Ethical, legal, and Social Issues in Biomedical Informatics

MEDICAL INFORMATICS
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Color coding:
Important
Notes

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Introduction ....

- Hospital Information systems and Electronic Medical Records (EMR) and e-health applications is becoming widely implemented or accepted

- Motivated by the great **benefits** to patient care, and health care in general

- However having medical records on-line, is increasing the **risk** of exposing private and sensitive information to unauthorized

- Many assume that the confidentiality of electronically stored patient information is the most important ethical issue in health informatics. Although confidentiality and privacy are indeed of vital interest and significant concern, the field is rich with other important ethical issues, including:

When we talk about ethics the first thing that comes to mind is, privacy and confidentiality of patient information and this is only one part of it.

Ethical Issues in Health Informatics:

- **Confidentiality** of electronic patient information
- Proper selection/use of informatics **tools** in clinical settings
- Determination of **who** uses these tools
- The role of system **evaluation**
- The **obligations** of system developers, maintainers, vendors
- The appropriate standards for interacting with industry
- The use of computers to **track** clinical outcomes to guide future practice

Considering ethical issues in health informatics-explore a significant intersection among several professions:

1. Healthcare clinicians
2. Healthcare administration
3. Applied computing
4. Ethics people involved in ethics

People who work in these professions need to understand and know how to apply ethics

Ethics historical ……

- Patient information should be used **only** in the **context** of providing health and medical care,

- Medical **Oath** of more than 2,000 years ago, and reinforced by acts and codes including the Code of Ethics of the American Medical Association and the federal Privacy Act of 1973.

- Eventually, **security** and **privacy** of information in healthcare is becoming a public concern. Privacy generally applied to people while **confidentiality** is best applied to information.

Ethical Issues in Health Informatics:

- Human **values** should govern both research and practice in health professions.
- Health informatics, like other health professions, encompasses **issues** of appropriate and inappropriate **behavior**, of honorable and disreputable **actions**. practitioners share an important **obligation** to explore the moral underpinnings and ethical challenges related to their **research** and **practice**.
- Health Informatics constitutes a source of the most important and interesting ethical **debates** in all health care professions.

> There's still a big debate on who can access patient information.

To answer the clinical question,

"What should be done in this case?"

Several Questions should have enough attention, such as:

1.What is the problem?

2. What resources are available and what am I competent to do?

3. What will maintain or improve this patient's care?

4.What would produce the most desirable results (e.g., in public health)?

5. How strong are my beliefs in the accuracy of my answers to questions above.

Similar considerations determine the appropriate use of informatics tools.

Ethical Issues in Health Informatics:

- Health Informatics Ethics is encompassing ethical issues resulting from the utilization of technology and health informatics tools in managing healthcare and patient **information** and **delivering** health and medical services.

- **Ethics:**

  - is a **<u>social</u>** concept of good behavior. It is a collective concept that evolves gradually, usually over years, as a result of interaction between individuals living or working together

> Ethics highly depend on the social concept in different places and different times. What is ethical here might not be ethical somewhere else, and what is is ethical now may have not been ethical 20 years ago.

Legal and regulatory matters:

ethical and legal issues often overlap.

➤ **Ethical** considerations apply in attempts to determine what is good or meritorious and which behaviors are desirable or correct in accordance with higher principles.

➤ **Legal principles** are generally derived from ethical ones but deal with the practical regulation of morality or behaviors and activities .

➤ **laws** directly tell us how to behave under various specific circumstances and prescribe remedies or punishments for individuals who do not comply with the law.

For example, in a neighborhood with schools and children walking around people agreed (without documenting) that the speed limit should be 20. It is ethical to follow that speed limit. Then someone put a camera there and said that there is a fee of 200 for anyone going past the speed limit. Now it is considered law.

Ethics Resources:

1) Codes of ethics

Ethics codes are formal documents that list ethical principles and duties. Such as World Health Organization (WHO) code of ethics and International Medical Informatics Association (IMIA) code of ethics.

2) Case studies

There are often available reference to similar ethical conflicts and situations in the past that may have been resolved in a certain manner. These cases can be applied as jurisprudence.

> For example in patients on life support and there is a debate on whether they should stop it or continue, they look at previous similar cases and make a decision based on that.

3) Ethics committees and personnel

Organizations can have committees and trained staff to discuss and resolve ethics issues. These may include ethics boards or ethics professionals that are contacted for consultation when ethical conflicts occur. Ex. food and drug administration

4) Informal discussions

Chats with friends or colleagues can lead to informal advice about how an ethical conflict can be resolved.

Stakeholders in Health Informatics Ethics

- It is important to identify the stakeholders involved in the health informatics setting because ethical conflicts arise as a result of interactions between these stakeholders.

1. **Patient**
2. **Healthcare professionals**
3. **Institutions and employers Society**
4. **Regulator**
5. **Others** ex.
   Manufacturers

Stakeholder: anyone who is involved in a situation, either affected or effector.

You should differentiate service providers (ex. Ministry of health) from regulators (ex. FDA, decide on what drugs should be used in practice, and Saudi commission for health specialties, decide on who can practice medicine).

Electronic Medical Records

- Medical records contain information about patients , such as:

  height , weight, blood pressures, and notes about diseases and incidents like flu, cuts, or broken bones.

  fertility and abortions, emotional problems and psychiatric care, sexual behaviors, sexually transmitted diseases, HIV, substance abuse, physical abuse problems, and genetic predispositions to diseases, etc.

- Disclosure of such information can harm concerned person by causing **social** embarrassment or prejudice, by affecting insurability, or by limiting ability to get and hold a job.

- Of course, such damage can occur no matter whether medical records are in paper or electronic form.

Medical records…

- Medical records serves a variety of functions for organizations not involved directly in care:
    - <u>Insurers</u> (government and private) to justify payment for medical services rendered, and to detect fraud.
    - <u>Quality reviews</u>, administrative reviews, and utilization studies to manage the <u>business</u> aspects of health care.
    - Used for societal purposes, such as, social service and welfare system management, law enforcement, screening and licensing and determining life insurance eligibility.
    - Medical <u>research</u>, public health management
    - <u>Education</u> and medical training

Ethics in Health Informatics

There are three concepts involved in protecting health care information:

- **Privacy** :the right and desire of a person to control the disclosure of personal health information.

- **Confidentiality** : the controlled release of personal health information to a care provider or information custodian under an agreement that limits the extent and conditions under which that information may be used or released further.

- **Security**: a collection of policies, procedures, measures, and safeguards that help maintain the integrity and availability of information systems and control access to their contents.

Privacy: concerned with individuals
Confidentiality: concerned with data, information, and people who have access. Protect information from the inside
Security: Also concerned with information and data. Prevent access of information from unauthorized individuals. Protect information from the outside.

The standard view of appropriate use:

- The standard view state that, when adequate decision-support tools are developed, they should be used as <u>supplementary and subservient</u> to human clinical judgment. e.g. clinical expert systems

- Consequences of the standard view:

1. Practitioners have an obligation to use any computer-based tool <u>responsibly</u>, through adequate user training and by <u>understanding</u> of the system abilities and limitations.

2. Practitioners must not <u>abrogate</u> their clinical judgment reflexively when using computer based decision aids.

- The standard view states that when adequate (and even exemplary) decision-support tools are developed, they should be viewed and used as **supplementary** and subservient to human clinical judgment.

- Progress should be measured in terms of whether clinicians using a CDS tool perform **better** on specific tasks than the same clinicians without the tool

Physicians have to make their own decisions and only use DSS as a support system

Appropriate users and educational standards:

Who should use a healthcare related computer application???!!!

- user of systems include physicians, nurses, student to health sciences, patients, and insurance and government evaluators

- Are members of all these group appropriate users?

The standard view of appropriate use:

- Users of most clinical systems should be health professionals who are qualified to address the question at hand on the basis of their licensure, clinical training and experience. Software systems should be used to augment or **supplement**, BUT to replace such individual's decision making.

- All uses of informatics tools, especially in patient care, should be preceded by adequate training and clear instruction, which should include review of all available forms or previous product evaluations.

Obligations and Standards for systems Developers and Maintainers

- Users depend on the <u>developers</u> and <u>maintainers</u> of a system and must trust <u>evaluators</u> who have validated a system for clinical use.

- Health care software applications are among the most complex tools in the technological area, which commits system developers, designers and maintainers to **adhere** to **standards** and acknowledge their moral **responsibility**.

Obligations and Standards for systems Developers and Maintainers

- People who develop, maintain and sell healthcare computing systems and components have obligations which include holding **patient** care as the leading value.

- Professional-patient relationship principal- also applies to the people who produce and attend to healthcare information systems.

- Quality standards should stimulate scientific progress and innovation while **safe guarding against systems error and abuse.**

e.g. evaluation criteria:

- How well have individuals been trained to use it?
- What are the anticipated long term effects on how departments interact?
- What are the long-tern effects on the delivery of medical care?
- Will the system have an impact on the control in the organization?
- To what extent do effects depend on practice setting?

Ethical principles for appropriate use of decision support system:

1- A computer program should be used in clinical practice only after appropriate **evaluation** of its **efficacy, safety and documentation** that it performs its intended task at an acceptable cost in time and money.

2- Users of most clinical systems should be health professionals who are **qualified** to address the question at hand on the basis of their licensure, clinical training, and experience. In addition, software system should be used to augment or supplement, NOT to replace individuals decision making.

3- All uses of informatics tools, especially in patient care, should be preceded by adequate training and instructions.

Physicians should understand that the decision is theirs. CDSS is only there to help them.

All users should get adequate training according to their own personal needs.

Technologies Helps Protect Health Care Information

- In paper-based patient records, access control is almost entirely <u>manual</u> and procedural, Technological security tools are an integral part of EMR systems and offer varieties of advantages:

    - Confidentiality and privacy
    - Information and data security
    - The appropriate use of informatics tools in clinical sitting.
    - The determination of who should use such tools.
    - The role of system evaluation.
    - The obligations of system developers, maintainers, and vendors.
    - Use of computer to track clinical outcomes to guide future practice.
    - Audit trail

Importance of computer application in healthcare:

at the highest level with respect to ethics and security, it serves five key functions:

- *Availability : ensuring that accurate and up-to-date information is available* when needed at appropriate places.

- *Accountability : ensure that health care providers are responsible for* their access, and uses of information are based on a documented need and right to know

- *Perimeter Definition : knowing and controlling the boundaries of trusted* access to the information system, both physically and logically.

- *Role-Limited Access : enabling access for personnel only to information* essential to the performance of their jobs, and limiting the real or perceived temptation to access information beyond a bona fide need.

- *Comprehensibility and Control : ensuring that record owners, data stewards,* and patients can understand and have effective control over appropriate aspects of information privacy and access.

- In the United States, Federal Register, Health Insurance Portability and Accountability Act of 1996 (HIPAA) and National Committee on Vitaland Health Statistics have strongly emphasized the importance of health privacy.

- The National Research Council has discussed indetail the limitations of Federal and State protection, technical approaches and organizational approaches for protection of privacy in medical records.

- In Australia, Parliament passed the Health Record and Information Privacy Act (HRIPA) in 2002

Privacy and Confidentiality:

- In the united states, a key federal initiative, the Health Insurance Portability and Accountability Act (HIPAA) of 1966, called for the legislative or executive branch of government to establish the first-ever nationwide protection of electronic patient records .

Health Insurance Portability and Accountability Act (HIPAA):

- In 1996, the Health Insurance Portability and Accountability Act (HIPAA) was endorsed by the U.S. Congress.

- HIPAA is composed of several sets of standards like transactions and code sets, privacy and security.

- The main purpose of the standards are to modify the administration of health insurance claims and lower costs, to give patients more easily access to their health care information.

HIPAA (cont.)

- **HIPAA calls for:**
  - ➢ Standardization of electronic patient health, administrative and financial data.
  - ➢ Unique health identifiers for individuals, employers, health plans and health care providers.
  - ➢ Security standards protecting the confidentiality and integrity of "individually identifiable health information," past, present or future.

HIPAA (cont.)

- HIPAA's administrative simplification provision is composed of four parts, each of which have generated a variety of rules and standards.

- **The four parts of administrative simplification are:**

  - ➢ Electronic health transaction standards.

  - ➢ Unique identifiers.

  - ➢ Security and electronic signature standards.

  - ➢ Privacy and confidentiality standards.

> Unique identifiers means that when a person accesses the system you can get their information (name, department, etc.) from their username

HIPAA (cont.)

Overview of the Privacy Rule:

● Gives patients **control** over the use of their health information.
● Defines **boundaries** for the use/disclosure of health records by covered entities.
● Establishes national-level **standards** that healthcare providers must comply with.
● Helps to limit the use of PHI and minimizes chances of its inappropriate disclosure.
● Strictly **investigates** compliance-related issues and holds violators accountable with civil or criminal penalties for violating the privacy of an individual PHI.
● Supports the **cause** of disclosing PHI without individual consent for individual healthcare needs, public benefit and national interests.

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