

***MEDICO - LEGAL  
&  
THE eHR PRIVACY***

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26<sup>th</sup> MAY 2009

# DEFINITIONS

- **MEDICO-LEGAL**

Pertaining to legal aspects of the practice of medicine (as malpractice or patient consent for operations or patient information)

# DEFINITIONS

- **MEDICO-LEGAL**

Pertaining to both medicine and law.

Medico legal considerations are a significant part of the process of making many patient care decisions and determining definitions and policies for the treatment of mentally incompetent people and minors, the performance of sterilization or therapeutic abortion, and the care of terminally ill patients.

Medico legal considerations, decisions, definitions, and policies provide the framework for informed consent, professional liability, and many other aspects of current practice in the health care field.

Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

# DEFINITIONS

- **ELECTRONIC HEALTH RECORD (eHR)**

The electronic health record includes all information contained in a traditional health record including a patient's health profile, behavioural and environmental information. As well as content the EHR also includes the dimension of time, which allows for the inclusion of information across multiple episodes and providers, which will ultimately evolve into a lifetime record

(Mon, 2004, Amatayakul, 2004).

# DEFINITIONS

- **ELECTRONIC HEALTH RECORD (eHR)**

Contains all personal health information belonging to an individual;

Is entered and accessed electronically by healthcare providers over the person's lifetime;

and

extends beyond acute inpatient situations including all ambulatory care settings at which the patient receives care.

Ideally it should reflect the entire health history of an individual across his or her **lifetime** including data from **multiple providers from a variety of healthcare settings.**

## **The proposed electronic health record will:**

- Contain all personal health information of an individual patient, from the patient's first admission or attendance at the hospital;**
- Be entered electronically by healthcare providers at the point of care over the patient's lifetime;**
- Have information readily available and accessed by all healthcare providers attending to the patient.**

**The information is organised primarily to support continuing, efficient, and quality healthcare.**

**The record is under the control of the consumer and is stored and transmitted securely.**

# DEFINITIONS

- **PRIVACY**

- Privacy is a **fundamental human right**. It underpins human dignity and other values such as freedom of association and freedom of speech. It has become one of the most important **human rights** of the modern age.
- Privacy is recognized around the world in diverse regions and cultures. It is **protected** in the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and in many other international and regional human rights treaties. Nearly every country in the world includes a right of privacy in its constitution. At a minimum, these provisions include rights of inviolability of the home and **secrecy of communications**.

# DEFINITIONS

- **PRIVACY**

- Most recently written constitutions include **specific rights to access and control one's personal information**. In many of the countries where privacy is not explicitly recognized in the constitution, the courts have found that right in other provisions. In many countries, international agreements that recognize privacy rights such as the International Covenant on Civil and Political Rights or the European Convention on Human Rights have been adopted into law.

# DEFINITIONS

- **PRIVACY**

- Some viewpoints on privacy:
- In the 1890s, future United States Supreme Court Justice Louis Brandeis articulated a concept of privacy that urged that it was the individual's "right to be left alone." Brandeis argued that privacy was the most cherished of freedoms in a democracy, and he was concerned that it should be reflected in the Constitution.<sup>[5]</sup>
- Robert Ellis Smith, editor of the *Privacy Journal*, defined privacy as "the desire by each of us for physical space where we can be free of interruption, intrusion, embarrassment, or accountability and the attempt to control the time and manner of disclosures of personal information about ourselves."<sup>[6]</sup>
- According to Edward Bloustein, privacy is an interest of the human personality. It protects the inviolate personality, the individual's independence, dignity and integrity.<sup>[7]</sup>
- According to Ruth Gavison, there are three elements in privacy: secrecy, anonymity and solitude. It is a state which can be lost, whether through the choice of the person in that state or through the action of another person.<sup>[8]</sup>
- The Calcutt Committee in the United Kingdom said that, "nowhere have we found a wholly satisfactory statutory definition of privacy." But the committee was satisfied that it would be possible to define it legally and adopted this definition in its first report on privacy:
- The right of the individual to be protected against intrusion into his personal life or affairs, or those of his family, by direct physical means or by publication of information.<sup>[9]</sup>
- The Preamble to the Australian Privacy Charter provides that, "A free and democratic society requires respect for the autonomy of individuals, and limits on the power of both state and private organizations to intrude on that autonomy...Privacy is a key value which underpins human dignity and other key values such as freedom of association and freedom of speech...Privacy is a basic human right and the reasonable expectation of every person."<sup>[10]</sup>

# MEDICO – LEGAL BENEFITS OF eHR

- Improved access to legible patients health records
- Standardised documentation
- Automatic notification of laboratory results
- Increased efficiency of information transfer between healthcare professionals
- Reduce vulnerability to malpractice claims

# MEDICO – LEGAL ISSUES IN A PATIENT RECORD SHARING ENVIRONMENT

- There are many issues to be addressed, from a medically liability perspective, the key issues fall within principal categories:
  - Ownership and stewardship of data
  - Privacy and consent
  - Access to information
  - Accuracy for information

# 1. OWNERSHIP AND STEWARDSHIP OF DATA

- **Medical Practitioner's Perspective:**
  - Intellectual Property Rights associated with ownership of patient's health records belong to the medical practitioner who has written them
- **Patient's Perspective:**
  - Medical records belong morally and ethically to the patient
  - The personal info that the medical practitioner had recorded belongs to the patient
  - The results of investigations belong to the patient and these may be released to him/her when requested

# 1. OWNERSHIP AND STEWARDSHIP OF DATA

- **Issues:**

- Data may come from various sources, as well as access and record maintenance
- Identifying who are responsible for the management of data contained in eHR
- Roles of health care professionals as data stewards regarding the collection, use, disclosure and retention of personal health information in eHR
- The actions of health care professionals and information pertaining to them will be visible through the electronic record

# 1. OWNERSHIP AND STEWARDSHIP OF DATA

- **Solutions:**
  - Guidelines/policies on the maintenance of patients' eHRs.
  - Design of eHR must permit the contributors to meet their regulatory obligations regarding patients records
  - Ensure that the roles regarding ownership/data stewardship of the eHR are clearly articulated among health care professionals.

# 1. OWNERSHIP AND STEWARDSHIP OF DATA

- **Solutions:**
  - Health care professionals informed about anticipated uses, accesses, or disclosures, of his personal information and should have the opportunity to consent to these.
  - Legislation that applies to protect of the health care professional's personal information
  - Establishment of data sharing agreements

## 2. PRIVACY AND CONSENT

- **Issues:**
  - **Patient Information** is accessible to a greater number of people than a traditional paper record, therefore increases the vulnerability of confidential information to inappropriate access.,
  - Patients have a right of access to their personal health information and a right to ensure their information remains confidential

## 2. PRIVACY AND CONSENT

- **Issues:**
  - **Health Care Information.** The actions of health care providers and information pertaining to them will be visible. Eg management, prescription practices, infection rates, patient volume.

## 2. PRIVACY AND CONSENT

- **Solutions:**

- Health care providers are bound by obligations imposed by their own professional legislation which incorporate issues of confidentiality of information.
- Code of ethics – healthcare professionals owe ethical duty of confidentiality to patients. Should not reveal the source

## 2. PRIVACY AND CONSENT

- **Solutions:**

- Personal health information of patient were collected on the basis of consent, which may be implied or express.
- Proper consent requires the patient to have knowledge about how his personal health information will be used and disclosed in the eHR system

## 3. ACCESS TO INFORMATION

- **Issues:**
  - Integrated EHR may lead to unauthorized access to patient's health record.
  - Patient may request access to his personal data. Some 'sensitive' personal data may be detrimental to the patient or liable to cause serious harm to the patient's mental or physical health. It may even endanger his life.

## 3. ACCESS TO INFORMATION

- **Solutions:**

- The information maintained in an EHR should only be accessible by health care professionals who “need to know” that information for patient care or if authorized by legislation for other purposes.
- To define which individuals should have access to what information and how security protocols should be utilized to limit individual access.
- Institute effective mechanisms for ensuring that the information contained in EHRs will not be accessed by unauthorized persons or for unauthorized purposes.

# 3. ACCESS TO INFORMATION

- **Solutions:**

- Though the health care professionals have rights of ownership, they should obtain consent from the patient or next of kin before any release of information from the health records to any third party. He may deny disclosure if there is no written consent from the patient, or his legal next-of-kin or guardian, for release of the contents of the record to a third party.
- A healthcare professional may deny disclosure of the contents of patient's record, if in his considered opinion, the contents if released may be detrimental or disparaging to the patient, or any other individual, or liable to cause serious harm to the patient's mental or physical health or endanger his life.

## 4. ACCURACY OF INFORMATION

- **Issues:**

- Improper use of eHRs - documentation of events before they actually occur.
- Lack of time synchronization between various electronic charting systems - e.g. a baby is born before a caesarian section is performed.
- Relying solely on electronic capture of physiological data lead to e.g. failure to document 90 minutes worth of vital signs data during surgery.

## 4. ACCURACY OF INFORMATION

- **Issues:**

- Data is contributed by many health care professionals. Inaccurate information contained in an EHR potentially increases the risk of a patient suffering an adverse event, as other health care professionals could rely on this incorrect information when making subsequent treatment decisions.

## 4. ACCURACY OF INFORMATION

- **Solutions:**

- Design of the system that prevent recording of an event before it actually happens.
- Reminder system
- Provide patients with the ability to restrict access to their personal health record and the opportunity to correct personal health information contained in the EHR (but should not seek to change any entries made by the practitioner in the course of consultation, diagnosis and management as these are made by the practitioner based on his clinical judgment.)

# CASE



# MEASURES TAKEN TO AVOID MEDICO-LEGAL CASES

- To establish good parameters to guide eHR implementation
- Laws/legislations introduced or amended to specifically tackle the issue on the use of EHRs.
- A simple, stand-alone implementation of an EHR e.g. within a group of practice – reduce risk of unauthorized access.

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- It is important for healthcare professionals to familiarize themselves with the key concepts of related laws that may be used in litigation with regards to the use of EHRs.

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Codes of practice for healthcare professionals under specific laws that govern healthcare professionals:**
  - Medical Act 1971
  - Dental Act 1971
  - Nurses Act 1950
  - Registration of Pharmacists Act 1950
  - Medical Assistants (Registration) Act 1977
  - Optical Act 1991
  - Allied Health Bill 200\_

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Guidelines on Medical Records by Malaysian Medical Council:**

- “While patients have right of such access to their Medical Records, they may be permitted to inform the practitioner of any **factual errors** in the personal patient information. They **should not seek to change any entries** made by the practitioner in the course of consultation, diagnosis and management as these are made by the practitioner based on his clinical judgment.”

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Private Healthcare Facilities and Services Act 1998**
  - The manner of access to medical reports and medical records have been incorporated under the Private Healthcare Facilities and Services Regulations 2006.

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Telemedicine Act 1997**
  - Section 3. Persons who may practise telemedicine.
  - Section 4. Certificate to practise telemedicine.
  - Section 5. Patient's consent.
  - Section 6. Regulations.
- Is yet to be enforced

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Personal Data Protection Bill**

- No existing legislation under MOH that contain explicit provision empowering MOH in the collection, use and disposal of personal data, especially collection of “sensitive” personal data and collection of data for research, audit, quality assurance and health epidemiology study.
- MOH to be regulated under the Personal Data Protection Bill by prescription of collection, use and disclosure of any personal data.

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Personal Data Protection Bill**

- Bill is at the drafting stage and is under the responsibility of Kementerian Tenaga Air dan Komunikasi (KTAK).
- “Personal data” will be defined to cover all aspects of healthcare (preventive medicine, medical diagnosis, medical research, rehabilitation and the provision of care, treatment and management of healthcare services).

# RELEVANT LAWS INVOLVED IN MEDICO-LEGAL CASES

- **Personal Data Protection Bill**

- “Access principle” - it is not an absolute rights for the patient to access and request for correction of his personal data.
- The Bill provides for situations whereby a doctor may refuse patient’s request to access and correct his personal data.

**Terima kasih**

