

USING FAMILY HISTORY: LEGAL AND ETHICAL CONSIDERATIONS

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Presentation Overview

- Consensus / divergence
- Ethical implications
- Legal implications
- Consensus re-visited
- Case study

Ethical Implications Overview

- Biomedical ethical conflicts
- Patient confidentiality
- Duty to warn
- Informed consent
- Right not to know
- Genetic discrimination

Consensus

- Most relationships raise both legal and ethical questions
 - Patient's disclosure of familial risks to relatives
 - No recognized legal obligation
 - Mixed on ethical issues between patient and family
 - Clinician's disclosure of familial risks to relatives
 - Uncertain legal obligations
 - No ethical consensus

Law v. Ethics

- Considerable overlap in how issues are framed
- No congruence even where consensus reached on each
 - Issues analyzed/resolved differently under law than ethics
 - Resolved similarly between patient and physician
- Settled legal issues subject to development of new doctrine

Ethical – Biomedical Ethics

- Biomedical ethics in context of family History
 - Autonomy & Confidentiality
 - Beneficence
 - Non-Maleficence
- Reframing of the patient / provider model
 - Dual nature of genetic information
 - Medicalization of the family

Ethical – Patient Confidentiality

- Privacy v. confidentiality
- Core tenets of patient autonomy at stake:
 - Trust in providers
 - Lack of coercion in informed decision-making

Ethical – Duty to Warn

- Definition of duty to warn
- Ethical implications
 - Biomedical ethics in conflict
 - Balancing harms
- Professional position categories
 - (1) Impermissible
 - (2) Intermediary
 - (3) Ethically justified

Ethical – Duty to Warn cont...

Position 1: Disclosure Impermissible

- Confidentiality backbone of patient / provider relations;
Patient obligated to disclose familial risks
- AMA framework
 - Physicians obligated to protect patient confidentiality
 - Physicians should offer pre / post test Counseling
 - Physicians must have adequate genomics training which is reinforced throughout their professional lifetime
- ASCO in agreement but with two additional points
 - Disclosure of familial risk best fulfilled by patient
 - Physician obligated to inform patient of risk the importance of risk disclosure

Ethical – Duty to Warn cont...

Position 2: Intermediary

- Patient bears ultimate responsibility to disclose familial risks
- Circumstances for direct disclosure by physicians is heavily restricted
 - Patient consent as a universal requirement
- No firm duty to warn rule
- Genetic Miranda warning

Ethical – Duty to Warn cont...

Position 3: Ethically Justifiable

- Position gaining ground domestically and abroad
- Framework
 - All efforts to encourage patient disclosure have failed
 - Harm to the relatives from non-disclosure is imminent and serious
 - At-risk relatives are identifiable
 - Harm from failing to disclose outweighs harms from disclosing
 - Information that is disclosed is the minimum necessary to allow for appropriate protective actions by the relatives.

Ethical – Informed Consent

- Generally, providers must ensure the knowing and voluntary consent of patients.
- Conflicting patient moral duties
 - Familial risks have implications for kin
 - Patients may have obligations to these kin
 - Truly voluntary consent may be in question
- Genetics & Autonomy
 - Does dual nature of genetic information eliminate true patient autonomy?

Ethical – Right Not to Know

- Definition of right not to know
- Harms?
 - Knowledge of disease risk is harmful but...
 - Ignorance eliminates treatment options
- Autonomy?
 - Enhancement of autonomy or...
 - Contradiction of informed decision-making
- Explicit or implied consent?

Ethical – Genetic Discrimination

- History of genetic discrimination
 - Past discrimination over 20th century
 - Relatively few present-day documented cases
- Clinical implications
 - Provider's restricting services
 - Patient's fearing discriminatory actions

Legal Implications Overview

- Duty to diagnose
- Patient confidentiality
- Duty to warn
- Informed consent
- Right not to know
- Genetic discrimination

Legal – Duty to Diagnose

- Providers may face liability for failure to collect family history resulting in the failure to diagnose.
 - Failure to meet standard of care including using all diagnostic aids
 - Hernandez v. United States

Legal – Patient Confidentiality

- Disclosure without consent by providers may be considered a breach of their duty of confidentiality
- Possible claims may include:
 - breach of contract, interference with contractual relations
 - violation of privacy
 - violation of state or federal statutes
 - violation of the United States Constitution
 - negligent practice of medicine (malpractice)
 - breach of fiduciary duty
 - infliction of emotional distress

Legal – Duty to Warn

- A duty to warn relatives of genetic risks may still exist
- Requirements include:
 - A special relationship
 - Known, identifiable victim
 - Immediate, serious harm

Legal – Duty to Warn Cases

- Tarasoff v. Regents of the University of California (California 1976)
- Safer v. Pack (New Jersey 1996)
- Pate v. Threlkel (Florida 1995)
- Molloy v. Meier (Minnesota 2004)

Legal – Informed Consent

- State statutes and common law take a variety of different approaches to informed consent
 - Some limit provider liability
 - Some define affirmative obligations of providers

Legal – Right Not to Know

- No legal right not to know has been formally recognized at common law
- Courts may recognize an obligation to respect patient's desire
 - Unclear what remedies would be available

Legal – Genetic Discrimination

- Significant variation in approaches and protections across states
 - May or may not include family history as genetic information
 - ERISA preemption
- Two federal laws have limited application:
 - ADA
 - HIPAA

Legal – Genetic Discrimination cont...

- Insurance
 - Katskee v. BCBS
- Employment
 - Terri Seargent
 - Burlington and North Santa Fe Railway

Legal – State Privacy Laws

Includes FH	Excludes FH	Ambiguous relative to FH	
Arizona Louisiana Massachusetts Michigan Rhode Island South Dakota Texas Wyoming	Alaska Arkansas Florida Missouri Oklahoma Oregon Tennessee	Alabama California Colorado Connecticut Delaware Georgia Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Maine Maryland Nevada Minnesota	Missouri Montana Nebraska New Hampshire New Jersey New York New Mexico North Carolina North Dakota Ohio South Carolina Utah Vermont Virginia Washington West Virginia Wisconsin

Consensus revisited

- Consensus on the duty to warn
 - Ethical
 - Legal
- Convergence
- Divergence

Case Study

John, a 30 year old male, has two siblings, Tom (35) and Emily (25). Their father Frank, alive at 65, was diagnosed with Colorectal Cancer (CRC) at 45, and Frank's brother, Mike, was diagnosed at 60 but passed away at 63. Tom was diagnosed with CRC at 32, had his tumor successfully resected.

The family does not openly talk about health issues. Furthermore, Tom elected not to pursue early colonoscopy screening post-surgery and adamantly refuses to talk about his cancer out of an expressed fear of the disease. Emily and John have never shown signs of cancer but have also never been formally evaluated by a gastroenterologist.