C-HELP | CENTRE FOR HEALTH EQUITY, LAW & POLICY

Submission to the
Ministry of Health and Family Welfare,
Department of Health Research
on

The Draft National Health Research Policy 2026

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About

The Centre for Health Equity, Law & Policy is a research, knowledge production forum which works on law & policy issues related to health, embedding its work in the right to health as envisaged within India's constitutional framework and her international commitments. It is located at the Indian Law Society, Pune.

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This submission highlights our comments and suggestions to Chapters 4, 5 and 6 of the draft Policy.

Chapter 4: Enabling Systems for Health Research

This chapter addresses the enabling systems required for research to produce public benefit including enabling pathways for public private partnerships. Our comments and recommendations stress on the need for certain provisions especially around data governance, accountability and other checks to ensure that research benefits national and public health interests

4.5.2 Public-Private Partnerships

Para 4.5.2.2 states that *Public-private partnership agreements shall include clear provisions related to intellectual property, publication and dissemination, technology transfer, and knowledge- sharing, while remaining aligned with public purpose and national interests. Appropriate incentive structures, including revenue-sharing or related mechanisms, may be developed where appropriate.*

At the outset, we submit that the draft Policy should unequivocally require that all public private partnership (PPP) agreements under this framework, must be proactively placed in the public domain, in accordance with the Right to Information Act, 2005. These PPP agreements entail the use of public funds, publicly health datasets and infrastructure, and pertain to public activity; transparency is paramount to ensure public accountability and enable independent scrutiny and oversight and build public trust.

Further, the current draft para has emphasis on commercial arrangements (e.g. IP) and pays little attention to governance and accountability, which are particularly important with regard to PPP in digital health technologies. We recommend that the paragraph on PPPs should be redrafted to include the below mentioned points. Alternatively, the Policy could also state that the Department of Health Research will develop a standard due diligence checklist or model contractual framework for PPPs generally, and particularly for PPPs involving Digital Health Technologies.

1. **Data governance and accountability:**
   PPPs should clearly define specific data sharing and governance arrangement:
   - Whether identifiable, de-identied or anonymised datasets are used or shared and what standards are used for de-identification or anonymisation
   - Purposes and permissible uses of data
   - Data sharing arrangements
   - Restrictions and safeguards on secondary use of data

- Data retention and deletion policies
- Organisational and technical obligations for privacy and data protection in compliance with DPDPA, ICMR National Ethical Guidelines, and research ethics principles.
- Monitoring, accountability and enforcement and penalties for violation of obligations

2. **Public value and benefit-sharing arrangements:**
   The para refers to “national interests.” However, PPP in public health should also protect public value. The paragraph should be amended to mention that the PPPs must ensure that publicly generated data and publicly funded research continue to serve public health objectives and prevent exclusive commercial control over outputs generated using public resources. The appropriate public health returns include not just technology transfer, but also preferential public sector pricing, affordable access, capacity building, non exclusive licensing or other equitable benefit sharing mechanisms.

3. **Transparency and algorithmic accountability:**
   Where AI is involved, PPP agreements should specify transparency provisions related to development, validation, performance and significant modifications of AI enabled DHTs used within public health systems.

4. **Lifecycle obligations:**
   DHTs require ongoing support and PPP agreements should specify obligations - for software maintenance, cybersecurity management, post-deployment monitoring and digi-HTA, performance evaluation and timely implementation of safety updates - on a lifecycle approach.

5. **Independent evaluation and audit rights:**
   - Vendors should not be the sole source of evidence on effectiveness. PPP agreements should have provisions facilitating independent audit and evaluation and should have access to appropriate data and evidence necessary for such evaluation.
   - The government should also retain audit and inspection rights and must have access to documentation necessary for it.

6. **Provisions to prevent vendor lock-ins:**
   Vendor lock-ins have become a major governance issue.PPP agreements should include provisions to use open standards where feasible, data portability, and clearly defined transition arrangements to minimise the risk of vendor lock-ins.

7. **Equity**

PPPs should be subjected to evaluation on equity considerations (accessibility, affordability, inclusion and digital divide issues) either as part of HTA on lifecycle approach or independently.

8. **IP rights and legitimate government oversight in national and public health interests**
   IP provisions should not be allowed to impede legitimate regulatory oversight, independent evaluation or post deployment HTAs. PPP agreements should include contractual mechanisms and exceptions on the ground of “national interest”, “public interest” or “public health” to provide confidential access to source code, training and validation datasets, software update histories and any other technical information considered necessary for undertaking auditing. This is consistent with legal developments. For instance, the EU AI Act states [1] that providers of high risk AI systems must provide technical documentation for assessment to competent authorities. This would also be consistent with the WHO's guidance on the Ethics and Governance of AI for Health, that commercial confidentiality should not prevent appropriate regulatory oversight, transparency and accountability.[2]

Chapter 5: Ethics, Integrity and Quality Standards for Health Research

This chapter lays out standards for ethics, integrity, quality, and data governance. Our comments and recommendations revolve around the importance of data protection and the need to prioritise the principles of privacy and data governance.

5.5 Data Access and Governance

Para 5.5.1 states that *This section addresses the standards that shall guide responsible access, reuse, security, and governance of health research data.*

While there is an uptick on the development of digital health as well as and use of AI in it is important to ensure that the research is done in a manner that respects the privacy, autonomy and data protection rights of the people.

1. **Recognise stewardship, not merely compliance:**

The chapter mentions that data sharing will be in compliance with Digital Personal Data Protection Act 2023 (DPDPA), and DHR/ICMR guidelines, but it must articulate that the principle underpinning health research data is public trust that requires responsible stewardship. The Policy must specifically state that as health research data increasingly functions as a strategic public resource, it shall be governed in conformity with the principles of stewardship, transparency, accountability,

proportionality, public value and benefit. The institutions collecting and processing health research data shall act responsibly and must ensure that their use promotes public health while protecting the rights and interests of participants and communities.

2. **Governance of secondary use:**

The Policy states that data sharing is the norm, but does not state who decides the secondary use of data sharing, which constitutes an important governance gap. The Policy must state that the secondary use of health research data must be subject to appropriate and independent review on parameters proportionate to the level of risk. Without some standards and review, secondary use risks becoming automatic.

The Policy should also acknowledge that decision-making regarding secondary use of health research data, particularly for AI development, commercial partnership or large-scale data linkage, entails questions of collective governance. Such decisions must not only be guided by considerations of public interest, public health value and equity; but must be shaped by meaningful engagement with the public and communities. In fact, the Policy should mandate the Department of Health Research to develop in a consultative manner a national framework to guide the governance of secondary use of health research data. Such a framework must establish principles and mechanisms for transparent and accountable decision-making regarding data access and use. The principles at the minimum, would include independent oversight, public participation, equitable benefit sharing and privacy-preserving data sharing. Such a policy must also explore the emerging collective governance models such as independent data access committees, data trusts and trusted research environments.

Further, the Policy should make a distinction between research for public health or scientific purposes and research to support commercial product development. In the case of the latter, it should be subjected to enhanced governance, including appropriate consent requirements, transparency regarding commercial use and equitable benefit-sharing mechanisms to ensure that public investment and publicly generated health datasets produce public value and contribute to improved public health outcomes.

3. **Specifically recognise and restate the privacy principles and safeguards:**

Even though the Policy refers to the DPDPA, since the DPDPA is an omnibus law, a health research policy should specifically restate the privacy and data protection principles. Accordingly, the policy must mention the principles of consent, data minimisation, purpose limitation, retention limitation and organisational and technical data protection and security safeguards.

Further, the Policy must go beyond simply mentioning that the institutional policy should be developed in accordance with DPDPA and DHR/ICMR guidelines and go on to state that such frameworks should specify the appropriate consent models for different categories of research, governance arrangements for secondary use of personal, de-identified and anonymised data, participant information requirements, data access procedures, and safeguards to ensure transparency, accountability and protection of participant rights.

4. **Better Transparency:**

The Policy must require institutions maintaining health research datasets to publish a repository of their data governance policies, data access procedures, governance arrangements, and categories of approved research purposes and secondary use.

5. **Focus on data quality:**

The Policy must require institutions to implement mechanisms to ensure the quality, completeness, and accuracy of health research data through its lifecycle.

6. **AI dataset documentation:**

The Policy must require that where health research datasets are used for AI development or validation, institutions must maintain documentation regarding their provenance, representativeness, known limitations and intended use and study limitations. This is necessary to support transparency and independent evaluation.

Chapter 6: Translation, Application and Public Benefit

This chapter addresses the pathways through which research evidence shall be translated into policy, programmes, clinical practice, products, and public benefit. Our comments and recommendations pertain to the use of Health Technology Assessments, especially in the context of digital health technologies and AI in healthcare.

Although the draft Policy adopts more contemporary principles in HTA such as reassessments, implementation learning, transparency, evidence generation and integration in decision-making, it still fundamentally remains a conventional HTA framework. Digital technologies are mentioned only once in Section 6.3.1, and thereafter they are treated identically to fixed technologies like pharmaceuticals or conventional medical devices.

1. **The Policy must acknowledge the need for a dedicated Digi-HTA framework:**

Conventional HTA is designed for pharmaceuticals and stable medical devices and does not adequately address the unique characteristics of digital health technologies, including AI-enabled medical devices or tools (hereinafter referred to

as DHTs). HTA is conventionally structured around clinical effectiveness, economic evaluation (including cost-effectiveness or cost-utility analysis), and budget impact analysis. These analyses are anchored in a clearly defined decision problem, which requires explicit delineation of *who* a technology is for (population), *what* is being assessed (intervention), *what it is compared against* (comparator), and *what effects matter* (outcomes). However, the assumptions underpinning the conventional HTA framework (PICO framework) do not translate well to DHTs for the following reasons:

- First, it assumes stable, well-defined interventions (eg, a drug) whereas DHTs are dynamic and evolve through software updates, retraining, and adaptive learning. This makes it difficult to define a single, stable "intervention" for assessment.
- Second, appropriate comparators are often absent or ill-defined. DHTs frequently augment, reorganise, or replace workflows rather than substitute for a single clinical alternative.
- Third, outcomes are multi-dimensional and system-level, encompassing access, efficiency, safety, usability, and equity - many of which are not captured by Quality Adjusted Life Years (QALYs) or disease-specific clinical endpoints.
- Finally, performance is contextual, as the same digital tool may perform differently across settings, populations, and health systems, undermining the population homogeneity assumed in the PICO framework. This challenges the implicit assumption that evidence generated in one setting can be readily generalised to another.

Several countries have recognised these limitations of conventional HTA frameworks for assessment of DHTs and have developed or are in the process of developing dedicated HTA frameworks suitable for digital health technologies.[3] Finland has established a national Digi-HTA framework, the United Kingdom has developed the NICE Evidence Standards Framework (ESF) and Digital Technology Assessment Criteria (DTAC) for DHTs, and Germany has introduced the DiGA Fast-Track pathway for the assessment and reimbursement of digital therapeutics.[4]

Recommendation - The Policy should therefore explicitly recognise Digital Health Technology Assessment as a complementary methodology.
Insert after 6.3.1 – "*Digital health technologies, including Software as a Medical Device (SaMD), AI-enabled medical devices, digital therapeutics and clinical decision support systems, should be assessed using Digital Health Technology Assessment methodologies that complement conventional HTA by incorporating digital-specific technical, organisational and implementation domains."*

2. **The Policy must expand the domains of assessments necessary for HTA of DHTs:**

Para 6.3.2 states that HTA will look at comparative clinical and cost-effectiveness, affordability, feasibility, and equity implications. In light of the multifaceted aspects and risks associated with DHTs, Digi-HTA should retain these core principles of conventional HTA while incorporating additional domains such as cybersecurity, interoperability, privacy and data governance, usability, accessibility, equity, implementation readiness and AI-specific considerations. Such an approach would align India's HTA ecosystem with emerging international best practices while ensuring that digital innovation remains both clinically valuable and responsive to the needs of an equitable public health system.

The HTA of digital tools in India demonstrates the limitations of applying traditional HTA to DHTs. For instance:

- HTA of two AI-assisted TB screening tools, qXR and Genki[5], focused on diagnostic accuracy and operational feasibility, without assessing privacy and data governance, algorithmic bias across sub-populations, training data representativeness, explainability or interpretability.
- HTA of telemedicine-enabled ear screening considered only cost-effectiveness and feasibility in service delivery,[6] but overlooked important issues such as data quality variability across settings, human-AI interaction that could affect outputs and outcomes, digital infrastructure availability, scalability risks, and privacy and data protection concerns associated with clinical images.

As seen from the above examples, HTA of DHTs relying solely on clinical and cost-effectiveness does not align with evidence-informed policy and decision-making, as it leaves out several crucial aspects of DHTs. In the UK, the ESF framework for DHTs, in addition to clinical and economic evidence, considers factors such as the technology's function, evidence in proportion to the risk classification, usability, implementation considerations, and real-world effectiveness. DHTs are also subjected to DTAC, which includes parameters such as clinical safety, data protection, technical security, interoperability, accessibility and usability.[7] Similarly, Finland’s Digi-HTA framework incorporates domains such as usability, accessibility, interoperability, cybersecurity, data protection, and organisational impacts.[8]

Further, while some equity concerns can be addressed by evaluating parameters such as accessibility, usability, and real-world performance, these do not capture the distributional impacts of adopting DHTs in healthcare systems, including their effects on patterns of access, resource allocation, and existing health inequities. Hence, it is important to emphasise a distinct parameter of equity and ethics, for a more holistic assessment. Without this, Digi-HTA may legitimise technologies that deepen existing inequities.

Recommendation - Expand 6.3.2 to recognise that Digi-HTA incorporates additional domains relating to data governance, equity, technical performance, digital infrastructure, implementation and AI-specific domains.

3. **The Policy must explicitly recognise the need for real-world data and data infrastructures to support HTA and Digi-HTA:**

Para 6.3.3 of the Policy states that HTA shall be conducted using best available evidence and Indian data. Indeed, meaningful HTA requires continuous generation of high-quality real-world data on clinical outcomes, costs, utilisation, and health system performance. However, research shows that HTA in India suffers due to inadequate local evidence, fragmented datasets and limited data accessibility.[9]

These problems are amplified for Digi-HTA. In addition to traditional clinical and economic evidence, Digi-HTA requires evidence on implementation, interoperability, usability, workflow/health system integration, organisational impacts and real-world use across diverse settings. Without robust data infrastructures to produce such locally relevant and longitudinal data, Digi-HTA risks relying mainly on vendor-supplied evidence or small pilots, thereby undermining the credibility, independence and generalisability of HTA findings.

The challenge is even greater for AI-enabled DHTs. RCTs are insufficient as the sole evidentiary basis for AI-enabled DHTs, as they are software-driven, evolve rapidly, and are context-dependent. Their HTA would require a broader evidence base that includes clinical evaluation with technical validation, real-world evidence and ongoing post-deployment monitoring. In the absence of such a broad evidence base, a DHT may end up in use after providing (at most) a far lower tier of evidence for its effectiveness (i.e. a small-scale pilot study showing self-reported outcomes, without a control group) and compliance with more generic concerns. This creates a risk that DHTs are deployed despite limited independent evidence of their effectiveness, safety or value for money. Resultantly, health systems may invest scarce resources in DHTs that may appear safe or technically functional but offer limited clinical benefit in real-world settings.

While real-world data are necessary for HTA and Digi-HTA, expanding data infrastructures and linkages also raises important privacy, confidentiality and data governance issues, particularly when longitudinal datasets are linked across multiple sources. Without adequate privacy safeguards, there is a risk of excessive data collection, function creep, re-identification and unauthorised secondary use of data. Therefore, implementation of data infrastructures should be accompanied by robust privacy and data governance safeguards, including data minimisation, purpose limitation (public interest use and transparency in use for secondary purposes), use of de-identified and anonymised datasets as much as possible, and necessary organisational and technical data protection standards.

Recommendation – The Policy should recognise real-world evidence generation as a core component of HTA and support the development of privacy and data security preserving data infrastructures to support evidence generation.

4. **Explicitly recognise post-deployment assessments on a lifecycle approach:**

Although the Policy recognises the need for reassessments, the triggers for reassessment remain relevant only for conventional technologies. The policy at para 6.3.7 states that reassessments shall occur *"when new comparative evidence emerges, price or cost structures change, implementation data indicate suboptimal outcomes, or superior alternatives are identified."* While for conventional HTA, this is adequate, it is not sufficient for Digi-HTA, because it assumes that reassessment is triggered only by changes in evidence or market conditions. It does not recognise that for DHTs, the technology itself may change.

For software, AI and digital health technologies, reassessment should also be triggered by changes such as: significant software updates or version changes, modifications to AI algorithms or model retraining, changes in intended purpose or functionality, newly identified cybersecurity vulnerabilities, interoperability changes, significant changes in real-world performance, evidence of algorithmic bias or inequitable outcomes, and major changes in deployment context (e.g., expansion from tertiary hospitals to primary care). These circumstances or events are not adequately covered by the term "new comparative evidence" because the trigger is often a modification to the technology itself. Digi-HTA therefore requires a lifecycle approach to generate evidence post-deployment through systematic and periodic reassessments on the basis of real-world evidence.

Recommendation - The Policy should adopt a lifecycle approach to Digi-HTA by explicitly recognising technology-specific triggers for post-deployment reassessment. These reassessments should be informed by real-world evidence to ensure that digital health technologies remain safe, effective and fit for purpose throughout their lifecycle.

5. **Expand objective of HTA and especially Digi-HTA:**

Para 6.3.2 of the draft Policy currently states that HTA is intended *"…to inform procurement, pricing and benefit-package decisions."* While these have been central objectives of HTA, increasingly HTA is used to inform decisions around adoption, reimbursement, scale-up, continued use, reassessment and, where necessary, discontinuation. HTA is increasingly recognised as a multidisciplinary process that informs the value of health technologies at different points in their lifecycle. This is particularly necessary for digital health and AI-enabled health technologies, as their performance and safety may evolve after deployment and therefore require iterative evidence generation and reassessment through their life cycle. Restricting the objective to procurement and pricing may narrow its role and significance within the

health systems and evidence-informed policy. The Policy itself recognises in different places that it is important to look at implementation and de-implementation of ineffective practices.

Recommendation - The objective of HTA should be expanded - *"…to inform adoption, procurement, pricing, reimbursement, benefit-package decisions, continued use, and disinvestment of health technologies."*

References

[1] The EU Artificial Intelligence Act, 2024, art. 26

[2]World Health Organisation, “Ethics and governance of artificial intelligence for health” 62 (2021)

[3]OECD Health Working Papers No. 177,“Towards identifying good practices in the assessment of digital medical devices: Insights from several OECD countries”2025, available at https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/04/towards-identifying-good-practices-in-the-assessment-of-digital-medical-devices_e35198b0/b485ee1f-en.pdf, (last accessed July 27, 2026)

[4]Emanuele Arcà, Dorothea Heldt, Martina Smith, “Comparison of health technology assessments for digital therapeutics in Germany, the United Kingdom and France.”Digit Health. 11 20552076241308704 (2025)

[5] Health Technology Assessment in India, “Health Technology Assessment of AI-Assisted CXR for Interpretation for Tuberculosis: A Rapid Health Technology Assessment” (2023), available at,https://htain.dhr.gov.in/images/pdf/Policy_Briefs/77.AI_based_cXR_Interpreation_Policy_Brief.pdf, (last visited July 27, 2026)

[6] Health Technology Assessment in India, “Health Technology Assessment of Telemedicine-Enabled Otoscope for Ear Disease Prevention” (2022), available at https://htain.dhr.gov.in/images/pdf/Policy_Documents/34.Telemedicine_enabled_otoscope.pdf.(last visited July 27, 2026)

[7] Using the Digital Technology Assessment Criteria (DTAC), available at: https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-developers/all-developers-guidance/using-the-digital-technology-assessment-criteria-dtac/ (last visited July 27, 2026)

[8] J Haverinen,T Mustola,R Järvinen,P Falkenbach “Finnish health technology assessment model for digital health technologies.”,The European Journal of Public Health, 35(Suppl 4) https://doi.org/10.1093/eurpub/ckaf161.656

[9] Shankar Prinja, Laura E. Downey, Vijay K. Gauba & Soumya Swaminathan “Health Technology Assessment for Policy Making in India: Current Scenario and Way Forward” PharmacoEconomics Open, 2018,, available at https://link.springer.com/article/10.1007/s41669-017-0037-0; (last accessed July 27, 2026)