JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Section C

Case, Application of Framework Part 1

Overview

- Review case
- Apply framework to the case

Case

- Dr. Patel is a medical oncologist in private practice. She is collaborating with other colleagues on a clinical trial of a novel breast cancer regimen. Dr. Patel explains the availability of the trial to a long-time patient and prospective subject, Mrs. Singh. Dr. Patel explains how in this trial Mrs. Singh will be randomized to receive standard treatment for her breast cancer or a novel breast cancer regimen. The novel regimen has been shown to be effective in the U.S. but has not yet been tested in India.

Note: Based on case 4.3 in Murphy, Timothy. (2004). *Case studies in biomedical research ethics*. Boston: MIT Press.

Case

- Dr. Patel describes the study procedures to Mrs. Singh. She reviews with Mrs. Singh the procedures that she will undergo that are the same as those she would undergo if she was not enrolled in the trial and the extra procedures she will undergo if she joins the trial (e.g., extra blood draws, scans). Dr. Patel adds that during the length of the trial, study-related costs (i.e., procedures and medications) will be covered by the trial sponsor. The sponsor will also reimburse Mrs. Singh for the incidental expenses related to her participation (e.g., local transport by taxi, lunch).

Note: Based on case 4.3 in Murphy, Timothy. (2004). *Case studies in biomedical research ethics*. Boston: MIT Press.

Case

- Dr. Patel will receive Rs 100,000 for each patient she enrolls. These funds will pay additional staff hired to coordinate the identification and enrollment of eligible patients, will cover follow-up, and will provide Dr. Patel with an incentive to enroll patients in the study. Mrs. Singh provides her informed consent to enroll in the study.

Note: Based on case 4.3 in Murphy, Timothy. (2004). *Case studies in biomedical research ethics*. Boston: MIT Press.

Application of the Framework

- Review the facts of the case
  - Dr. Patel participating in trial
  - Mrs. Singh is a patient of Dr. Patel
  - Dr. Patel approaches Mrs. Singh about enrollment in an RCT
  - Novel treatment under study has been found effective in U.S. trials
  - Sponsor covering patient and physician study-related costs
  - Mrs. Singh provides her consent to enroll

Framework: Concerns/Challenges

- Identify the potential moral concerns, or challenges raised by the case
  - Physician-investigator
  - Patient
  - Study design

Concerns/Challenges Regarding the Physician-Investigator

- Identify the potential moral concerns or challenges raised by the case
  - Physician-investigator
    - Role, responsibility
      - Physician/investigator-patient relationship
      - Respect for persons
    - Conflict of interest?
      - Financial gain?
      - Incentive to enroll patients?

Concerns/Challenges Regarding the Patient

- Identify the potential moral concerns or challenges raised by the case
  - Patient
    - Enrollment in hope of medical benefit?
      - Offer enrollment affirmation by physician
    - Enrollment to defer costs of care?
    - Pressure to enroll given relationship with physician?
      - Enrolls with idea to please physician
      - Enrolls to avoid negative effect on care
    - Availability of treatment after trial is completed

Concerns/Challenges Regarding the Study Design

- Identify the potential moral concerns, or challenges raised by the case
  - Study design
    - Conflict of interest
      - Best interest of patient vs. best interest of future patients
    - Permissible to conduct an RCT when treatment found to be effective in U.S.

Framework: Principles/Requirements

- Which ethical principles/requirements are associated with each moral concern, challenge raised?
  - Principles/requirements meant to remind user of range of issues that might be relevant

Principles/Requirements for the Physician-Investigator

Physician-investigator	Principle/requirement
Role responsibility	Integrity/responsibility ▪Professional competence ▪ Regulatory compliance Beneficence ▪Precaution and risk minimization ▪Scientific validity Justice ▪Fair selection of study population • Protection of vulnerable populations Respect for persons ▪ Voluntariness

Principles/Requirements for the Physician-Investigator

Physician-investigator	Principle/requirement
Conflict of interest	Integrity/responsibility ▪Accountability and transparency

Principles/Requirements for the Patient

Patient	Principle/requirement
Enrollment in hope of benefit	Beneficence ▪Precaution and risk minimization Respect for persons ▪Voluntariness Integrity/responsibility ▪Accountability and transparency •Independent ethics review
Enrollment to defer costs	Respect for persons ▪ Voluntariness

Principles/Requirements for the Patient

Patient	Principle/requirement
Pressure to enroll	Respect for persons ▪Voluntariness
Availability of treatment after trial	Respect for persons ▪ Post-trial access to beneficial interventions

Principles/Requirements for the Study Design

Study design	Principle/requirement
Conflict of interest	Beneficence ▪Precaution and risk minimization
OK to conduct RCT?	Beneficence ▪ Scientific validity ▪ Favorable risk-benefit ratio Integrity/responsibility ▪ Accountability and transparency • Independent ethics review