Instantiating the Consent Manager architecture in India's health data landscape: Policy brief and recommendations

Roundtable details

Agenda: Instantiating consent managers in India's health data regulatory landscape (link to Zoom recording)

Date and time: 14 October 2022, Friday, 5 PM IST – 6:30 PM IST

Speakers:

1. Abhishek Jain (Swasth Digital Health Foundation)
2. Aditya Bansal (National Health Authority)
3. Dr. Akshay S Dinesh (Independent physician and community health practitioner)
4. Arjun Venkatraman (Bill and Melina Gates Foundation – India office)
5. Amiti Varma (Centre for Mental Health Law and Policy)
6. Parag Agarwal (Meddo)
7. Raunaq Pradhan (Bajaj Finserv)
8. Shefali Malhotra (Centre for Health Equity Law and Policy),
9. Dr. Surajit Nanda (Raxa Health)
10. Vivek Eluri (Resolve to Save Lives)

Facilitator: Soujanya Sridharan (Aapti Institute)

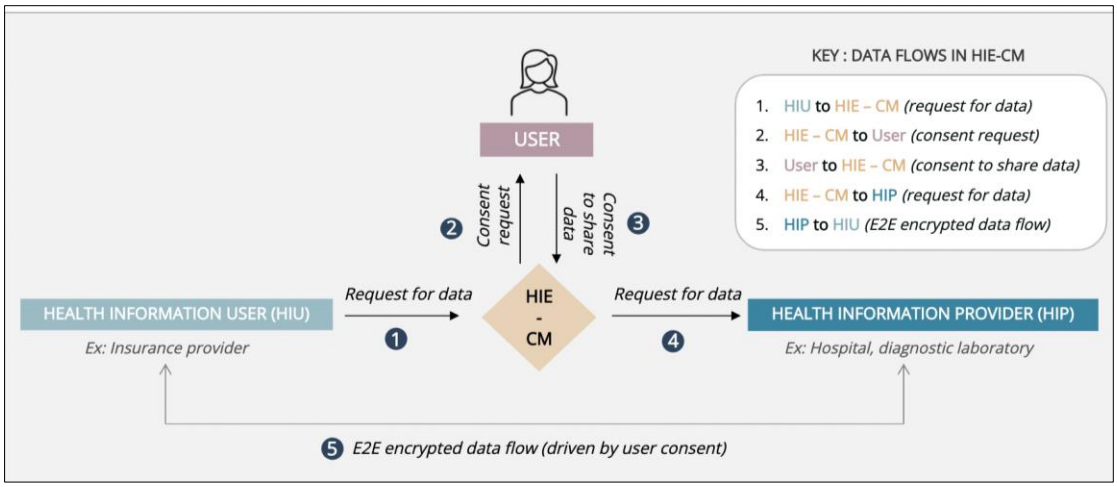
Context

Consent managers (CM) are defined in the **Digital Personal Data Protection Bill, 2022** as **data fiduciaries** which enable a user to 'give, withdraw, review and manage' their consent for data sharing through an 'accessible, transparent and interoperable platform'. The express aim of the consent manager architecture is to **uphold individual privacy** and impart greater control to a data principal over one's data.

More recently, the definition of consent managers has undergone significant revision, particularly in the context of India's health data ecosystem. Consequently, India's flagship healthcare digitization program - the Ayushman Bharat Digital Mission's Health Data

Management Policy, 2022 (HDMP, 2022) defines CMs (Consent Manager) as a "**digital system which facilitates exchange of health information and management of consent**". Additionally, the CM framework has been subsumed within a broader category referred to as the "Health Information Exchange – Consent Manager" (HIE – CM) under the HDMP, 2022. Crucially, the **conception of CM in the healthcare ecosystem significantly departs from the definition of CM in the Personal Data Protection Bill, 2022 in which fiduciary responsibilities constitute the anchor for consent provisioning.** As such, this difference in conception and treatment of CMs in policy presents critical implications for the instantiation of the HIE-CM architecture in healthcare.

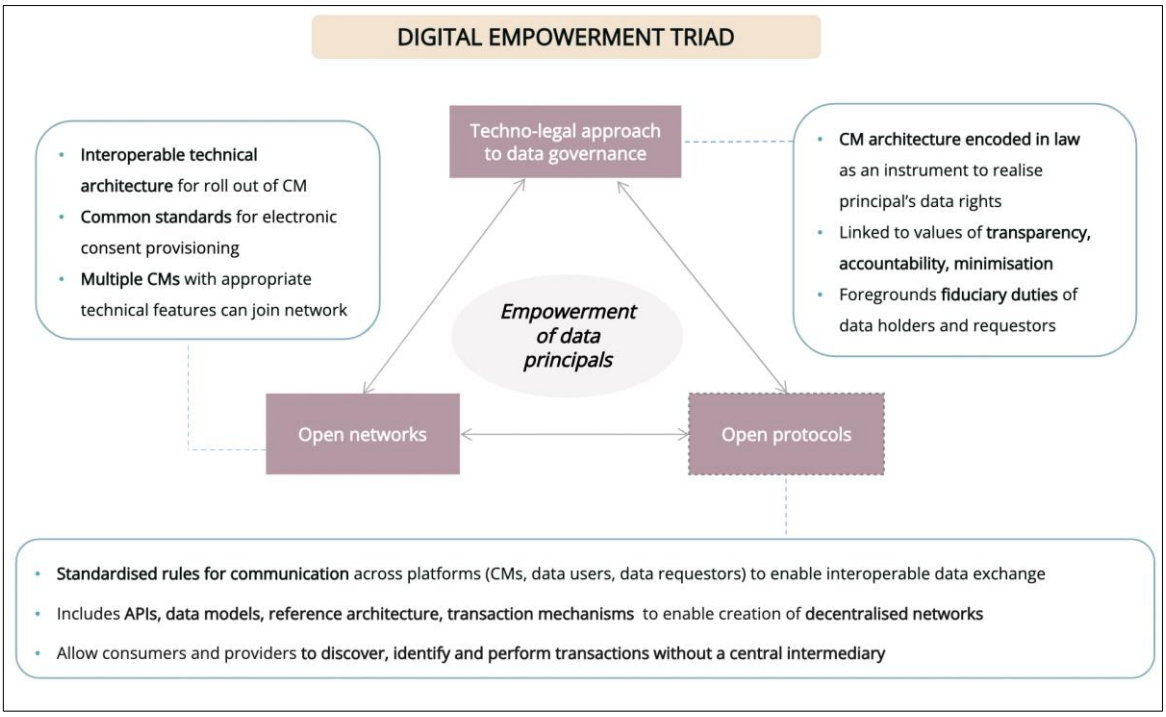
Nonetheless, the HIE-CM architecture is significant inasmuch as it facilitates consent-driven data sharing. In fact, once this architecture is fully operationalized, **India would be among the earliest jurisdictions to recognize and adopt a tripartite model for data sharing**. Such a precedent promises to unravel valuable insights for other jurisdictions looking to implement consent-driven, responsible health data sharing.



Tripartite model of health data exchange under the HIE-CM *(Source: Aapti analysis)*

Thus, the HIE-CM architecture forms the lynchpin of an approach to health data exchange that relies on three pillars - **techno-legal approach to regulation, open networks and open protocols.** The combination of these pillars has come to constitute what is termed as

the **"digital empowerment triad,"** helping create the requisite regulatory scaffolding necessary for responsible, citizen-centric health data exchange.



Digital Empowerment Triad *(Source: Aapti analysis – draft; request before citing)*

Despite the many promises and opportunities afforded by the HIE-CM, there exist certain concerns about its operationalization within India's health data exchange landscape. For one, the legal, regulatory, and administrative discourse on health data governance is emerging slowly but is rather nascent. This is particularly true of the developing world, including India, where **operational frameworks for data rights or privacy protection are still being contemplated or non-existent,** in some cases.

In such a milieu, exploring India's foray into digitization of health services access and delivery merits further inquiry. This is particularly interesting for a country whose health

digitalization experience is marked by breakdowns and unprecedented barriers produced by its linguistic diversity.

To this end, the roundtable unpacked the considerations for instantiating the HIE-CM through a multi-stakeholder dialogue with representatives from industry, academia, civil society, and public agencies. Insights from the discussion are highlighted below and presented as recommendations for the National Health Authority that is leading the work on rolling out the HIE-CM framework. Additionally, certain policy recommendations for governance of HIE-CM have been chronicled to inform India's forthcoming data protection legislation, developed under the aegis of the Ministry of Electronics and Information Technology.

Recommendations

Based on the insights shared during the roundtable discussion, certain observations and recommendations have been drawn up for the **National Health Authority and the Ministry of Electronics and Information Technology**. The recommendations delve into themes around **digital literacy and socialization of consent mechanisms, HIE-CM, and the role of data intermediaries, enabling infrastructure for HIE-CM, best practices for HIE-CM roll out, privacy and data rights.**

1. **Envisage a role for offline intermediaries within the HDMP, 2022:** Prevailing digital divide in the country has emerged as a debilitating bottleneck to the digitization of health systems. Further, the advent of telemedicine, particularly in rural India, makes paper-based consent increasingly unviable and begs transition towards electronic consent frameworks. Such concerns are only magnified in the context of the roll-out of the HIE-CM that crucially relies on digital literacy of patients/users to make informed consent decisions for access to and exchange of their health data and related records. While the HIE-CM is designed to address these issues, it necessarily hinges on knowledge of and access to technical interface to

authorize health data exchange. The relatively low rates of smart phone penetration (66.21% of total population) and patchy internet infrastructure stymie adoption of digital health services.

In such a context, it becomes imperative leverage existing mechanisms for healthcare service delivery to play the role of intermediaries between patients on the one hand and healthcare providers on the other. Community health practitioners in rural India, such as ASHA and Anganwaadi workers, can help bridge the gap between healthcare providers and the patient community. Thus, offline intermediaries in the nature of community health workers can expand access to digital health services and overcome the anonymity characteristic of platformized models to introduce human intervention in ways that enhance trust in the HIE-CM and allow for informed decision-making. Lastly, offline intermediaries temper the worst effects of the paternalistic paradigm of the physician-patient relationship and work in the best interests of patients to ensure that their health data and records are shared only after obtaining meaningful informed consent.

2. **Expand functions of HIE-CM under the HDMP, 2022:** The current definition of the HIE-CM under the new draft of the HDMP, 2022 merely regards HIE-CM as digital systems that facilitate exchange of health information and management of consent. Thus, HIE-CM is poised to play the role of data-blind layer that allows for data flows between health information users and health information providers, after notifying and obtaining consent from the user or patient to whom the information relates. In turn, HIE-CM allows for users to give, withdraw, and modify their consent along several variables such as time, type of information, date of expiration, among others. Granular as consent may be within the HIE-CM, the presence of multiple variables risks burdening users with complex decision-making processes. Moreover, abiding concerns about digital literacy mentioned above can manifest as "consent fatigue" - a situation in which patients/users are actively dissuaded from engaging with data sharing decisions due to complex and incomprehensible terms of data use presented by platforms such as the HIE-CM.

A plausible solution to this crisis of consent provisioning is an expansion in the role of the HIE-CM itself in a manner that allows regulators to inscribe advisory functions within its framework. Consequently, the HIE-CM ceases to be a mere digital layer for health information exchange and works as a trusted agent in consultation with patients about the use and exchange of their health data as well as management of their consent. The advisory functions are best captured through the prism of data stewardship – an approach to data governance that is responsible, rights-preserving, and participatory such that individuals and communities are empowered to make data decisions. In the healthcare ecosystem, data stewards such as MiData have illustrated pathways for responsible, community-driven health data exchange. To ensure consent fatigue is not an impediment, MiData reviews every request for data sharing through its ethical review board and advises its members who then vote on the data sharing request – enabling consultative and democratic consent management in the process. The HIE-CM should seek to incorporate such best practices within its framework to meaningfully represent the interests of its users.

3. **Build comprehensive enabling infrastructure for roll out of HIE-CM:** The HIE-CM is one part of a broader set of 'building blocks' that make up the Ayushman Bharat Digital Health Ecosystem. The technical infrastructure so furnished under the ABDE fulfills two pillars of the digital empowerment triad – the institution of open networks and open protocols. To this end, the HIE-CM can help solve persistent data taxonomy issues by introducing uniform standards and taxonomy for health data interoperability. However, the creation of technical infrastructure for health data exchange must be complemented by the institution of robust regulatory frameworks to govern the infrastructure such that a techno-legal approach is embedded in the design of the HIE-CM.

The Health Data Management Policy, 2022 (HDMP) is a promising first step towards the constitution of a governing framework for the HIE-CM but presents

several glaring omissions in turn. For one, the HDMP fails to articulate the legal basis for the insertion of the HIE-CM as an intermediary between patients and providers. Secondly, the provisions for grievance redressal under the HDMP extend only to harms caused by data fiduciaries (ex: hospitals, clinics, and insurance companies) and not the HIE-CM itself. In the event that the HIE-CM should violate a data principal's consent or act in contravention of the HDMP, there is little scope to redress harms arising from such action. As a result, the HDMP falls short of surfacing meaningful controls for accountability to ensure that all parties handling a patient's data, including the HIE-CM, follow utmost standards of due diligence and act in accordance with the Policy. It is recommended that the NHA revise the provisions of the HDMP, 2022 to include processes for grievance redressal to hold the HIE-CM accountable.

4. **Harmonize definition and function of the HIE-CM in line with the provisions of the Digital Personal Data Protection Bill, 2022:** Section 7 (6) of the DPDP Bill, 2022 explicitly designates CMs as data fiduciaries that manage a data principal's consent preferences, while remaining accountable to and acting on behalf of the data principal. This characterization of CMs as data fiduciaries is a promising first step towards responsible data intermediation that anchors the data principal – CM relationship within a rubric of accountability such that CMs are obligated to act in the best interests of users. The twin duties of care and loyalty attributed to fiduciary/principal-agent relationships is a significant development that merits inquiry. While the DPDP Bill, 2022 is silent on the specifics of rules to govern CMs, it is expected to lay out norms for grievance redressal to address harms arising from CM's actions.

   Given that this definition of CMs as data fiduciaries finds mention in the foundational legislation of India's data regulation landscape, it becomes incumbent upon other public agencies – such as the NHA – to imbibe this principle within the HDMP, 2022. The definition, roles and functions of the HIE-CM should be modelled

along the precedent set for by the DPDP Bill, 2022 such that fiduciary responsibilities as well as accountability to data principals are explicitly ascribed to entities managing health data in India.