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This lecture is part of Spring 2020 – Covid-19 Pandemic – Online Education

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CANCER RISK ASSESMENT – BIOETHICS

Cancer Genetics Risk Assessment and Counseling
Ethical, Legal and Social Implementations

Bioethical Issues in Cancer Genetic Testing

- Bioethical tenets can guide health care providers in dealing with the complex issues surrounding predictive testing for hereditary cancer.
- The tenets of
  - beneficence,
  - nonmaleficence,
  - autonomy, and
  - justice

are part of a framework needed to balance the complex and potentially conflicting factors surrounding a clinician's role in respecting privacy, confidentiality and fair use of genetic information obtained from cancer genetic testing.

Beneficence

- Medical care is to provide benefit through appropriate health care
- Using early detection and effective treatment protocols to improve outcomes
- Providing beneficent care may go beyond medical outcomes of treatment to encompass the patient's life circumstances, expectations, and values
- Consideration of the patient's psychological and emotional ability to handle the testing and results disclosure process can help avoid doing harm

Nonmaleficence

- Bioethical code that directs health care providers to do no harm, inclusive of physical and emotional harm, and acknowledges that medical care involves risks and benefits
- Taking measures to minimize the adverse effects of cancer prevention, treatment, and control
- Taking precautionary measures to prevent inadvertent disclosure of sensitive information.

Autonomy

- Autonomous decision making respects individual preferences by incorporating informed consent and education
- Individuals have the right to be informed about the risks and benefits of genetic testing
- Have right to freely choose or decline testing for themselves.
- Important to consider the sociocultural context and family dynamics

Justice

- Refers to the equitable distribution of the benefits and risks of health care.
- Ensuring access to cancer genetic services
- The availability of predictive genetic testing should not be dependent on ethnic background, geographical location, or ability to pay.
- Genetic discrimination should not be a result of predictive testing
- Equitable distribution balances individual rights with responsibilities of community membership

- **Privacy and Confidentiality: Disclosure of Patient's Genetic Information**

One practical suggestion for facilitating family-based communication is providing patients with education and information materials to facilitate disease susceptibility discussions with family members. The next section discusses the legal, legislative, and ethical basis for balancing patient confidentiality with duty to warn.

- **Disclosure in research**

Privacy and confidentiality also applies to research, such as population secreening for genetic diseases. Essential to family-based recruitment strategies is informing potential research participants how their personal information was obtained by the researcher, why the researcher is approaching them, what the researcher knows about them, and for what purpose the information will be used, whether or not they decide to participate.

- **“Duty to warn”**

“Duty to warn” requires balancing the bioethical constructs of beneficence and autonomy with other factors such as case proceedings, legislation, and professional societies’ recommendations.

- **Employment and Insurance Discrimination**

Genetic information obtained from genetic susceptibility tests may have medical, economic, and psychosocial implications for the individual tested and his or her family members. The potential for employment and insurance discrimination is a common concern for individuals considering genetic testing.

Case scenarios involving ELSI issues in cancer genetic testing

- Duty to warn versus privacy
- Patient’s right to know versus family member’s autonomy
- Right to know versus right not to know
- Beneficence versus paternalism

- Advances in omics (e.g., genomics, epigenetics, metagenomics) open new opportunities for risk prediction and risk-based screening interventions.
- Omics-based risk factors (e.g., genetic mutation, genetic and epigenetic variations) could be combined with personal and environmental risk factors (e.g., body mass index, age, lifestyle) to predict the risk of developing certain cancers.
- Such individualized prediction of the risk of cancer would then support risk-adapted screening and prevention strategies.
- For instance, a woman identified at higher risk of breast cancer could be advised to start mammography screening earlier or more frequently than the general population and consider taking medication for preventive purposes.
- Targeting those most likely to benefit from screening would increase the benefits of screening (e.g., earlier diagnosis) and decrease potential harms (e.g., overdiagnosis).

- Implementation of a risk prediction approach in clinical practice impacts the ethical, legal, and regulatory aspects of current tests, strategies and programs related to cancer screening.
- For instance, proposing a reduction in the screening frequency for women at lower risk or addressing the particular nature of results derived from epigenetic factors may raise new ethical, legal, and regulatory considerations.
- Adequate management of the ethical, legal, and regulatory issues related to the implementation of a risk prediction approach is essential to ensure optimal translation of science into clinical practice.

Steps for implementing risk prediction for women’s cancers.

For each implementation step:

- their recurrence in the documents consulted (laws, policies, and literature),
- the importance of their impact on end-users (women, health-professionals, and health authorities),
- their likelihood of arising under the risk prediction approach, and
- the complexity required to appropriately address

Points to Consider for Future Implementation of Omics-Based Risk Prediction

- Health services planning
- Legal, regulatory and policy frameworks should adequately support implementation and be adapted if necessary
- Measures to mitigate the potential creation or reinforcement of social inequities should be anticipated
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- The risk assessment process and the omics test should be clearly explained
- Consent and data/sample collection
- Information provided should be adapted to the specificities of omics-based risk prediction

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- Risk calculation and communication of results
- Consideration should be given as to whether the omics test will reveal any unsolicited findings
- Potential impacts of the results on family members should be assessed and managed
- Clear information on appropriate follow-up measures and available health services should be provided
- Specificities of epigenetic results (where applicable) should be taken into account
- Storage of data and residual samples
- Storage of data and residual samples for research purposes should be under a clear and ethically acceptable framework

References

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- Anderson EE, Hoskins K. Journal of Health Care for the Poor and Underserved. 2012 Nov;23(4 Suppl):34-46