

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

Stephen Olufemi Sodeke, PhD, MA
Bioethicist & Professor of Allied Health Sciences
MSM/TU/UAB CCC Partnership Summer Institute
Tuskegee University Kellogg Conference Center
Wednesday, July 22, 2015

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>
- Animated Introduction to Cancer Biology. Accessed 3/9/2015 <https://www.youtube.com/watch?v=46Xh7OFkkCE>
- Benitez-Bribiesca, L. *Assessment of Apoptosis In Tumor Growth: Importance In Clinical Oncology and Cancer Therapy* In When Cells Die: A Comprehensive Evaluation of Apoptosis and Programmed Cell Death. Richard A. Lockshin, Zahra Zakeri, and Jonathan L. Tilly (Editors). Wiley-Liss Publication, Inc. 1998. pp. 453 – 482.
- 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)

- Cancer Research In Crisis. Accessed 3/9/2015. Available at http://www.salon.com/2013/09/01/is_cancer_research_facing_a_crisis/
- Why Don't We All Have Cancer? Accessed 3/9/2015. Available at: <https://www.youtube.com/watch?v=Qja4z1HGDQo>
- Cancer: The Forbidden Cures and the Business of Cancer. Accessed 3/9/2015. Available at: <https://www.youtube.com/watch?v=NAMYAoiCSsI>
- "Disrupting Cancer" Accessed 3/9/2015.
<http://www.cbsnews.com/videos/disrupting-cancer/>
- Blau, CA, Liakopoulou, E (2013). "Can we deconstruct cancer, one patient at a time?". *Trends in Genetics* **29** (1): 6–10. doi:10.1016/j.tig.2012.09.004
- R. Chen, *et al.* **Personal omics profiling reveals dynamic molecular and medical phenotypes.** *Cell*, 148 (2012), pp. 1293–1307
- J.S. Welch, *et al.* **The origin and evolution of mutations in acute myeloid leukemia.** *Cell*, 150 (2012), pp. 264–278.
- Ashley, E. A. (2015). "The precision medicine initiative: A new national effort". *JAMA* **313** (21): 2119–20.

Helpful References (3 of 3)

- Press Release. FACT SHEET, President Obama's Precision Medicine Initiative, January 30, 2015. Accessed 7.14.2015 from <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>
- NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy website under the "Researchers" tab (<http://gds.nih.gov/06researchers1.html>) at: http://gds.nih.gov/pdf/NIH_guidance_elements_consent_under_gds_policy.pdf.
- Levi A. Garraway, Jaap Verweij and Karla V. Ballman (2013). "Precision Oncology: An Overview". *J. Clinical Oncology* **31** (15): 1803–1805. [doi:10.1200/jco.2013.49.4799](https://doi.org/10.1200/jco.2013.49.4799)
- Jeff Shrager, Marty Tenenbaum (2014). "Rapid learning for precision oncology". *Nat Rev Clin Oncol* **11** (2): 109–118. [doi:10.1038/nrclinonc.2013.244](https://doi.org/10.1038/nrclinonc.2013.244)

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
- High-Profile Scientific Journals involved—(Nature, Cancer Research, Science, PNAS)
- “Impact factor” and “Reproducibility factor”
- Should we embark on a “soul-searching” mission?

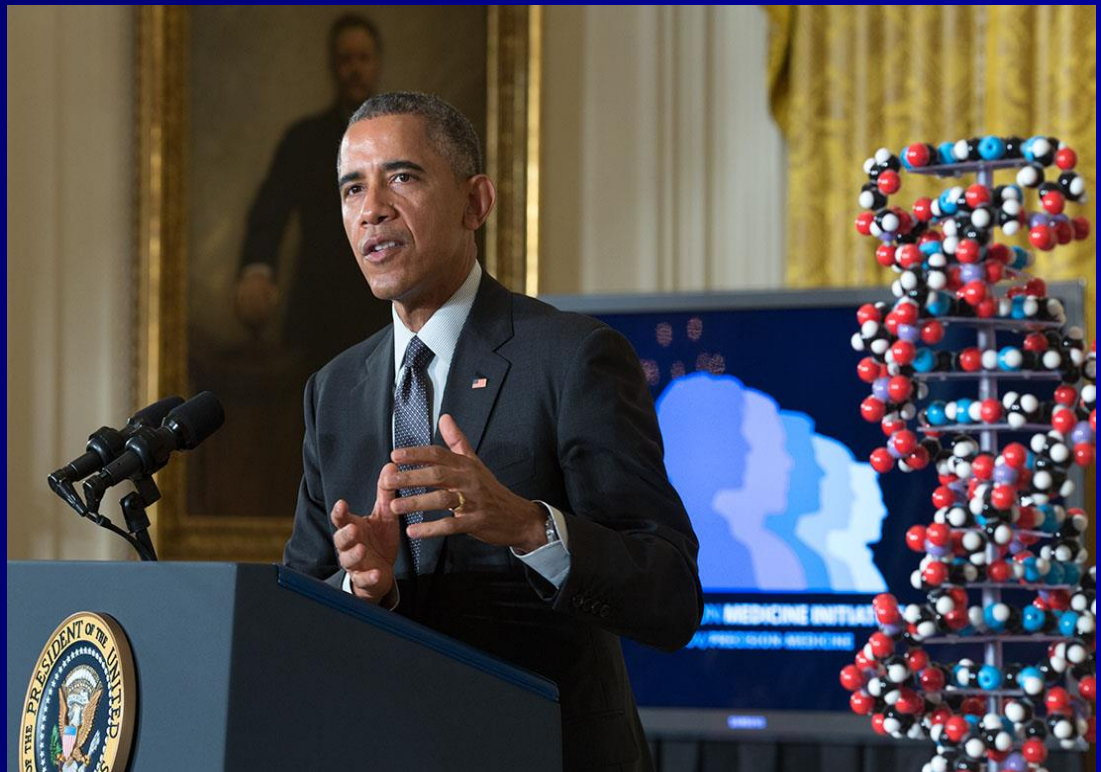
Precision Medicine Initiative: The Clarion Call from President Obama. January 30, 2015

- 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

NIH's Near-Term Goals

- Innovative clinical trials of targeted drugs for adult and pediatric cancers
- Use of combination therapies
- Knowledge to overcome drug resistance
- www.nih.gov/precisionmedicine

7/27/2015

NIH's Longer -Term Goals

- Create a research cohort of >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.
- Pioneer a new model for doing science that emphasizes engaged participants, responsible data sharing, and privacy protection.

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

* Wilson W, Warren R, Sodeke S, and Wilson N. PAWJ, 2013

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

<http://www.cbsnews.com/news/billionaire-doctor-fights-cancer-in-unconventional-way/>

Group Activity: Bioethical Analysis of “Disrupting Cancer” Project

- Recall 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)

“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

Exploring Moral/Ethical Dilemmas or Issues (1 of 2)

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?

Exploring Moral/Ethical Dilemmas or Issues (2 of 2)

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?

Justifying Actions or Options (2 of 3)

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?

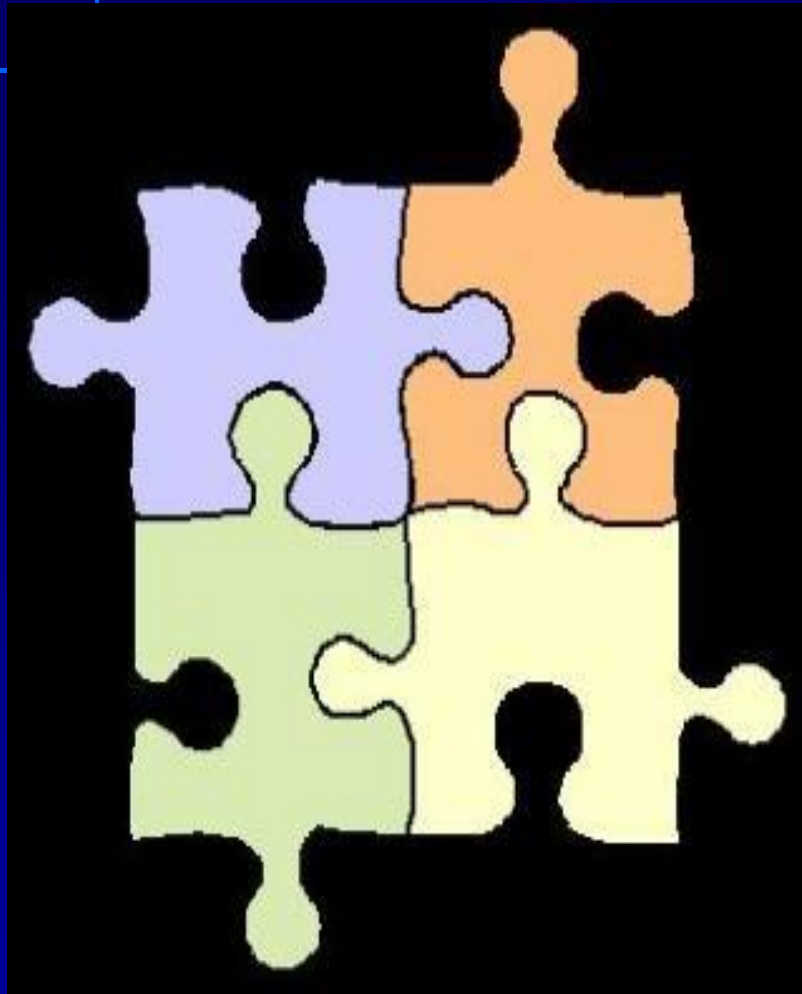
Objective 5

- 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!



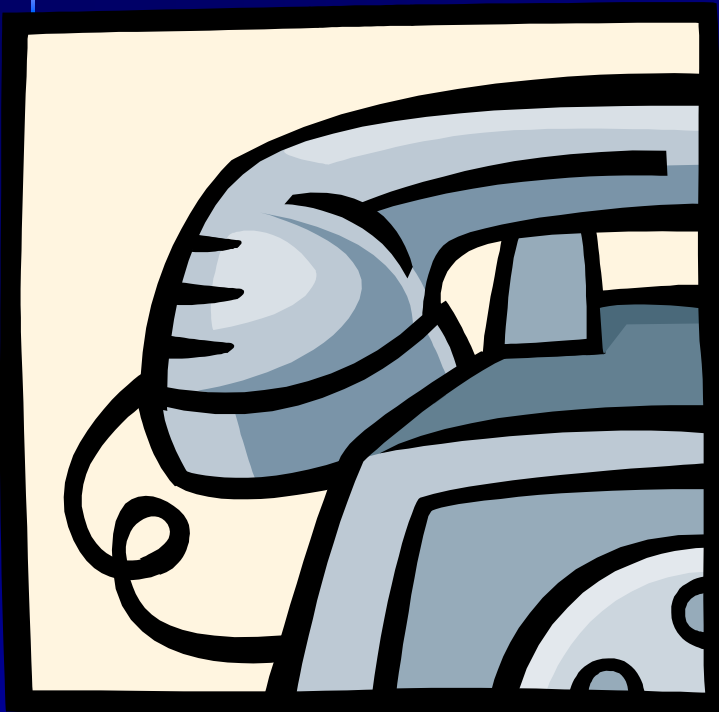
7/27/2015

- 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.

sodeke@mytu.tuskegee.edu



Tuskegee University National Center for Bioethics



■ **“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!