Transform Health has with adjacent efforts such as the Lancet & Financial Times Commission should also be harnessed to build alignment and buy-in and to engage additional subject matter expertise.

Introduction to the health data governance landscape

Digital, data, and universal health coverage

Health data are governed by a range of instruments, policies, and norms across a multitude of public and private platforms.^{xiii} Dozens of stakeholders, alliances, and partnerships are pushing the world closer to UHC, and many are thinking about how data governance, including data privacy, security, ownership, and sharing –should be used in the service of this goal.^{xiv,xv} The ‘universal’ aspect of UHC requires consideration of how to expand benefits and services, in principle, to all people and communities of the world. Data-led action can inform these efforts but strong health data governance is required to bridge them. Digital technologies also play an accelerating role in UHC, but legal and regulatory infrastructure for the data that those digital tools work with has been inconsistent. That said, around the world there are examples where strong data governance, and data privacy in particular, has fostered trust and brought positive improvements to health care.

To establish where Transform Health can bring the most value in promoting a global health data governance framework, it was first necessary to define what work was already underway, and what could be built upon. Transform Health places a high priority on collaboration and alignment with other organizations conducting similar or adjacent work. Our landscape analysis focused on questions such as:

- What are existing best practices for governing health data?
- What regulations are being implemented and enforced? Why and why not?
- What data governance priorities are being addressed by the global health community? Which need more attention?

Objectives

Conducting a landscape of specific data governance approaches, often captured in policy, uncovers what has already been tried across geographical contexts and governance levels to identify common factors and components. Further, because we sought input through key informant interviews and a survey on what had been done in the past and what could be done in the future, the landscape helped define possible solutions to current barriers.

The landscaping focused on guidance, and also on enforceable or binding data governance, often executed through regulations or policies, which hold those who collect and use data accountable for its privacy, security, ethical use, and equitable benefit sharing. We examined existing analyses and other ongoing work and investigated whether today’s policies, regulations, and frameworks are effective (e.g., whether they are being implemented and followed).

The objectives for this data governance landscape included:

- Reviewing the current state of policy in governance and regulation of health data in global, regional, and national level contexts.
- Identifying strengths and weaknesses, where possible, of existing health data governance policies and schemes.
- Determining gaps in health data governance policy where regulation is missing, inadequate, or in need of updating.
- Defining recommendations for the approach to a global health data governance framework, if one is developed.
- Developing recommendations for Transform Health actions.

The impact of COVID-19

The COVID-19 pandemic has raised the profile of health data governance to new levels, particularly around issues of data privacy, data sharing, and who has access to data.^{xvi} Access to and collection of all types of data during contact tracing has taken many forms, with adapted and novel digital solutions launched every week to contain the spread of the virus. Surveillance of the outbreak, and sharing of the data produced from that surveillance between countries and partners, has raised important questions about who governs data, and how.^{xvii} These questions have generated renewed demand for the global health community to set standards for data governance.^{xviii} The pandemic has brought attention to the importance of ensuring diverse voices are consulted for how data are collected, shared, and used to ensure all populations are represented in and benefit from the data, while also having their privacy protected.

Layers of the review

Globally and locally, health data governance practices are determined by many different regulations and guidelines that operate at different levels of health systems and global governance structures. To meet this complexity, this landscape investigated regulation at various levels. At the global level, the landscape reviewed normative policy and regulatory mechanisms, the work of multilateral organizations such as WHO and OECD, and the objectives and products of global alliances such as the G7/G20 partnership. An analysis of the approach and implementation of the EU General Data Protection Regulation (GDPR) was also included, as this policy is one of the most far-reaching data governance mechanisms in place to date. A few policies from the United States were also added, such as the Health Insurance Portability and Accountability Act (HIPAA) and a selection of state-based data protection laws.

To examine how data governance regulation was established and implemented at the regional level, we selected the African Region (AFRO) as designated by WHO.^{xix} To address data governance at the national level, we investigated the national data governance enabling environments in India and Tanzania. These two countries provide an interesting comparison—

both are pursuing stronger data protection policies, but their epidemiological burdens are quite different, as are factors such as population density, government decentralization, and local technology sectors. These geographies were selected for analysis based on the interests of Transform Health. Although restricting the landscape to these contexts created natural limitations as discussed below, the data governance world is large and it was necessary to define guardrails for this analysis in order for its conclusions to be effective.

Results

Through the landscape we identified 113 documents from across sectors, including copies of the policies themselves, peer-reviewed journal articles, guidance documents, and reports on data governance topics. (See Annex I for additional information on the literature review literature review.) Six key informant interviews were conducted with ten experts from the multilateral, government, and nonprofit sectors. Six respondents also completed the online survey in full.

Data governance policy and regulatory approaches

The policies and regulations addressed in the review ranged widely, from formal data protection and data security policies within national or regional contexts, such as the US HIPAA law,^{xx} the EU GDPR, and India's forthcoming Personal Data Protection legislation, to governance guidance on a variety of data governance topics, such as the global guidelines developed by WHO and OECD on health data governance, AI principles,^{xxi} and privacy standards.

From key informant interviews and the literature review, four distinct approaches to data governance, data privacy, and data rights emerged and were repeatedly mentioned. Each was championed by a country who was promoting their preferred approach, and each approach varied by its level of protection:

- **Stringent, individually centered.** Best illustrated by the GDPR and championed by EU members, as well as South Africa, India,^{xxii} and subnational regions such as the state of California in the United States.
- **Relaxed, commercially centered.** Promotes few regulations on the collection or use of data, and privacy guidelines are more relaxed than the GDPR. These countries often have a series of regulations that were created to quickly address narrow data privacy concerns rather than establishing a more concrete, overarching data governance framework and philosophy. The United States is an example of this approach, with patchwork policies such as HIPAA for governing health data, the Family Educational Rights and Privacy Act (FERPA) for governing education data, and the Fair Credit Reporting Act (FCRA) for governing consumer credit data.
- **Stringent, government/state centered.** Embodied by China's current data sovereignty laws. Some components can also be found in other countries, such as Tanzania and India.
- **Relaxed, innovation centered.** Highlighted by Japan at the recent G20 meetings, a 'middle road' approach to data privacy that promotes building trust in technology.

The approach in the EU, best illustrated by the GDPR, was cited most frequently. It was mentioned both in survey responses and in interviews as a model policy and standard for effective data governance, because it has refined the definition for data protection and has established vital obligations around accountability. The US approach promotes fewer

regulations on the use of data, and its privacy guidelines are more relaxed than the GDPR.^{xxiii} For example, when GDPR was being drafted, there was a risk that public services such as cancer registries would be blocked from operating due to GDPR's stringent protections on privacy.

GDPR centers data privacy on the rights of the individual, particularly through its data privacy 'bill of rights,' which gives individuals control over how their data are collected, managed, and used. On the other end of the spectrum is China, which was mentioned in two interviews as being a separate model for data privacy, one that is centered on the power of the government to control and use data. Finally, Japan was highlighted as a leader in driving a 'middle road' approach to data privacy titled 'free data flows with trust,' which borrows some of the tenets of the GDPR while also adhering to the US priority of ensuring free flow of data, especially for commercial use, without major privacy restrictions. However, Japan is also grappling with how to balance the need to share data widely, against the need to protect the privacy of individuals. Japan is also the prior leader of the G20 partnership of nations and used this platform to promote this middle road approach to data privacy. It remains to be seen whether the current G20 leader, Saudi Arabia, will continue on the same path.

African Region

In the African Region, as defined by WHO, countries have followed the lead of regional bodies such as the Economic Community of West African States (ECOWAS)^{xxiv} and the Southern African Development Community (SADC)^{xxv} in developing data protection policies that cover common elements such as individual rights and the creation of data protection authorities. Data governance and privacy challenges in Africa are similar to those seen across the globe, including identity theft, data breaches, and cyber incidents that lead to public mistrust in how governments and private entities manage private data. Many countries in this region have been influenced by China's and Russia's stringent, state-centered approaches to data governance and violate digital rights in order to use data for surveillance and other purposes without express consent.^{xxvi} Key informants expressed concern that the COVID-19 pandemic has given governments a reason to further crack down on digital rights and increase surveillance and said that it may be difficult to reverse this course once the pandemic has subsided. This issue is not unique to the African Region, but we noted that it is a key concern of data rights activists in countries such as Nigeria.

In East Africa, the Digital REACH (Regional East African Community Health) partnership has committed to develop an East African Health Cloud as well as regionally coordinated surveillance and research programs, which will require data governance regulations to secure the necessary data sharing.^{xxvii} The African Centres for Disease Control and Prevention also supported efforts to improve data sharing and use across borders to support disease surveillance. While numerous countries in the region have adopted national-level data protection policies and have a data protection authority or agency, countries have been slower to coordinate data sharing at the regional level. In addition, many countries, such as Rwanda, continue to be challenged by data breaches and abuse of data, which has led to a decrease in trust of the data collection system. It was clear that countries do borrow and adapt the policies

of their neighbors, even when there is no coordinated collaboration.^{xxvi} To support more formal collaboration there is a need to share and amplify effective policies in regional and global venues that support peer-to-peer sharing.

Tanzania

Tanzania has implemented a variety of policies governing data sharing and data privacy, although many are several years old. These include the Electronic and Postal Communications Act of 2010, the HIV and AIDS (Prevention and Control) Act of 2008, the Universal Communication Service Access Act of 2006, and the Banking and Financial Institutions Act, also of 2006. Many of these examples are from outside of the health sector, as Tanzania's data regulatory authority is dispersed between several agencies and offices. Recently, Tanzania launched its new National Digital Health Strategy, which includes a guide for the development of policies and guidelines related to data management, sharing, access, and privacy at different levels of its health system. The country is also finalizing the Tanzania Data Protection Act, which will combine and define privacy provisions across sectors, including health, and is expected to align with pieces of the EU GDPR and legislation from India and South Africa. Since starting the Data Use Partnership (a Tanzania government-led initiative to improve the national health care system through better use of health information) in 2017, the country has also released plans for its enterprise architecture, which also includes guidelines and definitions on the flow of data and controls around access and standards. Tanzania is a good example of the opportunities to align technological guidelines for digital tools and systems, data policy, and data-led decision-making.

India

In India, much of the data governance focus has been on the Personal Data Protection Bill,^{xxviii,xxix} currently stalled in Parliament, which imposes requirements for data protection on most businesses and provides a statement of individual data rights. Concerns remain, however, on the exemptions that exist for the government to collect and use data without notifying citizens.^{xxx} India's policy arc started with a focus on Aadhaar, a unique identification system, and the privacy needs surrounding enrollment and data use, with its Supreme Court determining formally that individuals have a constitutional right to privacy.^{xxxi} India's legislation is most commonly compared to the EU GDPR.²⁸ Compared to the GDPR, India's policy gives more discretion to national data authorities to determine standards, and it extends protection to inferred data, which has a high commercial value. Because of India's large export industry and its growing commercial sector, the new law will be one of the most globally influential data governance policies when it is enacted. India has enacted a detailed roadmap for technical standards and general processes for health data access, sharing, and repositories through its National Digital Health Blueprint.^{xxxii} India is also the only country veering toward recognition of some kind of collective community rights to data. 'Community rights' is mentioned in its draft e-commerce policy and in the terms of reference for a committee of experts exploring frameworks of governance for non-personal data. The connection from this concept of 'community rights' to health data, however, has not yet been made.^{xxxiii,xxxiv}

Ownership and implementation

One of the aims of this landscape was to identify what regulatory mechanisms could be used to house a global health data governance framework. Essentially, who should own and drive a framework forward and who should be accountable for its development and progress?

Although there was no consensus on where a framework should be housed, interviewees and survey respondents stated that national governments and civil society should have a leadership role in the process to develop a global framework leveraging a human-centered design approach.

Further, the WHO was mentioned in nearly every interview as a stakeholder who will need to be involved if such a framework is to have the credibility necessary for successful implementation and adoption. Other global stakeholders who were also mentioned included the OECD and the US Centers for Disease Control and Prevention (CDC). There are limitations to any one owner. OECD's focus is on a subset of high-income countries, though it covers a broad range of sectors. Since WHO has a global mandate, it is well positioned to be the primary driver. Both agencies have conducted extensive work in data management and privacy.

In terms of measuring the effectiveness of the regulations reviewed in the landscape, several experts have begun to analyze the enforcement success of the EU GDPR. These analyses are focusing on concerns that insufficient resourcing of and cooperation among data protection authorities have led to administrative backlog and public perception that GDPR is not being effectively enforced.^{xxxv} With GDPR being just two years into implementation, it is seen as a work in progress in terms of compliance and enforcement, but also noted for its success in bringing attention to individual data rights and providing a framework for other geographies to adapt and replicate.^{xxxvi} These are lessons that will need to be translated to any global health data governance framework that is created.

Desired global framework components

There were several items that multiple interviewees, survey respondents, and articles mentioned as important to consider as framework components,^{ix} based on the success of or challenges with earlier policies:

- Common, harmonized global framework based on vetted principles.
- Common definition of data ownership and privacy. [Note: this was most frequently aligned with the data privacy bill of rights in the GDPR.^{xxxvii}]
- Strong data collection, access, and sharing policies that delineate who has view permissions and edit permissions.
- Guidance on digital identifiers.
- Mechanisms of notification and accountability for when data breaches occur.
- Consideration around security for individuals and how data are accessed and used.

- Ensured ability to use data for research purposes is human-rights based and applies informed consent procedures.
- Coordinated plan for managing large volumes of data that has clear guidelines based on globally accepted standards.
- Clear guidance on how to govern emergency data collection and use powers, particularly when data are collected using digital tools. This guidance should specifically address how long these emergency measures can remain in place, how to determine when governments must revert back to standard practice, and considerations for data collection in humanitarian contexts where non-state actors may also play a prominent role in collecting sensitive data.^{xxxviii}
- Anti-discrimination guidelines and requirements for owners of digital data collection tools to be transparent about their processes, with additional foci on gender and vulnerable population equity.
- “People-centered” policy framework approach.
- Norms and frameworks of ownership not only of data but also of the benefits from various data-based processes for the relevant data subjects—both individuals and communities. Such benefits have to be justly and equitably shared, with specific regard to the original sources and subjects of data.
- Approach that considers ‘digital’ and ‘data’ governance to be part of one governance continuum.^{ix}

Analysis and discussion

Several themes emerged from the landscape beyond the review of data governance approaches and components. Many addressed common challenges that improved data governance measures could address, or failings in previous policy efforts:

- **There are too many conflicting data governance approaches and policies, which are simultaneously too restrictive yet also ineffective.** This occurs because of a lack of support and political will. Health systems are awash with data; a lack of data is not the challenge. Instead, the global health community lacks policies to support data collection, management, and use for the public good. Strong regulation is important to combat misuse of data, data privacy breaches, and use of data to stigmatize illness.
- **Enforcement of current data privacy protection is difficult.** One key informant noted that “there are actual public health harms when data are not protected”. As discussed above, accountability and enforcement are complicated precisely because of the wide range of regulations, many of which are not enforced. For example, compliance with OECD recommendations is not legally enforceable, though members do agree to adhere to them and report on progress. Enforcement represents an area of great potential for improvement, and even with the best protections, breaches may still occur.
- **Trust in data collection is low due to the lack of strong feedback loops.** Particularly for data collection conducted through digital tools, several sources noted a lack of trust was common when data—or insights from that data—were not shared back in some way with the population from which they were collected. As Tiffin et al.^{xxxix} state, the historical systems of data mining moved in only one direction: up. If this system is not addressed through data governance, communities will see no clear benefit to adopting data sharing models, and they will be reluctant to participate.
- **Differing ideas on data sovereignty.** Many national policies consider data to be the property of the government, not the individual nor parties outside of the country’s borders. India’s current and proposed laws require certain types of data to be stored on servers located in the country. There were also concerns cited in East Africa literature about regional collaboration on surveillance and data sharing due to data sovereignty considerations, despite ongoing global partnership efforts.^{xxvii} The approaches championed by Japan and the United States would loosen such restrictions, but there is a risk that countries could lose any control over what data are collected on populations within their borders. Key informants noted that one solution to this challenge could be aligning data privacy policies with the enterprise architecture of national health information systems to ensure that data can be efficiently accessed by the government and other stakeholders while ensuring privacy protections remain intact.

Further building on the list of ideal framework components above, the key informants in particular provided great detail on several areas where they see potential for improvement in global data governance, with some notable limitations:

- **True engagement of the private, for-profit sector in data governance.** One noted challenge was how to adequately enforce offline principles in an online environment, especially environments that are proprietary and privately owned. Facebook was given as a relevant example of this type of community. In the United States and a handful of other countries, regional collaboration for similar communities can be accomplished through a federated data system; however, that is not possible everywhere. Further, many existing regulations, such as the US HIPAA rule, do not cover the ‘internet of things’ and other privately owned digital technologies which collect large volumes of health data. Several informants noted the real risk that companies who are able to harvest large, relatively unprotected volumes of data are at a significant advantage in determining how data are used and protected.

“Facebook is not a country, but it has over 2 billion people.” – ‘Gbenga Sesan, Paradigm Initiative

Despite these challenges, informants all emphasized that the private sector must be included in the development of any data governance frameworks, partly because the speed of technological change is driven by the private sector. Although many global normative bodies do not have strong formal relationships with the private sector, in the informants’ view it is in the best interest of governments to work with the private sector on data governance, or risk being left behind while the private sector creates parallel data processes and rules. Managing these engagements was viewed as a big challenge for governments because many do not have the expertise or experience to navigate large partnerships with the private sector, particularly multinational companies. Private-sector organizations may also resist partnering with governments on any data regulations because they benefit financially from environments that allow them to use and sell personal data with limited restrictions. However, these difficulties represent an opportunity to closely collaborate with the private sector in developing a framework as well as supporting national-level governance so that countries are better equipped to align partnership activities with their national priorities.

- **Underrepresentation and inequity.** The importance of reducing bias and increasing inclusive participation in data governance and particularly digital data governance was mentioned across all of the data collection sources. Biases in technology have been well documented, and both key informants and the literature warned against translating our analog biases to the digital world.^{x1} Beyond the digital connectivity divide, key informants also noted that the design and deployment of new technologies is shaped by who has access to big data and who can transcend regulatory

frameworks. These issues need to be addressed through any data governance frameworks.

Survey respondents were asked to explain who they currently believe are adequately consulted in the development of data governance policies and which actors are still largely left out. Respondents agreed that governments and medical organizations or councils such as the Centers for Disease Control and Prevention play the biggest role. On the other hand, medical professionals, individual citizens, and civil society groups are not seen to play a large enough role in designing policies.

This was also the case for women, historically marginalized and vulnerable populations, and youth. Women in particular were seen as overrepresented in informal industries, and therefore often not tracked by data collection systems or engaged in the design of health systems. Language was also flagged as a barrier to inclusion; according to respondents, many of the high-level dialogues on digital and data governance and rights occur in English, effectively leaving out a large part of the global populace. Still others noted that the centers of decision-making in data governance are frequently far from the communities that these policies are intended to impact. However, respondents did emphasize that this is something that can be addressed through better data governance and through better governance of the digital health sector as a whole. As one informant from OECD noted, there is a serious lack of equity in the digital economy today, and the global community needs to avoid building a world that perpetuates or exacerbates unequal outcomes through digital and data means.

- **Policy must keep up with innovation.** The final opportunity noted by respondents was the desire to create data governance mechanisms that are technology neutral and can stay relevant for regulating future innovation, either through frequent strategy renewals or by enforcing existing regulations more efficiently. When new regulation is needed, consider a model like that of OECD/Singapore—a regulatory ‘sandbox’ where experts are able to test regulations in a controlled environment to see what the effects are. Using similar means, Transform Health could partner with governments and other stakeholders to test how improved data governance regulation could work. This could include framework laws that provide the larger legal framework and principles, with adequate flexibility for rapid changes and evolution in actual rules and regulation to account for such a fast-moving policy and regulatory area.

COVID-19 considerations

The current COVID-19 outbreak was mentioned in every key informant interview and most survey responses. The literature on the topic of data governance related to COVID-19 is currently thin because it is a new research focus, and relatively little peer-reviewed literature has been published on the pandemic thus far. However, that has not deterred several global normative bodies from issuing guidance to address this challenge, including WHO and the European Commission.^{xvii} Grey literature surveyed suggested that data governance challenges

associated with COVID-19 are bigger, but not new.^{xii} Experts have noted that the challenges presented by COVID-19 are similar to those faced by the humanitarian sector.^{xliii} Informants also noted that the rate of data flow has exponentially increased, benefiting the pandemic response but requiring significant time to support collaborations and overall data management.

Other considerations related to COVID-19 raised through the landscape include:

- The speed at which governments are able to take on and relinquish emergency powers. Governance mechanisms will be required to define how emergency data collection and use measures are phased out as the pandemic subsides, and to prevent misuse during the pandemic.
- Data sharing during a pandemic can be complicated. Respondents encouraged stakeholders to continue to be vigilant about proactively defining where and how data are shared.
- Governments have used emergency powers to push through policy changes in order to use private sector technologies to collect and share sensitive health data. One example is HIPAA's incorporation of new technologies including WhatsApp, Facebook Messenger, and Zoom as permissible for telehealth services. Experts have noted that this policy change was made rapidly without full review of potential vulnerabilities associated with these sensitive data and that it will be difficult to reverse and will likely remain permanent. This could have far-reaching implications for future health data policy and regulation of private sector technologies^{xliiii}
- Public health authorities are realizing that standards of reporting vary within health systems. Without a renewed commitment to using similar data structures, it is impossible to have national-level aggregated data. This can result in a backlog of records that are not properly structured, creating huge reporting delays and gaps in information. Some facilities are taking the steps to restructure data standards, but it will take time.

Gaps in the landscape

The grey literature reviewed for this landscape often focused on specific elements of certain policies or how they differ from policies in other countries or regions, rather than the status of implementation, how effective the policies were, or how different stakeholders are regulated. There is also ample discussion in the literature about concerns regarding what is included in current policies or how they are drafted, but little significant evidence yet to support these hypotheses or discussions beyond what has been mentioned here. Much data governance, data privacy, and data rights legislation is still in draft form—which is important because there is no way to know what is currently included in the actual draft legislation.

The interviews and survey results came from representatives of international governments, multilateral actors, and nongovernmental organizations. Future efforts could focus on gathering additional input from civil society organizations, patient rights groups, or other grassroots

organizations, including those based in LMICs. It would also be wise to directly engage the for-profit private sector, both at the subnational level and at the global level.

Further, future research could explore parallel processes that may be happening in other topical areas, such as education, to compare learnings and processes. Broadening engagement and understanding could help further define best practices for a global data governance framework.

This landscape and the recommendations did not specifically consider healthcare delivery in humanitarian settings, including questions of how data management and privacy requirements are realized in circumstances where it is difficult to maintain the informed consent of vulnerable populations and where information security is difficult to ensure. Future research also should look more closely at data management considerations specifically related to the use of artificial intelligence and other automated decision systems in healthcare as this area continues to develop and more literature is available on this topic.

Glossary

DATA FOR HEALTH. Data that do not specifically describe the health status of individuals, but are used to support health decisions, such as demographic data, telecommunications data, and weather data.

DATA GOVERNANCE. The overall management of the availability, usability, integrity, and security of data used in an enterprise. A sound data governance program includes a governing body or council, a defined set of procedures, and a plan to execute those procedures.^{xliv}

DATA PRIVACY. Ability of a citizen to make their own decisions about how their personal data are collected and used.

DATA PROTECTION. Measures that keep data safe from unauthorized access.^{xliv}

DATA RIGHTS. Refers to rights that have been detailed for individuals that state what control they should have over how their data are collected, processed, and used. The EU's General Data Protection Regulation (GDPR) outlines eight individual data rights that include rights to be informed; of access; to rectification; to erasure; to restrict processing; to data portability; to object; and in relation to automated decision-making and profiling.

DECOLONIZE. Decolonizing global health and development involves identifying and disabling assumptions constructed during colonial times regarding racial and civilizational hierarchies. It also involves defining, identifying, and disabling problematic structures of privilege that have informed programming, funding, and operations in the sector.^{xlvi}

DIGITAL AGE. The digital age is defined by the introduction of computers and the resulting availability of large amounts of information. As we have progressed into the digital age, digital technology has been accepted as mainstream and is on its way to being fully immersed in our society rather than being thought of as a separate consideration (e.g., we will move from labeling activities as 'digital health' to digital technologies just being part of standard health care).

DIGITAL HEALTH. The systematic application of information and communications technologies, computer science, and data to support informed decision-making by individuals, the health workforce, and health systems, to strengthen resilience to disease and improve health and wellness for all.

HEALTH DATA. Any data that relate to the physical or mental health of an individual, or to the provision of health services to the individual. Any personal data that reveal information about an individual's health status, such as immunization status, blood pressure readings and diagnostic results.

HUMAN-CENTERED DESIGN. A creative approach to problem solving that focuses on listening to and co-designing with the intended users so that a solution can be developed that is tailored to their needs.

PERSONAL DATA. Any information that can help to identify you as a person.

POLICY FRAMEWORK. Set of principles and long-term goals that form the basis of making rules and guidelines and give overall direction to planning and development for an organization.

STAKEHOLDER. Any person who is affected by or interested in the consequences of a campaign, project, or other intervention; stakeholders include the planning team, end users, beneficiaries, and funders.

UNIVERSAL HEALTH COVERAGE. When all people and communities can use the promotive, preventive, curative, rehabilitative, and palliative health services they need, of sufficient quality to be effective, while ensuring that the use of these services does not expose the user to financial hardship.

Annexes

Annex I. Landscape review methodology

This landscape used a mixed methods approach including reviewing literature, conducting key informant interviews, and collecting survey data.

Layers of the review

The landscape focused on three layers of data governance: the global level, including the work of multilateral organizations such as the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD); the regional level via the African Region; and the national-level contexts of India and Tanzania. Select regulations from the United States and Europe were also included in the landscape to examine the influence and implementation of the EU General Data Protection Regulation (GDPR) and the US Health Insurance Portability and Accountability Act (HIPAA).

Our research questions, which formed the basis of all data collection approaches, included for example:

- What are the existing best practices for governing health data?
- Where are regulations being used or not being used, and why? Who is being held accountable, or not being held accountable, for the use and misuse of data?
- What health data governance needs are priorities for the global health community? What is being addressed, and what isn't?
- What are the barriers to future regulation of health data? What is still needed to address data governance in public health emergencies while also accelerating progress toward universal health coverage?
- What governance adaptations are possible, or will need to be made, as digital innovation accelerates?

Key informant interviews

After consultation with members of the Transform Health Data Policy Circle, inquiries for key informant interviews were sent to several experts and organizations with technical expertise in data governance and digital rights. Six key informant interviews were conducted with experts from the OECD, the Government of India, the Carnegie Endowment for International Peace, the World Economic Forum, and the Paradigm Initiative.

Survey

To complement and supplement the literature review and key informant interviews, and to broaden the base of input from individuals with subject matter expertise in data governance,

data privacy, and digital health, we developed a survey and sent it to a list of experts and members of the digital health community, including the Governance Small Working Group of the Digital Health and Interoperability Working Group housed by the WHO Health Data Collaborative. Over two dozen responses were received. We received complete responses from six individuals and organizations from India, Tanzania, Estonia, and Canada.

Literature review

To investigate the landscape of health data governance regulations and their privacy implications, a review of existing literature was conducted using the methods below. The literature review was restricted to grey literature and peer-reviewed journal publications that addressed the geographical layers as described above.^{xlvii}

Key terms

For the purposes of this landscaping, 'health data' refers to 1) any data that relate to the physical or mental health of an individual, or to the provision of health services to the individual and any personal data that reveal information about an individual's health status, such as immunization status, blood pressure readings and diagnostic results., and 2) compiled 'health data' from communities, research subject cohorts, health program clients, health facilities, administrative regions (districts, provinces, villages, etc.), or other groupings up to the national level of a health system.

Search methods

Peer-reviewed published literature. Web searches of PubMed, *The Lancet*, and *WHO Bulletin* special series on digital and data, and PATH digital and data governance white paper citations.

Grey literature. WHO and OECD libraries, reports from the Centre for International Governance Innovation (CIGI), International Association of Privacy Professionals (IAPP) resources on COVID-19 data preparedness, and PATH digital and data governance white paper citations. Hand searches were also conducted of national-level official policy files and the eHealth strategy inventory.

Snowball sampling. Using literature identified through the methods described above, the research team also examined citations and references for additional resources. References from key informants were pursued to reveal additional sources of information.

Limitations

To establish guidelines for the landscape review, we adhered to the following scope limitations:

- The landscape did not review regional, national, or subnational regulations and policies aside from the African Region and the national contexts of Tanzania and India.
- The landscape restricted its review of US policy to the most widely cited data privacy policies.

- For multilateral organizations and alliances, the landscape limited its review to regulations or guidelines produced by WHO, OECD, G7/G20, and United Nations agencies.
- Proprietary private-sector policies were not included in the landscape. The review focused on public-sector regulations and publicly accessible grey literature.
- Reports and other documentation that did not regulate or suggest regulations of data were considered out of scope.
- Finally, although the report recommendations include suggestions for how the regulatory landscape for health data governance could be improved, the landscape review did not seek to define what the text of a regulatory policy or governance framework should entail.

Due to the COVID-19 outbreak, we were unable to reach as many respondents using the survey as we had hoped to. This may be an item that Transform Health can address through future research. We also were not able to reach certain types of key informants we had hoped to interview, such as the private-sector representatives.

Annex II. Global policy tools

At the global level, a number of potential avenues exist for policy change to accelerate digital health transformation in pursuit of universal health coverage. Each of these potential approaches differs slightly across a few key defining characteristics and has unique advantages and drawbacks that impact both the type and speed of change that can be achieved.

Defining characteristics

Scope. Each policy mechanism is inherently bound by the legal authorities under which it is approved or endorsed. For example, resolutions passed by the World Health Assembly are limited in scope to the health mandate of the World Health Organization. Similarly, resolutions passed by the World Trade Organization Council are limited to matters directly related to trade. As a result, many issues have migrated to less restrictive or less formalized mechanisms such as the G7/G20 and the UN General Assembly given the much broader mandate of those organizations and the greater flexibility this allows.

Mechanism. As noted above, global policy mechanisms vary greatly in their mandates, and similarly vary greatly in the actual policymaking mechanism, although there are some broad similarities across the sector. Generally speaking, all global policy mechanisms are member state (or national government) driven and member states are the formal voting members of the bodies that pass policies. Having said that, the exact process and power dynamics of each agency or mechanism vary in their specifics and thus impact the feasibility of particularly contentious policy changes.

Enforceability. Related to the legal status of the policy change mechanism, the various mechanisms available have varying degrees of legal enforceability as well as scope of enforceability. Resolutions passed by the governing bodies of UN technical agencies (such as WHO, ITU, etc.), for example, are only binding on that institution and not on member states or other bodies. General Assembly resolutions can be binding on member states if the text can be successfully negotiated. On the other end of the spectrum, G7 and G20 declarations have no legal enforceability whatsoever. This difference in legal status has clear implications, especially for concerns around data privacy and appropriate safeguards.

Timeline. It goes without saying, but the confluence of scope, enactment mechanism, and concerns about enforceability has a profound impact on the time required to successfully navigate the policy development and enactment process, with commensurate impact on the resources required to support the effort.

Examples of global policy tools

Type of policy tool	Scope	Mechanism	Enforceability	Timeline
<p>UN General Assembly Resolution: United Nations General Assembly (UNGA) resolutions are arguably the “gold standard” of global policy. They are passed by the full UNGA and represent a unified expression of global will.</p>	<p>UNGA resolutions are limited in scope only by the will of member states and their capacity to achieve a negotiated consensus.</p>	<p>UNGA resolutions must be agreed on a consensus (or at least non-objection) basis by all UN member states. Even a single objector can exercise veto authority and prevent passage of a resolution, though the political consequences of doing so are severe. Resolutions must be proposed and championed by member states, and the space for civil society to formally engage in the process is very limited.</p>	<p>As the expression of all UN member states, UNGA resolutions can be framed as legally binding commitments, though they can also be framed as simple calls for member states to undertake certain actions. The distinction is entirely down to how the specific resolution language is framed.</p>	<p>UNGA resolutions typically take 24–36 months from inception to approval, assuming that consensus can be reached among member states.</p>
<p>UN Technical Agency Resolution: Within the UN system a number of technical (or “specialized”) agencies have specific mandates over technical fields such as health, telecommunications, trade, and other areas. Each of these agencies has its own governance body and process for promulgating global standards and norms for that technical field.</p>	<p>Each agency’s mandate is strictly limited to the technical area defined in its charter. As a result, any resolutions or standards put forward by that agency or its governing bodies must be limited to that specific scope. The World Health Assembly (the governing body of the World Health Organization [WHO]) can only pass resolutions related specifically to health, for example.</p>	<p>Speaking broadly, UN technical agencies’ governing bodies—who are responsible for passing policy changes—consist of member states, and pass resolutions either by majority voting or by consensus. The approach to civil society’s involvement in the process, however, varies greatly by agency. The International Telecommunications Union (ITU) explicitly provides for a civil society/industry advisory group with formal standing, whereas WHO only allows civil society as observers.</p>	<p>Resolutions passed by the governing bodies of UN technical agencies are only binding on that specific agency. They can provide guidance and lend a voice to calls for member states to take actions, but this is not enforceable.</p>	<p>Resolutions by technical agency governing bodies typically take at least 12–24 months, though particularly contentious topics can drag on for years.</p>

Type of policy tool	Scope	Mechanism	Enforceability	Timeline
<p>Joint UN Technical Agency Agreement: For a variety of topics, no one UN agency has the full mandate necessary to address the issue, as in the case of the intersection of trade and health. In these cases, multiple UN agencies can enter into a formal agreement to work collaboratively within their mandates to fully address the topic. A leading example of this type of agreement is the World Health Organization–World Trade Organization–World Intellectual Property Organization tripartite agreement on trade, intellectual property, and health.</p>	<p>The scope of such multipartite agreements is defined by the combined mandate/scope of the agencies and groups party to them.</p>	<p>Multipartite agreements must first be negotiated by the agencies involved, and then approved by those agencies’ governing bodies, composed of member states.</p>	<p>Similar to single-agency resolutions, multipartite agreements are only binding on the agencies themselves, not on member states.</p>	<p>Given the multiple approval and negotiation processes involved, agreements across agencies typically take longer than single agency resolutions, and span across annual governance cycles. A reasonable assumption for a relatively non-controversial topic is 3–4 years.</p>
<p>G7/G20 Declarations/Frameworks: Unique from international agreements under the auspices of various parts of the UN system, the G7 and G20 also traditionally produce declarations or calls to action at their annual meetings.</p>	<p>Declarations are unlimited in scope, though they are typically tied to the priority agenda items defined by each country’s presidency of that session.</p>	<p>As discussion or consultative bodies, the G7 and G20 undertake a somewhat more informal process than other international forums. Each session proceeds slightly differently, though generally speaking declarations are drafted to reflect the priorities of that year’s president as well as the content of the discussions held in the run-up to the meeting.</p>	<p>G7 and G20 declarations are not enforceable at all and only represent a statement of the consensus of the attendees at that meeting.</p>	<p>Declarations are actually one of the most rapidly-moving international policy tools. They are typically agreed in a 3–6 month process in advance of the annual meeting and endorsed by heads of state at that meeting.</p>

Type of policy tool	Scope	Mechanism	Enforceability	Timeline
<p>Framework Convention/ Treaty: Framework conventions or treaties are arguably the most reliably enforceable global policy instrument. The most prominent example is the Framework Convention on Tobacco Control.</p>	<p>Conventions or treaties are limited in scope only by what can be successfully negotiated among countries. Similar to multipartite agency agreements they may also include multiple UN agencies as implementing partners to the agreement.</p>	<p>As an agreement between countries, conventions must be agreed by them. Unlike other policy instruments, however, treaties must also then be ratified or approved through whatever national processes are required in each country in order to enter into effect for that country.</p>	<p>Conventions and treaties are legally binding and enforceable for countries who have ratified/approved/acceded to them. This makes them a powerful tool for change, but also creates barriers to negotiating them.</p>	<p>Given their enforceability, treaties and conventions are the most arduous international policy instrument to negotiate. A meaningful convention can take a decade or more to negotiate, followed by a further period of waiting for countries to ratify the treaty before it becomes binding.</p>

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