

ETHICS, HIPPOCRATES, HIPAA AND COMPLIANCE

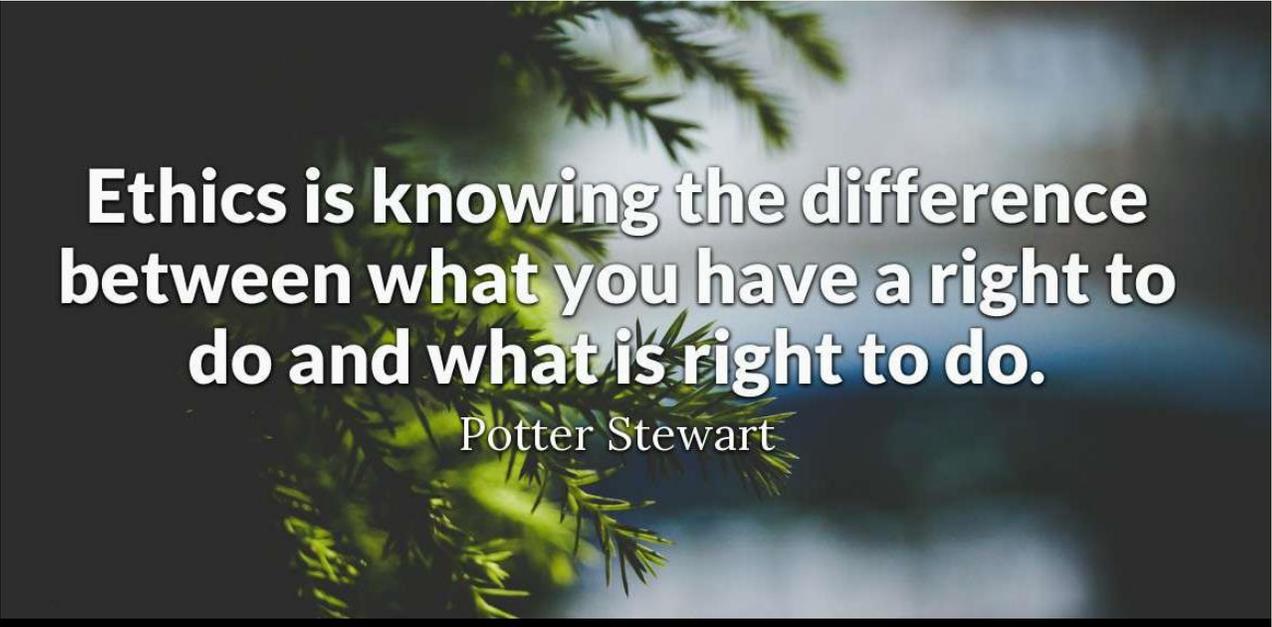
Kathleen W McNicholas MD, FACS, JD, LLM

Ethics

Ethics is the activity of man directed
to secure the inner perfection of his
own personality.

— *Albert Schweitzer* —

AZ QUOTES



**Ethics is knowing the difference
between what you have a right to
do and what is right to do.**

Potter Stewart

“I know it when I see it”

- Colloquial expression
- Attempt to categorize an observable fact or event
- Although category is subjective or lacks clearly defined parameters
- 1964 US Supreme Court Justice Potter Stewart
- Threshold test for obscenity in *Jacobellis v. Ohio*
- “I know it when I see it, and the motion picture involved in this case is not that.”
- That was “hard core pornography”

Medical ethics

- CODE of Hammurabi in 2000 BC
- Hippocrates and Maimonides- OATHS codifying the practice of Medicine
- Sacred TRUST of physician to protect and care for the patient
- Set of VALUES for physicians
- Teaching and learning
- Primacy of benefiting the sick according to one's ability and judgement
- High principles and ideals
- "...To treat the ill to the best of one's ability, to preserve a patient's privacy, to teach the secrets of medicine to the next generation..."

Classic Version of the Hippocratic Oath

- “I swear by Apollo Physician and Asclepius and Hygeia and Panaceaia and all the gods and goddesses, making them my witnesses, that I will fulfil according to my ability and judgement this oath and this covenant”
- ETHICS
- ...What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.
- COMPLIANCE
- If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot. (SELF REGULATION)

Modernized version of Hippocratic Oath

- “What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about.”

Dr. Louis Lasagna

Biomedical Ethics

Autonomy

Patient's Right to make own choice

Beneficence

Acting with best interest of patient in mind

Nonmalifcence

Do No Harm

Justice

*Treat others fairly and equally,
Distributive Justice*

Thomas Percival

- 1800s
- Complexity of medical environment in hospitals
- Concept of shared professional responsibilities
- Manchester Infirmary Rules
- Professions' compact with society
- Coined terms “medical ethics” and “professional Ethics”

Seven Principles of Health Care Ethics

• Autonomy	Patient has right to make their own decisions
• Beneficence	Care should benefit the patient
• Nonmalificence	Do no harm
• Justice	What is fair to all patients and society
• Confidentiality	Protection of personal information
• Veracity	Truth telling
• Role Fidelity	Follow job description; work within credentials

1847 Code of Medical Ethics of the American Medical Society

- Landmark in medical professionalism
- Derived from Percival's earlier work
- First National Code of Ethics for any profession
- Compact defining obligations to:
 - Patients
 - Colleagues
 - Community
- Reciprocity

AMA Code of Ethics

- Implied social and economic rewards for those in profession
- Put patient interests first
- Required competence of practitioners
- Guarded public's health

AMA Code of Ethics

- Respect for autonomy and for patients
- Beneficence and Fiduciary responsibility
- Trust
- Fidelity

Ethical considerations supporting privacy and confidentiality.

Respect for Autonomy

- Patient's right to decide sharing of personal information
- Different consideration for expressly consented, authorized, and endorsed disclosures

Beneficence and Fiduciary Responsibility

- Commitments to protect and promote patients' health-related and other interests
- Commitments to avoid causing loss or harm to one's patients
- Types of harm
 - *Economic such as employment discrimination or identity theft*
 - *Social harm, such as stigmatization or damage to family relationships (HIV disclosure or genetic information)*
 - *Legal harm, such as prosecution for drug related offenses*

Trust

- Trust is the bedrock of the patient-physician relationship
- Privacy protections required in treatment
- Consistent, reliable privacy protection practices within and across professions and institutions in provision of health care and conduct of research

Fidelity

- Implicit or explicit promises of confidentiality must be factored in when evaluating whether the ethical considerations supporting an exception to confidentiality are “overriding”.
- Generally recognized exceptions to the duty to maintain confidentiality including communicable disease to public health authorities and suspected child abuse to child protection agencies.

Confidentiality of Personal Health Information

- Deeply held value in clinical and professional ethics
- Indispensable pillar of provider-patient relationship
- Patients secure in sharing sensitive personal information
- Duty to protect the confidentiality of patient information

Medical Professionalism Values

- Active
- Ongoing
- Iterative
- Debate
- Advocacy
- Leadership
- Education
- Study
- Enforcement
- Continual transformation
- No capitulation to efforts or circumstances that undermine Ethics, Values, or Medical Professionalism

Legal Duty Regarding Patient Confidentiality

- Source of the obligation?
- On whom is the duty imposed?
- What are limits of the duty?
- What remedies are available for breaches of confidentiality?
- Does system of legal protections effectively balance
 - *Patient Rights?*
 - *Provider duties?*
 - *Social interests?*

Constitutional Right of Confidentiality

- Constitutional Right to privacy of medical information
- Balancing test to determine whether the government entity's interest in disclosure is substantial enough to outweigh the individual's privacy interest.

Common Law Duty to Maintain Confidentiality

- Most states –private cause of action against a HCP who impermissibly discloses to third parties confidential information obtained in the course of treatment
- Depending on jurisdiction, the claim may be phrased as follows:
 - *breach of contract*
 - *act of malpractice*
 - *breach of fiduciary duty*
 - *act of fraud/misrepresentation*
 - *breach of specific civil statute permitting award of damages.*

Statutory Protection of Confidentiality

- Statutes must be read to determine the following:
 - *Type of information protected from disclosure*
 - *who has duty to maintain confidentiality*
 - *Standard of care applied to determine a breach*
 - *circumstances under which confidentiality may be breached*
 - *circumstances under which the duty terminates*
 - *relationship between state and federal law.*

Relationship of Law and Ethics

- Some believe that law is too blunt an instrument to deal with the delicate, intimate, and highly variable situations that characterize bioethics
- Law may protect patients from medical dominance and overreaching
- Undesirable consequences of the “legalization” of an obligation or “medicalization” of a personal or social problem
- Legal standards setting a floor for acceptable behavior may be criticized for stimulating a drive to the bottom and a diminution of a commitment to ethical behavior
- Obligations defined by law do not encompass the complete moral obligations of the health care professional.

Permitted disclosure of information in the public interest without first obtaining the individual's explicit permission

- Required by law
- Public health activities
- Reporting of victims of abuse, neglect or domestic violence
- Reporting for health oversight activities
- Judicial or administrative proceedings
- Law enforcement purposes
- Information to coroners, medical examiners, and funeral directors about decedents
- Information for organ donation
- Certain research purposes
- Disclosures to avert a serious threat to health or safety
- Specialized governmental functions
- Workers' compensation

Additional permitted disclosure Access Requiring an opportunity to Object

- If individual is given an opportunity to object disclosure can be made to family, friends, or others involved in the individual's involvement in the subject's care.
- When the subject of the PHI is present, the disclosure can be made if the individual does not object to the disclosure, or if under the circumstances, one can reasonably infer in the exercise of PROFESSIONAL JUDGEMENT that the individual does not object.
- If the individual is not present or is incapacitated, a disclosure may be made if, in the exercise of PROFESSIONAL JUDGEMENT, the disclosure is in the best interest of the individual, and the disclosure is limited to the PHI relevant to the party's involvement in the individual's care.

16 Del. C. sec 1009A- Privacy

16 Del. Code sec 2006- Confidentiality and access to data

- The Delaware Legislature declares that it is their express intent “that a patient’s right of confidentiality shall not be violated in any manner.”
- The collection, compilation, data analysis, and dissemination of reports must be done in a way that protects patient privacy. The state agency must maintain the confidentiality of patient identifiable information.
- Additionally unprofessional conduct includes willful violation of a patient’s confidentiality. Permissible methods of discipline include fines or suspension or revocation of a physician’s license.

Patient Confidentiality and HIPAA

- HCPs subject to wide spectrum of laws and regulations governing the maintenance and disclosure of information.
- Comprehensive nation-wide policy regarding patient privacy established by HIPAA (1996).
- Series of Rules promulgated by DHSS including Privacy, security, and enforcement (2003) and Breach Notification Rule (2013)
- HIPAA applies unless a state law is more stringent

December 2000 version of Privacy Rule

- Written Consent
 - *Personal Identifiable Health Information related to “treatment, payment, or healthcare operations (TPO)”*
- Disclosure for other purposes
 - *More elaborate patient authorization*

August 2002 Privacy Amendment

- Eliminated requirement for patient consent for release of health information for TPO

- Updated Requirements:

- *Notification of patients of entities' privacy policies*

AND

- *A good-faith effort to secure a written acknowledgment from the patient*

Transformation of Healthcare

- Private practitioner
 - Autonomy and self regulation
 - Organization of common group of physicians
 - Employee of hospitals and systems
-
- Physicians obligated to adhere to an ethical ideal and professional values
 - Focus on providing care in the best interest of patients
 - Conflict between values and needs of patients and “regulations”
 - Autonomy and self regulation

Federalization of Health Information Privacy

- Federal rules establish a floor that “evens out” the basic level of protection across states
- Federal rules impose specific obligations on specified health care entities rather than focusing solely on physicians and other HCPs
- Federal laws explicitly permit states to enact more protective rules as long as they do not conflict with federal laws.

Professionalism

- Is Professionalism all about following the rules?
- Whose Rules ?
- Were the rules generated by the profession ?
- Generated by the organization ?
- Is there a Hard to untangle mash-up of the two ?

- Sources of conflict and guidance
- Adherence to Law with guidance of Compliance experts
- Avoidance of CONFLICTS

AMA Code of Medical Ethics (revised 2001)

- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health care professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
- VIII. A physician, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

Code of Ethics for Compliance Professionals

- Obligations to Public
 - promote compliance with the spirit and letter of the law
 - exemplify highest ethical standards in professional conduct
 - contribute to public good
- Obligations to Employing Organization
 - highest sense of integrity
 - unprejudiced and unbiased judgement on their behalf
- Obligation to profession
 - uphold integrity and dignity of profession
 - advance effectiveness of Compliance and ethics programs
 - Promote PROFESSIONALISM in compliance and Ethics

Compliance and HIPAA Privacy Monitoring

- Privacy notices
 - Notice of Privacy Practice (NPP)
 - Computer monitors and PCs
 - Whiteboards
 - Documents containing PHI
 - Printers, copiers, or fax machines
 - HIPAA requires healthcare entities to be more vigilant in protecting patients' privacy
 - Protecting a patient's confidentiality is not just a patient's expectation. It is a regulatory requirement.
-
- John Falcetano Compliance Today March 2019

Medical Profession and Compliance Code Of Ethics

- Physician Responsibility
 - PATIENT
 - Health care System

- Compliance Professional Principles
 - Obligations to the public
 - Obligations to the employing organization
 - Obligation to the Profession

Central Ethical and Compliance Requirements

- Balance legitimate interests in effort to obtain information
- Address risks to individuals of inappropriate sharing of information
- Provide adequate training in policies and procedures
- HIPAA training
- Provide mechanisms to discuss and review related events
- Provision of flexibility for handling complex situations and cases
- Acknowledge the sensitive nature of confidential information that could disrupt fiduciary relationships.

HIPAA

- Improve Medicare Program
- Improve Medicaid Program
- Promote efficiency of the health care system by encouraging the development of an electronic health information system
- Encourage national standards and requirements for the electronic transmission of health information

HIPAA

- Complex regulatory framework
- Violation may result in a significant civil penalty or criminal liability or both
- Regulations do not provide a private cause of action or remedy for patients
- Privacy of Health information
- Security of electronic records
- PHI BUT NOT “PATIENT”

HIPAA Regulations

- Innumerable administrative hoops
- Questionable benefit to patients

OR

- Support for professional judgement
- Quality of Medical Care

HIPAA

- Not all aspects of HIPAA are grounded in ethical practices
- Overall thrust consistent with the ethical practice of medicine and surgery
- General alignment of legal and ethical requirements
- Reasonableness and good judgement- Professionalism

HIPAA “Misunderstandings”

- Obstacles to family support
- Barriers to Proper care and treatment in crisis situation
- Rigid/ Inflexible

- HIPAA....BUT..... PERHAPS.... IT DEPENDS

HIPAA RESPECTS individual autonomy

- Certain limitations on sharing health information with family members, friends, and others without patient's agreement
- Patient must have opportunity to agree or object to sharing information
- Provider is not permitted to share information about patients who currently have capacity to make own health care decisions and object to sharing the information (generally or to specific persons)
- UNLESS there is a serious and imminent threat of harm to health

Opioid Laws and Physician Autonomy

- In most areas of medical practice, physicians are regulated at the state level
- Limited federal dictates
- Most medical decision- making authority between individual physicians and their patients
- Goal is to preserve physicians' needs, in accordance with professional judgement

- OPIOID CRISIS.

Opioid Regulations in context

- Role of medical profession in proliferation of opioids and consequent addictions
- Government interest in addressing opioid epidemic
- Recent state interest in regulating physician autonomy
- Patchwork of regulations that significantly limit physician autonomy
- Physician autonomy allows physician to meet fiduciary obligation, putting needs of the individual first BUT
- Regulations may harm patients in limiting access to treatment and support and
- Create an environment in which physicians are limited in their ability to meet their fiduciary duties to their patients

Opioid Crisis AND HCPs

- October, 2017
- President Trump's call to action in public health emergency
- Guidance on when and where HEALTHCARE PROVIDERS (HCPs) can share PHI
- HHS brought all resources to bear to address the crisis
- “We know that support from family members and friends is key to helping people struggling with opioid addiction, but their loved ones can't help if they aren't informed of the problem”. Acting HHS Secretary Eric D. Hargan
- “Our clarifying guidance will give medical professionals increased confidence in their ability to cooperate with friends and family members to help save lives.” HHS Press office

HIPAA and physician Response to the Opioid Crisis

- Misunderstandings
- Obstacles to family support
- Crucial to proper care and treatment
- Crisis situation
- Broad ability to share health information with patients' family members with certain crisis situations without violating HIPAA privacy regulations
- Policy considerations
- Right thing to do
- The ETHICAL thing to do

Response to Opioid Epidemic and HIPAA

- Office for Civil Rights at the U.S. Department of Health and Human Services (HHS)
- Advisory Opinion

Disclosure permitted

- May share information with patient's loved ones in certain emergency or dangerous situations.
- Informing persons in a position to prevent or lessen serious and imminent threat to a patient's health or safety
- “It is critical for HCPs to understand how they can share information without violating the HIPAA Privacy Rule”
- Caveat: “It is important to note that state or other privacy laws may also apply. HIPAA does not interfere with state laws or medical ethic rules that are more protective of patient privacy.

Disclosure when individual has decision making capacity

- May only share information WITHOUT CONSENT
- if sharing information is for purpose of avoiding or lessening an imminent threat to patient's health or safety
- good faith basis to believe person could reasonably lessen or prevent further harm from continued use or abuse after discharge.
- Goals
 - Avoid further overdose
 - Decrease ongoing dependence
 - assist in seeking treatment

May share **SOME** health information **WITHOUT** patient's permission in individual who is disoriented, unconscious or otherwise incapacitated

- Family or close friends
- Involved in care of patient
- Decision in best interest of patient
- Provider may exercise judgement to advise family or friends
- Information directly related to family or friend's involvement in care or payment of care
- About overdose, treatment and information directly related to the patient's care.
- BUT, generally could not share medical information unrelated to the overdose without permission.

HIPAA anticipates that a Patient's decision making capacity may change in course of treatment

- Decision- making capacity may be temporary and situational
- No need to rise to level of appointment by law of another decision maker
- HCPs decide if sharing information is in best interest
- How much and what type is appropriate to share
- While patient is incapacitated
- Information shared must be related to the person's involvement with patient's health care or payment for such care.

Decision making capacity changes during course of treatment

- Recovery from initial incapacitation
- Provider MAY share information with family or others without consent to prevent future overdose if:
 - In Patient's best interest
 - information shared is related to person's involvement in patient's health care

HIPAA recognizes patient's personal representatives according to state law.

- Personal representatives have right to request and obtain any information about patient that the patient could obtain.
- Health care decision making authority under state law.
- Authority through parental relationship between parent or guardian of an un-emancipated minor, or through written directive, health care power of attorney, appointment of a guardian a determination of incompetency, or other recognition consistent with state laws to act on behalf of individual making health care related decisions.

Avoid Disclosure

- Family member with no involvement in care or treatment
- Good faith effort to explore treatment or care relationship

To comply with HIPAA

- Doctor informs family, friends, or caregivers of opioid abuse after determining:
 - *Based on facts and circumstances*
 - *That patient poses a serious and imminent threat to his or her health through continued opioid abuse*
 - *Follow up to discharge*

HIPAA – “Floor” of privacy protection

- Ethical obligation of patient privacy
- Weigh Ethical concepts that include consideration of HIPAA
- HIPAA regulates
- Ethics and Professionalism
- Professional judgement (BEST INTERESTS)
- Good Faith efforts
- OCR advisory re: HIPAA

Summary

- HIPAA has created a voluminous chapter in health care organizations' compliance plans
- Recognition that PHI disclosure practices are often decentralized and more extensive than expected
- Attaining compliance has required changes in how and by whom PHI is disclosed
- Although health care providers have long had an ethical commitment to confidentiality, the specific requirements of HIPAA have required adjustments in operations
- Continued focus remains the best interest of the patient. Find solutions which are legally and ethically compliant and medically appropriate.

Many Thanks

- Julie Shephard
- Eileen Grena
- Pam Beech
- The Delaware Law School
- The Students and practitioners of Compliance and Ethics

- Kathryn Travers Farrell RN, BSN, MSN