Opportunities and Challenges for Reporting Findings from Clinical Cancer Research Back to Participants: Clinical Bioethics Perspective

Gregory A. Abel, MD, MPH
Professor of Medicine
Harvard Medical School

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Dana-Farber Cancer Institute

Outline (10 minutes!)

- Introduction to biomedical ethics frameworks
- Practical applications for today
  - *Collecting and reporting PROs in RCTs*
  - *Reporting research results to participants*

A Sample of Bioethical Frameworks

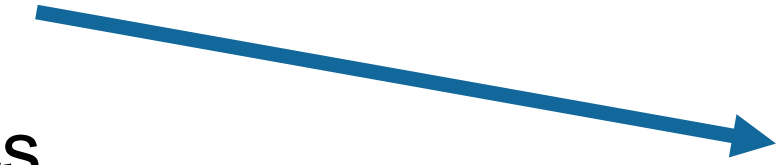
Medical ethics…

"the analytical activity in which the concepts, assumptions, beliefs, attitudes, emotions, reasons and arguments underlying medico-moral decision making are examined critically."

Siegler, *Clinical Medical Ethics,* 2013

Bioethical Frameworks

- Principlism
- Virtue Ethics
- Utilitarianism
- Deontology
- Feminist Ethics (ethics of care)
- Narrative Ethics



- **Autonomy** – Respecting patients' right to make informed decisions
- **Beneficence** – Acting in the patient's best interest
- **Non-Maleficence** – Avoiding harm
- **Justice** – Ensuring fair distribution of healthcare resources

Childress and Beauchamp, *Camb Q H Ethics*, 2022;
Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

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• Ethical behavior is driven by **moral character and virtues** (e.g., honesty, compassion, integrity)

• Instead of strict rules, asks **"What would a good doctor/researcher/patient do?"**

Childress and Beauchamp, *Camb Q H Ethics*, 2022;
Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

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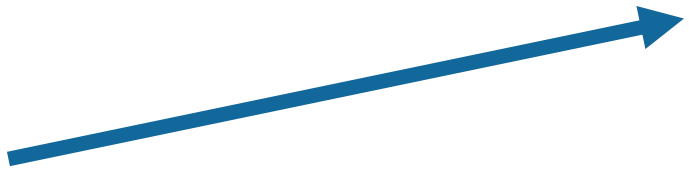

• Ethical decisions should **maximize overall benefit and minimize harm**

• **Greatest good for the greatest number** – but may sacrifice individual rights for broader benefit

Childress and Beauchamp, *Camb Q H Ethics*, 2022;
Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

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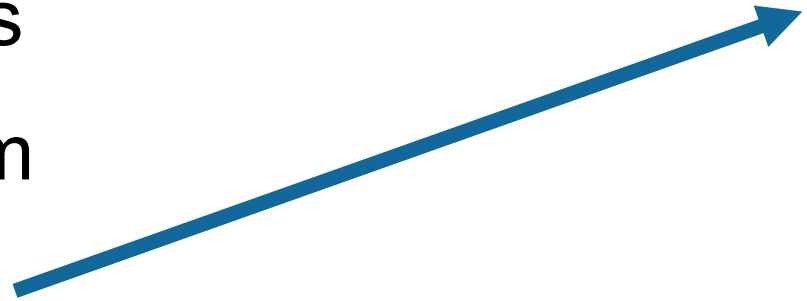

- Ethics is based on **moral duties and obligations**, not just outcomes
- Some actions are **inherently right or wrong**, regardless of their consequences

Childress and Beauchamp, *Camb Q H Ethics*, 2022;
Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

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• Ethics should focus on **relationships, context, and care** rather than abstract principles or rigid rules.

• Prioritizes **empathy, compassion, and power dynamics**, especially regarding **vulnerable populations**.

Childress and Beauchamp, *Camb Q H Ethics*, 2022;
Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

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• Ethics should be rooted in **individual stories and lived experiences** rather than universal rules

• Highlights the importance of **listening to patient narratives** to understand how illness shapes identity, autonomy, and decision-making

• Recognizes that **illness not just a biological condition but a deeply personal and social experience**

Childress and Beauchamp, *Camb Q H Ethics*, 2022; Bioethics' Conceptual Tool Kit. *Hastings Cent Rep*, 2023

Application: Collecting and Reporting PROs in Clinical Trials

PROs and Oncology Trials

- Surrogate end points increasingly used to show efficacy
- **Collection** of PROs in inconsistent but increasing
- **Reporting** of PROs often delayed or does not happen
- Lack of requirement for PRO reporting can lead to publication bias

Patel, *JAMA NO*, 2024; Kemp *BMC Med* 2017

PROs and Surrogate Endpoints

- **Social/scientific value** undermined when PROs are not reported
- PROs improve **scientific validity** of conclusions when using surrogate end points
- **Informed consent** may be violated when not reported
- Future patients need data to inform risk/benefit ratio

Blackstone, *JCO*, 2025

Recommendations

Researchers:

- Incorporate meaningful PROs and include patient voices in trial design
- Clear analysis and publication plan for PROs ahead of time
- Follow existing best practices (such as SPIRIT-PRO)
- Use well-validated surrogate end points

Journal editors:

- Show that they are interested in publishing PRO data
- Modify publication guidelines to set expectation for rigorous PRO reporting

Regulators:

- Consider requirement to include PROs when surrogate end points used
- Surrogate end points must be well-validated
- Requirement for post-approval trials after accelerated approval with surrogates

Blackstone, *JCO*, 2025

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Application: Returning Results to Research Participants

Ethics Consultation

- How should an oncology **research team** communicate with patients informed at the time of consent that their results from a research test would not be returned, when the study finds these results are **strongly associated** with metastatic recurrence?

- Informed consent? Data rigorous? Data actionable?

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Discussion