Ethics in Biomedical and Health Informatics: Users, Standards, and Outcomes

10.1 Ethical Issues in Biomedical and Health Informatics:
- Confidentiality of electronically stored patient information (most important)
- Appropriate selection and use of informatics tools in clinical settings;
- Determination of who should use such tools;
- Role of system evaluation;
- Obligations of system developers, maintainers, and vendors;
- Appropriate standards for interacting with industry;
- Use of computers to track clinical outcomes to guide future practice.
- In addition, informatics engenders many important legal and regulatory questions.

To consider ethical issues in healthcare informatics is to explore a significant intersection among: healthcare informatics, healthcare delivery and administration, applied computing and systems engineering, and ethics.

10.2 Health-Informatics Applications: Appropriate Use, Users, and Contexts
10.2.1 The Standard View of Appropriate Use
The standard view states that decision-support tools should be viewed and used as supplementary and subservient to human clinical judgment. Because:
- The clinician knows and understands the patient's situation and can make compassionate judgments better than computer programs.
- Clinicians, and not machine algorithms, are the entities whom the state licenses, and specialty boards accredit.

The standard view may be seen as a tool for both <u>error avoidance</u> and <u>ethically optimized action.</u>

10.2.2 Appropriate Users and Educational Standards

Set of ethical principles for appropriate use of decision- support systems:

1. A computer program should be used in clinical practice only after appropriate evaluation of its efficacy and the 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. Software systems should be used to augment or supplement, rather than to replace or supplant, such individuals' decision making.

3. All uses of informatics tools, especially in patient care, should be preceded by adequate training and instruction, which should include review of applicable product evaluations.

10.2.3.1 Ethics, Standards, and Scientific Progress

To give a flavor of how a comprehensive evaluation program can ethically optimize implementation and use of an informatics system, consider these ten criteria for system scrutiny:

1. Does the system work as designed?

2. Is it used as anticipated?

3. Does it produce the desired results?

4. Does it work better than the procedures it replaced?

   5. Is it cost effective?

   6. How well have individuals been trained to use it?

   7. What are the anticipated long-term effects on how organizational units interact?

8. What are the long-term effects on the delivery of medical care?

9. Will the system have an impact on control in the organization?   10. To what extent do effects depend on practice setting?

10.3 Privacy, Confidentiality, and Data Sharing

10.3.1 Foundations of Health Privacy and Confidentiality

In most communities of the United States, the contacts of patients who have active tuberculosis or certain sexually transmitted diseases are routinely identified and contacted by public health officials so that the contacts may receive proper medical attention.

Most recently, the need for **robust syndromic surveillance** has been asserted as necessary for adequate <u>bioterrorism preparedness</u>, as well as for earlier detection of naturally occurring disease outbreaks

10.3.2 Electronic Clinical and Research Data

10.3.2.1 Technological Methods

10.3.2.2 Policy Approaches

10.3.2.3 Electronic Data and Human Subjects Research

How can you use patient information in a research without breaking confidentiality?

1-The first is to establish mechanisms to anonymize the information in individual records or to decouple the data contained in the records from any unique patient identifier.

This task is not always straightforward; it can be remarkably dif- fi cult to anonymize data such that, when coupled with other data sets, the individuals are not at risk of re-identification. A relatively rare disease diagnosis coupled with demographic data such as age and gender, or geographic data such as a postal code, may act as a surrogate unique identi- fi er; that is,

detailed information can in combination serve as a data fingerprint that picks out an individual patient even though the patient's name, Social Security number, or other (official) unique identifiers have been removed from the record.

2-The use of institutional panels, such as medical record committees or institutional review boards. Submission of database research to appropriate institutional scrutiny is one way to make the best use of more or less anonymous electronic patient data.

10.3.2.4 Challenges in Bioinformatics

Bioinformatics or computational biology provides an exciting ensemble of new tools to increase our knowledge of genetics, genetic diseases, and public health.

- How, to what extent, and by whom should genomic databases be used for clinical or public health decision support?
- Are special rules needed to govern the study of information in digital genetic repositories (or are current human subjects research protection rules adequate)?
- Does data mining software present new challenges when applied to human genetic information?
- What policies are required to guide and inform the communication of patient-specific and incidental findings?
- Are special protections and precautions needed to address and transmit findings about population subgroups?

10.4 Social Challenges and Ethical Obligations

The need for data on clinical outcomes is driven by a number of important social and scientific factors. Perhaps the **most important** among these factors is the **increasing unwillingness of governments and insurers to pay for interventions and therapies that do not work or that do not work well enough to justify their cost.** Health informatics helps clinicians, administrators, third-party payers, governments, researchers, and other parties to collect, store, retrieve, analyze, and scrutinize vast amounts of data—though the task of documenting this is itself a matter of research on what has come to be called "meaningful use."

10.4.1 Vendor Interactions

10.4.2 Informatics and Managed Care

There are, however, three reasons why it is problematic to rely exclusively on clinical computer programs to guide policy or practice in these ways:

1- As we argued earlier with the standard view of computational diagnosis (and, by easy extension, prognosis), human cognition is, at least for a while longer, still superior to machine intelligence

2- Decisions about whether to treat a given patient are often value laden and must be made relative to treatment goals. In other words, it might be that a treatment will improve the quality of life but not extend life, or vice versa

3- Applying computational operations on aggregate data to individual patients runs the risk of including individuals in groups they resemble but to which they do not actually belong.

10.4.3 Effects of Informatics on Traditional Relationships

Many clinical decisions are not exclusively medical—they have social, personal, ethical, psychological, financial, familial, legal, and other components; even art might play a role

10.4.3.2 Consumer Health Informatics

If physicians and nurses have not established relationships based on trust, the erosive potential of apparently authoritative Internet resources can be great. Physicians once accustomed to newspaper- inspired patient requests for drugs and treatments now face ever increasing demands that are informed by Web browsing. Consequently, the following issues will gain in ethical importance with each passing year:

• Peer review: How and by whom is the quality of a Website to be evaluated? Who is responsible for the accuracy of information communicated to patients?

•Online consultations: There is no standard of care yet for online medical consultations. What risks do physicians and nurses run by giving advice to patients whom they have not met or examined in person? This question is especially important in the context of telemedicine or remote-presence health care, the use of video teleconferencing, image transmission, and other technologies that allow clinicians to evaluate and treat patients in other than face- to-face situations.

•Support groups: Internet support groups can provide succor and advice to the sick, but there is a chance that someone who might benefit from seeing a physician will not do so because of anecdotes and information other- wise attained. How should this problem be addressed?

10.4.3.3 Personal Health Records

PHRs are now commonly linked to so-called **"personal health applications"** (PHAs) which provide ways of moving beyond simple static storage of one's medical history. Most provide some sort of primitive decision support, if only in linking to additional information about a particular disease or condition. Others include more ambitious decision-support functionality.

10.5 Legal and Regulatory Matters

10.5.1 Difference Between Law and Ethics

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

- **Ethics** offers conceptual tools to evaluate and guide moral decision making.
- **Laws** directly tell us how to behave (or not to behave) under various specific circumstances and prescribe remedies or punishments for individuals who do not comply with the law.

10.5.2.1 Liability Under Tort Law

Products are physical objects, such as stethoscopes, that go through the processes of design, manufacture, distribution, sale, and subsequent use by purchasers.

Services are intangible activities provided to consumers at a price by (presumably) qualified individuals.

(1) Harm by intention —when a person injures another using a product or service to cause the damage
(2) The negligence theory
(3) Strict product liability. Providers of goods and services are expected to uphold the standards of the 10 Ethics in Biomedical and Health Informatics: Users, Standards, and Outcomes community in producing goods and delivering services. When individuals suffer harm due to substandard goods or services, they may sue the service providers or goods manufacturers to recover damages.
Malpractice litigation in health care is based on negligence theory.
For strict product liability to apply, three conditions must be met:
1. The product must be purchased and used by an individual.
2. The purchaser must suffer physical harm as a result of a design or manufacturing defect in the product.
3. The product must be shown in court to be "unreasonably dangerous" in a manner that is the demonstrable cause of the purchaser's injury

10.5.2.2 Privacy and Confidentiality

HIPA A's privacy standards became effective for most health care entities, and its security standards. A major impetus for the law was that the process of **"administrative simplification"** via electronic recordkeeping, prized for its potential to increase efficiency and reduce costs, would also pose threats to patient privacy and confidentiality.
At its core, HIPAA embodies the idea that individuals should have access to their own health data, and more control over uses and disclosures of that health data by others. Among its provisions, the law requires that patients be informed about their privacy rights, including a right of access; that uses and disclosures of "protected health information" generally be limited to exchanges of the "minimum necessary"; that uses and disclosures for other than treatment, payment and health-care operations be subject to patient authorization; and that all employees in "covered entities" (institutions that HIPAA legally affects) be educated about privacy and information security.
HITECH also contained many changes to HIPAA privacy and security requirements, strengthening the regulations that affect the collection, use and disclosure of health information not only by covered entities, but also the "business associates" (contractors) of those covered entities, and other types of organizations engaged in health information exchange.

10.5.2.3 Copyright, Patents, and Intellectual Property
Intellectual property protection afforded to developers of software programs, biomedical knowledge bases, and World Wide Web pages remains an underdeveloped area of law. Although there are long traditions of copyright and patent protections for non-electronic media, their applicability to computer-based resources is not clear. Copyright law protects intellectual property from being copied verbatim, and patents protect specific methods of implementing or instantiating ideas.
It is clear that copyright law does not protect the "look and feel" of a program beyond certain limits.

How many individual, unprotected facts can someone copy from a copyright-protected database before legal protections prevent additional copying? A related concern is the intellectual-property rights of the developers of materials made available through the World Wide Web. Usually, information made accessible to the public that does not contain copyright annotations is considered to be in the public domain.

10.5.3 Regulation and Monitoring of Computer Applications in Health Care
10.5.4 Software Certification and Accreditation
-What should be uncontroversial is that any system of regulation, review or certification must be based on and, as a matter of process emphasize, certain values. These might include, among others, patient-centeredness, ethically optimized data management practices, and what we have here commended as the "standard view" that is, human beings and not machines practice medicine, nursing and psychology.
-To make any system of regulation, review or certification ethically credible, government and industry leaders must eventually make explicit that attention to ethics is a core component of their efforts.

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