Cancer Research and the Demand for Precision Medicine: What Would It Take To Get From Here To There? What Should We Do?

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Helpful References (1 of 3)

- From a healthy Cell to a cancer cell. Accessed 3/9/2015. Available at: https://www.youtube.com/watch?v=8LhQllh46yI
- Precision Medicine Near-term Goals“.nih.gov
- Precision Medicine “Long-term Goals“.nih.gov
- Rogers, W., Mackenzie, C., and Susan Dodds. Why bioethics needs a concept of vulnerability. International Journal of Feminist Approaches to Bioethics, Vol. 5, No. 2, Special Issue on Vulnerability (Fall 2012), pp. 11-38
Helpful References (2 of 3)

- Why Don’t We All Have Cancer? Accessed 3/9/2015. Available at: https://www.youtube.com/watch?v=Qja4z1HGDQo
Helpful References (3 of 3)


Objectives of the Dialogue

- **Illustrate** the current state of affairs with an article-”Cancer Research In Crisis”- highlighting the cancer revolution and the care challenges it poses for all concerned.
- **Engage** attendees in a discussion of the point of the idea of bioethics in problematizing the revolution.
- **Stimulate** a reflection on the CONCERNS OF BIOETHICS.
- **Illustrate** with a video-clip the MORAL/ETHICAL DILEMMAS with some new and promising approaches to cancer precision medicine and how to resolve them.
- **Facilitate** a discussion on the ethical challenges to consider as cancer researchers and research move forward.
Objective 1

- Current state of affairs and the cancer research revolution
“Cancer Research In Crisis Article”
Central Issues and Concerns

- Reproducibility of research findings in pre-clinical research is a major problem, making eventual cancer therapeutics still trial-and-error unabated
- Funding innovative work is important but attempts to replicate published works should also be funded
- “Impact factor” and “Reproducibility factor”
- Should we embark on a “soul-searching” mission?
Precision Medicine Initiative: The Clarion Call from President Obama. January 30, 2015

- No more one-size-fits-all treatment approach
- Individual differences in genes, environments, and life-styles will be taken into account
- Better prediction of which treatment is most efficacious for a patient through clinical trials
- Individuals and families can invest in and manage their own health
- Collaborative public and private efforts will be needed
PMI Objectives

1. More and better treatments for cancer (NCI)
2. Creation of a national research cohort (NIH)
3. Commitment to protecting privacy and security of data
4. Regulatory modernization (HHS)
5. Public-private partnerships

- Precision Medicine Initiative (PMI): The Clarion Call from President Obama; January 30, 2015
# Precision Medicine Goals

<table>
<thead>
<tr>
<th>NIH’s Near-Term Goals</th>
<th>NIH’s Longer -Term Goals</th>
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<td>- Innovative clinical trials of targeted drugs for adult and pediatric cancers</td>
<td>- Create a research cohort of &gt;1 million American volunteers who will share genetic data, biological samples, and diet/lifestyle information, all linked to their electronic health records if they choose.</td>
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<td>- Use of combination therapies</td>
<td>- Pioneer a new model for doing science that emphasizes engaged participants, responsible data sharing, and privacy protection.</td>
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<td>- Knowledge to overcome drug resistance</td>
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<td>- <a href="http://www.nih.gov/precisionmedicine">www.nih.gov/precisionmedicine</a></td>
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What Is Precision Medicine?

- Precision medicine is an emerging approach for disease prevention and treatment that takes into account people’s individual variations in genes, environment, and lifestyle.

What Is the Precision Medicine Initiative?

- The Precision Medicine Initiative is the plan that will generate the scientific evidence needed to move the concept of precision medicine into clinical practice.
Why Is Precision Medicine Possible Now?

- Advances in the sequencing of the human genome
- Improved technologies for biomedical analysis
- New tools for using large datasets
Objective 2

- The point of the idea of bioethics in problematizing the revolution
The Point of the Idea of Bioethics

- Bioethics = Human endeavor or activity
- Research = Human endeavor or activity
- In all human endeavor, there is potential to:
  -- Benefit or harm
  -- Respect or disrespect people’s dignity
  -- Be Just (fair) or unjust
  -- Treat people with care and empathy or be insensitive
  -- Include or exclude people from matters pertaining to their well-being
  -- Be Racist or antiracist
The Point of the Idea of Bioethics

Using Bioethics Lens enables us to:

- Query actions
- Encourage scrutiny
- Alert us about moral sensibilities and chasms
- Proactively inculcate in all of us the "bioethical maturity"
- Inform appropriate policy and law
Tuskegee Bioethics Center Ethical Framework

In our practice of bioethics, we appeal to three ethical perspectives:

- Mainstream bioethics
- Integrative bioethics
- Public Health Ethics

Objective 3

- Reflection on some concerns of bioethics
SOME CONCERNS OF BIOETHICS (1 of 2)

- The health and well-being of all persons
- Differential access to goods, services and opportunities for better life by race.
- The impact of “bad science” on our health and well-being
- Privacy protection and safety issues
- Enrollment in research without being properly informed
- Inappropriate use of research study design and data
SOME CONCERNS OF BIOETHICS (2 of 2)

- Appropriate engagement of research participants
- Coercion of research participants
- Disproportionate representation in research
- Exploitation of research participants
- Manipulation of research participants
- Misuse of power where power differential exists
- Empowerment of research participants in the use of their own data
Objective 4

- Identifying and resolving moral/ethical dilemmas in promising approaches for cancer precision medicine
Group Activity: Bioethical Analysis of “Disrupting Cancer” Project

- Watch the documentary “Disrupting Cancer”
- Review Analytical Framework
- Discuss questions from the standpoint of stakeholders
- Decide if anything should be done
- Examine options
- Choose the best option(s)
- Justify the best option(s)
Framework for Bioethical Decision Making: One Approach

- FOTC  POSH  WBTD  WHDN
- FOTC  =  Facts Of The Case
- POSH  =  Preferences Of Stake Holders
- WHDN  =  What Happens if we Do Nothing?
- WBTD  =  What would be Best To Do?
Disrupting The Conventional Way To Think About Cancer?

Dr. Soon-Shiong
Group Activity: Bioethical Analysis of “Disrupting Cancer” Project

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“Disrupting Cancer” (1 of 2)

- FACTS OF THE CASE
  - Summarize the case
  - What ethical issues loom large?
  - Who are the stakeholders?
  - What are the interest of the stakeholders?
  - Who will benefit? Who can be harmed?
“Disrupting Cancer” Project (2 of 2)

- STAKEHOLDERS AND INTERESTS
  - Cancer patients
  - Parents or Families
  - Attending Physicians/Research Investigators
  - Clinical Research Community
  - Nurses
  - Office of Human Research Protections; IRB
  - Sponsoring Institutions: NIH, NCI, FDA, ONC
  - Private Pharmaceutical Companies
  - Society at Large
DISCUSSION QUESTIONS

- What is particularly troubling or exciting to you about this documentary and what you know about cancer? Genetically-based clinical trials?
- What bioethical issues loom large in the project?
- Who are the “persons of interest” featured in this project?
- Can any harm be done? To whom?
- Are claims made ethically problematic? Why? Why not?
DISCUSSION QUESTIONS

- Do you have any sympathy or admiration for any person or group featured in the Documentary? Why? Why not?
- What lessons can we learn from this project at an individual level, institutional level, societal level?
- Should the work be permitted to proceed? Why? Why not?
Examining Options or Actions and Consequences

DISCUSSION QUESTIONS

- What, if anything, would you like to be different if we are to prevent unethical acts from happening?
- What options do we have?
- What are the consequences of the options?
- What is/are the best option(s)?
- How shall we justify this option(s)?
Justifying Actions or Options (1 of 3)

Key Bioethical Questions

- Does this action respect the sanctity of life?
- Is this action edifying or uplifting for the target of the action?
- Would the most ethical person I know take this action?
Key Bioethical Questions

- How would I feel if this action were done to me?
- Would I do the action to those closest to me (brother, sister, mother, father, uncle, aunt)?
- Does this action match my words to those who know me well?
Justifying Actions or Options (3 of 3)

Key Bioethical Questions

- Is this action consistent with what I believe to be good?
- Will I feel guilty as a result of taking this action?
- Is this action at odds with or in compliance with rules and regulations?
- Is the action legal?
Objective 5

- Ethical Challenges to consider as we move forward with cancer research and precision medicine
What Should We do?: Anticipate and Communicate

- **Soul-searching** is most appropriate.
- Be informed and vigilant. Be a **change-agent**.
- **Humility** is essential. Vulnerable people, whether sick or healthy, need to be given substantial respect out of integrity and human dignity.
- **Informed consent** is a process that must be conducted for all medical care and clinical research. **Informed decision** is critical.
- Never feel pressured to consent to any study or project until you have fully understood what it is all about.
Remember!

- Each one of us is a “piece” of the Jigsaw Puzzle in our efforts to confront and resolve the bioethical issues embedded in pre-clinical research, cancer health disparities, clinical care, and clinical research; and in fighting cancer in new ways.

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“All that is necessary for evil to triumph is for good people to do nothing".

-- Edmund Burke

Can you hear me now? THANKS for playing along!