



RESPONSES TO THE INVITATION

FOR PUBLIC COMMENT

Consultation Paper

on Healthcare

Professionals

Registry

1st AUGUST, 2021



Facilitated by: The India Digital Health Network, Lakshmi Mittal and Family South Asia Institute at Harvard University

EXECUTIVE SUMMARY

We are delighted to see the progress with the National Digital Health Mission's work and are pleased to provide feedback as invited.. In keeping with prior submissions from the India Digital Health Network at Harvard's Lakshmi Mittal South Asia Institute, this response has been collaboratively drafted by domain experts from India and the US.

Prior submissions including responses to the Government of India's National Digital Health Blueprint (NDHB), Personal Data Protection (PDP) Bill, the White Paper of the Committee of Experts on the Data Protection Framework for India; drafts of NITI Aayog's National Health Stack; are accessible at: <u>https://mittalsouthasiainstitute.harvard.edu/india-digital-health-net/</u>

Responses are submitted by chapter and questions posed for consultations. Where applicable, other comments are added.

The key messages and themes of our comments on the Health Facilities Registry (HFR) are summarized below:

• Required enrolment

Please consider requiring enrollment through regulation by appropriate authorities and ministries. It is not unreasonable to push for compulsory enrolment. Given the large number of unregulated practitioners and facilities across India, required registration can be vitally important in recognizing the credentialed workforce. Consider a phased rollout, similar to the rollout of the National Provider Identifier (NPI) in the United States. It can begin with providers that bill public or private insurance, are part of the public healthcare system and government health programs, or initially those that are doctors, nurses, and community health workers. For equity and fairness, the NDHM should eliminate barriers to registration and expand modes of data entry to include bulk imports and facility-initiated registration (with appropriate verification).

• Scope of HPR

The document describes the patient-centered and ecosystem-centered views of the registry to address the question of who should be included in the registry. We submit that this may not be the best conceptual framework for this decision. The registry must deliver value to both patients and the ecosystem, and whether a provider sees a patient directly or not is an arbitrary and brittle test to determine their value to the patient. Instead, our position is in-line with the definition of a practitioner in Fast Healthcare Interoperability Resources (FHIR): all individuals who are involved, directly or indirectly, in care delivery to patients as part of their formal responsibility should be included in the registry.

• Verification of credentials

The vast numbers of unregistered medical practitioners in India is a critical reason why we advocate that all practitioners be enrolled in the registry, and with verified credentials. Additionally, the availability of verified credentials will enable multi-authority

attribute-based encryption schemes for role-based access where credential attributes are used to determine access¹. The registry must prioritize solutions for collecting, verifying and updating provider qualifications including basic, post-graduate, specialty and subspecialty training. This will yield benefits to patients as well as the ecosystem. We discuss ways to enable different data entry modes while maintaining credential verifiability. Where applicable, a governing body or a registered facility (educational institute or healthcare institution) associated with the professional would verify.



Image 1: Pictorial demonstration of healthcare professional profile and verification of attributes by concerned authorities

• Data veracity

Consider a core set of qualifications (basic, graduate and post-graduate training) that must be verified by the specific certification authorities; the remainder qualifications can be displayed as self-reported. The source of verification should be publicly available in all cases. Distributing verification to multiple sources will mitigate instances of self-verification arising out of conflicts of interest (for eg. owners of small clinics verifying their own and workers' credentials). We suggest working with governing bodies like the National Medical Council, Central Council of Indian Medicine, Central Council of Homeopathy, to set up a mechanism for verification of foreign qualifications and certification. Additionally, there should be a mechanism in place for the public to report discrepancies. Data that are entered must also not be able to be deleted or removed; an audit trail of changes must be maintained.

• Digitally signed transactions

Digital signatures and digital certificate management are important aspects which the document has not discussed. Adoption of a Health professional ID (HPID) will dramatically increase the effectiveness and efficiency of administrative, financial and clinical digital healthcare transactions. Additionally, non-repudiation will be guaranteed by digital

¹ Saksena N, Matthan R, Bhan A, Balsari S. Rebooting consent in the digital age: a governance framework for health data exchange. BMJ Global Health 2021;6:e005057. doi:10.1136/bmjgh-2021-005057

signatures, driving trust and improving patient safety. For example, NDHM may consider requiring the inclusion of HPID in digital transactions like e-prescriptions.

• Federated architecture

Considering health is a state subject, in terms of technical architecture, we may do well to adopt a federated architecture for the registry. A federated registry may be a practical approach while states can adopt any technical means they feel appropriate in their contexts and programmes, while still sharing minimal information with the central authority. In such a case, the HPR may be deemed a level 1 registry with identifiers referencing other level 2 registries at state or other authorities, public or private.

• Further study of key registries

There are several national and international registries that can help in the design and operational planning of the Health Professionals Registry. We point to the National Provider Identifier (NPI) system for healthcare providers in the USA; Open Researcher and Contributor ID (ORCID) and Health and Care Professionals Council (HCPC) for researchers; National Council for Vocational Training's trainee registry and the National Skills registry by NASSCOM domestically.

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 Health Professionals Registry.

Sincerely, On behalf of our co-respondents,



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Setting the Context

- As referenced in Section 2.2.1 of this paper, are there any other technical, operational or structural challenges that exist in India that may be addressed with a nationally recognized platform such as the HPR?
 - a. How should these gaps be prioritized for solutioning?
 - b. Are there examples of robust digital registries of health professionals (other than for doctors, nurses and midwives) that are widely adopted and used at the state level or below?

Lack of Credentialing Data

Untrained and informal healthcare providers provide a significant proportion of care to large swathes of the Indian population, in particular in rural India and socio-economically disadvantaged communities in urban areas². Moreover, private healthcare providers can practice outside the scope of their qualifications putting patients and families at risk of harm with little recourse³. This is not only a problem for patients; it is also a problem for other players in the healthcare ecosystem. Patients and families seeking healthcare cannot easily know the qualifications of their chosen provider, nor can they necessarily seek out appropriately qualified providers with verified credentials.The availability of credentials will eventually also help match claims with licenses and scope of practice.

The Healthcare Professionals Registry can address this dire need in India's health ecosystem by requiring authenticated enrolment.

Self-reported credentials must be flagged until they are verified by the credentialing agency (third-party, or accreditation or licensing organization itself, preferably almost always digitally in due course). Conversely, licensing organizations may themselves push updates to the Registry, which individuals must have an opportunity to rectify through reasonable means.

All data must follow the principles of non-repudiability and be self-maintainable.

These basic data about qualifications and credentials must be public. Consider requiring the display of a QR code or short ID that patients can use to verify the credentials of the provider they are visiting (via SMS-based services, not requiring smartphones). This is not an unreasonable expectation, as professionals and facilities, across disciplines, are often expected to display their operational licenses.

²Jishnu Das. Mapping Medical Providers in Rural India: Four Key Trends. https://www.cprindia.org/research/reports/mapping-medical-providers-rural-india-four-key-trends (accessed 20 Jul 2021).

³ Pandit MS, Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective. Indian J Urol. 2009;25(3):372-378. doi:10.4103/0970-1591.56206 (accessed 20 Jul 2021).

Consider making all additional information as optional or maintained in lower tier databases with linkages to the HPR. These secondary registries may contain additional data that may be accessed via consent, contract or regulation, by other ecosystem players for free or fee. Such role based access may differ from case to case. Example: Government Hospitals require information about other places of practice for practitioners availing 'non-practicing-allowance,' and may require it, while a private employer may not. By entering into a contract with a government hospital, a physician consents to uploading information about all facilities she is affiliated with.

For an example of a technical (non-health) registry that is widely adopted and includes verified credentials, consider the registry of Indian Training Institute trainees maintained by the Ministry of Skill Development and Entrepreneurship⁴.

- As discussed in Section 2.3, are there other international case studies or best practices that should be studied to inform the design of the HPR platform?
 - a. Which best practices should be adopted from these international models?
 - b. How do we tailor these best practices for the Indian context?

The evolution of the National Provider Identifier (NPI) system in the United States is instructive⁵. The NPI is a 10-digit intelligence free number that is required for all healthcare providers and entities that supply, bill or receive payment for healthcare and transmit electronic health information. The NPI is stored along with provider details including primary practice address, mailing address, phone, taxonomy, license number, and status in a public database called the National Plan and Provider Enumeration System (NPPES)⁶. Some fields that are collected as part of the NPPES (for eg. the social security number (SSN)) are private but most fields are public.

The NPI is required, but implementation was phased, beginning with providers that billed government insurance, and later expanding to other providers over a two year timeframe. In the Indian context, such phased rollout may first include those providers that bill government insurance plans, are employed by the public healthcare system, or are doctors and nurses. Setting the requirement will also sharpen the debate about what data fields are required in the registry and what fields must be private. We urge the NDHM to adopt this stance and foster the public-private collaboration needed for implementation.

⁴ <u>https://www.ncvtmis.gov.in/Pages/Certification/CertifiedTraineeSearch.aspx</u> (accessed 20 Jul 2021).

⁵ Breza A. The Complete History of the NPI Number - BulletinHealthcare. <u>https://www.bulletinhealthcare.com/the-complete-history-of-the-npi-number/</u> (accessed 20 Jul 2021)

⁶ CMS. NPPES. <u>https://npiregistry.cms.hhs.gov/</u> (accessed 20 Jul 2021)

Stakeholders

- As discussed in 3.1, is this a correct list of stakeholders for the HPR platform?
 - Are there key stakeholders that have not been addressed?
 - Should any of the listed stakeholders be considered 'out of scope' for the HPR platform?

Consider law enforcement and medico-legal stakeholders, in the context of what data they may access and under what circumstances. Data exchange should be facilitated either by consent (explicit), by contract (implicit?), or mandate (law?). All access trails must be auditable.

- As discussed in 3.1, is this the right set of product applications / incentives?
 - Are these potential incentives / product applications correctly framed?
 - \circ $\;$ What are the risks associated with these potential applications / incentives?
 - How should these potential applications / incentives be prioritized against each other?

On incentives

For healthcare providers: The Health Professionals Registry will enable "Care Services Discovery" (CSD).

- (1) The vast majority of doctors in the country practice in small, private, independently run practices. The healthcare professionals registry will enable easier discovery of providers which carries the additional advantage to providers of greater market reach.
- (2) The health registry will enable providers to easily report and update their qualifications including additional specializations, certifications, or expansions in scope of practice to potential employers and to patients. Adoption of a national unique health professional identifier would make billing and payments more efficient and save providers administrative costs.

Uniquely identifying providers will help facilities and administrators (and individual providers themselves) to monitor practice patterns for quality control. Role based access must of course be by consent, contract or regulation, but can prove to be extremely valuable, even for anonymized feedback. Example use-case: Given the rampant misuse of antibiotics by providers across the country, consider a quarterly report provided to all practitioners summarizing regional practice patterns of antibiotic usage, national benchmarks, and the individual's own performance. Such behavioral nudges have been shown to be valuable in influencing physician behavior.

On risks

The availability of a public registry of all providers, their practice location, qualifications and taxonomy will inevitably be used for targeted advertisements by stakeholders in the digital health ecosystem⁷. Such actions can be counterproductive to meeting aims of patient-centeredness and healthcare quality; analysis of matched industry payments and prescribing patterns in the US healthcare system has shown that providers who receive industry payments are more likely to prescribe branded drugs and the effect is modified by the size of payments⁸. Consider introducing or supporting deterrents to such physician targeting.

⁷ Breza A. The Complete History of the NPI Number - BulletinHealthcare. <u>https://www.bulletinhealthcare.com/the-complete-history-of-the-npi-number/</u> (accessed 20 Jul 2021).

⁸ Jones RG, Publica COP. Matching industry payments to medicare prescribing patterns: An analysis. <u>https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf</u> (accessed 20 Jul 2021)

Who is the platform for?

• As discussed in 4.2 and 4.3, is this the right conceptual framework through which to address the question of who should be included in the HPR platform? Are there other potential models or approaches that can be considered?

We submit that this may not be the best conceptual framework for deciding who should be included in the Health Professionals Registry. We raise two concerns. Firstly, we disagree with framing this debate as a choice between delivering value to patients or patients and the ecosystem. The registry *must* deliver value to both. Secondly, whether a provider interacts directly with the patient may not be the appropriate test of whether they are delivering value to the patient. Take the example of a radiologist: by the proposed criterion, radiologists should be excluded from the registry since they often do not interact with patients. They also transmit healthcare data and bill for healthcare services. Similarly, in imaging centers, imaging technicians prepare the patient for X-RAYs and MRIs and do the bulk of direct patient interaction. Yet in the patient-centered formulation, they are excluded from the registry. As would be lab technicians. Beyond misclassifications, the criterion will also suffer over time as technology and training enable task-shifting and will change clinical workflows. In the not too distant future, technicians in small healthcare facilities may do all of the direct patient interaction in an encounter while being remotely supervised by medical practitioners. What if an EKG is remotely interpreted by a cardiologist?

The HL7 FHIR practitioner resource covers all individuals who are engaged in the healthcare process and healthcare related services as part of their formal responsibilities, including technicians, scientists, radiographers, IT personnel, and even receptionists¹. In the Indian context, this would include practitioners of indigenous systems of medicine, community and village healthcare workers, counsellors, etc. While the Health Professionals Registry will have contextual APIs and may define its own API standards, we would advise adopting HL7 FHIR Practitioner⁹ and PractitionerRole¹⁰ resources (with appropriate extensions) for syntactic interoperability of the core Health Professional profile. This would ensure that NDHM data exchanges respect one single standard.

The Health Professionals Registry will need to make the process of registration simple, support multiple modes of data entry including self-registration and facility-based registration, and consider phased and required enrolment as we have proposed above. Consider working with relevant stakeholders among state and central government agencies, and professional bodies, to require enrollment.

• As discussed in 4.2 and 4.3, are there other key features, implications or risks that must be addressed?

⁹ Practitioner - FHIR v4.0.1. <u>https://www.hl7.org/fhir/practitioner.html</u> (accessed 20 Jul 2021).

¹⁰ PractitionerRole - FHIR v4.0.1. <u>https://www.hl7.org/fhir/practitioner.html</u> (accessed 20 Jul 2021).

The Health Professionals Registry must enable digital signature of health records and other digital documents. Currently, the FHIR profile for prescription records defined by the National Resource Centre for EHR Standards (NRCeS) does not mandate the inclusion of a Health Professionals ID and we did not find mention of digital signature capabilities in the Health Professionals' Registry. If digital documents are signed and attested, they could be used as legally valid references. Documenting the Health Professionals' ID would increase transparency and accountability across the ecosystem, and would be an exemplar globally.

• Other comments:

Listed HP categories. Tables in 4.2.2 and 4.3.2 list paramedical professionals. A definition of these HPs as stipulated in 'The National Commission for Allied and Healthcare Professions Act, 2021' under *Chapter I, Section 2* should be used¹¹. In this Gazette, the government has stipulated the categories and professions that come under allied and healthcare professionals. There are 10 categories of allied health professionals and several professions listed under each of these categories. Every professional category mentioned here should be included in the Health Professionals Registry. Additionally, consider clarifying the category under which the Mid Level Health Providers (MLHP) are currently represented.

On deletion of records: In 4.2.4 #3 The document states: "HPs...may retire from practice...and hence their records would need to be excluded from the HPR in order to maintain data quality." Data must not be deletable from the registry - at least not for a very long time (several decades). All changes must be tracked and audit trail maintained. Even if a health professional becomes inactive or retired, consider not deleting the record, as past issued documents may still have references. These provider linked records would be of much value to patients (who may survive providers, often by decades, and for research - for an even longer period of time). Consider, instead, indicating that the provider is no longer active (suspended, retired, or simply active or inactive).

Consider including time-stipulations to the credentials uploaded, as several licenses and certifications are time-bound, and re-licensing, re-certification is required. After the end of the time period, previously verified data should be reverted to self-declared or non-verified status and require re-verification by the relevant verifier (health facility or educational institution).

With respect to data fields in the Health Professionals Registry (4.2.3 #2), we recommend that standards like HL7 FHIR with MDDS codings or similar data standards be used to align to a common and widely used standard¹².

¹¹ The National Commission for Allied and Healthcare Professions Act, 2021. <u>https://egazette.nic.in/WriteReadData/2021/226213.pdf</u> (accessed 20 Jul 2021)

¹² National Committee on Meta Data and Data Standards for Health Domain <u>http://egovstandards.gov.in/sites/default/files/Part%20I%20MDDS%20Overview%20Report_0.pdf</u> (accessed 20 Jul 2021)

How should HPR data be managed?

• As discussed in 5.3, is the proposed mode for data entry appropriate? Are there other modes of data entry in India to be considered?

Given the task of enrolling all healthcare professionals, it is imperative that the Healthcare Professionals Registry make the process as easy as possible.

Self-registration cannot be the only mode of entry. Consider supporting facility-/programme-initiated registration, and bulk imports enabled by APIs. A primary health center may be able to enrol the ASHA workers that work in its catchment areas and update their place of work, for example. Similarly, when a facility enrols in the Health Facility Registry, it should be able to register all associated professionals in bulk. The registry should also enable state medical councils or the national medical council to populate practitioners in the Indian Medical Register. These imports may still need to be verified by the appropriate authority depending on where the import originated from.

Over time, enrolment may be possible through multiple mechanisms, but credentialing would need to be directly authenticated (via APIs) by the accrediting organization, regardless of enrolment facilitation. Consider regulatory and financial mechanisms to require accrediting organizations to be compliant with automated credential authentication / verification.

There should be a mechanism to notify health practitioners when they are listed on the registry and check and edit errors.

• As discussed in 5.4, are the HP data types proposed appropriate? Are there any other data types on healthcare professionals that must be collected from a public health, regulatory or legal perspective?

Demographic information: Is the address included in demographic information residential or address of practice?

Place of practice: Please consider providing clarification on what is meant by "Affiliated Health Facility" or "Affiliated Government Health Programme." Does affiliated mean facilities in the facility register that have reported the health professional as one of their employees? Can facilities that are not registered in the Health Facility Register verify the place of work of a health professional? Our view is that only facilities registered in the Health Facility Register should be allowed to verify the place of practice after associating the professional with their facility. Verification of credentials cannot be completed by the facility unless it is an accredited training institution. A health professional should be able to show multiple places of practice and the registry should maintain a record of all previously reported places of practice.

Other attributes:

- In case licenses and certificates are not included in educational information, these fields need to be added, with their expiration dates.
- (2) The category or role (doctor, surgeon, nurse, ASHA) of the provider should be listed in the profile and it should be linked with the verified license or certificate. A provider should be able to claim multiple roles or entries of the taxonomy (for eg. a health professional may be a nurse as well as a researcher). For the taxonomy, we point the committee to the provider taxonomy created by the National Uniform Claim Committee (NUCC) in the US which could serve as an example of process and end-product.
- (3) Please also consider inclusion of the following attributes: language, photo identification, communication (phone/email). The latter attributes could be made private by the provider.

• As discussed in 5.5, are the proposed modes and conditions for data verification appropriate? Are there any other rules, regulations or operational challenges that should be considered?

The following is unclear: Is the facility responsible for verification of all or components of the Health Professionals Registry record? Is the facility able to verify the health professional's educational information, in particular the place of education? Additionally, can facilities that are not registered in the Health Facility Register verify the place of work of a health professional?

Verification can be federated, with universities, medical council(s), professional bodies, health facilities and other entities, each allowed to verify specific data elements. We propose that Health facilities should only be able to verify place of work except in the case where the facility has an accredited training program and issues professional certificates.

Verifications should be time-bound to ensure the data is up to date and updated over time. With regards to public verification, the platform should only be open to verification from the public to report discrepancies or irregularities.

An operational suggestion for implementing institutional verification of individuals: consider how eRA (<u>https://era.nih.gov)</u> has implemented eCommons Accounts for researchers linked to the National Institute for Health (NIH) and institutions create or affiliate a lifetime ID for individuals¹³.

• As discussed in 5.6, how can the HPR – HFR linkage functionality be implemented and approved? How can professionals and facilities be incentivized to link their records?

¹³ eRA Commons. <u>https://era.nih.gov/reg-accounts/register-commons.htm</u> (accessed 20 Jul 2021)

Any facility registered in the Health Facility Register and generating digital documents to be exchanged through the NDHM Health Information Exchange should be required to have the health professional identification referenced in the document. Having enabled such electronic means of verifying references and authenticity is also essential for ecosystem services (e.g Labs collecting samples, ePharmacies dispensing medications). Consider requiring enrolment in HRP / HFR through appropriate authorities/ministries.

• 5.6 Public comments are invited on potential applications or risks of this proposed functionality

We suggest expanding the HPR-HFR linkage to include other ecosystem players. This would allow training institutes, for example, to issue e-certificates that are automatically reflected on the Health Professionals Registry. The document does not specify whether other ecosystem players will have uni-/bi-directional linkage to the HPR.

In cases where HPs work simultaneously at multiple facilities in contravention of administrative rules, facilities with such HPs in their employment will probably avoid registering them. This is a challenge to the accuracy of the platform.

- As discussed in 5.7 and 5.8, are there alternative models for data governance that have not been addressed in this section?
 - $\circ~$ Within the proposed models, feedback and comments on the proposed features, benefits and risks are invited
 - Within the proposed models, feedback and comments on potential security risks, vulnerabilities and strategies for mitigation are invited
 - Within the proposed models, feedback and comments on potential technology solutions to ensure robust data governance are invited
- Other Comments

Re 5.2 Lifecycle of an HPR Record. Since the health professional ID will be linked to the healthcare provider across their lifetime, their record will likely include updates to credentialing, place of work and licensures. The workflow for maintaining records after registration and reverifying is not laid out; please consider articulating this. To improve HPR adoption, the workflows and processes should be friction-free.

Enterprise architecture

In terms of technical architecture, since health is a state subject, a decision has to be made to use a completely centralized registry or a federated one. A federated registry may be a practical approach while states can adopt any technical means they feel appropriate in their contexts and programmes, while still sharing minimal information with the central authority. In such a case, the HPR may be deemed a level 1 registry with identifiers referencing other level 2 registries at state or other authorities.

ASHAs in the Health Professionals Registry

ASHAs must be included in the health professionals registry. ASHA-Soft, used by Govt of Rajasthan and ASHA-nidhi, used by Govt. of Karnataka for wage transfers. are examples of existing systems that could be leveraged to populate the registry^{14,14,15}. The National Institute of Open Schooling conducts an ASHA Certificate Program - such certification programs cna also be leveraged to onboard professionals to the registry ^{16,17}.

¹⁴https://health.rajasthan.gov.in/content/raj/medical/national-health-mission/en/nhm-additionality/e-Initiatives/asha -soft.html#

¹⁴<u>https://krch.karnataka.gov.in/</u>

¹⁵ http://www.upnrhm.gov.in/Home/ASHADatabase

¹⁶<u>http://nhm.gov.in/images/pdf/communitisation/asha/Orders-Guidelines/Letter_ASHA_Certification.pdf</u>

¹⁷<u>https://voc.nios.ac.in/projects/asha/objective-of-asha-certification.php</u>