Ethics of Precision Medicine in Low to Middle Income Countries

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Presentation Overview

• Describe context for genomics research in developing countries
• Review ethical challenges with precision medicine (Biorespositories and data banks)
• Discuss impact of actors and The courts on genomic ethics
• Suggest ethical framework and guiding principles for expansion of Precision Medicine
Today’s Challenge

POP = population; GNI = gross national income per capita (international dollars); LE = life expectancy at birth; LMIC = low- and middle-income countries
Precision Medicine

– Requires development of Biorepositories and data bank

• Prognostic biomarker anticipates the likely outcome of the illness, and may inform further therapy

• Pharmacodynamic biomarkers measure the effect of a drug on the disease.

will respond to the drug.
  – E.g. Trastuzumab and HER2, Tamoxifen and estrogen receptor

• There are many ethical challenges to consider and resolve
Havasupai Indian Tribe Case

• Tribe has high prevalence of diabetes
• Community members consented and provided blood samples for studying “medical/behavioral disorders”
• Researchers used and shared samples for many studies unrelated to diabetes (genetic basis of diabetes)
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Mello et al: NEJM 2010: 363: 204-7
My Medical Choice: Angelina Jolie

• Her Mother died at age 56 from Breast Cancer
• Tested for BRCA1 and BRCA2 mutations at cost of $3,000 to $4,000 from Myriad Genetics

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Association for Molecular Pathology
V. Myriad Genetics Inc.

- A naturally occurring DNA segment is not patent eligible
- cDNA which is not naturally occurring is patent eligible
- A naturally occurring DNA segment is not
Implications of Supreme Court Ruling

- Elimination of monopoly on Genetic testing
- Race for manipulation of DNA and boon for biotechnology companies to expand genetics research
- Potential reduction in price of genetic testing
  - Rapid expansion of genetic testing for other diseases
  - Expanded panel and discovery of more incidental mutations
- Race for manipulation of DNA and boon for biotechnology companies to expand genetics research
Ethical Issues related to Cases

- Do donors retain property interests in collected samples? and how important is donor input?
- What constitutes adequate informed consent?
- Disparities in access to quality care, genetic testing and counseling exists
- Is genetic testing for breast cancer necessary for all? and how important is donor input?
- Are there enough trained genetic counselors for the anticipated increase in number of screenings?
- What constitutes adequate informed consent?
- Disparities in access to quality care, genetic testing and counseling exists
Human Heredity and Health in Africa (H3Africa)

- Partnership with Wellcome trust/NIH/AfSHG
- Promote contemporary Genomics research by African Investigators
- Develop genomic and genetic research in Africa to address emerging prevalence of CNCD
- To develop data on Africans that will provide better ancestral representation in Genomic studies
- Create biorepositories and data banks
- Improve health of Africans
Ethical Challenges on Evolving Trend for Genomics and Precision Medicine

• Will testing information be coded for anonymity in a way that permits linkage to identity of those tested?
• How will incidental findings that may involve deletions of unknown significance, paternity issues be handled?
• Who will have control to use samples for additional
  • Will testing information be coded for anonymity in a way that permits linkage to identity of those tested?
  • How will incidental findings that may involve deletions
Preparing for Precision Medicine

- Improved patient informed consent process
- Sensitivity to privacy issues, stigma, discrimination and community needs
- Developing policy that requires clinical genetic testing to be followed by competent counseling
- Train and sensitize providers to need for counseling
  - Improved patient informed consent process
  - Sensitivity to privacy issues, stigma, discrimination and community needs
- Better data security and stewardship in bio-repositories
- Developing policy that requires clinical genetic testing
Informed Consent for Biorepositories and Data Banks

- Specific consent
  - Participants are recontacted for consent for each new use of samples

- Tiered consent
  - Menu of options presented at enrollment; general permission, consent for future use

- General permission
  - Permission for all future uses that are IRB approved

- Presumed consent
  - Samples will be used for future research unless they object
Preparing for Precision Medicine

• Public discussion and community engagement
• Setting a standard for precision of informed consent
  – Specific, tiered, general provision and presumed consent
  – Reliability of anonymity protections
  – Recontacting policy
  – Handling incidental discoveries
  – Contacting biologic relatives with results
  – Use of information for research and diagnostic purposes
• Maintaining and securing data in bio-repositories

Adapted from Kaplan: Plos Medicine, Sept 2013
Precision Medicine and Justice

• Greater genetic variability within a racial/ethnic group than between racial/ethnic groups.
• Nevertheless, some genotypes are more common in particular ethnic/racial groups.
• Genotypes more common in minority ethnic groups should NOT be ignored.
  – This will require that minorities participate in genetic research.
• We need to make sure that individuals (of any and all racial and ethnic groups) with rare genotypes do not become therapeutic orphans.
• We need to use our genetic knowledge to reduce and not to exacerbate health care disparities.