# Ethical, Legal, and Social Issues in the Translation of Genomics Into Healthcare

**Laurie Badzek**, LLM, JD,MS,RN,FAAN
**Mark Henaghan**, LLB
**Martha Turner**, PhD, RN-BC
**Rita Monsen**, DSN, MPH, RN, FAAN

March 2013

# Purpose and Relevance

- Understanding is essential
  - Testing
  - Informed consent
  - Confidentiality and privacy
  - Biorepositories
- Rapid discovery
- Slower translation
- Ethical, legal, and social concerns

# Ethical Foundations

1. Professional codes of ethics, e.g., ANA Code of Ethics for Nurses; also UK, Canada
2. Ethical principles, e.g., autonomy, justice
3. Deontology
4. Feminism
5. Utilitarianism

see Beauchamp & Childress, or others

# Ethical Foundations

examples

- a single act may benefit one but harm another
- consider intended and unintended consequences
- simultaneous conversations at many levels
- disparities in access and availability; age; health; gender; $$; ethnicity; geography
- desire to be informed/uninformed

# Ethical Foundations

Ethically, the best resolution is one that infringes least on values of those involved.

# Legal Foundations

Human Genome Organization's principles:

1. Remember that not to act is to make a decision
2. Create law in context of human rights*
3. Consider those benefitted or disadvantaged by new knowledge
4. Base responses on good science, rather than ignorance, mythology, or religion.
5. Incorporate global mechanisms.

see Kirby 1997

# Legal Foundations

- Universal Declaration on Bioethics and Human Rights, UNESCO, 2005
  - Only internationally accepted source.
  - Based on Universal Declaration On The Human Genome And Human Rights, 1997 and
  - International Declaration on Human Genetic Data, 2003.
- 14 principles, 2 are key, human dignity and human rights

# Human Dignity

- Don't reduce individuals to genetic characteristics, respect uniqueness and diversity of every individual.
- Demands that every individual give an informed consent to both the taking and the ultimate use of genetic samples.

# Human Dignity

examples:

- New Zealand study, 2006
- Havasupai tribe v. Arizona Board of Regents, 2008

# Informed Consent

- A process that requires clear, specific communication
- Professionals must foster a relationship of trust and confidence
- Ensure understanding of what is at stake and what decision-making authority they have.
- Difficult when knowledge is incomplete
- Obligates professionals to be up to date

# Informed Consent

Decision-making capacity is essential to informed consent.

- Any exceptional use of genetic material without a patient's consent must be narrowly defined, and the patient must benefit from that use.
- example: children

# Duty to Inform

Healthcare professionals should talk to their patients about the importance of advising family members of any genetic information that could affect their health.

# Genetic/Genomic information

- Central to the person but extends beyond across generations and over time
- Privacy and confidentiality honored as with any other healthcare information.
- Of interest to many: employers, insurers etc
- Genetic Information Nondiscrimination Act, GINA (2008) protects but has limits

# Human Rights

- Combines human dignity with concepts of equal availability to, and benefits from….
- Potential to expand and reduce disparity
- Improved health outcomes should be available to all, e.g. Herceptin

# Future of Health Care

Direct-to-Consumer (DTC) genetic testing

- Now widely available, multiple uses
- Problems with reliability, understanding results
- Few governmental regulations guide process

- •http://www.ncbi.nlm.nih.gov/gtr/

# Future of Health Care

Incidental findings

- raise ethical and legal issues,
- e.g. non-paternity, genetic variants with health implications, knowledge development over time
- possibilities of incidental findings must be discussed before testing.

# Future of Health Care

Biorepositories

- Numbers always increasing
- Specimens shared by researchers, logistics exponentially expanding, outside scope of existing regulations
- Potential to trace specimens to donors,
- Nurses participating in research trajectory must engage in ethical discourse and policy development to establish appropriate rules and procedures.

# The Challenges

- Balancing science and discovery with societal best interests and protection of moral interests
- More questions than answers
- Continued discussion, community engagement, governmental supports are needed

# Health Professional Competency

Secretary's Advisory Council on Genetics, Health and Society, 2011:

> Recognizing the complexity of translating, interpreting and delivering genetic information has been identified as a growing need for education and training across disciplines.

# Competencies for RNs and APRNs 2009 Professional Responsibilities:

1. recognizing the impact of one's own values in providing patient care,
2. advocating for genomic access and informed consent,
3. incorporating new technology,
4. tailoring genomic information based on patients' culture and literacy, and
5. evaluating genomic knowledge and skills.

# Graduate Competencies, 2012

1. Facilitating ethical decision-making,
2. applying ethical principles,
3. implementing strategies to resolve genomic issues,
4. informing healthcare and research policy as it relates to genomics, and
5. understanding how genomics research can affect human biology and disease to improve health outcomes.

# Graduate Competencies, 2012

Additionally, for doctorally prepared nurses

- responsibility of leading genomic research
- translating its findings into nursing practice.

# Health Professional Competency

Without genomic competency:

- Less safe, less effective patient care
- The risk of negative patient outcomes
  - liability
  - moral distress

# Conclusion

- Continuous and rapid developments
- Complex ethical, legal and social issues
- Obligation for competence
- Many helpful resources available
  - Ethical, Legal and Social Issues in the Translation of Genomics Into Healthcare
  - http://onlinelibrary.wiley.com/doi/10.1111/jnu.12000/abstract

# Webinars
## http://www.genome.gov/27552312

- **Tuesday, April 2, 2013, 3:30-4:30 p.m. Eastern Presenter**: Deborah MacDonald, Erika Santos ***Integration of Genomics in Cancer Care*** **Presenter**
- ***Physical, Psychological, & Ethical Issues in Caring for Individuals with Genetic Skin Disease*** Dr. Diane Seibert
- ***Reserve your Webinar seat now at:***

**https://www1.gotomeeting.com/register/278458513**