Comments for National Health Authority on Unified Health Interface Consultation Paper

Background

Consumer Unity & Trust Society (CUTS) expresses its gratitude to the National Health Authority (NHA), for inviting comments and suggestions on the Consultation Paper on the Unified Health Interface (UHI).[1]

About CUTS

In its 37 years of existence, CUTS has come a long way from being a grassroots consumer-centric organisation based in Jaipur to opening overseas Resource Centres in Vietnam,[2] Africa,[3] Switzerland,[4] and most recently in the United States of America[5]. It continues to remain an independent, nonpartisan, and non-profit economic policy think tank while opening various programme centres, namely: Centre for International Trade, Economics & Environment (CITEE)[6]; Centre for Consumer Action, Research & Training (CART)[7]; Centre for Human Development (CHD)[8]; and Centre for Competition, Investment & Economic Regulation (CCIER)[9]. It has been working towards enhancing the regulatory environment through evidence-backed policy and governance-related interventions across various sectors and national boundaries. Further details about CUTS are available here.

Having conducted various studies and events, pertaining to e-commerce (such as: Internationalisation of Micro and Small Enterprises through e-commerce and e-commerce in the Context of Trade, Competition and Consumer Protection in India)[10], as well as on Data Protection (such as: Consumer Impact Assessment of Data Localisation,[11] and Understanding the Impact of Data Localization on Digital Trade)[12], Data Sharing,[13] and Encryption[14], CUTS has observed a few critical issues in the draft architecture. These have been discussed in subsequent sections, along with a few recommendations to address them.

---

[1] [1] Consultation Paper on Unified Health Interface, available at: https://ndhm.gov.in/assets/uploads/consultation_papersDocs/UHI_Consultation_Paper.pdf

[2] http://cuts-hrc.org/en/

[3] http://www.cuts-international.org/ARC/

[4] http://www.cuts-geneva.org/

[5] http://www.cuts-wdc.org/

[6] https://cuts-citee.org/

[7] https://cuts-cart.org/

[8] https://cuts-chd.org/

[9] https://cuts-ccier.org/

[10] https://cuts-ccier.org/e-commerce/

[11] Objective: Assessing the impact of restriction of cross-border data flows on consumers, among other stakeholders, on parameters, such as quality of service, innovation, data privacy, data security etc. Expected Outcome: presenting an evidence-based impact of data localisation, to the government and other stakeholders. https://cuts-ccier.org/consumer-impact-assessment-oncross-border-data-flow/

[12] Objective: Understand and analyse the importance of digital exports for India's GDP and economy, along with the possible impact of data localisation barriers on Indian exports of digital goods and services. Expected Outcome: build detailed and holistic understanding of the economic implications of existing and/or proposed data localisation barriers on India's digital exports, while producing evidence to study alternatives to data localisation measures which are prohibitors to free data flows, in order to help policy makers in India and around the world to take an informed and appropriates and on data localisation. https://cuts-ccier.org/pdf/projectbrief-dtdl.pdf

[13] https://cuts-ccier.org/npd/

[14] https://cuts-ccier.org/understanding-consumers-perspective-on-encryption/

CUTS Submission

CUTS congratulates NHA on proposing to take an important step towards empowering citizens and enhancing health service delivery. The strategic foresight on having a unified architecture on healthcare information is a progressive step. While the consultation paper asks specific questions on several aspects which have been answered in the subsequent sections, CUTS would like to provide a few broad suggestions to address select lacunas in the proposed interface. These have been discussed below.

I: Broad Submissions

The proposed unified health interface (UHI) seems to be based on some broad principles that expressly or implicitly appear throughout the document. Key concerns about such principles are laid out below:

1. **Rights of Consumers:** Under the National Digital Health Ecosystem (NDHE), a consumer is uniquely identified using an e-Health ID. A forced implementation of NDHE without obtaining the consent of the consumers for accessing healthcare may have disastrous consequences and impact their privacy. Such forced implementation has been carried out earlier with the Covid-19 vaccination program and the Co-WIN portal. Here, the generation and assignment of a unique health ID was non-consensual. The consumers/citizens were neither made aware nor asked for explicit consent about the creation of a unique health ID and linking of the data. They came to know about the same only after the vaccination was complete as the information was visible on the vaccination certificate. There was no option provided to opt out. This is a severe violation of the fundamental right to privacy. While the aim of having continuity of care through the proposed e-Health ID may be desired by most consumers, some consumers may prefer privacy and may not want Health Service Providers (HSPs) to store their health data in the first place. Further, some consumers may also prefer anonymous medical care due to social stigmas (like accessing abortion services).Therefore, forced implementation should not be done. Further, since a large section of the population is not digitally connected, it is bound to be left out of the NDHE and a forced implementation will restrict access to health services for them.

   Recommendations: Accessibility of all healthcare services without the requiring NDHE should be ensured. Further, the principle of continuity of care should be provided only as an option even for consumers willing to participate in the NDHE. The consumers (data principals) should have the choice and ultimate authority of opting in and opting out of the NDHE. Further, the consent to participate in the NDHE should be explicit and not implied. Principles like the right to be forgotten should remain with the consumer. NHA may refer CUTS submission on the Health Data Management Policy for issues pertaining to privacy and data protection.[15]

[15] https://cuts-ccier.org/pdf/cuts-submission-of-comments-on-health-data-management-policy.pdf

2. **Capacity to ensure Informed and Granular Consent:** While the National Digital Health Mission (NDHM) has maintained that the principle of granular consent will be upheld and consent will be explicitly sought, the capacity of data principal to provide informed consent may differ based upon their knowledge and belief systems and the same has not been adequately highlighted in the draft. Thus, those data principals who may not realise the value of their health data may provide uninformed consent. Further, a data principal may also be not adequately equipped to understand the process of medical diagnosis and thus, may not understand the extent of previous health record sharing needed for current diagnosis and examination by an HSP. This may result in sharing of non-required personal health information which is against the principle of data minimisation. Moreover, granular consent may also cause consent fatigue to data principals and they may resort to providing namesake consent. The draft falls short on discussing these challenges faced by the consumers and providing solutions for the same.

   Recommendations: Explicit and informed consent is required for each piece of a medical record. Therefore, steps to empower consumers to understand granular consent are important. In this regard, NDHM may mandate End-User Application (EUAs) to carry out literacy campaigns for their registered data principals. Further, to lessen consent fatigue, NDHM may give guidelines to the EUAs for simplifying the process of obtaining consent by having features like pop-up notifications on the EUA mobile app, etc. The NDHM should aim at empowering and building the capacity of the data principals adequately so that they may be able to provide informed consent and at the same time, prioritise usage convenience.

3. **Ownership of Health Data and Assumptions of it being a Public Good:** Personal health data is owned by an individual. Along with envisioning UHI as a public good, assumptions have also been made that the personal health data of a data principal will be a public good. Processing personal health data should only be used for the public good after anonymisation. The draft doesn't provide clarity on several issues with respect to how data can be used as a public good.

   Recommendation: Standardisation (using Fast Healthcare Interoperability Resources (FHIR) or other standards) and digitisation of health data makes data processing much easier. While processing of health data for policy formulation and better healthcare service delivery is required, the same should be first anonymised and made de-identifiable. Processing of any anonymised data should be in consonance with the Report by the Committee of Experts on Non-Personal Data Governance Framework.[16] *If the NHA plans on making the personal health data available for third party sharing and processing, the same should be in consonance with the Data Empowerment and Protection Architecture (DEPA)*[17] *such that the data principal has the complete authority over sharing her data. Further, anonymisation and processing of such data should only be done after defining the purpose and receiving consent from the data principal. Given the sensitivity of health data, if a data principal refuses to let their data being anonymised and used for processing, the same should be respected.*

[16] https://ourgovdotin.files.wordpress.com/2020/07/kris-gopalakrishnan-committee-report-on-non-personal-data-governance-framework.pdf
17 http://www.niti.gov.in/sites/default/files/2020-09/DEPA-Book.pdf

4. **Accountability and Grievance Redress Challenges:** The NDHM has maintained that it will only provide redressal only for grievances related to the digital open platform and not for the quality of healthcare. In the light of the Personal Data Protection Bill proposing to set up a Data Protection Authority which would be empowered to redress grievances of consumers, a consumer may be disempowered because of a lack of clarity in selecting the relevant authority to approach. Further, serious concerns regarding accountability and grievance redress persist even for a digital open platform for which the draft does not provide any clarity. For instance, there is no clarity on who will be held accountable if HSPs make an incorrect/wrongful health entry in the Electronic Health Records (EHRs) of patients and they receive faulty treatment from a new HSP.

   Recommendations: A clear set of guidelines should be laid out for consumers to have clarity with respect to grievance redressal. The NDHM may also provide an arrangement for channelizing grievances not falling under its domain to appropriate forums. Further, fixing accountability-related loopholes need to be done. Situations that may generate grievances may be identified by NDHM and guidelines may be issued beforehand.

II: Specific Submissions

Reference	Issues and Remarks
Chapter 1: 1.7 Questions for Consultation	
1.7.1 Please refer to section 1.6.3. The Telemedicine Guidelines were issued by The Board of Governors of the Medical Council of India (MCI) in March 2020. Stakeholders are requested to go through them and suggest changes to the policy, if any, to ensure the adoption of telemedicine and e-pharmacy. **(**Page No. 13)	Telemedicine Guidelines **(3.7.2.2)** mentions that patient records, reports, documents, images, diagnostics, data, etc. (Digital or non-Digital) utilized in the telemedicine consultation should be retained by the Registered Medical Practitioner (RMP). Here, Telemedicine Guidelines should replace RMPs with Health Information Providers. Further, in telemedicine guidelines (**3.7.1.3)**, RMPs have been provided immunity against breach of confidentiality "if reasonable evidence to believe that patient's privacy and confidentiality has been compromised by a technology breach or by a person other than RMP"; healthcare services will also be provided by HSPs which can include hospitals and other health providers. However, these HSPs should be held accountable for compromising the privacy and confidentiality of patients. Therefore, the telemedicine guidelines should be changed accordingly to incorporate the role of HSPs and state accountability mechanisms. Further, an HSP/RMP may be able to record/ retain previous health logs through the means of physically copying/ screenshots, etc. There is a threat to the patient's privacy and adequate guidelines need to be incorporated in this regard.

Reference	Issues and Remarks
Chapter 2: 2.4 Questions for Consultation	
2.4.1 As a stakeholder in the health ecosystem, what benefits and risks do you see if an open network approach to digital health services is implemented? Please respond with details. (Page No. 18)	The open network to digital health services has several benefits. Interoperability will be possible which increases the likelihood of competition in the market as more HSPs will be able to come online. It will also enable healthcare aggregators to offer better services. However, a few risks exist which should be addressed. While using and participating in the NDHE is purely voluntary, there is a risk of the HSPs mandating the use of the service in a de facto manner. In this case, adequate guidelines may be issued periodically. Further, a de facto mandate may severely affect socio-economically weaker sections since there is a huge digital divide and their exclusion from healthcare is a big concern. Further, apart from the digital divide, there also is a huge lack of digital literacy. Since bridging the digital divide and ensuring digital literacy is not a mandate of the NHA, it should develop a strategy in partnership with the Ministry of Electronics and Information Technology (MeitY) and Ministry of Education to ensure a filling up the gap. The NHA may refer to comments submitted by CUTS to MeitY on Strategy for National Open Digital Ecosystems[18] where suggestions for awareness campaigns are made.
Chapter 3: 3.8 Questions for Consultation	
3.8.1 The primary stakeholders in the UHI ecosystem are mentioned in section 3.3. While the list is more indicative than exhaustive, are there any other primary or secondary stakeholders that should be considered while building the interface? If yes, please outline their role in the UHI ecosystem. (Page No. 24)	A large section of the population gains access to healthcare through the National Health Mission. Here, under the National Rural Health Mission, the Accredited Social Health Activist (ASHA) and Auxiliary Nurse Midwives (ANMs) play a huge role in providing preventive healthcare. While the draft mentions that they are being considered while preparing Healthcare Professionals Registry, it fails to identify them as HSP in section 3.3. The ASHA and ANMs should be considered as stakeholders and be included as HSPs. Further, e-pharmacies and e-clinics are also stakeholders which have not been explicitly identified in the draft.

[18] https://cuts-ccier.org/pdf/submission-to-ministry-of-electronics-and-information-technology-on-strategy-for-national-open-digital-ecosystems.pdf

Reference	Issues and Remarks
3.8.2 The proposed objectives of UHI and UHI Network have been detailed in sector 3.4. Please share your comments on the comprehensiveness of these objectives, methods to ensure these objectives are adhered to. Please comment if there are other objectives which must be included in section 3.4 (Page No. 24)	The proposed objectives are comprehensive and provide a complete list for meeting the expectations of all stakeholders. However, a one-time verification of entities may not be sufficient to ensure that all HSPs are genuine and providing good services to users. An HSP may operate illegally and provide substandard quality services. While the rating mechanism may address the issue to a certain extent, NHA should identify periodic auditing mechanisms to ensure that only genuine HSPs are on boarded.
3.8.3 UHI will support a range of digital health services and is expected to evolve with time. How should digital health services be phased in the upcoming versions of UHI? (Page No. 24)	Rolling out of UHI is the most crucial thing for ensuring that the NDHE thrives. A mission mode implementation is not desirable as the issues around protecting personal data are important. The implementation should be done in a controlled and phased manner and should be aligned with the adoption of other data-related legislation and frameworks in India. The NDHM can adopt a sandbox approach where feature-wise adoption and scaling up should be envisioned. The features linked to sharing personal data and ensuring the privacy of users may be rolled out only after the enactment of the Personal Data Protection Bill 2019 or similar legislation. Further, anonymisation and sharing of personal data should not be allowed until the Government of India adopts a framework for governing non-personal data like the Non-Personal Data Governance Framework prepared by the Committee of Experts. Further, sharing data with third parties should not be allowed until the DEPA or similar framework is adopted by the Government of India. The adoption of UHI should be in synergy with the data protection and privacy regime being developed.
Chapter 4: 4.3 Questions for Consultation	
4.3.1 Have all incentives/disincentives for various stakeholders to participate been covered in chapter 4? If not, please provide the list and mention the role and description of the stakeholder. (Page No. 28)	Currently, many hospitals want patients to access only those labs/pharmacies with which they have existing partnership and reject reports obtained from non-partnered labs on the pretext of accuracy. Such partnerships between hospitals and lab/pharmacies are anti-competitive in nature. With UHI, patients will have access to more labs/pharmacies and will tend to access the ones which provide cheaper and better services. This is a welcome move as hospitals as it will increase competition in the market.

Reference	Issues and Remarks
4.3.2 For the disincentives mentioned in chapter 4 and the ones provided as an answer to the question above, please provide details on possible mitigating measures that may be taken to minimize the impact of said disincentives. (Page No. 28)	In order to address the problem of accuracy of reports from labs, a possible solution is to ensure that only good quality labs/pharmacies which have registration/accreditation to operate are on boarded so that the hospitals/doctors can accept the reports produced by them easily. Further, partnership of hospitals with labs/pharmacies should be discouraged as it is anti-competitive in nature.
Chapter 5: 5.3 Questions for Consultation	
5.3.1 In the proposed discovery model in section 5.1.3.1, EUAs are expected to present all responses returned by the Gateway to the user and allow the user to choose the HSP. Should any alternate models be allowed? If yes, provide details. **(**Page No. 37)	While the model suggested seems to be appropriate, there is a threat of advertisements of certain HSPs being shown by EUAs which may mislead patients (as in the case of Google search). The discovery model should discourage advertisement and showcase results only from the repository which NHA has prepared. This will not only promote platform neutrality but will also ensure that data of users is not being used to target advertisements, thus protecting privacy of users.
5.3.2 Are there any challenges to the proposed approach to the pricing of services detailed in section 5.1.3.2? Please suggest other alternate pricing models that must be supported by the Gateway. **(**Page No. 37)	As UHI is environed as a public good, users should not be charged for UHI Gateway. Such charges should rather be taken from business side users of UHI like HSPs, HSP Applications (HSPAs) and EUAs.
5.3.5 The proposed approach for allowing users to share ratings for the HSPs as well as EUAs has been laid out in 5.1.3.5. Please comment on the same and share any other approach that might be adopted. **(**Page No. 37)	Users value privacy. Therefore, some of them may not be willing to make public comments about services sought because of stigmatization of several health issues like mental and sexual health issues. However, they may also be willing to flag concerns with the quality of service. Therefore, along with the provision of making public ratings, a mechanism of anonymous rating should be provided. It should be verified and ensured that such ratings are done by end-users who have actually sought service from an HSP. This will give privacy to the user as well as ensure that reviews are real.

Reference	Issues and Remarks
Chapter 6: 6.5 Questions for Consultation	
6.5.1 What approaches, other than the ones mentioned in chapter 6, should be considered for managing and governing the UHI gateway? Please provide details. (Page No. 40)	With respect to the development of software for the UHI gateway, a better approach is to have open-source codes as they can be examined and audited by independent developers. This will help in building trust among the users as well as other institutions. (Example: The source code of the Aarogya Setu app was made public to build trust among the public and civil society organisations). The same approach should be adopted from UHI. Further, to build trust among users, NDHM should consider a sandbox for patients to try out UHI with dummy health data.
6.5.2 What should the UHI Gateway charge in the initial few years of operation? How can this model evolve over time? (Page No. 40)	A commission per transaction-based pricing model should be adopted where business side services like HSPs, HSP Applications and EUAs should be charged the commission. The advertising model where HSPs can advertise their products on EUAs should be discouraged because it may lead to end-users being misled. For increasing adoption and entry of new HSPs on UHI, a threshold transaction limit may be defined against which the UHI charges may be set to the minimum. In the future, price modelling (using mathematical tools) needs to be done based upon multiple factors like the number of users, number of users accessing the service, the number of transactions being made, etc. The service charges should be calculated based upon the requirement to ensure the sustainability of the UHI Gateway. The model should be based on a no-profit no-loss principle so that consumers' welfare is maximised.
Additional Comments	
1.4.5.4 Standardisation of the formatting of health records like diagnostic reports, discharge summaries, prescriptions, consultation notes, and immunization records to make them interoperable. (Page No. 9)	Here, blanket mandatory rules for the adoption of standardised health entry cannot be feasible because of factors like lack of awareness and lack of digital services in the country, etc. Most HSPs will be ill-equipped to immediately deal with such norms. However, larger hospitals chains may be incentivised to adopt this first.

Reference	Issues and Remarks
1.5.2.4 User Applications: Insurers	There should be a provision provided from calming health insurance like Ayushman Bharat within the UHI. Such a provision will benefit consumers greatly as they will be saved from the hassle of making payments and then approaching the insurer. This will promote cashless payment and the Digital India initiative, ultimately benefitting the consumers.
5.2.1.1 Patient Experience: The patient logs into a EUA of their choice using their Health ID. This also enables their EUA to get access to the medical history associated with the Health ID, if consented by the patient. (Page No. 35)	While this will enable users to view their past medical health records, the EUA should not be able to store medical history associated with any e-Health ID. Such access should be provided by developing a set of APIs so that only the user gets access to her medical records. Further, the EUA should not be able to use this for data for selling and monetisation purposes.

Conclusion

CUTS International looks forward to National Health Authority accepting the suggestions given above, and assisting NHA in its endeavours of empowering consumers and individuals. For any clarifications/further details, please feel free to contact Prince Gupta (prg@cuts.org) and/or Setu Bandh Upadhyay (sbu@cuts.org).

****