Implementation Guide for using the Model Law on Health Data Governance to Strengthen National Frameworks

SECTION 9: COMMUNITIES' RIGHTS IN THEIR COMMUNITY HEALTH DATA

This section establishes the legal framework for recognizing and protecting the rights of communities in relation to their collective health data. The section ensures that communities have a formal, recognized role in the management and decision-making processes concerning their community health data, thus safeguarding their collective interests.

At the core of this section is the principle that communities should have control over how their health data is used, shared, and managed. This is facilitated through the establishment of representative bodies that act on behalf of the community, ensuring that the community's voice is central to any decisions made regarding their health data.

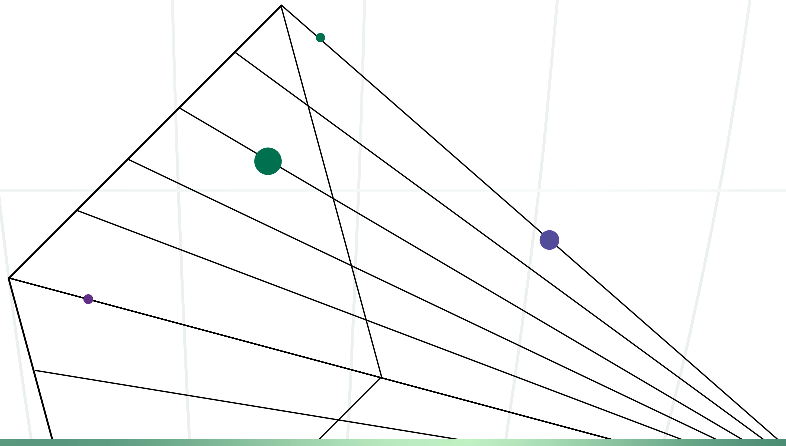
The section also emphasizes the protection of individual rights within the community framework, ensuring that collective decisions do not override the rights of individual community members as established under existing data protection laws. Additionally, mechanisms are provided for resolving disputes within the community, including the right of individual members to seek recourse if they disagree with decisions made by the representative body.

By recognizing communities as key stakeholders in the governance of their health data, this section promotes a more equitable, inclusive, and respectful approach to health data governance, aligning with broader goals of social justice and community empowerment.

KEY DEFINITIONS

Community is defined as a group of individuals who share a common geographic location, heritage, culture, or social identity, and who collectively contribute to health data and includes but is not limited to indigenous communities, patient groups with specific health conditions, and populations within a defined geographical area.

Community health data is a subset of health data that contain information that is significant to the identity, heritage, cultural practices, or collective health of a community as a whole. Note that **community health data** may / may not overlap with personal health data.



RATIONALE

COMMUNITY REPRESENTATION

This provision ensures that communities, which consist of individuals sharing common geographical, cultural, or social identities, have a formal and recognized way to participate in decisions regarding their collective health data. By acting through a representative body, the community's interests are collectively managed and protected under this model law. Community health data often reflects sensitive and culturally significant information. Empowering communities to have a say in how their data is used aligns with principles of autonomy, respect, and collective rights. It helps safeguard against the exploitation of such data and ensures that the community benefits from its use.

ESTABLISHMENT OF REPRESENTATIVE BODIES

This provision mandates the relevant national authority to establish clear and transparent criteria through subsidiary legislation for recognizing representative bodies. It also ensures that mechanisms are put in place to support the effective functioning of these bodies. Representative bodies must be legitimate and effectively operational to genuinely represent the community's interests. Transparent criteria for their recognition and support mechanisms are essential for maintaining trust in the governance of community health data and ensuring that these bodies can function independently and effectively.

COMMUNITY CONSENT FOR DATA PROCESSING

The requirement that a community's health data can only be processed with the community's consent ensures that the community has control over how its data is used. This consent can be conditional, providing communities with leverage to negotiate benefits or protections. Consent is a foundational principle of data protection. For communities, particularly marginalized or indigenous groups, this consent requirement is vital for protecting their collective rights and ensuring that data use aligns with their values and interests.

CONDITIONAL CONSENT

Allowing communities to condition their consent on specific benefits ensures that they can negotiate terms that directly benefit them, while also safeguarding against conditions that might contravene other legal norms. For example, in countries like Nigeria and South Africa, providing any reward beyond compensation for reasonable costs incurred by individuals who provide biological samples is illegal. Conditional consent provides flexibility and empowers communities to secure tangible benefits from the use of their health data. This can include anything from monetary compensation to healthcare services and fostering a more equitable relationship between data controllers and communities. The legal constraints on rewards ensure that such conditions are ethically and legally sound.

GUIDELINES FOR CONSENT CONDITIONS

The relevant national authority is tasked with establishing guidelines to ensure that conditions attached to community consent are fair, reasonable, and legally compliant. These guidelines help standardize the process of attaching conditions to consent, ensuring that these conditions do not undermine legal norms or the rights of individuals within the community. They also provide clarity for both communities and data controllers, preventing potential disputes or ethical issues.

PROTECTION OF INDIVIDUAL RIGHTS

This provision clarifies that community consent does not override the rights of individual members as provided in existing data protection legislation. This dual layer of protection ensures that individuals retain their rights even when their data is part of a collective dataset. It is crucial to ensure that, where community rights conflict with individual rights the latter takes priority. This ensures that individuals within a community do not lose their data protection rights when community data is being processed.

DISPUTE RESOLUTION

Providing community members with the right to petition their representative body and seek a review from the Health Data Court if their concerns are not addressed ensures that dissenting voices within a community are heard and can be legally acted upon. This mechanism is essential for maintaining transparency and accountability within the community's decision-making process. It ensures that the community's governance is democratic and that individual members have recourse if they believe their interests are not being adequately represented.

DATA SECURITY OBLIGATIONS

This provision places a legal obligation on data controllers to protect community health data by implementing technical and organizational measures to prevent unauthorized access, loss, or destruction of the data. Given the sensitive nature of community health data, it is critical to ensure that it is securely managed. This provision safeguards against breaches that could harm the community or undermine trust in health data governance.

ENHANCED NEGOTIATING POWER

It is more likely that the representative body – as opposed to individual data subjects - will have the necessary negotiating power and capacity to negotiate on an equal footing with healthcare researchers and companies when community consent is requested.

OTHER OPTIONS OF FORMULATING THE SECTION

COLLECTIVE CONSENT MECHANISM

Instead of requiring a single representative body, the section could allow for the possibility of multiple representative bodies within a community, each with specific mandates (e.g., cultural, health-related). This would allow for a more nuanced approach to managing different types of community health data.

INDEPENDENT OVERSIGHT BODY

An alternative approach could involve establishing an independent oversight body that reviews and approves the criteria for representative bodies and the conditions attached to community consent. This would add an additional layer of accountability and ensure that the interests of all community members are considered.

ENHANCED TRANSPARENCY MEASURES

The section could require data controllers to publicly disclose the terms of community consent, and the benefits provided to the community. This would ensure transparency and prevent exploitation or misuse of community health data.

REVERSED ONUS

An alternative approach to the default of individual consent would be to resort to community consent as default, provided that any individual data subject could opt-out of this consent. This approach could be particularly useful in rural areas where access to all affected data subjects could be practically impossible. Care would need to be taken to ensure that this section is not abused or incorrectly applied.

NOTES ON INTERACTION WITH OTHER SECTIONS

HEALTH DATA COURT (SECTION 6)

The Health Data Court's role in adjudicating disputes related to community health data is critical. The Court's ability to review decisions made by community representative bodies ensures that the rights of individual community members are protected, and that the community's governance process is fair and transparent.

INDIVIDUAL RIGHTS; PORTABILITY OF ELECTRONIC MEDICAL RECORDS (SECTION 7)

The protection of individual rights within the community context ties directly into the broader framework of individual privacy rights. Both sections emphasize the importance of consent and the protection of personal data, ensuring that individual rights are not overshadowed by collective community decisions.

USING HEALTH DATA IN THE PUBLIC INTEREST (SECTION 11)

The community consent provision interacts with the public interest use of health data. It ensures that communities have a say in whether their data is used for public interest purposes, and that such use is subject to the conditions they set.

OFFENCES AND PENALTIES (SECTION 15 AND 16)

The security obligations imposed on data controllers are reinforced by the offenses and penalties sections, which provide legal consequences for breaches. This interaction ensures that there are robust mechanisms in place to enforce the protection of community health data.

DEVELOPING MECHANISMS AND GUIDELINES

To guide the relevant national authority in developing both mechanisms in subsidiary legislation and guidelines under this section, the following reference documents and existing instruments can be consulted:

UN DECLARATION ON THE RIGHTS OF INDIGENOUS PEOPLES (UNDRIP)

This document provides important principles regarding the rights of indigenous communities, including their right to control over cultural heritage which may include collective data. It can inform the development of mechanisms for recognizing representative bodies.

CONVENTION 169 - INDIGENOUS AND TRIBAL PEOPLES CONVENTION, 1989 (ILO 169)

This international labour convention outlines the rights of indigenous and tribal peoples, including their right to participate in decisions affecting their communities, which can inform the criteria for representative bodies.

GDPR'S RECITAL 75

The GDPR highlights the need to consider risks to the rights and freedoms of individuals, including collective risks, which can inform the development of guidelines for community consent conditions.

IMPLEMENTATION TIPS

Some countries have existing laws which define what a "community" is and provide various powers and impose duties on the community heads. Examples of these laws are tribal / first nations legislation. A comprehensive review of any legislation as well as consultation with these communities is necessary to ensure they are aware of their expanded rights and duties set out in the model law.

INTERNATIONAL CONSIDERATIONS

In addition to the international instruments mentioned above, the IHR emphasize the need for accurate and timely data collection and sharing during public health emergencies. However, these regulations also stress the importance of respecting individual and community rights in the process. The IHR's principles for transparency, collaboration, and respect for privacy are directly relevant to how communities manage and share their collective health data. The UDHR and the ICCPR provide a framework for protecting individual rights, including privacy, autonomy, and participation in decision-making processes. This section's emphasis on balancing collective community decisions with individual rights must align with these international human rights standards to ensure that community governance mechanisms do not override personal freedoms. Other international frameworks, such as the Convention on Biological Diversity (CBD), also recognise the rights of indigenous and local communities to control their own resources and data which could provide legal backing for the community health data governance models established in this section, ensuring that communities are empowered to make decisions over their collective health data. The WHO and the United Nations (UN) promote the equitable involvement of communities in public health decision-making, particularly in contexts involving health data. The section's principles for community empowerment and inclusive governance should align with these global health equity guidelines to ensure that marginalised or vulnerable communities have a voice in decisions that affect their health and well-being. The OECD's Guidelines on Data Governance and the FAIR Principles (Findability, Accessibility, Interoperability, and Reusability) for data stewardship, set out best practices for managing collective datasets, including community health data. The section's establishment of community representative bodies to oversee health data governance must comply with these guidelines to ensure responsible data management and ethical use. The PIP Framework and similar global health data-sharing agreements emphasise the importance of data access for public health preparedness and response. The section must balance the need for community control over health data with global obligations to share critical health information during pandemics, while ensuring that communities are informed and consent to such data-sharing practices.

Health Data Governance

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Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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