WHAT WE CAN LEARN ABOUT RESEARCH ETHICS FROM EXPERIENCED SUBJECTS

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Dealing with a potentially fatal cancer is difficult for anyone, but doctors with cancer face a special challenge. They're accustomed to giving medical care, not receiving it. And they know better than most what their future might look like.

Dr. William Tierney, an internist with Indiana University School of Medicine, wasn't happy being known all of a sudden as "the guy with cancer."

"You want to be normal, not self-pitying or any more dependent than you have to be," says Tierney.

For Dr. Elizabeth McKinley, an internist with Case Western Reserve University School of Medicine, knowledge that she had cancer hit her at odd times, sapping her hope.

"I'd find myself just weeping," she recalls, asking herself, "Will I see my kids get older? Am I going to die? Will I be in pain? Will my husband be all right?"

Tierney learned he had lymphoma at the age of 48.
Malignant: Medical Ethicists Confront Cancer
Silent Partner Chapters

• 1 Subject Perspectives: The Missing Element in Research Ethics
• 2 Personal Knowledge and Study Participation
• 3 The Everyday Ethics of Human Research
• 4 The Hidden World of Subjects: Rule-Breaking in Clinical Trials
Silent Partner Chapters

- 5 Participants as Partners in Genetic Research
- 6 Terminally Ill Patients and the “Right to Try” Experimental Drugs
- 7 Embedded Ethics in Developing-Country Research
- 8 Research Subjects as Literary Subjects
- 9 How to Hear Subjects
Combination Chemotherapy and Radiation in Treating Patients With Stage III or IV Head and Neck Cancer (Paradigm Trial)

Purpose

RATIONALE: Drugs used in chemotherapy, such as docetaxel, cisplatin, fluorouracil, and carboplatin, work in different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Combining chemotherapy with radiation therapy may kill more tumor cells. It is not yet known which regimen of chemotherapy and radiation therapy is most effective in treating head and neck cancer.

PURPOSE: Randomized phase III trial to compare the effectiveness of two different regimens of chemotherapy and radiation therapy in treating patients who have stage III or stage IV head and neck cancer.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Head and Neck Cancer</td>
<td>Drug: carboplatin</td>
<td>Phase 3</td>
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<tr>
<td></td>
<td>Drug: cisplatin</td>
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<td>Drug: docetaxel</td>
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<td></td>
<td>Drug: fluorouracil</td>
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Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment
My Options

• Tumor Board Recommendation: 4 Chemotherapy drugs + radiation

• Trial: Random assignment to receive 3 chemotherapy drugs + radiation OR 1 chemotherapy drug + radiation OR a different chemotherapy drug + radiation
What I Learned (1)

• Clinical Equipoise = Experts Uncertain about Which Treatment is Best

• In Equipoise, Patient-Subject has Reasonable Chance of Receiving the Best Treatment

• But Equipoise is Fuzzy in Cancer Trials
What I Learned (2)

• Time-Consuming Parts of Study Enrollment = Treatment Delay

• Treatment Delay Is Unrecognized Research Burden for Seriously Ill Prospective Subjects
What I Learned (3)

- Diagnosis of Serious Illness Increases Dependency on Doctors

- Doctors Describing Trials Can Easily Influence Patients on Enrollment Decisions

- I was Lucky to Have a Doctor Who Supported My Freedom to Say No to Trial
What I Learned (4)

• Some Ethicists and Others Argue that Everyone Has a Duty to Participate in Research

• Advocates of Duty Haven’t Acknowledged the Burden This Would Impose on Seriously Ill Patients
Learning from Other Subjects

• Personal stories of research participation

• Empirical Studies of Subjects’ Perceptions and Views

• Research Subjects in Fiction
The Subjectivity of Subjects

• Subjects Are People, Too!

• Subjects Are Moral Agents Who Don’t Necessarily See Research the Way That Experts Do

• Researchers Watch Subjects, but “The Watched Can Watch As Well”
Deception in Research

• Deception Goes Two Ways -- Subjects Don’t Always Do What Researchers Tell Them To

• Some Subjects Successfully Conceal This from Researchers, Reducing the Value of Study Findings

• Subject Deception Is a Neglected Ethical Problem
Everyday Research Ethics

• Subjects Want Courtesy and Professional Behavior From Researchers

• Rudeness, Arrogance, and Disorganization Lead to Resentment and Study Drop Outs

• Ethical Principle of Respect for Persons as Subjects See It
Choosing for Dementia Patients

- Ethical Guidelines Tell Surrogate Decision Makers To Choose What Patient Would Want If Competent
- But Empirical Studies Show Surrogates Focus As Much or More on Patients’ Current Best Interests
- Surrogates Take Patients’ Own Views into Account, Too
- Reality Doesn’t Match Ethical Guidelines
A Famous Research Subject

FRANKENSTEIN
MARY SHELLEY

WITH A NEW FOREWORD BY WALTER JAMES MILLER
AND AN AFTERWORD BY HAROLD BLOOM
“An original and urgent work of art . . .
Among the finest plays of the decade.”
—DONALD LYONS,
THE WALL STREET JOURNAL

WINNER
of the
PULITZER
PRIZE

Wit

A Play by
Margaret Edson
the normals

a novel

David Gilbert

INSPIRED SLEEP

A Novel

Robert Cohen

author of The Here and Now
Subjects As Real Research Partners

• Experienced Subjects Belong in IRBs, Research Ethics and Policy Advisory Groups

• Experienced Subjects Belong in Patient-Centered Research Activities

• Challenges Exist But Are Manageable

• For More Egalitarian Model, Consult People Who Know What It’s Like to Be Subjects