



Policies and Procedures in eHealth

Foundational Curricula:

Cluster 10: Leadership & Management

Module 18: Administration, Leadership and Management of eHealth

Unit 3: Policies and Procedures in eHealth

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Unit Objectives



- Describe relevant information systems and engineering policies and procedures as required at organizational, regional, national, international, and multi-national levels
- Identify appropriate documentation management policies and procedures to ensure data quality and integrity
- Describe various policy and the regulatory frameworks
- Describe internal and external reporting requirements



Policies and Procedures in eHealth



Policies reflect the "rules" governing the implementation of the organization processes. **Procedures** stand for an implementation of policy and should evolve over time as new tools emerge and new processes are designed.

- The need for eHealth becomes more evident and it is already widely used in many countries. Effective development of information and communication technologies and its integration into health care processes is deemed to be best achieved through the creation of an eHealth strategy, with the support of policies at the global and local levels.
- These policies can facilitate patient mobility and data exchange, across both international borders and regional boundaries within countries.



Policies and Procedures in eHealth (cont'd)



- Policies and regulatory procedures in eHealth (and healthcare in general) require a great amount of national and international laws and regulations which are then implemented in practice at the local, regional or national level
- The illustration collects topics related to policies and procedures, and they are introduced and discussed in this unit

Policies and Procedures in eHealth

Regulations:

- GDPR
- MDR

Incident Reporting System

Policy documentation

Documentation management

Reporting requirements for employer, employee or customer



Information systems and engineering policies and procedures (cont'd)



Information systems and engineering policy target areas vary across countries and regions. The policy documents may focus on:

- **hardware standards, web standards and mHealth**
- **eHealth budget for the sustainability of systems**
- **use of modern wireless telecommunication**
- **backup measures**





Documentation management policies and procedures

Documentation can be defined as the process of accumulating and classifying documents to enable easy secondary use. The aim of **documentation management**, on the other hand, is about promoting accurate and effective decision making based upon reliable information derived from consistent interpretation.

- Effective documentation helps to make informed decisions, ensures the continuity of patient care and, and represents the legal evident when defending claims of negligence or in substantiating the care that was provided to a patient.





Policy and the regulatory frameworks



A **policy framework** is document that sets out a set of principles or long-term goals, which may be used in negotiation or decision-making to guide a more detailed set of policies, or to guide ongoing maintenance of an organization's policies.

- **Health 2020 European health policy framework:**

- adopted in September 2012
- two strategic objectives; constructed around equity, gender and human rights and improved governance for health



- **The new European Union medical devices regulation:**

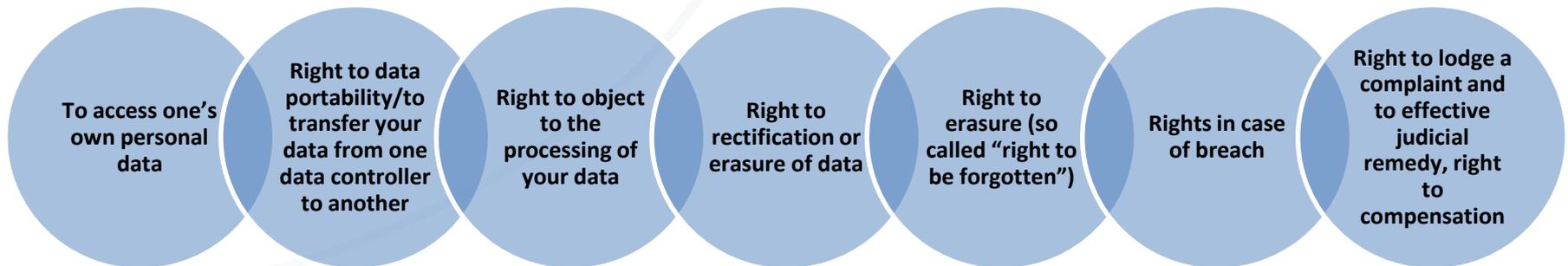
- entered into force on 25 May 2017, apply from 26 May 2020 and 2022 respectively
- to make sure that medical devices are safe while allowing patients to benefit of innovative health care solutions in a timely manner.



Policy and the regulatory frameworks (cont'd)



- **EU General Data Protection Regulation:**
 - entered on 24 May 2016, applies after 25 May 2018
 - Europe's new framework for data protection laws
 - to protect the rights of data subjects and confidentiality of their personal health data, whilst preserving the benefits of processing data (including digital images) in patient medical care and diagnosis and for research and public health purposes
 - the rights to patients (and consumers) regarding data:





Internal and external reporting requirements

The **report** tells the enforcing authorities for occupational health and safety about serious incidents and cases of disease. Also, an increased risk of an incident is reported..

- It can be better identified where and how risks arise and whether they need to be investigated.
- The **responsible person** for reporting may be the employer of an injured person, a self-employed person or someone in control of premises where work is carried out.
- The figure below presents examples of steps taken in a reporting procedure





Internal and external reporting requirements (cont'd)

- **Hazard Reporting by Employee** is defined as the responsibility to identify hazards and report them to the supervisor
 - Ultrasound machine seems to gain more heat than usual, a burn risk to the patient, electrical malfunction?
- **Incident Reporting by Employee** is the statement regarding a deviation from acceptable patient care
 - Mistake noticed in the care process, e.g. the practitioner did not take a symptom into account when making the diagnosis





Internal and external reporting requirements (cont'd)

- **Injury Reporting by Employer** is defined as the log about any illness or injury to an employee that causes time lost from the job or treatment beyond first aid
 - A nurse has a sprained back from carrying heavy package that broke down during lifting and requires a sick leave
- **Medical malpractice action by patient** is the written complaint demanding payment based on a healthcare practitioner's provision of failure to provide healthcare service
 - The patient files a complaint of mistake made in his or her care, e.g. a nerve damage during a surgery causes chronic pain





Unit Review Checklist

- Describe relevant information systems and engineering policies and procedures as required at organizational, regional, national, international, and multi-national levels (PB01)
- Identify appropriate documentation management policies and procedures to ensure data quality and integrity (PB03)
- Describe various policy and the regulatory frameworks (PB04)
- Describe internal and external reporting requirements (PB02)



Unit Review Exercise/Activity



1. Find out in which situations may confidential health information be disclosed to third parties e.g. social welfare of other health organization.
2. Find out about how can a patient report an error on her/his health record.
3. Every workplace has hazards. Identify hazards associated with shifts and job assignments in your organization.



Unit Exam



1. Which of the following arguments best describes policies?
 - a) Policies are the implementation of orders
 - b) Policies are suggested actions or recommendations
 - c) Policies are the directives that codify organizational requirements

2. Which of the following statements about documentation is true?
 - a) Documentation consists of material that provides official information that serves as a record for secondary use
 - b) Emails may be used as evidence in a future investigation or proceeding when care is being questioned
 - c) Any email concerning the care of a specific patient should be considered to be documentation
 - d) All of the above



Unit Exam (cont'd)



3. Which of the following is not a right given to patients by the GDPR?
 - a) To obtain a copy of any information in the record
 - b) To ask to correct any factual error they see in their medical records
 - c) To protection of their health data
 - d) To ask the health care provider not to keep medical records

4. Break in sterile technique that causes harm to the patient requires reporting
 - a) True
 - b) False