

# Keynote Address: Ethical & Legal Considerations on Innovation and Policy in Psychiatry



## Minnesota Psychiatric Society

*Improving Minnesota's mental health care through education, advocacy and sound psychiatric practice.  
Our vision is physician leadership creating the nation's highest quality, affordable and accessible system of mental health care.*

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## Disclosures

- Rebecca Brendel, MD, JD, DFAPA
  - APA President
  - Associate Director of the Center for Bioethics and Director, Master of Bioethics Program, Harvard Medical School
  - Community Advisory Board, Osmind (beginning June, 2023)
  - AMA Council on Ethical and Judicial Affairs
- Alison Crane, JD
  - APA Deputy General Counsel
  - No conflicts to disclose

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## How do ethics and policy keep up with innovation in psychiatry?

- Ethical considerations are always present in practice and evolution of psychiatry, including with respect to innovations
- Innovations may create opportunities for improved patient care
- Ethical framework can help bridge gaps and ensure they enhance good without causing harm
  - Principles of beneficence and nonmaleficence
  - Helps psychiatrists respond to complex and novel situations with understanding of their ethical implications and to make ethically sound decisions

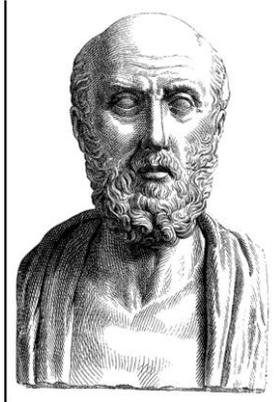
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## Traditional Approaches to Ethics

- What defines or is the origin of good or right?
  - Duty – Deontology
  - Outcomes – Consequentialism
  - Character – How to be

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## Duty: Hippocratic Oath(s)



1881 Young Persons' Cyclopedia of Persons and Places Upload by RedWolf 05:45, Jan 10, 2005 (UTC)

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## Traditional Approaches to Bioethics

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  - Duty – Deontology
    - Relevance: oaths, covenants, pledges
    - Many origins; may come into conflict
  - Outcomes – Consequentialism
    - Relevance: public health, benefit, effect size
    - How do we measure? Are there constraints?
  - Character – How to be
    - Relevance: Moral exemplars, what would X do
    - Is character really “global”

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## Outcomes: Public Health



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## Virtue: Konark Temple Entrance



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    - Is character really “global” – influence of environment

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## What Is Ethics?

*“Ethics is the study of how to make hard choices in the face of conflicting values.”*

*-- E. Crigger PhD*

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## Ethics: Methods

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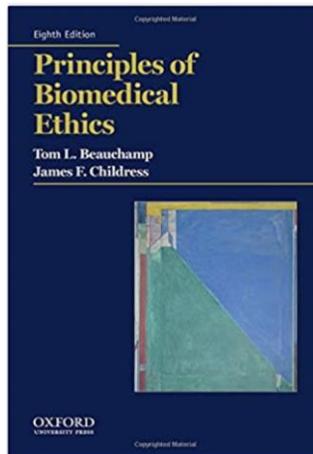
## Ethics: Methods

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# The Principles of Biomedical Ethics



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## Balancing Many Considerations

- Principles (vs. rules) derived from common morality
- Four Principles (Beauchamp and Childress)
  - Autonomy
  - Beneficence
  - Nonmaleficence
  - Justice
- Prima facie vs all-things-considered: balancing
- Moral regret/ residue
- Method = balancing

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# *Autonomy*

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Autonomy



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## Introduction

- For B&C, *respect for autonomy* is one of four principles of biomedical ethics
- Contrary to frequent interpretations, ***respect for autonomy does not have moral priority over other principles*** (8<sup>th</sup> p. ix)
- Two parts:
  - ***Negative component***: autonomous actions should not be subject to controlling constraints by others.
  - ***Positive component***: respectful treatment and actions that foster autonomous decision making.
- “Respect for autonomous choices”
- May be overridden by other principles

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## *Beneficence*

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## Beneficence: Definition

- We ought to contribute to the welfare of others
- ***Assumption of beneficence in medicine/ health care***
  - Specific vs general
- “Morality requires that we contribute to the welfare of others”
  - BUT, how much benefit
  - Utility a consideration, not overriding
- NOT ALL BENEFICENCE IS OBLIGATORY

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## *Nonmaleficence*

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## Nonmaleficence: Definition

- One ought not to inflict evil or harm
- Intentional avoidance of actions that cause harm
- ***Prima facie principle that requires the justification of harmful actions***
- Typically **does** override other principles – perhaps most stringent?

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*Justice*

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## The Concept of Justice

- Terms like “fairness” and “desert” (what is deserved), and “entitlement” are used to understand the concept of justice
- May be understood as: **“Fair, equitable, and appropriate treatment in light of what is due or owed to affected individuals or groups”**
- Formal principle: **Persons equal in whichever respects are deemed relevant should be treated equally**
- Provides no criteria for determining whether two or more individuals are in fact equals → Not enough

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## Material Principles of Justice

- Explicitly identify the substantive properties for a claim for a particular distribution
- E.g., principle of need declares that important resources (including health care) should be distributed according to need
- Identifying material properties may prove difficult and often controversial
- Many examples

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## Examples of Material Principles

- **Utilitarian** – maximize social utility, efficiency, the most good for the most people (e.g., COVID CSC)
- **Libertarian** – maximize liberty, free-market
- **Communitarian** – fair distribution from conceptions of good in moral communities
- **Egalitarian** – equal liberty and access to opportunity
- **Capabilities** – means necessary for flourishing
- **Wellbeing** – means for dimensions of wellbeing
- **Restorative and Reparative** – compensate for prior acts/ wrongs

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## Justice in Practice

- Not so easy to bring it all together: Difficult though possible
- What is just in healthcare?
  - Who is included and who benefits?
  - Who gets access?
  - ‘Vulnerable’ populations
  - A decent minimum?



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## How Does This All Work?

- Balancing among considerations (principles)
- Bringing voices in
- Telling stories
- Engaging cases
- Considering relationships
- Addressing injustice
  
- Ethics is multilayered complex work!
  - That's why it's best done in a group ... the Ethics Committee

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## APA Resources: APA Ethics Committee

- APA Ethics Committee is comprised of 6 members, 5 consultants, 3 corresponding members, and 6 fellows.
- Current membership:

<u>Members</u>	<u>Consultants</u>	<u>Corr. Members</u>	<u>Fellows</u>
Charles Dike, MD (Chair)	Oyedji Ayonrinde, MD	Gregory Barber, MD	Sabrina DeLeon, MD
Daniel Anzia, MD	Joanna Brandt, MD	Donna Chen, MD	Diego Garces Grosse MD
Philip Candilis, MD	Ariana Nesbit, MD	Tobias Wasser, MD	Etujie Halbert, MD
Catherine May, MD	Paul Noroian, MD		Rachel Kay, MD
Tia Powell, MD	Kamille Williams, MD		Gregg Robbins-Welty, MD
Christopher Thomas, MD			Mary-Catherine Skoulos, MD

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## Ethics Resources for APA Members

- All APA members are bound by ethical code for medical profession as defined in *Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry*
- APA Ethics Committee responsibilities include:
  - Preparing annotations to update those *Principles*
  - Responding to requests for guidance on ethical issues faced by APA members
  - Providing educational information on ethical issues
  - Handling appeals of ethics complaints against APA members

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## Ethics Resources for APA Members

- [Psychiatry.org/ethics](https://www.psychiatry.org/ethics)
  - *Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry*
  - Ethics complaint process and procedures
  - *APA Commentary on Ethics in Practice*
    - Practical guidance for managing ethical dilemmas that come up in day-to-day practice
  - *Opinions of Ethics Committee on the Principles of Medical Ethics*
    - Committee's responses to specific ethics questions raised by APA members
  - Additional resources
    - Resource Documents
    - Recommended resources for trainees on understanding how to approach situations ethically
    - *Psychiatric News* Ethics Columns
    - COVID-19 related guidance

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## Ethics Resources for APA Members

APA members who have a question about an ethical problem they are trying to solve may contact the Ethics Committee for guidance

[APAethics@psych.org](mailto:APAethics@psych.org)

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## Ethics Resources on Innovation

- Do existing Ethics Committee resources address innovation in psychiatry?

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## Innovation - APA Commentary on Ethics in Practice

- Topic 3.4.2

“When usual treatments have failed, psychiatrists may offer non-standard or novel interventions using a shared decision-making approach grounded in the patient’s informed consent and a thorough discussion of risks, benefits, and alternatives to the innovative treatment. Since innovative practice sometimes leads to important scientific advances, it should not be categorically discouraged; however, because it may prove ineffective or even harmful, psychiatrists should proceed with caution in their use of clinical innovation.”

- Topic 3.4.6

“Innovations in internet and communications technology over the past several decades have the potential to improve access to, delivery of, and quality of psychiatric care. However, these advances may also pose potential challenges to sound and ethical practice. While each type of technology and situation requires a case-by-case analysis, psychiatrists should be aware of potential ethical challenges in its use before using the technology in providing patient care. Psychiatrists are responsible for obtaining sufficient knowledge about the technologies they employ to respect patient confidentiality and deliver competent care. Psychiatrists must be aware of their responsibility to maintain professional boundaries in their internet activities”

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## Specific Questions Received

- Ethics Standards to Follow Regarding Exhibit and Sponsorship Interactions?
- Emotional Support Animals
- Mobile Mental Health Apps
- Psychedelics

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## Received question: Operational ethics standards to follow which impact exhibit and sponsorship interactions with members?

- **APA Commentary on Ethics in Practice:**
- “Across all fields of medicine, organizational fundraising must be conducted with sensitivity so as not to exploit the relationship of trust that the physician has with the patient...to be ethically acceptable, fundraising in psychiatry must be based in trust and honesty and in the fulfillment of goals of shared importance to the organization and the donor. Most importantly, philanthropic activities must be non-exploitative. Individual psychiatrists must not approach their patients for funds or initiate identification of specific patients for their institutions to solicit, as this may adversely affect the therapeutic relationship and cannot sufficiently safeguard the patient from exploitation”
- “Psychiatrists should recognize that industry has obligations beyond patient welfare, including primary obligations to shareholders that psychiatrists do not share. All psychiatrists should be aware of the potential conflicts that interactions with industry pose between business objectives and the psychiatrist’s clinical or research responsibilities.... At a minimum, psychiatrists should disclose their affiliations, relationships and financial involvement with Industry to their patients in clinical settings and to audiences in professional presentations, even if they believe they are inconsequential.”

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## Sponsorship Interactions Continued – Commentary, Topic 3.4.4

- Addressing conflicts of interest should be guided by three principles:
  - Primacy of patient welfare
  - Independence of the psychiatrist’s judgment
  - Disclosure
- The guiding principle should be that the patient’s interest rises above that of the psychiatrist or industry

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## Sponsorship Interactions Continued — Opinions of APA Ethics Committee

- **A.11:** Clinicians should not be involved in requesting donations from their patients because that inserts the clinician's institution's needs into the patient-provider relationship, violating the fiduciary nature of that relationship
- **B.4:** For a psychiatrist to place material in the waiting room advertising the needs of a research group, even though it would seem to be an entirely voluntary participation on the part of the patient, may be interpreted as a recommendation to the patient to participate in research, and may imply an endorsement on the part of the psychiatrist.
- **L.2:** It is unethical for psychiatrists to accept fees for referring patients for clinical care, research, or any other service.

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## Sponsorship Interactions Continued — Accreditation Council for Continuing Medical Education Standards for Integrity and Independence in Accredited Education

- Tracks same approach for clinical practice noted by Ethics Committee: avoid bias, ensure independence, and practice disclosure
- Standard 1: Ensure content is valid by having a clear, unbridgeable separation between accredited education and marketing/sales
- Standard 2: Prevent bias by having content decisions made without influence or involvement of ineligible companies and ensuring education is free of marketing/sales
- Standard 3: Presenters identify, mitigate and disclose relevant relationships
- Standard 4: Ensure education remains independent from any commercial support
- Standard 5: Manage ancillary activities to ensure education is separate

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## Emotional Support Animals (ESAs)

- Ethics Opinion N.23
- 3 issues:
  - Integrity: psychiatrists must not write a letter they don't believe is true
  - Doctor-Patient relationship: denying an ESA letter request may feel like it harms alliance, but allowing patient to manipulate psychiatrist into false position is also harmful to relationship
  - Federal and state regulations: ESAs do not receive protections given to service animals under ADA and other laws

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## ESAs Continued

- Resource Document (2022) and Psych News Alert 4/4/23
  - Psychiatrist must consider whether patient truly has a chronic mental impairment caused by a psychiatric condition (defined in DSM-5-TR) and whether requested ESA would alleviate that impairment, as well as the patient's ability to care for the animal and the ability of the animal to serve in role as an ESA
  - At this time there is not a strong evidence-base regarding clinical benefits of ESAs for psychiatrist symptoms or disorders
  - Given limited evidence supporting ESAs it is ethically permissible to decline to write letters; when deciding whether to write a letter psychiatrist should weigh risks including taking into consideration secondary ethical obligations to public health and be aware of potential ethical concerns regarding role conflict

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## Mobile Mental Health Apps

- This technology is continuously and rapidly advancing – they may raise promise of increasing access to healthcare
- Innovation raises questions about how to determine appropriate use, ethical concerns, and how to effectively use them to provide mental health care
- Psychiatrists should judiciously review pros and cons of devices and applications with an eye toward legal and ethical risks (e.g., HIPAA)
- Resources, including APA App Advisor, provide models for performing such evaluations

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## Mobile Mental Health Apps Continued

- Key ethical principles to consider and discuss with patients include:
  - Confidentiality – privacy/security of data collected
  - Beneficence and non-maleficence – what benefits might app provide? What evidence is available about its expected benefit and potential harms?
  - Autonomy, truthfulness, doctor-patient relationship – what are patient's goals in using and how does psychiatrist's goals conform to them?
    - Psychiatrist needs to be clear about their commitment with regard to the app (e.g., will information entered be received and reviewed immediately)
    - Be vigilant to avoid boundary crossings and violations when therapeutic relationship steps outside of traditional setting
  - Informed consent process – including psychiatrist's interests related to app
  - Apps must be used only as aid in care delivery and not replace interactions

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## Psychedelics

- Ethics Committee Resource Document (2022)
- Psychedelic therapies remain in early stage of research – importance of maintaining research equipoise to remain neutral while scientific process investigation proceeds
  - Unbiased stance on safety and efficacy until there is data from clinical trials
- Optimism should be balanced with acknowledgment that more work needs to be done before embracing of psychedelics is justified
- Need to enhance diversity and equity – work to engage marginalized populations in psychiatric research on psychedelics
- Distinctive features of psychedelic research could require “enhanced consent” (acute, intense changes in consciousness)

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## Other Topics

- Duty to separate religious or personal beliefs from impacting psychiatric practice?
  - *Resource Document on Interface of Religion, Spirituality, and Psychiatric Practice*
- How do we separate professional boundaries vs personal beliefs?
  - *Resource Document on Religion and Commentary Topic 3.2.7 (“care should be exercised when the psychiatrist enters political discussions with the patient”)*
- What is the psychiatrist’s responsibility to address racial inequities in practice?
  - *Ethics Opinion N.33 (“To provide competent care, a psychiatrist should cultivate an awareness of the adverse effects on mental health that result from racism and ethnoracial discrimination”)*

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Questions?