Digital health in India – As envisaged by the National Health Policy (2017)

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It has been now more than a year that the (third edition of the) National Health Policy 2017 (NHP-2017)[1] of India has been notified. While the accompanying situation analysis[2] did not mention anything about digital health, the policy correctly identified[3] the need for creating many new institutions like the National Digital Health Authority (NDHA).

Now, let us look at where do we stand 2 years later, regarding the ushering in of digital health in India. I am recapitulating what I had previously put up in my blog post[4] and updating the current status.

First, let us glance at some of the key provisions of the NHP-2017 as mentioned in the various sections. Just beneath the quotes from the relevant sections of the NHP-2017, I'm commenting on certain issues for thought.

Health Management Information (Section 2.4.3.3) (The Section 2.4.3.3 refers to the Section 2.4.3.3 of the National Health policy, 2017)

1. Ensure district-level electronic database of information on health system components by 2020
2. Strengthen the health surveillance system and establish registries for diseases of public health importance by 2020
3. Establish federated integrated health information architecture, Health Information Exchanges and National Health Information Network by 2025.

Comments

The NHP-2017 focuses on digital technology, right from the beginning. Some timelines are also proposed here. However, while some states have been doing very well, some others are lagging. We would further elaborate on this aspect toward the end.

Organization of Public Health Care Delivery (Section 3.3)

For effectively handling medical disasters and health security, the policy recommends that the public healthcare system retain a certain excess capacity in terms of health infrastructure, human resources, and technology which can be mobilized in times of crisis.

In order to leverage the pluralistic health care legacy, the policy recommends mainstreaming the different health systems. This would involve increasing the validation, evidence and

research of the different health care systems as a part of the common pool of knowledge. It would also involve providing access and informed choice to the patients, providing an enabling environment for practice of different systems of medicine, an enabling regulatory framework and encouraging cross referrals across these systems.

Comments

Here, there is a need for more caution because the other streams of medicine – namely, Ayurveda, Yoga and Naturopathy, Siddha, Unani, and Homeopathy – follow entirely different principles from those followed by modern medicine. Therefore, cross referrals may add to the complexity and confusion, ultimately harming the patient.

Medical Education (Section 11.1)

The policy recognizes the need to revise the under graduate and post graduate medical curriculum keeping in view the changing needs, technology and the newer emerging disease trends.

Comments

There have been a lot of issues regarding the Medical Council of India and the National Board of Examinations in the past, followed by a proposed revamping through the National Medical Commission.[5,6] Despite all the proposed changes, one of the essential features that is amiss is the incorporation of health informatics essentials in all branches of health professional education. Without doing that, a smooth adoption of digital health is extremely difficult.

Public Health Management Cadre (Section 11.8)

The policy proposes creation of Public Health Management Cadre in all States based on public health or related disciplines, as an entry criteria.

Comments

In the continuation of the previous section, health information management must be embedded as an integral part for health and hospital management. Health informatics weds both health information technology and health information management. Scaling up, public health informatics combines health informatics and population demographics.

Health Information System (Section 13.12)

The objective of an integrated health information system necessitates private sector participation in developing and linking systems into a common network/grid which can be accessed by both public and private healthcare providers. Collaboration with private sector consistent with Meta Data and Data Standards and Electronic Health Records would lead to developing a seamless health information system. The private sector could help in creation of registries of patients and in documenting diseases and health events.

Comments

Most of the times, various health information systems do not talk to each other and therefore, there is a dire need of standards for interoperability. I would discuss this issue in greater details toward the end, where I would talk about the Clinical Establishments Act (CEA).

Regulation Of Clinical Establishments (Section 14.2)

A few States have adopted the Clinical Establishments Act 2010. Advocacy with the other States would be made for adoption of the Act. Grading of clinical establishments and active promotion and adoption of standard treatment guidelines would be one starting point. Protection of patient rights in clinical establishments (such as rights to information, access to medical records and reports, informed consent, second opinion, confidentiality and privacy) as key process standards, would be an important step. Policy recommends the setting up of a separate, empowered medical tribunal for speedy resolution to address disputes/complaints regarding standards of care, prices of services, negligence and unfair practices. Standard Regulatory framework for laboratories and imaging centers, specialized emerging services such as assisted reproductive techniques, surrogacy, stem cell banking, organ and tissue transplantation and Nano Medicine will be created as appropriate.

Comments

Discussed below separately.

Medical Devices Regulation (Section 14.5)

The policy recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India. The policy supports harmonization of domestic regulatory standards with international standards. Building capacities in line with international practices in our regulatory personnel and institutions, would have the highest priority. Post market surveillance program for drugs, blood products and medical devices shall be strengthened to ensure high degree of reliability and to prevent adverse outcomes due to low quality and/or refurbished devices/health products.

Comments

Medical Devices Rules, 2017 has come into force with effect from 1stday of January, 2018. It has included in the Part-I of the first schedule Parameters for classification of medical devices other than *in vitro* diagnostic medical devices. There, Software as Medical Device is defined as(iii, The number (iii) refers to the Clause number (iii) of the Schedule I of the Medical Devices Rules, 2017) Software, which drives a device or influences the use of a device, falls automatically in the same class. This is indeed a very forward-looking and welcome legislation, ahead of the times in our country.[7]

Health Technology Assessment (Section 22)

Health Technology assessment is required to ensure that technology choice is participatory and is guided by considerations of scientific evidence, safety, consideration on cost effectiveness and social values. The National Health Policy commits to the development of institutional framework and capacity for Health Technology Assessment and adoption.

Comments

We can combine these aspects with the digital health technology, described in the next section.

Digital Health Technology Eco-System (Section 23)

Recognising the integral role of technology (eHealth, mHealth, Cloud, Internet of things, wearables, etc.) in the healthcare delivery, a National Digital Health Authority (NDHA) will be set up to regulate, develop and deploy digital health across the continuum of care. The policy advocates extensive deployment of digital tools for improving the efficiency and outcome of the healthcare system. The policy aims at an integrated health information system which serves the needs of all stake-holders and improves efficiency, transparency, and citizen experience. Delivery of better health outcomes in terms of access, quality, affordability, lowering of disease burden and efficient monitoring of health entitlements to citizens, is the goal. Establishing federated national health information architecture, to roll-out and link systems across public and private health providers at State and national levels consistent with Metadata and Data Standards (MDDS) and Electronic Health Record (EHR), will be supported by this policy. The policy suggests exploring the use of "Aadhaar" (Unique ID) for identification. Creation of registries (i.e. patients, provider, service, diseases, document and event) for enhanced public health/big data analytics, creation of health information exchange platform and national health information network, use of National Optical Fibre Network, use of smartphones/tablets for capturing real time data, are key strategies of the National Health Information Architecture.

Application Of Digital Health (Section 23.1)

The policy advocates scaling of various initiatives in the area of tele-consultation which will entail linking tertiary care institutions (medical colleges) to District and Sub-district hospitals which provide secondary care facilities, for the purpose of specialist consultations. The policy will promote utilization of National Knowledge Network for Tele-education, Tele-CME, Tele-consultations and access to digital library.

Leveraging Digital Tools For Ayush (Section 23.2)

Digital tools would be used for generation and sharing of information about AYUSH services and AYUSH practitioners, for traditional community level healthcare providers and for household level preventive, promotive and curative practices.

Comments

This is a very correct decision, and the first job for the proposed NDHA will be to formulate a robust National Digital Health Strategy/Policy, in consultation with all the stakeholders.

The first constituents of the Authority will lay down the rules of the game as to how will digital health be adopted in India. The earlier the NDHA is set up and functional, the better it will be for India to avoid a digital health mess in future. Any delay in the process might make us deal with noninteroperable legacy systems, as has been the case in many developed nations. However, cross referrals and sharing disparate information among different systems of medicine may add to the complexity and confusion, ultimately harming the patient.

Health Research (Section 25)

The National Health Policy recognizes the key role that health research plays in the development of a nation's health. In knowledge based sector like health, where advances happen daily, it is important to increase investment in health research.

Strengthening Knowledge For Health (Section 25.1)

The policy envisages strengthening the publicly funded health research institutes under the Department of Health Research, the apex public health institutions under the Department of Health and Family Welfare, as well as those in the Government and private medical colleges. The policy supports strengthening health research in India in the following fronts-health systems and services research, medical product innovation (including point of care diagnostics and related technologies and internet of things) and fundamental research in all areas relevant to health-such as Physiology, Biochemistry, Pharmacology, Microbiology, Pathology, Molecular Sciences and Cell Sciences. Policy aims to promote innovation, discovery and translational research on drugs in AYUSH and allocate adequate funds towards it. Research on social determinants of health along with neglected health issues such as disability and transgender health will be promoted. For drug and devices discovery and innovation, both from Allopathy and traditional medicines systems would be supported. Creation of a Common Sector Innovation Council for the Health Ministry that brings together various regulatory bodies for drug research, the Department of Pharmaceuticals, the Department of Biotechnology, the Department of Industrial Policy and Promotion, the Department of Science and Technology, etc., would be desirable. Innovative strategies of public financing and careful leveraging of public procurement can help generate the sort of innovations that are required for Indian public health priorities. Drug research on critical diseases such as TB, HIV/AIDS, and Malaria may be incentivized, to address them on priority. For making full use of all research capacity in the nation, grant-in-aid mechanisms which provide extramural funding to research efforts is envisaged to be scaled up.

Drug Innovation And Discovery (Section 25.2)

Government policy would be to both stimulate innovation and new drug discovery as required, to meet health needs as well as ensure that new drugs discovered and brought into the market are affordable to those who need them most. Similar policies are required for discovering more affordable, more frugal and appropriate point of care diagnostics as also robust medical equipment for use in our rural and remote areas. Public procurement policies and public investment in priority research areas with greater coordination and convergence between drug research institutions, drug manufacturers and premier medical institutions must also be aligned to drug discovery.

Development Of Information Databases (Section 25.3)

There is also a need to develop information data-bases on a wide variety of areas that researchers can share. This includes ensuring that all unit data of major publicly funded surveys related to health, are available in public domain in a research friendly format.

Research Collaboration (Section 25.4)

The policy on international health and health diplomacy should leverage India's strength in cost effective innovations in the areas of pharmaceuticals, medical devices, health care delivery and information technology. Additionally leveraging international cooperation, especially involving nations of the Global South, to build domestic institutional capacity in green-field innovation and for knowledge and skill generation could be explored.

Comments

For health research and innovation, the government's role of encouraging standards for interoperability and allowing open data for analysis will go a long way.

Clinical Establishments (Registration and Regulation) Act

In 2012, the Ministry of Health and Family Welfare (MoHFW) amended the CEA (2010)[8] and added[9] Clause "9 (iv): The clinical establishments shall maintain and provide Electronic Medical Records (EMR) or Electronic Health Records (EHR) of every patient as may be determined and issued by the Central Government or the State Government as the case may be, from time to time."

Comments

The Act had initially taken effect in the four states, namely, Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all union territories (UTs) since March 1, 2012, vide Gazette notification dated February 28, 2012. The states of Uttar Pradesh, Uttarakhand, Rajasthan, Jharkhand, Bihar, and Assam have adopted the Act under Clause (1) of article 252 of the constitution. As of December 2018, only 11 states – Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, Uttar Pradesh, Bihar, Jharkhand, Rajasthan, Uttarakhand, Assam, and Haryana, and all UTs except Delhi have adopted the Act.[10]

The Ministry has notified the National Council for Clinical Establishments and the Clinical Establishments (Central Government) Rules, 2012, under this Act vide Gazette notifications dated March 19, 2012, and May 23, 2012, respectively.

The Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single-doctor clinics. The only exception will be establishments run by the armed forces.[11]

The good point is the enactment of the necessity for EMR/EHR. The MoHFW has been notifying standards for EHR since August 2013 and the second edition of the guidelines were

notified in December 2016.[12] That is the right way to move forward. However, health being a state subject, not all the states are equally keen to adopt it.

Concurrent list

The seventh schedule of the Constitution of India[13] lists "Health" (Public health and sanitation; hospitals and dispensaries) under the Item 6 of List-II (State list). As expected, like the union ministry, health ministers of various states have also agreed to equipping Primary Health Centres (PHCs) and Community Health Centres (CHCs) with latest technology.[14]

Comments

However, as seen in the previous section, the CEA has not yet been adopted by most of the states of India. Therefore, although the CEA mandates EMR/EHR, most of the states are not yet bound to follow it. As health is neither in the Union list nor in the Concurrent list, it may be prudent to include it in the Concurrent list. In that case, adoption of digital health would be much smoother.

Some Other Relevant Happenings

While a draft bill was circulated for public comments[15] and is also available through the EHR Standards Helpdesk in the National Health Portal,[16] the fate of the NDHA is still unknown. Meanwhile, the Allied and Healthcare Professions Bill, 2018, was introduced in the Rajya Sabha by the MoHFW, Shri. Jagat Prakash Nadda on December 31, 2018. The Bill seeks to regulate and standardize the education and practice of allied and health-care professionals.[17] This bill includes health and information management professionals as one of the recognized categories.

In a related note, the Union Cabinet has approved the restructuring of National Health Agency as "National Health Authority" for better implementation of Pradhan Mantri – Jan Arogya Yojana (Ayushman Bharat).[18]

India has hosted the 4th Global Digital Health Partnership Summit and the International Digital Health Symposium in the last week of February 2019. This also shows the commitment of India toward strengthening digital health globally.[19] Here, the "Delhi Declaration"[20] was adopted to accelerate and implement the appropriate digital health interventions to improve the health of the population at national and subnational levels, as appropriate according to the national context.

Conclusions

While the NHP-2017 is bold in its thoughts and foresight, for facilitating digital health, the ground realities do not appear to have been considered well enough. Early setting up of a functional NDHA is essential for India to avoid a digital health mess in future. Inordinate delays might make us deal with noninteroperable legacy systems. The first job for the proposed NDHA will be to formulate a robust National Digital Health Strategy/Policy, in consultation with all the stakeholders. Caution needs to be exercised before cross referrals and sharing disparate information among different systems of medicine. Health informatics

education must be embedded as an integral part for health and hospital management. As health is neither in the Union list nor in the Concurrent list of the Constitution of India, it may be prudent to include it in the Concurrent list. In that case, adoption of digital health would be much smoother. India will then be recognized as a significant global player in digital health.

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