RESPONSES TO THE INVITATION FOR PUBLIC COMMENT

Consultation Paper on

Unified Health

Interface (UHI)

1st SEPTEMBER, 2021

Facilitated by:

St John's Research Institute ThoughtWorks Technologies India Private Limited

EXECUTIVE SUMMARY

We are delighted to see the progress with the National Digital Health Mission's work and are pleased to provide feedback on the proposed Unified Health Interface (UHI).

This response has been collaboratively drafted by domain experts in health and technology, several of whom have authored earlier responses to the Government of India's National Digital Health Blueprint (NDHB); Personal Data Protection (PDP) Bill; drafts of NITI Aayog's National Health Stack; and recent drafts of NDHM's Health Facilities Registry and Health Professionals Registry (available at: https://mittalsouthasiainstitute.harvard.edu/india-digital-health-net/). Here, our responses are organized by chapter and consultation question. Where applicable, additional comments are made at the end of the chapter.

The key messages of our comments on the UHI are summarized below:

- Enable high quality choices: Helping patients navigate choice is as or more important as giving them choice. There is high risk for attrition if patients become overwhelmed by choices or perceive poor quality choices. We recommend several mitigating strategies: only allow verified providers to use UHI; allow End User Applications (EUAs) to customize choice architectures so long as they allow patients to see all results; let patients connect information like their health insurance or record to see personalized results about recommended services, providers and cost; a patients' view of a provider's ratings should span all EUAs and not be limited to the ratings on their EUA; service request parameters and Health Service Provider Application (HSPA) responses should use structured vocabularies, terminologies, code sets and classification systems.
- Build trust and credibility: As compared to platforms where there can be tight controls on quality, an open network needs to enable such guarantees by design. We recommend that only providers who have verified credentials be allowed to operate on the UHI platform; provider credentials and verifications be clearly displayed; patients have access to up-to-date qualitative and quantitative measures of service quality and reliability; patients and providers can mutually verify each other's identity; grievance redressal be timely and robust; providers who are less tech-savvy or see older, poorer, more rural patients (less likely to leave feedback) are not disadvantaged in service discovery.
- **Digital Equity:** We recommend that digital equity and inclusion be a key objective of the UHI. The CoWin app demonstrated that digital healthcare booking services can have the unintended consequence of exacerbating healthcare disparities between the digitally savvy and older, poorer, rural and other digitally disadvantaged segments of the population. In order to move towards greater inclusion and equity, several aspects of the UHI workflow need to be examined: how to ensure consent is given and informed, can patient's delegate consent to a proxy, etc. We anticipate that a large number of patients and consumers will require assistive services (the help of an ASHA, family member or dedicated patient navigation services) to leverage UHI; we recommend that the

UHI accommodate such access while designing protocols and standards. We also urge UHI to ensure that EUAs meet minimum WCAG/ WAI¹ accessibility standards.

- Open technology governance: We appreciate NHA's emphasis on technology governance in UHI, and commend the process NDHM has followed for the Health Data Exchange so far. Technology governance has got a huge role to play in influencing technology and innovation policy in the right direction, ensuring that we reap the benefits of emerging technologies while preventing or mitigating potential negative effects. We urge NHA to take cues from Java and HL7 FHIR community processes to ensure an even more open participatory and inclusive process for technology governance, where ideation, formation and specification of standards happen democratically and transparently. In addition, we recommend that an iterative approach of standards progressing through DRAFT=>TRIAL USAGE => NORMATIVE process will enable rolling out standards that are inclusive and appropriate in health service delivery. In this regard, we also advocate for approaches like RBI's "Regulatory Sandbox" in FinTech space, allowing for testing and rapid iterations of all critical components of the design, and simultaneous testing of alternate models; provide interoperability testing labs; and continuously solicit feedback and respond to the ecosystem.
- Multidirectional interface: The current workflow outlined in the UHI does not specify whether providers can initiate service requests with the patient, to book their service (follow-up) or the service of another provider (referral). We recommend that providers be able to make both types of requests to patients through UHI. This will help ensure patients follow-up with their provider, shift from episodic care to care continuum, and support population health and accountable care models. Patients can of course decline such requests and providers can be restricted to making such requests only with patients whom they are actively treating.

We are very grateful for the time, attention and counsel provided by all contributing authors. And finally, we thank the NDHM and NHA for this opportunity to respond to the consultation paper on UHI.

Sincerely,

On behalf of our co-respondents,

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¹ https://www.w3.org/TR/mobile-accessibility-mapping/

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Answers to Consult Specific Questions

Chapter 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 adoption of telemedicine and e-pharmacy.

Section 1.3.3 of the telemedicine guidelines¹ states that Registered Medical Practitioners (RMP) must complete a mandatory online course within 3 years of its notification; RMPs who fail to do so will not be allowed to provide telemedicine services. The guidelines do not state how this restriction will be enforced and, per our understanding, the Health Professionals Registry (HPR) does not collect and maintain information about course completion. We would recommend that MCI and NDHM consider leveraging the HPR as the single source of truth and maintain this information in the registry for each eligible RMP.

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.

An open network for health services will have myriad benefits for patients, providers and technology service providers. Providers will benefit from larger available and obtainable markets. Patients will have greater choice of providers (with less discovery and geographic limitations), more information for decision-making, and possibly lower cost care (as competition expands). More technology service providers can emerge with lower costs of acquiring physicians or using standard protocols.

There are some key challenges that we foresee and need to be addressed:

Challenges for the platform

An attempt to create a single uniform standard applicable across all health domains and pan-india may be premature, take substantial time, and lead to a suboptimal experience for patients and providers. We envision different healthcare service domains (eConsults, teleradiology, telediagnosis, mental health, chronic disease management) will need to agree on protocols and standards that make sense across India and the UHI will need to find a balance between a common minimum and contextualization for each domain. We recommend that a prototyping approach be followed (as detailed further in 3.8.3) coupled with the 'Dumb Network, Smart Endpoint' philosophy and architectural principles that helped develop the internet². We restate some of these here and make recommendations:

- 1. The Internet and its architecture have grown in an evolutionary fashion from modest beginnings, rather than from a Grand Plan.
- 2. The network's job is to transmit datagrams as efficiently and flexibly as possible. Everything else should be done at the fringes.
- 3. Its evolution depends on rough consensus about technical proposals, and on running code. Engineering feed-back from real implementations is more important than any architectural principles.
- 4. Nothing gets standardised until there are multiple instances of running code.

We therefore recommend the following:

- 1. UHI should only provide basic infrastructure, minimal rules and interop protocol (standards based).
- 2. It should assume that multiple sub-domains will evolve (or emerge) at their own pace -- and standards within each sub-domain should evolve, rather than a universal standard across all.

² https://datatracker.ietf.org/doc/rfc1958/

- 3. The philosophy of Hub-and-spoke or <u>Federated architecture</u> (FA) should be embraced, as also articulated in NDHB. FA is a pattern in enterprise architecture that allows interoperability and information sharing between semi-autonomous de-centrally organized lines of business (LOBs), sub-domains, IT systems and applications. It enables high flexibility and agility among independently cooperating components and at the same time reduces complexity significantly.
- 4. One can also imagine UHI as a network of "Exchanges" or "Hubs" -- where each Hub evolves and adopts its own standards, with varying players providing implementations -- while inter-hub communication happens over the UHI using agreed upon FHIR packets or profiles.
- 5. This will also enable sub-domain specific innovation in user-experiences & EUA -- which would otherwise be too restrictive if we attempt to standardize them today. For example, it isn't possible to imagine all future use-cases or journeys involving Teleconsultation Discovery, Delivery, Fulfillment and Feedback today.

Risks for patients:

There are over 1.2 million registered doctors in India, excluding AYUSH professionals, mid-level healthcare providers and organizations like hospitals, pharmacies, labs. The open network will provide ample choices to patients but this may also have the unintended consequence of paralyzing patient choice and attrition. Consider how the UHI could enable EUAs to customize discoverability; for eg. patients should be able to search by ailments, be recommended providers based on their healthcare history, and implement proprietary sorting or ranking algorithms.

Consider enabling patients to integrate information about their insurance into the UHI. This is important as increasing numbers of Indians are participating in some sort of risk pooling where the payor may also negotiate favorable rates with certain providers. It is unclear how the UHI would currently handle this. Consider allowing patients to integrate their insurance information into the UHI; EUAs could then use this information and display information like who is in-or-out-of-network and what is the charge specific to the patient's insurance plan vs. out of pocket.

Risks for providers:

As population health management strategies gain traction, health systems will want to send reminders, alerts, and other proactive messaging to patients given they have a provider-patient relationship (patient has availed care there previously), within a period limit and if patients so consented. This will also help with the issue of lost-to-followup.

Consider enabling providers to initiate referrals and follow-ups with patients through the UHI. Consider keeping the requests templated to avoid misuse.

Risks around trust and credibility:

As compared to platforms where patients can perceive tighter controls on quality, an open network may have less guarantees. Displaying practitioner credentials and verifications is important; simultaneously, consider a suite of quantitative and narrative reviews to help patients sift and choose services. Assisting consumers with information on quality and reliability of services as well as trustworthiness of HSPs is a key part of the platform. UHI may specify a core set of metrics and allow EUAs and HSPAs to add additional ones.

Advertising, phishing attempts, spam, and patient poaching are examples of negative practices that routinely occur and do a disservice to patients. UHI may amplify some or each of these practices. NDHM should consider technological or policy measures to mitigate these.

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.

We suggest the following stakeholders be considered while building the UHI interface:

- Allied health professionals: In keeping with the health professionals' registry, we suggest that all allied healthcare professionals like physiotherapists, psychologists, audiometrists, optometrists, prosthetists, masseurs be able to use the UHI with verified credentials.
- Health policy makers, researchers and regulators: These stakeholders may require access to anonymized or aggregated UHI data for health services planning, quality improvement, public health programming, etc. In other cases, identified data may be requested, for eg. by regulatory bodies wanting to conduct quality audits on providers. Consider specifying how these stakeholders can access the data, with what permissions and restrictions.
- Digital service providers: An emerging class of healthcare services, enabled by AI/ML or digital tools, may be offered to patients in lieu of traditional health service providers. For eg. patients may be able to get diagnostic, prognostic or second opinion services through an Al-enabled service (TB detection through chest radiography³, atherosclerotic cardiovascular disease outcomes prediction⁴); others may partake in digital chronic disease self-management programs. We envision these services also becoming UHI compliant and therefore should be considered as stakeholders.
- Medical suppliers: Would the UHI enable services like medical supplies (walkers, bed assists, oxygen cylinders), blood banks to be discovered and booked? In this case, we would consider these entities as key stakeholders.

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.

Under the objective of fair discoverability, the document states that 'every HSP...has an opportunity...[to] have their services discovered in an unbiased manner.' We seek clarification on what counts as biased and unbiased. Even if an EUA does not outright restrict results, the manner in which results are displayed can be considered restriction. We see several scenarios in which an EUA might reasonably filter providers; for eg. an EUA might first display in-network providers to patients who have connected their insurance

https://www.researchgate.net/publication/345308478 Reliable Tuberculosis Detection Using Chest X-Ray With D eep Learning Segmentation and Visualization

⁴ https://tools.acc.org/ascvd-risk-estimator-plus/

information; patients who search for common outpatient ailments (like cough) may be shown general practitioners before a specialist; if a patient searches for a practitioner for sexual health issues, an EUA might filter providers from the gateway that are unrelated. We recommend that TSPs be allowed to design the discovery interface and choice architecture but be required to provide an option for patients to see all results.

Under the objective of verification of entities, consider clarifying what is meant by 'genuine doctors'. Does this mean only providers with verified credentials will be able to participate in the UHI? We agree with this. Providers whose qualifications are unverified or pending or lapsed verification should not be presented on the UHI network to ensure patient safety. Additionally, consider establishing a governance mechanism to remove providers from the UHI network (this may also happen in the case of license withdrawal).

Beyond the listed objectives, we propose the following to also be objectives of UHI:

- 1) High quality data: With UHI enabling discovery and booking of services, patients will depend on the quality of data to make decisions. It is critical that UHI prioritize high quality data on the network. There can be wide range of data quality issues as explored by Mulgund et al⁵ and these need to be mitigated.
- 2) Transparency: To ensure that patients have a comprehensive view of the providers' quality, physician feedback collected on one EUA should be visible to patients using a different EUA. This data should not be considered as 'business data' to rationalize restricting access.
- 3) Accessibility: It is unclear how patients with no or low digital literacy will be able to benefit from the network. Considering telemedicine or telehealth services can be assisted by the community health workers, ANMs or ASHAs, we are unsure how implied consent, as mentioned in telemedicine guidelines, would be ensured in such scenarios. Consider developing a mechanism that tracks and allows delegated consent.
- 4) Digital Equity: The UHI will upend habits of healthcare seeking that have developed over a lifetime. Traditionally, patients went to a local provider to begin their care journey (the process of accessing the care they need). With the UHI, they will be expected to use an application, choosing from a large number of providers without much guidance. This could easily overwhelm patients and lead to disengagement as has been the case with telehealth provider platforms⁶. Rollout of the CoWin app showed that tools meant to improve access can have the unintended consequence of worsening access disparities among older, poorer, rural and other digitally disadvantaged segments of the population. In order to move towards greater inclusion and

⁵ Mulgund P, Sharman R, Anand P, *et al.* Data Quality Issues With Physician-Rating Websites: Systematic Review. *J Med Internet Res* 2020;**22**:e15916. doi:10.2196/15916

⁶ https://www.acutecondition.com/p/paas-companies-and-telehealth-engagement

equity, we advocate that UHI must be designed to accommodate the needs of all demographics to encourage their participation. We recommend:

- a) EUAs must be accessible to people with disabilities and meet minimum WCAG/WAI accessibility standards.
- b) A mechanism be developed whereby a community worker or family members can be delegated consent to discover and request services on behalf of the patient.
- c) Health and Wellness centers must be equipped with EUAs capable of providing services through assisted means without compromising patient's safety and privacy.

3.8.3 UHI will support a range of digital health services and is expected to evolve with time. How should the digital health services be phased in the upcoming versions of UHI?

As transactional as the arrangements between components of UHI may seem to be, we must recognise that human health is not a commodity. All components of the proposed architecture must enhance (and not imperil) access to care and quality of care, even for the millions that are not yet members of the digital grid.

In our response to the NDHB consultation paper⁷, we proposed a cyclic approach of testing, feedback (including grievance redressal) and rapid prototyping. We believe that such an approach is critical to the success of the NDHB, and reiterate the suggestion of the "Regulatory Sandbox" here.

As many of the components of the proposed architecture have not been tried in India and never at such a scale anywhere in the world, we recommend a prototyping approach, linked closely to a Regulatory Sandbox, that allows for testing and rapid iterations of all critical components of the UHI design. This prototyping environment will allow the rapid and simultaneous testing of alternate models, provide interoperability testing, and continuously solicit feedback and response to the system.

Please note that the existing NDHM Sandbox environment is different from what we are proposing here. Regulatory sandboxes allow live testing of new products or services in-situ in a controlled environment where regulators permit certain relaxations for the limited purpose of the testing. Regulatory Sandboxes must be accompanied by clear boundary conditions, data governance measures and risk mitigation strategies, as has been instituted, for example, in Singapore for telemedicine initiatives⁸. Guidance may

 $[\]frac{\text{https://bif5m4023k53ib5vt30v2wu8-wpengine.netdna-ssl.com/wp-content/uploads/2019/08/Response-to-the-Invitation-for-Public-Comment-National-Digital-Health-Blueprint.pdf}$

⁸ Ministry of Health Singapore [Website). Licensing experimentation and adaptation programme (LEAP)- a MOH regulatory sandbox. Available on:

 $[\]frac{https://www.moh.gov.sg/home/our-healthcare-system/licensing-experimentation-and-adaptation-programme-(leap)---a-moh-regulatory-sandbox\\$

be sought from the proposal of the Reserve Bank of India for regulatory sandboxes in the fintech⁹ space.

In terms of phasing digital health services, we believe the UHI-proposed flow: "Service Discovery => Booking => Fulfilment => Settlement" does not apply to all health services. While this may be suitable for services or products that can be represented by fixed unit or package pricing, it may not be appropriate for those that require adjustments and personalisation. For example:

- Services that may be catered to only when advised by Doctors
- Controlled medications that cannot be dispensed through teleconsultations
- Charges that are adjusted based on patient condition or employment to affiliated organisations
- Services that are multi-staged or offered through flexible or installment-based payment plans, for eg. for a surgery, a patient could pay 50% up front and the remainder in installments; similarly this could apply to orthodontic or orthopedic procedures.
- Consultation services that are offered free if availed within a certain period of time.
- A day-care procedure may require price adjustments post-surgery

We advise that NDHM start with a few service sub-domains (e.g. Teleconsultation), and evolve standards for other domains (teleradiology, telediagnosis, Mental Health, NCD etc) iteratively through feedback with the ecosystem.

⁹ RBI Framework for Regulatory Sandbox https://www.rbi.org.in/scripts/PublicationReportDetails.aspx?UrlPage=&ID=1161

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.

Incentives

Patients or End Users:

The UHI will not only widen access to teleconsultations and health services like lab tests, medicines, medtech devices; it could even enable new classes of health services to be offered as products or services that are not yet on the market. This includes digital therapeutics, wellness services or personalized risk stratification models.

Researchers and Policy Makers:

The UHI will generate data on healthcare utilization and service quality that is unavailable in India today. Health systems researchers must be able to access and analyze these data with appropriate protections to patient privacy.

Disincentives

Providers:

Traditionally, a provider can limit the number of patients they see or the kind of patients they see or double book appointments out of fear of last-minute cancellations, or temporarily suspend their services. It is unclear whether the UHI will enable this flexibility to providers; we would recommend that it does. Additionally, if patients can rate providers then providers need to be able to respond and their responses visible to all patients. Also consider enabling parameterized ratings vs simply a global rating. This will enable flexibility and be to the patients' benefit. Consider also clarifying how grievances related to inconsistent or flawed provider verifications will be handled.

UHI transaction data can also be potentially used by EUAs to influence the market in collusion with HSPs. NDHM can define guidelines for EUAs and HSPAs to prevent secondary sale/service of sensitive business intelligence/transactions data to build trust with the participating hospitals and other healthcare facilities.

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.

These are included in response 4.3.1

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.

This is a pertinent question with regards to fairness to both HSP and user. While EUAs should display responses without bias, they also have obligations to provide effective service to their users, who may even pay a fee for personalisation by EUA. EUAs may be using other supplementary sources, and/or personalisation rules to provide the best experience for their users. Please also refer to our response to 3.8.2 regarding insurance-based search and filtering certain providers. In our opinion

- EUAs may show curated or personalized content if the user so chooses, as long as EUA allows the user to see unfiltered results.
- EUA may also push their recommendations to the top, as long as they indicate so. e.g. showing clear tags "Promoted", "Sponsored" etc.
- EUAs may sort, filter, and group responses as they wish as long as the users are allowed to change such criteria.

At the same time, we recommend regular audits and proactive research of EUA apps or services for conformance to any guidelines.

To provide standardised and higher quality search results, we suggest that service request parameters and HSPA responses should use structured vocabularies, terminologies, code sets and classification systems. These may be maintained with the UHI.

5.3.2 Are there any challenges to the proposed approach to pricing of services detailed in section 5.1.3.2? Please suggest other alternate pricing models that must be supported by the Gateway.

We think the proposed approach is a good starting point. Please also see comments on 6.5.2. However, since NDHM is contemplating multiple UHI Gateways in future, it should establish guidelines on arriving at gateway charges across NDHM. The UHI gateway charges and EUA charges could be indicated clearly and could be passed on to the end users or absorbed by the HSP

5.3.3 Are there any other areas that must be supported by the Gateway for service fulfilment in section 5.1.3.3? If yes, provide details.

To ensure transparency and reduce the chances of collusion between HSPs and EUAs to game the ratings, we propose that service fulfilment metrics (# bookings, # bookings completed, # average wait time, # bookings cancelled) for services booked through one EUA must be made available to patients using any other EUA. This data should not be considered 'business data' and restricted.

We feel that adjustments to agreed services or products may be done at the time of fulfilment and the patients should be able to ask for a refund or a product replacement through the EUA. For example

- It may be discovered that a patient ordered both CBC and ESR, without knowing that the CBC Panel covers the ESR test as well. We must not assume that EUAs would have the capability or information to assist the user at the time of booking.
- A patient may neglect to share their insurance information with a provider who is empanelled with that insurance; in this case a correction would need to be done on the final charge.
- If a home monitoring product (pulse oximeter, glucometer, etc) delivered to a patient is faulty, the patient should be able to ask for a replacement.

Please refer to our response on 5.3.5 for more details on service fulfilment metrics.

5.3.4 Post-fulfilment, as described in section 5.1.3.5, covers ratings and grievances. Are there any other areas that must be supported by the Gateway for post service fulfilment in section 5.1.3.5? If yes, provide details.

Considering that grievances may be raised by users, HSP or EUAs, please clarify the statement in section 5.1.3.5, that "NDHM UHI will take responsibility for handling grievances related to digital open platforms only". We request that NDHM articulate the bounds and terms within which consumers can expect redressal.

Booking follow-up appointments with doctors should be seamless on UHI, otherwise patients may revert to availing services outside the UHI. The consultation paper describes the protocol as similar to SMTP but does not allow providers to initiate requests with patients. We recommend that UHI allow providers to initiate service requests with the patient, to book their service (follow-up) or the service of another provider (referral).

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.

We agree that HSP ratings will help build trust with consumers; at the same time, user ratings must not be the only measure of quality. Such ratings can be gamed and might also have the unintended consequence of putting smaller, more independent providers at a disadvantage.

EUAs displaying credentials and verifications of practices or services are important, and we recommend NDHM to consider quantitative and narrative reviews to help patients sift through services. UHI may specify a core set of metrics and allow EUAs and HSPAs to add additional ones. Certain metrics around service outcomes (# bookings, # bookings completed, # average wait time, # bookings cancelled) should be automatically computed; many patients may not leave feedback.

NDHM should think of making quality and performance data accessible to the ecosystem to be displayed along with feedback and ratings, so that end users can make informed decisions. Example of such potential information sources are

- NDHM envisaged Health Analytics¹⁰ building blocks with indicator themes of "Quality of Care", "Data Quality", "Wellness", "Public Health" etc
- Hospitals, Clinics or Labs are already doing statutory reporting. Quality metrics may be derived from such reporting and made publicly accessible. For example - number of TB patients treated monthly at a facility may be fetched from NIKSHAY
- Provider information may also be fetched by EUAs to display the credibility of information and may also be highlighted by EUAs. For example, an EUA might display whether a particular facility has NABH Pre Accreditation Entry Level certification, or a Doctor's proclamation of qualification is ratified.

In addition to the above, we will also encourage NHA to look into prevalent quality frameworks used in other countries.

- In USA, for quality measurement, Medicaid and Medicare Services has adopted "Meaningful Measures framework¹¹" to develop ePRO (Patient Reported Outcomes) and Patient Reported Experience Measures (PREM) programs.
- In the UK, NHS has been using the Quality and Outcomes framework (QOF) to incentivize GPs towards improvement of quality of general practice, and rewarding GPS for implementing "good practices" through a set of agreed "measures" (indicators) every year. In the NHS, GP payments are linked to QOF points accumulated, and while it will not be so in the Indian context, NDHM should consider mandating a set of "measures" for the service providers in the UHI.

¹⁰ Table 2.2 of NDHB - https://www.nhp.gov.in/NHPfiles/National Digital Health Blueprint Report comments invited.pdf

 $^{^{11} \} Meaningful\ Measures\ 2.0\ -\ \underline{https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization}$

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.

Standards specification process:

We commend the NHA and NDHM for the consultative process they have taken and the recognition of the importance of technology governance. We believe more can be done to define protocols and standards of the UHI in an open, participatory and inclusive process. Specifically, we ask NDHM to consider taking an open community process so that standards can be proposed and created through consensus with transparency.

To highlight the effectiveness of such process, we point to two successful examples of the community processes for defining technology standards: 1) Java Community Process (JCP¹²) and 2) HL7 FHIR Community Process (FCP¹³) and standard development process (FSDP¹⁴)

Briefly:

- 1) In the Java ecosystem, anyone can sign up to become a community member and propose new technologies or specifications through the Java Specification Requests. JSRs are reviewed publicly and passed through voting and the process is managed by an Executive Committee which is elected from and by the community members. The JSR also provides a free reference implementation of the source code and a Technology Compatibility Kit (TCK) to verify the specification. The process is open and transparent: JCP membership (free for individuals, paid for commercial entities), JSR committees (voting and TCK) are all available in the public domain. We recommend that free and open source Technology Compatibility Kit also be used in the case of the UHI components so that their use cases can be verified and help jumpstart HSPA and EUA development.
- 2) HL7 FHIR similarly has an open community process. In addition, they also lay out the standard development process, which we believe is relevant not just for UHI but for all NDHM specifications in general. This helps to indicate the level of stability and implementation readiness associated with specification. FHIR and other HL7 specifications achieve this through an approach of "DRAFT => TRIAL USE => NORMATIVE". Specifically the "TRIAL USE" is the phase where we think the Regulatory Sandbox approach (described in response to 3.8.3 above) can be used to test on real live use cases within a certain regulated environment.

¹² Java Community Process - https://jcp.org/en/introduction/overview

¹³ FHIR Community Process - http://fhir.org/community/process/

¹⁴ FHIR Standards Development Process - https://www.hl7.org/fhir/versions.html

Given the complex, novel architecture that is being proposed for the NDHM, we believe iterative and collaborative development, with consensus of stakeholders, is critical. We urge NDHM to establish a Technology Governance process through which it must oversee the use of Information and Communication Technology (ICT) in UHI to create value and manage the associated risks for the participants.

- Constitute formal committees and processes for Technology Governance not just for UHI but for all citizen services available through NDHM
- Research and publish acceptance reports, provider and consumer issues and requirements, to provide feedback to the technology and domain communities and committees.
- Publish IEC guidelines for consumers and providers.
- Setup forums and collaboration channels not just for HSP, HSPA or EUA but also for end-users and service domain groups
- Host seminars, lectures, conferences and workshops for soliciting feedback, experiences and sharing information
- Do advocacy and promotional activities on governance related issues
- Influence public policy through the service usage patterns observed on UHI. For example: Availability of services in a particular region, usage of services by demographics
- Adopt an open source policy so that digital public infrastructures are built over non-proprietary, free and open source technologies
- Proactively support or cultivate open source development, communities formation or engagements, create information and knowledge bases (e.g. NHS Digital¹⁵)

We agree with the approach of the UHI Gateway being operated by NDHM to start with before opening to others. Before that, NDHM also should come with a strong IT Systems Governance applicable within the UHI gateways for

- Performance management e.g. agreeing on Quality of Service (QoS) and Quality of Performance (QoP)
- Guidance and policies around data and risk management, specifically around data integrity and availability across the UHI gateways
- Information sharing e.g. ratings, data privacy and protections
- Observable metrics grievances, disputes, time for settlement etc
- Guidelines and processes for periodic audits of EUAs and HSPAs for identifying malpractices

¹⁵ NHS Digital - https://digital.nhs.uk/developer

6.5.2 What should the UHI Gateway charge in the initial few years of operation? How can this model evolve over time?

We think UHI Gateway should charge zero or the absolute minimum to start with. This would allow NDHM to more easily onboard HSPAs and especially EUAs and encourage more EUAs in the market.

Unlike UPI, where the primary flow is transfer of money either in PULL or PUSH mechanisms, UHI consists of multiple flows and steps in service booking and delivery, which may require significant infrastructure and computational capability. This may justify transaction fees by UHI Gateway, especially considering NDHM is contemplating extending UHI gateway to other organizations in future. As mentioned earlier, NDHM should look to establish guidelines on arriving at gateway chargers when they are opened up.

In future, Gateway(s) can opt for

- 1. Subscription basis
- 2. Pay per use basis

It may even consider slabs based on HSP transactions- for example, no charges for 1000 transactions within a period, subsequently 1000-5000 at X, and so on.

Gateway, can even have differential charges based on HSPs - for example, single doctor clinics where majority of Indians go for services, may be exempted from such fees.

6.5.3 Please share your views on the duration for which NDHM should manage and govern the UHI gateway, and if NDHM should open the path to multiple gateways. Please provide details on the benefits and risks of the options.

We think NDHM should operate and manage the UHI Gateway until it is widely adopted, accepted, and trusted; it is used for services beyond telemedicine; and policies and compliance are well established. At that point, while NDHM should continue to govern and set regulations for UHI, the operational aspects can be handled similar to NPCI or GSTN:

- 1. UPI is operated and regulated by National Payments Corporation of India (NPCl¹⁶), a section 8 not for profit organisation, established by RBI and Indian Banks' Association¹⁷
- 2. Goods & Services Tax Network (GSTN¹⁸) is a fully owned Government Company with equal shares of Central and State Government, managing the IT Infrastructure and Service backbone.

Regarding opening to other gateways, we see the following risks and benefits:

¹⁶ NPCI - https://www.npci.org.in/

¹⁷ Indian Banks Association - https://www.iba.org.in/

¹⁸ GSTN - https://gstn.org.in/about-us

Benefits - Specialized service domain networks can emerge e.g. Oncology and endocrinology, allowing supplementary services and better experiences for both providers and patients. Domain-specific standards may also be created, which NDHM can assimilate into national standards through due process.

Risks - Preferred networks might emerge and there is a possibility of manipulation. Gateways may try to price out or exclude certain EUAs or restrict which providers are serviced through their gateway; there may be collusion between gateways and certain HSPs for favorable pricing. Some measures may be taken to mitigate these risks: gateways must agree to a common set of policies and standards, EUAs must be allowed to operate across gateways uniformly. Still, there are work-arounds that might ultimately go against the objectives of the UHI.

These are speculations and we suggest that NHA revisit this question as the ecosystem evolves.

Additional Comments

In this section, we comment on parts of the document that are not covered under the posed questions, but we feel are important to discuss.

- The UHI consultation document does not mention if B2B Services can leverage UHI. For example: Would a hospital be able to book the services of another health service provider like a laboratory or pharmacy?
- UHI Protocols must ensure that HSPs cannot be aware of the EUAs making the request. It's quite likely that big organisations, aggregators and HSPAs will develop EUAs as well, and/or have business associations. UHI protocol should have measures to ensure that HSPAs should not be able to discriminate their responses to different EUAs.
- Section 5.2.2, Point 7 mentions "Post the completion of the consultation, the doctor can also rate the patient". We request clarification on the goal and use of this rating by the patient of the doctor.
- As more patients adopt the platform, providers may be inundated with booking requests.
 Consider allowing providers to turn off booking requests or placing limits on the number of booking requests in a time-period.