Ethical-legal Issues Generated by the Increased Use of Biotechnology in Health Care

Joseph A. Procaccino, JR., J.D., M.F.S.
Legal Advisor, Department of Medical Ethics Center
&
Adjunct Assistant Professor
Department of Preventive Medicine and Biostatistics, Uniformed Services University of the Health Sciences

Megan K. Applewhite M.D., M.A., F.A.C.S.
Associate Professor, Surgery and Bioethics
Chair of Bioethics, John A. Balint, M.D.
Albany Medical College,
Albany, N.Y.
&
Consultant Bioethicist
Department of Defense Medical Ethics Center
Uniformed Services University of the Health Sciences

James Giordano, Ph.D., M.Phil.
Depts. Neurology & Biochemistry
Pellegrino Center for Clinical Bioethics
Georgetown University Medical Center
&
Defense Medical Ethics Center

26 August 2021

1005-1105 ET

Presenters

James Giordano, Ph.D., M.Phil.
Depts. Neurology & Biochemistry
Pellegrino Center for Clinical Bioethics
Georgetown University Medical Center
and
Defense Medical Ethics Center
Washington, D.C.

Megan K. Applewhite M.D., M.A., F.A.C.S.
Associate Professor, Surgery and Bioethics
Chair of Bioethics, John A. Balint, M.D.
Albany Medical College,
Albany, N.Y.
and
Consultant Bioethicist
Department of Defense Medical Ethics Center
Uniformed Services University of the Health Sciences
Bethesda, Md.

Joseph A. Procaccino, JR., J.D., M.F.S.
Legal Advisor, Department of Medical Ethics Center
and
Adjunct Assistant Professor
Department of Preventive Medicine and Biostatistics,
Uniformed Services University of the Health Sciences
Bethesda, Md.

James Giordano, Ph.D., M.Phil.

- Dr. James Giordano is a Bioethicist with the Department of Defense (DoD) Medical Ethics Center (DMEC), Chief of the Neuroethics Studies Program, Scholar-in-Residence, leads the Sub-Program in Military Medical Ethics, and Co-director of the O'Neill-Pellegrino Program in Brain Science and Global Health Law and Policy in the Pellegrino Center for Clinical Bioethics.
- Dr. Giordano is also a Professor in the Departments of Neurology and Biochemistry at Georgetown University Medical Center, Washington, DC, USA. He is a Distinguished Visiting Professor of Brain Science, Health Promotions and Ethics at the Coburg University of Applied Sciences, Coburg, Germany, and was formerly the 2011-2012 J.W. Fulbright Foundation Visiting Professor of Neurosciences and Neuroethics at the Ludwig-Maximilians University, Munich, Germany.
- Dr. Giordano currently serves as Chair of the Neuroethics Program of the Institute of Electrical Electronic Engineers (IEEE) Brain Project, and an appointed member of the Neuroethics, Legal and Social Issues (NELSI) Advisory Panel of the Defense Advanced Research Projects' Agency (DARPA). He has previously served as Research Fellow and Task Leader of the EU Human Brain Project Sub-Project on Dual-Use Brain Science; an appointed member of United States Department of Health and Human Services Secretary's Advisory Council on Human Research Protections (SACHRP); and as Senior Science Advisory Fellow of the Strategic Multilayer Assessment Branch of the Joint Staff of the Pentagon.
- The author of over 290 publications in neuroscience and neuroethics, seven books, and 15 government whitepapers on neurotechnology, ethics and biosecurity, he is an Editor-in-Chief of the international journal Philosophy, Ethics and Humanities in Medicine; Associate Editor of the Cambridge Quarterly of Health Care Ethics; and Contributing Editor of Frontiers in Human Neuroscience.
- His ongoing research addresses the neurobiological bases of neuropsychiatric spectrum disorders; and neuroethical issues arising in and from the development, use and misuse of neuroscientific techniques and neurotechnologies in medicine, public life, global health, and military applications.

Megan K. Applewhite M.D., M.A., F.A.C.S.

Dr. Megan Applewhite is an Associate Professor in the Department of Surgery and Center for Ethics Education and Research at Albany Medical College, Albany, NY. She is also a Consultant Bioethicist for the Department of Defense Medical Ethics Center (DMEC).

Dr. Applewhite is the Director of the Alden March Bioethics Institute at Albany Medical College and holds the John A. Balint, MD, Chair of Medical Ethics in the College. She is a board-certified General Surgeon and is fellowship trained in Endocrine Surgery. Her undergraduate degree is in African American Studies from the University of Chicago and her medical degree is from Albany Medical College. She completed her General Surgery Residency at Lahey Hospital and Medical Center and her Endocrine Surgery training at the University of Chicago. She also completed a fellowship in Clinical Medical Ethics at the University of Chicago MacLean Center for Medical Ethics.

Her research interests include surgical ethics education, health care of the incarcerated patient population, utilization of limited resources, and quality of life after thyroid and parathyroid surgery.

Joseph A. Procaccino, JR., J.D., M.F.S.

- Mr. Procaccino is Legal Advisor for DoD DMEC centered at the Uniformed Services University for the Health Sciences (USUHS), and is an Adjunct Assistant Professor of Preventive Medicine and Biostatistics at USUHS where he teaches Medical Jurisprudence and Bioethical issues. He has been on the faculty at USUHS since 1991. He is also on the faculty of the Defense Department's Medxellence Program. He is currently serving in a re-hired annuitant role.
- Mr. Procaccino has served as the Legal Advisor to the Surgeon General, United States Air Force, and Senior Counsel for Health Affairs for the Air Force Judge Advocate General from 1993 until his retirement from Civil Service in that position in 2017. Prior to that, he was the Senior Medical Law Counsel for the Tort Claims and Litigation Branch of the Air Force Legal Operations Agency, beginning his Air Force tenure with that office in 1978. He also served as the legal representative to the Surgeon General's Medical Practice Review Board and Clinical Investigation Review Committee, and participated in the Department of Defense Health Affairs Committee for Risk Management and Quality Assurance.
- In addition to his government service, Mr. Procaccino has been appointed as an Adjunct Associate Professor teaching Health Law at the University of Maryland Graduate School, an Adjunct Assistant Professor at Central Michigan University, and as an Adjunct Instructor at Georgetown University teaching ethics and medical law.
- Mr. Procaccino was commissioned an officer in the U.S. Army Signal Corps in 1973. He subsequently served in the U.S. Army Reserve in both the Signal Corps and Military Intelligence Branch.
- He holds a Bachelor's Degree in both Classical Humanities and Political Science from George Washington University. He received his Juris Doctor degree from American University and a Master's degree in Forensic Medicine (Sciences) from George Washington University.

Disclosures

- Dr. James Giordano, Dr. Megan K. Applewhite, and Mr. Joseph A. Procaccino, Jr. have no relevant financial or non-financial relationships to disclose relating to the content of this activity.
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Learning Objectives

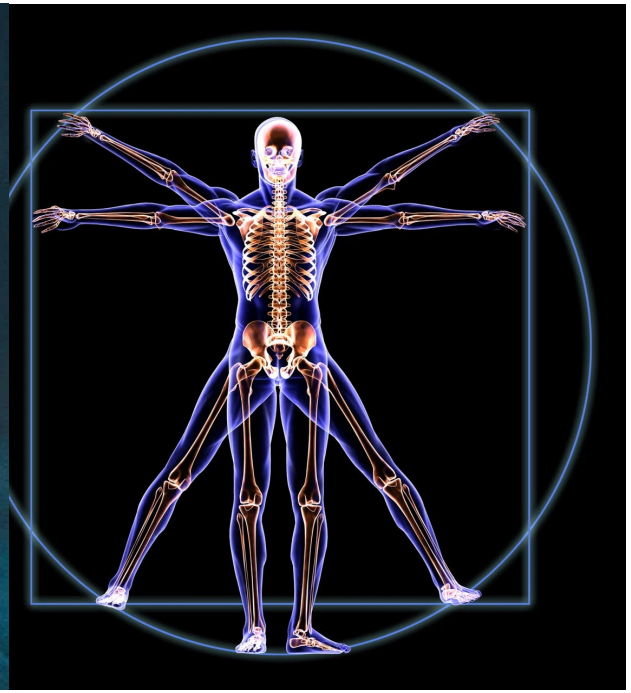
At the conclusion of this activity, participants will be able to:

1. Analyze the impact of biotechnological innovations on privacy, legal liability, and equity.
2. Discuss balancing risks and benefits of new technologies.
3. Outline novel aspects of surgical ethics.
4. Explain the challenges of informed consent when new approaches/new technology is incorporated to surgical care.

Bio-Science and Technology (BioS/T)…

The Dance of Tools-to-Theory-to-Tools…





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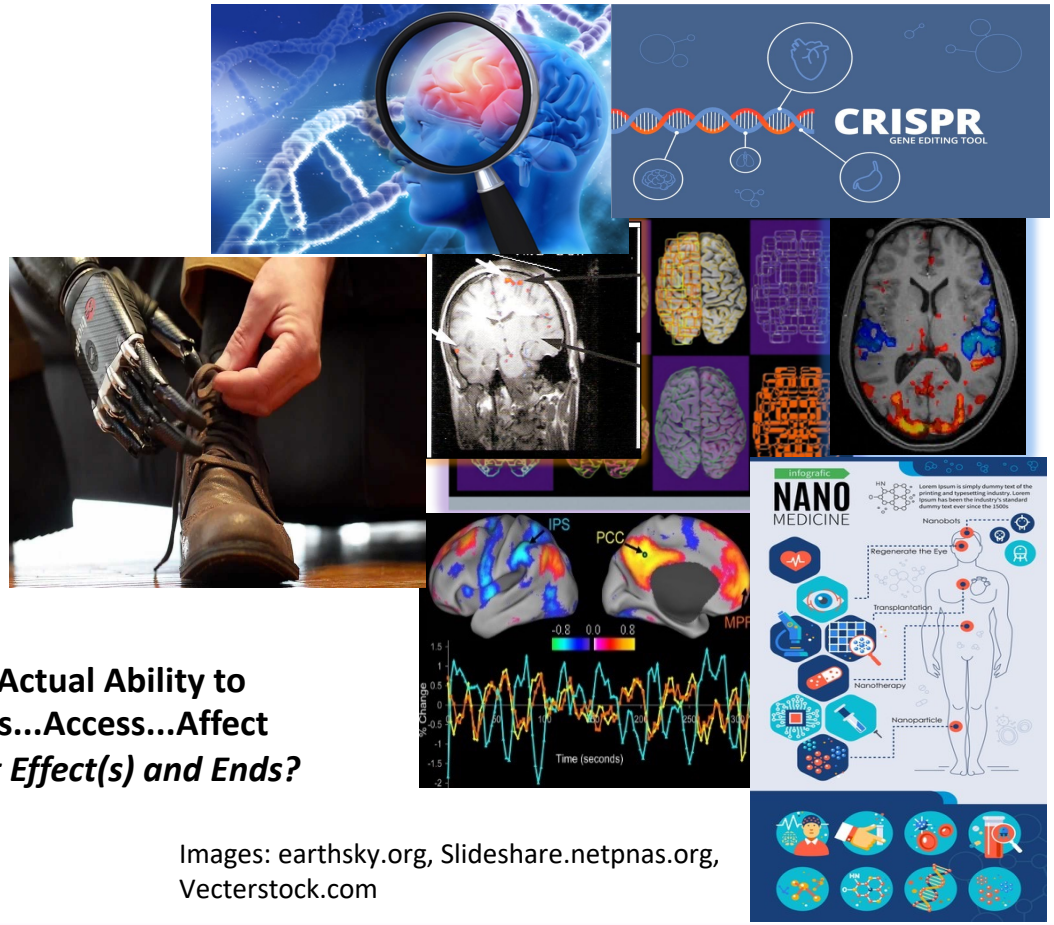
(BioS/T)

- **Assessment**
  - Biomarkers
  - Genetics/genomics
  - Imaging
  - Biomodeling/mapping
- **Interventional**
  - Technopharmaceutics
  - Gene Editing
  - Nanomaterial Systems
  - Transomatic Modulation
  - Implantable Devices
  - Brain Computer Interface (BCI)
  - Advanced Bioprosthetics
  - Robotics
- **Derivative**
  - Big Data
  - Artificial Intelligence (AI) technologies



A-3: **Actual Ability to Assess...Access...Affect**
To What Effect(s) and Ends?

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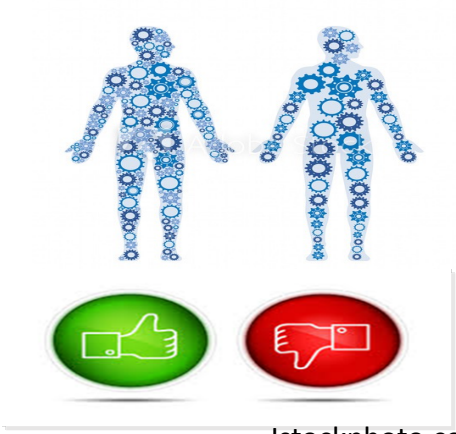
The Good, the Bad, and the Ugly

- **Good**
  - Diagnose and cure/treat disease
  - Facilitate/improve physiological and cognitive functions
  - Improve quality of life

- **Bad**
  - Misappropriated findings and meanings
  - Inapt use
  - Distributional asymmetries

- **Ugly**
  - Intentional mis-use (of information and capabilities)
  - Neglect of analysis, precaution, preparation
  - Use in warfare



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Bioethico-legal Issues & Risks

Technology-focal

- Unknowns of frontier science/technology
- Capabilities, limitations
- Validity, viability of use
- Runaway and Wexelblatt effects

Social

- Autonomy: Protection vs privacy
- Awareness, understanding, consent
- Treatment/protection/enhancement
- Norms, pluralization, diversity
- Justice: Provision/access
- Dual-use

Preparatory Paradigm

Any Consideration of Using BioS/T Should be Informed by...

6-W Questions:

- ***What*** **BioS/T is/are available for current use?**
- ***Why*** **is BioS/T considered or advocated or use?**
- ***Who*** **will receive BioS/T?**
- ***When*** **will BioS/T be considered (algorithm/protocol)?**
- ***Where*** **will BioS/T be administered (e.g.-hospital; clinic, school; worksite; home)?**
- ***Which*** **mechanisms will be in place for ongoing provision of services/resources?**

Preparatory Paradigm

As Framed by...

<u>6-C Considerations</u>:

- ***Capacities*** **and limitations of the BioS/T**
- ***Consequences*** **incurred by BioS/T on recipients, families, and society in the short, intermediate, and long-term**
- ***Character*** **of the research and recipient (e. g, patterns of cognition, emotion, and behavior) affected by BioS/T**
- ***Contexts*** **of need and value that influence use of BioS/T**
- ***Continuity*** **of research and clinical care**
- ***Consent*** **through provision most information possible**

Que será...

- Use-in-practice *will* incur unanticipated/deleterious effects
- Does NOT necessarily proscribe use
- DOES obligate need for:
  - Rigorous monitoring
  - Continuing R/D
  - Clinical engagement
  - Ethical guidance
  - Legal/policy Currency

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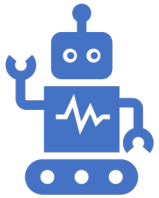
Technology and Surgery

- How to discuss new technology with patients
- No formal review process for surgical approaches or device utilization
- Discussions with patients perioperatively
- Unique discipline requiring creativity

Responsible Development and Application of Surgical Innovations: A Position Statement of the Society of University Surgeons

Variations

Minor modifications not requiring specific disclosure



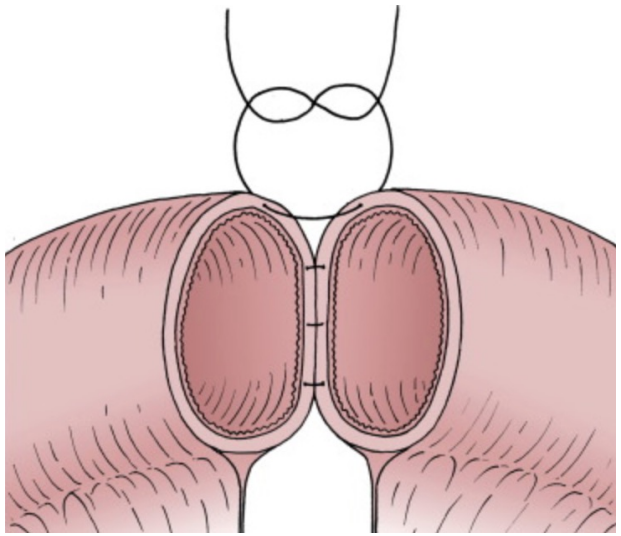
Innovations

Modifications of potential significance to the patient or that differ from local practice requiring disclosure

Research

Systematic investigations designed to develop or contribute to generalizable knowledge

Variations



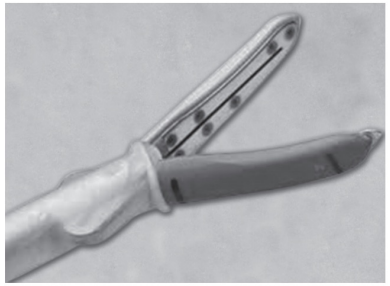


Fig. 1: View of LigaSure jaw

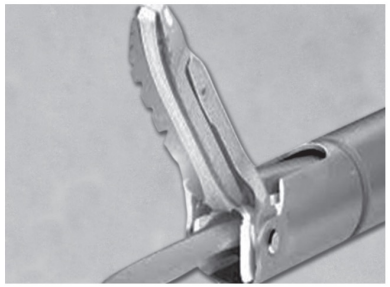


Fig. 2: View of thunderbeat jaw

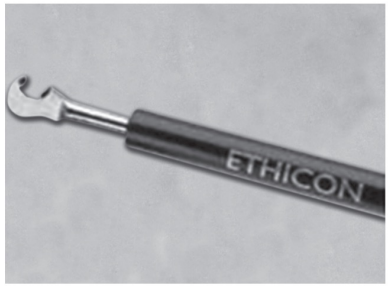
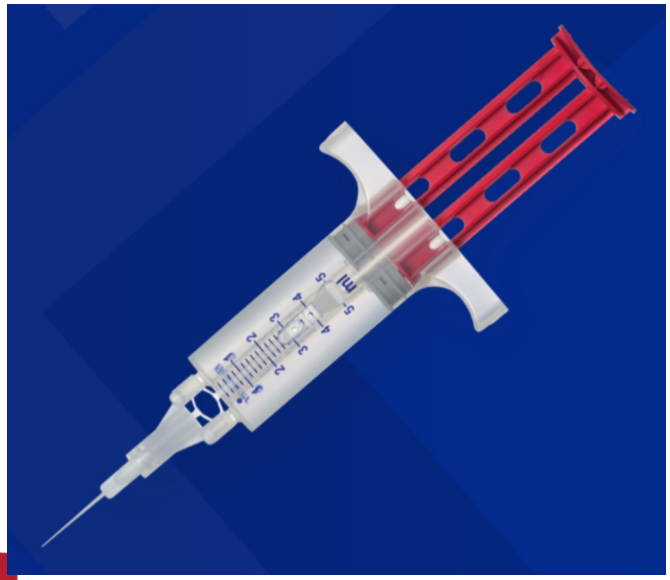


Fig. 3: View of harmonic jaw

Image: Target.com

Variations



Images: jnjmedicaldevices.com

Planned Innovation

- Is informed consent from the surgeon adequate to protect patients?
- Is new necessarily better? Or even equivalent?
- Is there a role for some type of oversight?

Oversight for surgical innovation

Peers or Departmental leadership

Surgical Innovation Committee

National Registry of Surgical Innovation

Institutional Review Board

Image: hhs.gov/aboutresearchparticipation

SOMETIMES

Research & Therapeutic Misconception

- ☑ When a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures.

DISCUSSION ISSUES

- INFORMED CONSENT
  - RISKS AND ALTERNATIVES
- STANDARDS OF CARE
  - EVOLUTION AND "WEANING IN" OF NEW INNOVATIONS/PRACTICES
- IMPLICATIONS FOR PROVIDERS
  - CREDENTIALING AND LICENSURE/SPECIALIZATION OF PROFESSIONS
  - IMPLICATIONS FOR CONCERNS ABOUT VIOLATIONS OF "PRIMUM NON NOCERE" ("DO NO HARM")
- COST AND EQUITY
- SAFEGUARDS AND LIABILITY
  - RESEARCH AND RISK/BENEFIT
- PRIVACY AND DUTY TO WARN

Key Takeaways

- Innovations need to be balanced with concern for patient risks, alternatives, and costs
- New techniques/advances may require a revisit of specialty training and scopes of practice
- Innovations cannot, like a switch, suddenly be turned on to the exclusion of present practices
- Pushing the envelope with the good intentions is necessary for advancement of surgery
- Appreciation of the value of early, mid, and late technology adapters
- Honesty and transparency with patients is paramount to respect their autonomous choice
- Early adapters of innovation in the OR have a particular responsibility to be thorough during the informed consent process
- Oversight for surgical innovation is built in to the profession, and may need formalization
- Technical and international convergences in bioscience and engineering are ever more rapidly fostering new developments with high clinical translatability
- Diverse circumstances, cultures and values can, and often do affect ethical-legal and social attitudes about use of emerging bioscience and technologies in practice
- Increasing 'what can be done' technically necessitates increased attention and address to 'what should (or should not) be done' in particular settings and under specific contingencies

References

Angelos, P. (2021). Ethical issues in surgical innovation. Retrieved from https://associationdatabase.com/aws/ACS/pt/sd/news_article/31920/_PARENT/DC_layout_details/false

Angelos, P. (2013). Ethics and surgical innovation: challenges to the professionalism of surgeons. *International Journal of Surgery, 11*(1), 2-5. https://doi.org/10.1016/S1743-9191(13)60003-5

Angelos, P. (2016). Ethics of Introducing New Surgical Technology Into Clinical Practice: The importance of the patient-surgeon relationship. *Journal of the American Medical Association Surgery, 151*(5), 405–406. https://doi.org/10.1001/jamasurg.2016.0011

Angelos, P. (2014). Surgical ethics and the challenge of surgical innovation. *American Journal of Surgery, 208*(6), 881 885. https://doi.org/10.1016/j.amjsurg.2014.09.013

References

Angelos, P., Krummel, T., Greenfield, L.J. and the Society of University Surgeons Surgical Innovations Project Team. (2008). Responsible development and application of surgical innovations: A position statement of the Society of University Surgeons. *Journal of the American College of Surgery, 206*(6), 1204-1249. https://doi.org/10.1016/j.jamcollsurg.2008.02.011

Broekman, M.L., Carrière, M.E., Bredenoord, A.L. (2016). Surgical innovation: The ethical agenda: A systematic review. Medicine (Baltimore), 95(25), e3790. https://doi.org/10.1097/MD.0000000000003790

Lidz, C.W., & Appelbaum, P.S. (2002). The therapeutic misconception: Problems and solutions. *Medical Care, 40(9)*, 55-63. https://doi.org/10.1097/01.MLR.0000023956.25813.18

U.S. Food & Drug Administration. (2019). Institutional Review Boards Frequently Asked Questions. January 1998. Accessed on April 22, 2021 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions

Questions

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1. Go to URL: https://www.dhaj7-cepo.com/content/aug-2021-ccss-exploration-innovations-health-care
2. Click on the REGISTER/TAKE COURSE tab.
   a. If you have previously used the CEPO CMS, click login.
   b. If you have not previously used the CEPO CMS click register to create a new account.
3. Follow the onscreen prompts to complete the post-activity assessments:
   a. Read the Accreditation Statement
   b. Complete the Evaluation
   c. Take the Posttest
4. After completing the posttest at 80% or above, your certificate will be available for print or download.
5. You can return to the site at any time in the future to print your certificate and transcripts at https://www.dhaj7-cepo.com/
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