

# Publishing In Empirical Bioethics: Challenges and Opportunities

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# Agenda

- Trends in empirical bioethics research
- Frameworks for empirical bioethics research
- *AJOB: Primary Research*
- Opportunities, common problems with submissions, strategies

# Rise of Empirical Bioethics

- Increased focus on:
  - Evidence-based medicine
  - Clinical ethics
- Shortcomings of bioethics
  - Too abstract
  - Removed from clinical reality
- Potential contributions
  - Translate abstract principles into solutions that are workable in practice
  - Help ethicists take into account the actual experiences of caregivers and patients
- Continued debate re: relation between data and ethics

Borry et al., 2005, *Bioethics*, 19(1)

# Trends in Empirical Bioethics Publications

- Review of articles from 9 bioethics journals, 1990-2003 (N = 4029 articles)
  - 10.8% used empirical design
    - 5.4% in 1990, 15.3% in 2003
  - 64.6% were quantitative; 32.2% qualitative
    - More than half of qualitative studies were in *Nursing Ethics*
  - 53.6% used a descriptive survey

Borry et al., 2006, *Journal of Medical Ethics*, 32

# Trends in Empirical Bioethics Publications

- Most frequent topics (out of 33 topics):
  - Prolongation of life and euthanasia (n = 68)
  - Theoretical perspectives (e.g., ethical reasoning) (n = 58)
  - Informed consent/ decision participation (n = 42)
  - Ethics education (n = 34)
  - Ethics committees and consultation (n = 30)

# Trends in Empirical Bioethics Publications

- Review of all articles from 3 health journals over 2 year period ('05 – '06)
  - 26 (2.22%) articles contained data relevant to research ethics
    - Only 7 contained relevant keywords
    - 12 contained keywords indirectly related to research ethics
    - 15 did not discuss ethical significance of findings

DuBois et al., 2008, *Journal of Empirical Research on Human Research Ethics*, 3(3)

# Trends in Empirical Bioethics Publications

- “Hidden” empirical research ethics
  - Articles that don’t appear in journal dedicated to empirical ethics
  - Articles that don’t include relevant keywords
  - Authors do not discuss ethical implications

DuBois et al., 2008, *Journal of Empirical Research on Human Research Ethics*, 3(3)

# Frameworks for Ethics Research

- Sugarman & Sulmasy framework
  1. Descriptive studies (e.g., attitudes, behaviors, and practices)
  2. Testing established or new norms
  3. Descriptions of facts relevant to normative arguments
  4. Slippery slope arguments

Sugarman & Sulmasy, 2011, *Methods in Medical Ethics*  
Sugarman, 2004, *Journal of Law, Medicine & Ethics*, 32

# Frameworks for Ethics Research

- Sugarman & Sulmasy framework (continued)
  5. Assessing likely consequences of choices
  6. Empirical testing of normative theories
  7. Case reports
  8. Demonstration projects

Sugarman & Sulmasy, 2001, *Methods in Medical Ethics*

Sugarman, 2004, *Journal of Law, Medicine & Ethics*, 32

# Frameworks for Ethics Research

- Kon framework
  1. Lay of the Land
    - Describing attitudes and practices
  2. Ideal versus Reality
    - Extent to which actual practice reflects the ideal
  3. Improving Care
    - Solving problems identified above
  4. Changing Ethical Norms
    - Bioethical analysis of multiple studies → recommend changes to ethical norms

Kon, 2009, *American Journal of Bioethics*, 9(6-7)

# Frameworks for Ethics Research

- Wynia framework
  - Understand and judge empirical ethics research from perspective of “So what?”
  - A research question is only worth pursuing if it could lead to a change in behavior that might improve care

Wynia, 2009, *American Journal of Bioethics*, 9(6-7)

# Bioethics Journals

- Accountability in Research
- American Journal of Bioethics
- American Journal of Bioethics: Neuroscience
- **American Journal of Bioethics: Primary Research**
- Bioethics
- BMC Medical Ethics (Open Access)
- Cambridge Quarterly of Health Care Ethics
- Christian Bioethics
- Clinical Ethics
- Developing World Bioethics
- Ethics & Behavior
- Hastings Center Report
- IRB: Ethics and Human Research
- Journal of Bioethical Inquiry (Open Access)
- Journal of Clinical Ethics
- **Journal of Clinical Research & Bioethics** (Open Access)
- **Journal of Empirical Research on Human Research Ethics**
- Journal of Law, Medicine & Ethics
- Journal of Medical Ethics
- Kennedy Institute of Ethics Journal
- Medicine, Health Care & Philosophy
- **Narrative Inquiry in Bioethics: A Journal of Qualitative Research**
- Nursing Ethics
- Theoretical Medicine and Bioethics

**Bold, underline**= focus on empirical research

# *AJOB Primary Research*

- Emerged from AJOB in response to increasing empirical submissions
- In 4<sup>th</sup> year of publication
- Current team in place @2.5 years
  - Editor-in-Chief: Robert Nelson
  - Associate Editors: Alexander Kon, Victoria Miller
  - Managing Editor: Emily Evans
- Independent of AJOB
- Average turn-around from submission to decision
  - 49 days

# *AJOB Primary Research*

- Manuscript submission
  - <http://mc.manuscriptcentral.com/primaryresearch>
- Contact if interested in reviewing
  - [editor.primaryresearch@bioethics.net](mailto:editor.primaryresearch@bioethics.net)

# Opportunities

- New questions
  - Whole exome sequencing
  - HPV vaccine
  - Fertility preservation
- New methods (applied to an old question)
  - Historiometry to understand wrongdoing in health care and research (DuBois et al., 2012, Ethics & Behavior)
  - Discourse analysis of consent discussions (Ness, Kiesling, & Lidz, 2009, Jour of Amer Acad Psych and Law)
- Relevance to broad range of clinicians and researchers
- Collaboration across disciplines
  - Enhances value-added, methods, etc.

# Opportunities

- Multiple disciplines:
  - Bioethics (roots in philosophy, theology)
  - Medicine
  - Genomics
  - Psychology
  - Nursing
  - Anthropology
  - Sociology
  - Public health
  - Law
  - Epidemiology
  - Statistics (and other methodology-focused disciplines, e.g., bioinformatics)

# Opportunities

- *AJOB Primary Research* recognizes diversity of approaches to empirical inquiry
  - Many disciplines welcome
  - Flexibility with respect to methodological approach
  - Structure of manuscript can fit the methodology
  - Less strict about word/page limits
  - Focus on integrity of methods

# Opportunities

- Mission of AJOB Primary Research
  - To advance the pursuit of empirical work in bioethics through the publication of primary research in bioethics and conceptual analyses of the relationship between descriptive and normative inquiry
- We welcome submissions related to:
  - Social scientific research applied to bioethical questions and health policy and health services research as it relates to bioethics
  - Evidence-based literature reviews
  - Commentary on new developments in empirical bioethics

# Opportunities

- Continued interest by funding sources:
  - Current NIH Program Announcement: “Research on Ethical Issues in Biomedical, Social, and Behavioral Research”
  - Greenwall Foundation

# Common Problems

- Lack of justification for and value-added of study:
  - What is the ethical question being addressed?
  - Why does it matter?
  - Why is the study needed?
  - What are the ethical and clinical implications?
    - Need to be explicit (topic alone is not enough)

# Common Problems

- Failure to address relevant background for broad audience
  - Conceptually
  - Methodologically
    - What is “good science” in your area?

# Common Problems

- Lack of rigorous methods or insufficient detail
  - Measures not reliable and/or valid (challenging in a new area)
- Failure to address methodological limitations
  - E.g., internal validity, bias, generalizability
- Leaping to conclusions (ethical or otherwise) not supported by the data

# Tips and Strategies

- Determine appropriate audience
  - Bioethics journal
  - Discipline-specific journal
    - Method-driven (anthropology; qualitative research)
    - Context-driven (palliative care; pediatrics)
- Choose keywords carefully
- Include relevant co-authors/collaborators from other disciplines
- Suggest possible reviewers (from your discipline or otherwise) to ensure timely and appropriate review

# Tips and Strategies

- Introduction
  - Provide clear rationale for study
  - Delineate the ethical question the study is addressing
  - Provide relevant background for broad audience
  - Avoid jargon
- Methods
  - Provide sufficient detail
  - Justify design choices
  - Include Analysis Plan (if applicable)
    - Consistency between aims/hypotheses → analysis plan → and results

# Tips and Strategies

- Discussion
  - Discuss ethical and clinical implications (“So what?”)
    - Be careful about what you can and cannot conclude based on data
  - Address limitations of the study
  - Describe remaining questions and areas for future research
    - Including current studies/plans

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