Unit 4: E-Health and Regulatory Framework

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UNIT STRUCTURE

1.1 LEARNING OBJECTIVES

After going through this chapter, you should be able to understand:

- Concept, functionalities and benefits of E-Health
- Electronic Health Records
- Enactments of different laws pertaining to E-Health

1.2 INTRODUCTION

As per the World Health Organization ("WHO"), E-Health means "the use of information and communication technologies ("ICT") for health". The definition, though very concise, is not very helpful. The European Commission has put forth a more elaborate definition of e-Health. e-Health refers to "tools and services using information and communication technologies that can

improve prevention, diagnosis, treatment, monitoring and management". Therefore, the expression e-Health may be safely said to include both tools and services that use ICTs for purposes connected to health.[134]

For several years now healthcare services have been facing pressure by citizens, patients, professionals and also by public and private institutions. The ageing of the population, higher standards of living, and more informed and educated citizens mean that both patients needs and patient expectations are growing. These rising demands, along with the appearance of new and costly health technologies and increasing budget restrictions, invite health managers to invest wisely in ICT and to carefully assess its opportunity cost in the current context of rising health expenditure and economic crisis.[135]

Investment in eHealth should be considered a decision of key importance for the health system. This means there must be, in addition to an accurate estimate of costs, an evaluation of its benefits, both in economic terms and in terms of improved quality and efficiency in the services provided. Nowadays, ICT tools must be included among the many instruments used in a health system, whose functioning can hardly be conceived without tools of this type.

1.3 CONCEPT, FUNCTIONALITIES AND BENEFITS

The concept of eHealth encompasses applications as diverse as electronic health records, different types of telemedicine, epidemiological surveillance, health portals, management systems and distance learning programs focused on health and medicine. Its users and beneficiaries are equally diverse. The applications help meet the needs of health professionals, those of patients and their families, those of healthcare authorities and experts and also those of input and service providers, among others.

There can be no doubt that eHealth represents an equitable, effective and efficient way to increase accessibility, safety and quality in healthcare. eHealth tools can be used to increase the availability of medical resources, thus optimizing care processes. They enable specialized

[134] Michael Kirby, Medical Technology and New Frontiers of Family Law, 1 AUSTL J FAM L 196, 212 [1987]
[135] Oh, Hans & Rizo, Carlos & Enkin, Murray & Jadad, Alejandro. (2005). What is eHealth? A systematic review of published definitions. World hospitals and health services: the official journal of the International Hospital Federation. 41. 32-40

knowledge to be taken to different places or to isolated locations, through distance appointments or teleconsultation. They facilitate the provision of timely healthcare, partnership projects, etc. They can also help reduce the costs incurred by systems and by families.[136]

In eHealth, two large spheres can be distinguished from one another, for purposes of analysis. There is, on the one hand, what is known as health informatics, that is, technological solutions for applications used to provide care, which allow information to be recorded and processed: electronic health records and department-specific applications, population management systems and systems that support planning and management are a few examples. And, on the other hand, there is telemedicine, which refers to health services and care provided from a distance. Applications already exist for many of the specialities: tele radiology, tele cardiology, tele dermatology, tele ophthalmology, tele pathology, tele psychiatry, and others.[137]

The case of tele radiology is a clear example of the advantages of telemedicine. Small or rural communities that cannot sustain an on-staff radiologist can benefit a great deal from the professional activity performed at a distance. Local hospitals can send images to a larger care center in order to obtain a second opinion, whether from the general radiologists who work in such centers or from radiologists with particular subspecialties. Emergency rooms can send, any time day or night, their images to affiliated centers or even to the homes of radiologists. Tele radiology as a teaching tool, can also enhance the quality of ongoing medical training. And finally, tele radiology offers direct benefits to the patient, by reducing the costs of transportation, accommodations and board that would be incurred if the patient had to travel to where the doctor is based.

The use of ICT can also bring significant improvements to the management of public health, in terms of areas of surveillance and also in the planning and overseeing health service management. ICT tools contribute to the design of safer, timelier and more reliable processes for data gathering and storage and also to better statistical use of the information. This has positive repercussions on the effectiveness and efficiency of the macro system that encompasses

[136] Ashok Vikhe Patil, K V Somasundaram and R C Goyal; Current Health Scenario In Rural India <http:// www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf>

[137] Awski, Szymon & Saberwal, Gayatri. (2014). In eHealth in India today, the nature of work, the challenges and the finances: An interview-based study. BMC medical informatics and decision making. 14. 1. 10.1186/1472-6947-14-1

everything from the analysis of health needs and problems to the evaluation of health outcomes obtained in the population.[138]

1.4 ELECTRONIC HEALTH RECORDS

An Electronic Health Record (EHR) is a digital version of a patient's health records. EHRs help eliminate the problems associated with physical records such as loss and lack of accessibility. EHRs can be stored centrally and accessed at any time, irrespective of where or when the information was collected. With EHRs, doctors are able to view their patient's complete medical history even if they are treating the patient for the first time. This would help reduce duplication of tests and facilitate the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

1.5 BASIC FUNCTIONS AND ELEMENTS OF EHR

While EHRs were initially developed to document clinical care, most can perform additional functions that can support good quality care. Common functions of EHRs include (Health Resources and Services Administration, 2014a).

- Recording patient demographics and care management data on patient visits.
- The clinical decision supports.
- Reports required for financial management, quality assurance, chronic disease management, and public health data collection.
- Consents, authorisations, and directives.
- Interfaces and interoperability required to exchange health information with other clinicians, laboratories, pharmacies, patients, and government disease registries.
- e-prescribing.
- Alerts and reminders.
- Medication reconciliation.

[138] Marcus E, Fabius R. What is E-health?
<http://www.acpenet.org/ Forums/Topical/Ehealth/Primer.htm>

- Commonly used screening tools and checklists.
- commonly used forms for schools, camps, and sports participation.
- Patient education.

Some systems might also include integrated practice management support that enables functions like billing, online scheduling, and patient portals. Examples of some basic elements of EHRs are provided below. This list is not exhaustive and designed to provide a glimpse into EHRs and some of their capabilities.

Some of the benefits of EHR can be classified into the following types:

- ***Accessibility and Availability***

Paper charts are for single users; they can only be seen by one person in one place. EHRs can be used by more than one person at a time, and they can also be accessed from different locations. This is one of the benefits that new users most quickly come to appreciate.[139]

- ***Multiple display modes***

EHRs also have the potential of offering various ways to view the information, since users sometimes prefer to see information in different formats depending on their needs. A good EHR must allow data display to be configured in different ways, offering these options to users. Another useful function in clinical practice is to be able to view trends. These can be generated instantly, by putting the trends shown by a lab value or a vital sign (such as blood pressure) into graphic form.

- ***Communication with other professionals***

EHR systems can serve as vehicles for communication among professionals. This capability need not be limited to physician-to-physician communication, but can also include other members of the healthcare team. Many EHR systems include features similar to e-mail or instant messaging, thus allowing the different professionals to send messages to other professionals involved in the care of this patient.

- ***Communication with patients***

[139] Bhatia JC, Cleland J: Health-care seeking and expenditure by young Indian mothers in the public and private sectors. Health Policy Plan 2001, 16(1):55–61

EHRs can also improve communication with patients. As mentioned above, the personal health record can potentially be used as a communication channel between the patient and the health team caring for the patient.[140]

- ***Data aggregation***

EHR systems also have data collection capabilities, which makes it possible to create data groups and summaries. To ensure effective data aggregation, it is vital that data quality be very carefully controlled and that medical knowledge is correctly represented (through the use of semantic constraints). This functionality can be applied to the reuse of stored information for purposes of clinical management, clinical research or the preparation of public health reports.

- ***Access to knowledge bases***

Another potential benefit of using an EHR system is that it permits access to knowledge bases in a contextual manner. This means that the EHR can provide contextual information concerning each patient and provide the user with information that is useful in decision-making, extracted from different knowledge bases.

- ***Integration with decision-making support systems***

Decision-making support is the ***raison d'être*** of EHRs. The aim of these applications is to contribute to the care process, offering support to professionals, showing updated contextual information and suggesting alternatives to their decisions. These computerized decision-making support systems are difficult to achieve and are not very advanced due to the complexity inherent in their development and implementation. They consist of a rule engine that uses information based on the patient (from his or her EHR) and information based on scientific knowledge (from the system's knowledge bases), with which they generate different outputs, such as reminders, alerts, diagnostic or treatment suggestions based on the automation of clinical practice guides, etc. Their ultimate goal is to prevent errors and to enhance care quality.[141]

- ***Cost benefits***

The issue of whether EHR system implementation brings cost benefits is a controversial one, with literature containing evidence in both directions. This inconsistency arises in part because of

[140] Loman P. E-Health: 'Putting health on the Net'. An FCG White Paper <http://www.fcg.com/webfiles/whitepaper/white_paper_files/wpEhealth.asp>

[141] Reddy KS, Patel V, Jha P, Paul VK, Shiva Kumar AK, Dandona L: Towards achievement of universal health care in India by 2020: a call to action. Lancet 2011, 377(9767):760–768

the different perspectives used for analyzing returns on investment (ROI) (the individual physicians, service providers, insurance companies, governments) and the type of health care system that predominates in each country. More information is needed before more precise calculations can be made of the ROI related to EHR systems.

1.6 INVESTMENT IN E-HEALTH

The healthcare sector as an industry is expanding rapidly in India and has not been as severely impacted by the economic slowdown as some of the other industries. India, one of the biggest emerging markets, is currently an important destination for Foreign Direct Investment ("FDI").[142] A significantly low presence of doctors in rural and semi-urban areas has led to limited access to proper healthcare facilities for people living in these areas. Telemedicine and e-Health are considered to be some solutions to this lack of access. The growth of the IT sector in India (which plays a crucial role in telemedicine) has led to the emergence of this sector in India. Tele-radiology has emerged as a fast-growing area with an increasing number of foreign hospitals active in this space. These hospitals consult Indian experts to provide opinions, i.e., on x-rays of patients in the hospital. Many hospitals have adopted the public-private partnership route to render services through telemedicine.

Some investment options are:

a) FOREIGN DIRECT INVESTMENT

Foreign investment into India is governed by the Foreign Exchange Management Act, 1999 ("FEMA"), the rules and regulations made by the Reserve Bank of India ("RBI"), and the Industrial Policy and Procedures issued by the Ministry of Commerce and Industry through the Secretariat for Industrial Assistance, Department of Industrial Policy and Promotion ("DIPP").[143]

The provisions pertaining to FDI are laid down in Schedule I of FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000. While the DIPP issues policy

[142] Oracle Corporation. CEO Perspective: Health Care Information Technology <http://www.hciv.com/profiles/oracle.pdf>

[143] Consolidated FDI Policy, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion, SIA (FC Division) <http://dipp.nic.in/ English/policies/FDI_Circular_2016.pdf>

guidelines and press notes/releases from time to time regarding foreign investment into India, it also issues a consolidated policy on an annual basis ("Consolidated FDI Policy"). Currently, foreign investment is regulated by the Consolidated FDI Policy of 2016. 100% FDI is permitted in most sectors under the automatic route, i.e., where prior approval of the government, specifically the Foreign Investment Promotion Board ("FIPB"), is not required. Generally, there are no restrictions prescribed for e-Health services, and therefore FDI up to 100% should be permitted without government approval. It may also be noted that FDI is permitted up to 100% under the automatic route in the hospital sector and the manufacture of medical devices. In the pharmaceutical sector, FDI is permitted upto 100% in Greenfield projects and 74% in Brownfield projects under the automatic route and FDI beyond 74% in Brownfield projects requires FIPB approval. Greenfield projects are new projects that are coming up in India while Brownfield projects are existing projects in India.

b) FOREIGN VENTURE CAPITAL INVESTMENT

Another vital means of investment is through venture capital investment by entities registered with the Securities Exchange Board of India ("SEBI") as foreign venture capital investors. While it is not mandatory for a private equity investor to register as a Foreign Venture Capital Investor ("FVCI") under the FVCI regulations,[144] there are some significant advantages to be gained by registering as an FVCI. An FVCI is exempt from compliance with the pricing guidelines under the Consolidated FDI Policy for the acquisition of securities at the time of entry as well as for the transfer/sale of securities at the time of exit. Secondly, in cases where the promoters of the company intend to buy back the securities from an FVCI, they are exempted from making an open offer under the Takeover Code. It should be noted that SEBI has been granting approvals to FVCIs only for investments in certain identified sectors, amongst them being research and development of new chemical entities in the pharmaceutical sector, and units of SEBI registered Venture Capital Funds ("VCFs"). Further, the Reserve Bank of India ("RBI") has made recent amendments to the foreign exchange control regulations to permit FVCIs to invest in SEBI registered Alternate Investment Funds ("AIFs").[145]

[144] SEBI (Foreign Venture Capital Investor) Regulations, 2000

[145] SEBI introduced SEBI (Alternate Investment Funds) Regulations, 2012 to govern domestic pooling vehicles. RBI has issued Notification no. FEMA. 355/2015 that permits AIFs and other investment vehicles to accept foreign investments under the automatic route

1.7 LEGAL AND REGULATORY FRAMEWORK

a) THE I.T. ACT, 2000

E-Health involves a constant exchange of information between the patient and the service provider. The patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information ("SPDI") under the Data Protection Rules.[146] When a body corporate collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered. Consent is one of the major requirements under the Data Protection Rules. Before a doctor or an institution does anything with a patient's data, they are required by law to obtain the recipient's consent in writing. The patient must be informed about the fact that the data is being collected, what it will be used for and whether it would be transferred to any third parties, along with the contact details of the agency collecting the information.

The Data Protection Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure. This requirement is fulfilled if the body corporate conforms to the international standard IS/ISO/IEC 27001 on "Information Technology-Security Techniques-Information Security Management System-Requirements" or similar standards that are approved and notified by the Central Government. As on date, no such standards have been notified.

In 2013, the Ministry of Communications and Information Technology came out with a clarification[147] which stated that body corporates that were collecting, storing, processing or transferring information out of a contractual obligation were not required to observe some of the requirements of the Data Protection Rules such as obtaining consent from the owner of the SPDI for collecting or disclosing the SPDI. The other requirements, however, must still be observed.

[146] Rule 3 of the Data Protection Rules defines Sensitive personal data or information of a person to mean such personal information which consists of information relating to (i) password; (ii) financial information such as Bank account or credit card or debit card or other payment instrument details; (iii) physical, physiological and mental health condition; (iv) sexual orientation; (v) medical records and history; (vi) Biometric information

[147] Clarification on The Information Technology (Intermediary Guidelines) Rules, 2011 under section 79 of the Information Technology Act, 2000 issued on 18th March, 2013 <http://deity.gov.in/sites/upload_files/dit/files/Clarification%2079rules_1.pdf>

b) OTHER SERVICE PROVIDERS REGULATIONS UNDER THE NEW TELECOM POLICY, 1999 (OSP REGULATIONS)

Service providers who render "Application Services" - which includes telemedicine services – using telecom resources provided by telecom service providers, are required to be registered as an 'Other Service Provider' ("OSP") with the Department of Telecommunications.

c) THE DRUGS AND COSMETIC ACT, 1940

The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India. In many foreign jurisdictions, there is a clear distinction between a drug that must be sold under the supervision of a registered pharmacist on the production of a valid prescription (signed by a registered medical practitioner) and those that can be sold by general retailers over-the-counter ("OTC"). OTC drugs have a different meaning in the context of Indian laws. The D&C Act requires that all drugs must be sold under a license.

The D&C Rules also state that prescription drugs can only be dispensed on the production of a prescription which is in accordance with the provisions of the rules. For a prescription to be considered valid under the D&C Rules, it must be in writing, signed and dated by the doctor issuing the prescription.

d) THE INDIAN MEDICAL COUNCIL ACT, 1956

The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with one of state medical councils have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients. The MCI Code also specifies that efforts are to be made to computerize medical records so that they can be retrieved quickly. Doctors are bound by the MCI Code and are required to submit a declaration to that effect. The apex body currently regulating the practice of medicine is the Medical Council of India. However, the proposed National Medical Commission Bill, 2016,[148] which has been drafted by the National Institution for Transforming India ("NITI Aayog"), intends to replace the current Medical Council of India with a 'National Medical Commission'. The passing of the National Medical Commission Bill would see a change in the current regulatory framework regulating medical practitioners.

[148] Proposed National Medical Commission Bill, 2016
<http://niti.gov.in/writereaddata/files/document_publication/MCI%20Bill%20Final.pdf>

e) THE CLINICAL ESTABLISHMENTS ACT, 2010

Establishments falling under the definition of a 'clinical establishment' under the Clinical Establishments Act would be required to register with the relevant authority and conform to the minimum standards as prescribed under the act. The Clinical Establishments Act is applicable in Arunachal Pradesh, Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Himachal Pradesh, Mizoram, Sikkim and all Union Territories except the NCT of Delhi. Certain states such as Maharashtra and Karnataka have their own state clinical establishment legislations.

1.8 LET'S SUM UP

The e-Health market presents a lot of opportunities, but with every opportunity, there are bound to be risks involved. Innovation in this sector is yet to reach a saturation point, with new products frequently being introduced in the market. The legislative framework to protect and regulate such developments will remain one step behind, as it is yet to be seen how the industry will mature. Regardless, regulators have taken note of the restrictions, and in many cases, the absence, of the law and are striving to formulate forward-looking policies and legislations. The NIPR is only one such example.

The Ministry of Health and Family Welfare recently set up ten panels led by the top brass of the DCGI's office. They have been entrusted with the revision of the drug regulations in order to bring about ease in compliance and adopting to the progressive changes in the industry.

1.9 FURTHER READING

- Gambarte, M. L., Lopez Osornio, A., Martinez, M., Reynoso, G., Luna, D., et al. (2007). A practical approach to advanced terminology services in health information systems. Stud Health Technol Inform, 129, 621-625.
- Greenes, R. A. (2007). Clinical decision support - the road ahead. Amsterdam: Elsevier Academic Press.

- Heimly, V., Grimsmo, A., Henningsen, T. P., & Faxvaag, A. (2010). Diffusion and use of Electronic Health Record systems in Norway. Stud Health Technol Inform, 160 (Pt 1), 381-385.
- McDonald, C. J. (1997). The barriers to electronic medical record systems and how to overcome them. J Am Med Inform Assoc, 4 (3), 213-221.
- Simon, S. R., Kaushal, R., Cleary, P. D., Jenter, C. A., Volk, L. A., et al. (2007). Physicians and electronic health records: a statewide survey. Arch Intern Med, 167 (5), 507-512.
- Sujansky, W. V. (1998). The benefits and challenges of an electronic medical record: much more than a "word-processed" patient chart. West J Med, 169 (3), 176-183.

1.10 CHECK YOUR PROGRESS: POSSIBLE ANSWERS

1) What is E-Health?

As per the World Health Organization ("WHO"), E-Health means "the use of information and communication technologies ("ICT") for health".

2) What is EHR?

An Electronic Health Record (EHR) is a digital version of a patient's health records.

3) What are the functions of EHR?

Common functions of EHRs include (Health Resources and Services Administration, 2014a).

- Recording patient demographic and care management data on patient visits.
- The clinical decision supports.
- Reports required for financial management, quality assurance, chronic disease management, and public health data collection.
- Consents, authorisations, and directives.
- Interfaces and interoperability required to exchange health information with other clinicians, laboratories, pharmacies, patients, and government disease registries.
- e-prescribing.
- Alerts and reminders.
- medication reconciliation.

- Commonly used screening tools and checklists.
- commonly used forms for schools, camps, and sports participation.
- Patient education.

4) How does the I.T. Act aid in E-Health?

The patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information14 ("SPDI") under the Data Protection Rules. When a corporate body collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

1.11 ACTIVITY

Explain the meaning, concept, functions and elements of E-Health and Electronic Health Records along with the legal enactments with respect it? (1000 words)