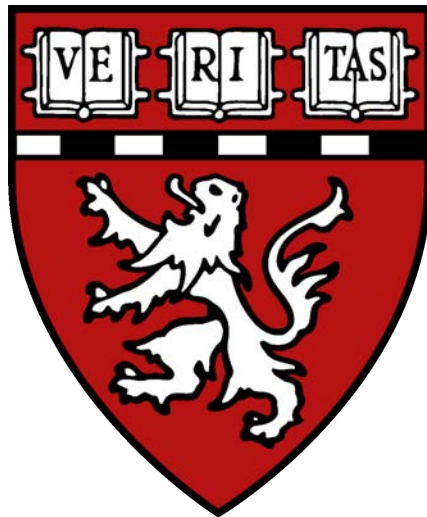


Master of Bioethics
CAPSTONE SYMPOSIUM



MAY 3, 2018

3 – 6:30 PM

Welcome

Rebecca Weintraub Brendel, MD, JD

*Director, Master of Bioethics Degree Program and
Assistant Professor of Psychiatry, Harvard Medical School
Director of Law and Ethics, Center for Law, Brain, and Behavior, and Associate Psychiatrist,
Massachusetts General Hospital*

The Value of the Capstone Program

Christine Mitchell, RN, MS, MTS

*Executive Director, Center for Bioethics, and
Director, Master of Bioethics Capstone Program, and
Lecturer on Global Health and Social Medicine, Harvard Medical School*

What Do Bioethicists Do?

Mary Faith Marshall, PhD, FCCM

*Professor, Department of Public Health Sciences
Director, Program in Biomedical Ethics, University of Virginia*

Closing Remarks and Invitation to Poster Presentations

Christine Mitchell, RN, MS, MTS

Natasha Aljalian

Capstone Mentor: Melissa Lopes, JD

Senior Research Compliance Officer, Harvard University Office of the Vice Provost for Research; Harvard Embryonic Stem Cell Research Oversight Committee Member; 2013-2014 Fellow in Bioethics, Harvard Medical School

Faculty Advisor: Rebecca Weintraub Brendel, MD, JD

Director, Master of Bioethics Degree Program, and Assistant Professor of Psychiatry, Harvard Medical School; Director of Law and Ethics, Center for Law, Brain, and Behavior, and Associate Psychiatrist, Massachusetts General Hospital

Revisiting the “14-Day Rule”—Can Bioethics Help?

The “14-day rule” prohibits in vitro experimentation on embryos beyond fourteen days post fertilization. This rule, which has been debated since its inception, has long stood as a bright line limitation on embryonic research around the world. Practically, the scientific community did not challenge the rule because scientists had been unable to grow embryos in vitro up to fourteen days. In May 2016, however, a lab in the United States and another in the United Kingdom sustained the embryo until 13 days post-fertilization, at which point they terminated research because of the “14-day rule”. In light of this development, the 14-day rule is under review. This Capstone project examined the genesis of the 14-day rule and analyzed historical support for, and challenges to, the rule. It considered the merits, scope, and future applicability of the rule, as well as bioethical, scientific, theological, and social science principles and positions relating to in vitro embryonic research and the rule. The importance of applied bioethics in addressing ongoing disagreements and in arriving at a potential way forward was confirmed.



Natasha Aljalian, JD, LLM, received a BA in psychology from Hofstra University; a JD from St. John's University School of Law where she was editor in chief of the Law Review and a Dolores Liebman Fellow; and an LLM in intellectual property law from Boston University School of Law, all with honors. She has practiced law in U.S. law firms and as in-house counsel, and has completed a federal judicial clerkship. She is admitted to the state bars in Massachusetts and New York. Her interests in bioethics are professional and personal. She plans to teach and engage in the areas of bioethics and law.

Theeb Alkahtani

Capstone Mentor: Alexandra Cist, MD

Faculty Associate, Center for Bioethics, and Instructor in Medicine, Harvard Medical School; Physician, Division of Pulmonary and Critical Care Medicine, Massachusetts General Hospital

Faculty Advisor: Anthony Breu, MD

Teaching Faculty, Center for Bioethics, and Assistant Professor of Medicine, Harvard Medical School, at the Brigham and Women's Hospital and VA Boston Healthcare System

Cultivating an Ethics Service at the King Saud University's Medical City

Along with other oil-producing countries in the Arabian Gulf, Saudi Arabia has experienced rapid economic development during the last sixty years. The Saudi health care sector has not kept pace with this rapid growth in general and more specifically lacks sufficient resources in medical ethics: not a single Saudi university offers medical ethics graduate or post-graduate courses. As a result, health care providers are often uncertain about the ethics of their practices. For example, at King Saud University Medical City and its five university hospitals with 1,500 beds, 1,400 physicians, 853 residents and fellows, survey data has shown that seventy-nine percent of the Medical City physicians were unaware of medical bylaws and sixty-eight percent gave wrong answers to questions about medical ethics. Although Saudi clinicians trained in the U.S. and Europe have increased awareness of medical ethics, there is a need to understand and define medical ethics in balance with Arab and Islamic culture for Saudi physicians more broadly. This capstone project used exposure to ethics committees and consult services in the United States to inform content recommendations and structural models for developing increased clinical ethics resources in Saudi Arabia. This work will be used to increase the ethics knowledge amongst Saudi physicians and to build ethics capacity in the Saudi medical system.



Theeb Ayedh Alkahtani, MD, is a lecturer in the Department of Family and Community Medicine at King Saud University, where he also served as acting supervisor for the Forensic Medicine and Toxicology Unit. He received an MBBS from King Saud College of Medicine and completed a medical internship in King Khalid University Hospital. He has longstanding interests in how theology, philosophy, Sharia law, and Arab culture contribute to bioethics.

Jessica Benoit Baker

Capstone Mentor: Candace Nelson, MA, ScD

Deputy Director, Office of Data Management and Outcomes Assessment, Massachusetts Department of Public Health

Faculty Advisor: Rebecca Weintraub Brendel, MD, JD

Director, Master of Bioethics Degree Program, and Assistant Professor of Psychiatry, Harvard Medical School; Director of Law and Ethics, Center for Law, Brain, and Behavior, and Associate Psychiatrist, Massachusetts General Hospital

The Final Rule and Research by Public Health Agencies: Does it go far enough to protect the public?

This capstone considered whether the new Final Rule to the Federal Policy for the Protection of Human Subjects—the “Final Rule”—provides sufficient ethical protections for research participants in the public health arena to serve as a guide for potential policies for the Massachusetts Department of Health (MADPH) Institutional Review Board. The Final Rule sets forth the ethical and regulatory standards for all human subject research sponsored or funded by the U.S. federal government. The purpose of the new regulations is to update research guidelines to better reflect the scientific and ethical realities of the 21st century. Key areas of concern in the revision included improving informed consent and patient education and protecting research participants’ privacy while still promoting scientific advancements to improve human health. After a lengthy comment and review process, the new Final Rule was issued in January 2017. The rule seems to promote flexibility for researchers, yet questions remain as to whether these changes go far enough in protecting the public, particularly in terms of privacy protections. IRBs should adopt policies beyond the requirements of the Final Rule in order to protect research participants and maintain public trust. Specific policy recommendations for the MADPH include: public engagement to determine community standards for informed consent and privacy protection; education about the importance of public health research; adoption of “broad consent” to facilitate secondary research; and development of internal policies to routinely review individual patient data (IPD) anonymization standards.



Jessica Benoit Baker, JD, received a BA in English from Davidson College, a BS in psychology from the University of Utah with highest honors, and a JD from Southern Methodist University. She has a legal background in public interest and health law and is admitted to the state bars in Florida and Texas. Jessica's interests include research ethics, public outreach, and the bioethical and regulatory frameworks of human subjects research. After graduation Jessica plans to work as a project manager for Vivli, a nonprofit developer of a global digital platform for clinical trial data sharing.

Lacey Brennan

Capstone Mentor and Faculty Advisor: Louise King, MD, JD

Director, Reproductive Ethics, Center for Bioethics, and Assistant Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School; Chief, Division of Minimally Invasive Gynecologic Surgery, Beth Israel Deaconess Medical Center

An Ethical Basis for Reforming Gynecologic Surgical Practice

Literature suggests superior outcomes for high-volume surgeons and for laparoscopic versus abdominal hysterectomies. Splitting clinical time between obstetrics and gynecology results in less surgical training for residents and lower surgical volumes for practicing gynecologists. This practice framework perpetuates suboptimal patient care. After hiring two dedicated laparoscopic surgeons, Beth Israel Medical Center (BIDMC) noticed a significant increase in the rate of laparoscopic hysterectomies. This capstone project used a retrospective chart review to quantify the impact of this shift in practice on patient outcomes by examining 2374 hysterectomy cases at BIDMC from 2006 to 2016 to correlate mode of hysterectomy, surgeon volume, OR time, complications, length of hospital admission, and costs. The preliminary results echo the literature and suggest that high-volume surgeons have lower intraoperative and postoperative complication rates despite the increased complexity of cases typically undertaken by high-volume surgeons. We have an ethical obligation to ensure patients are informed of all relevant risks, benefits and alternatives before they consent to surgery. If having a low-volume surgeon is a known risk factor for poor outcomes, patients must be informed of this risk. The results of this study will be used to increase transparency and to advocate for change in gynecologic surgical training and practice in order to improve surgical care for women.



Lacey Brennan, MD, received her MD from the University of Calgary. She completed her BMSc with honours specialization in pathology and toxicology at Western University. Lacey has an interest in reproductive ethics, particularly in advocating for ethical use of reproductive technology, increasing transparency in informed consent, and improving care for women with intellectual disabilities. She will be starting residency in obstetrics and gynecology at the University of Saskatchewan and hopes to continue doing work in bioethics throughout her career.

Manotri Chaubal

Capstone Mentors: Nancy E. Oriol, MD

Faculty Associate Dean for Community Engagement in Medical Education; Associate Professor of Anaesthesia, Harvard Medical School

Rainelle Walker-White, BS

Assistant Director, The Family Van, Harvard Medical School

Faculty Advisor: Louise King, MD, JD

Director, Reproductive Ethics, Center for Bioethics, and Assistant Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School; Chief, Division of Minimally Invasive Gynecologic Surgery, Beth Israel Deaconess Medical Center

Understanding the Boston Community's Concerns About Clinical Trials

Twenty-five years after the National Institutes of Health created the Revitalization Act of 1993 to increase the number of women and minorities in medical research, these groups still remain vastly underrepresented in research and clinical trials. Consequently, the typical research study sample is still disproportionately white, educated, of high socioeconomic status, and male. Given the rapid pace of advancement in personalized medicine, specifically through the precision medicine research program, *All of Us*, and potential for sickle cell CRISPR-Cas9 trials, it is crucial to address this evident disparity as a matter of justice. The purpose of this capstone project was twofold. The first aim was to gain a clearer understanding of the knowledge, attitudes, and experiences of Boston's predominantly minority community regarding clinical trials by directly engaging in dialogue with the clients of the Family Van, a mobile health unit that offers free health screenings to the working-poor in low-income communities in the greater Boston area. By maintaining a constant presence in the community and bringing care to those who have fallen through the cracks of the health care system, the Family Van staff and volunteers have created a network of trust within the community over the past twenty-five years. The second goal of the project was to codesign a method with community members for the Van to serve as a safe space for discussion and access to information about medical research for those interested. Future goals of the project include exploring how the Family Van may offer community members information and greater access to opportunities to participate in medical research.



Manotri Chaubal, BS, majored in biology at Virginia Commonwealth University, where she received the Lewis C. Goldstein Award of Excellence for a student majoring in biology. Her undergraduate research and academics focused on free health care delivery, public health policy, and regenerative medicine. She is interested in bioethical challenges surrounding recruitment and participation of minority groups in clinical trials. In the upcoming year, she plans to apply to medical school while conducting research on health care disparities in a clinical setting.

Alexandra Corwin Aguilar

Capstone Mentor and Faculty Advisor: Aaron S. Kesselheim, MD, JD, MPH

Teaching Faculty, Center for Bioethics, and Associate Professor of Medicine, Harvard Medical School; Associate Physician, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital

Stem Cell Tourism South of the Border: Mexico's direct-to-american-consumer stem cell industry

Breakthroughs in stem cell science have fueled the belief that "miracle cures" for untreatable diseases are widely available abroad. Mexico-based stem cell clinics have capitalized on this hope, offering unregulated and largely unproven stem cell therapies (SCTs) to Americans seeking cures not available in the U.S. This capstone project sought to identify Mexico-based clinics marketing SCTs directly to Americans through English-language websites, and evaluate their claims regarding safety, efficacy, outcomes, quality assurance, and oversight.

A total of twenty-two stem cell clinics were identified in the Mexican cities of Tijuana, Los Algodones, Monterrey, Mexico City, Puebla, and Cancun. While most clinics administer autologous SCTs derived from bone marrow or adipose, two clinics offer induced pluripotent and placental SCTs. Clinics in the study market SCTs for a wide variety of autoimmune, neurodegenerative, and pediatric conditions including autism, Down syndrome and cerebral palsy. Marketing claims regarding efficacy/outcomes ranged from: "get your life back [with SCTs]" to "Research supports ... [Down syndrome] patients undergoing stem cell treatment improve cognition by 60%." Regarding safety, disclosures ranged from "mortality is 0%" to "[procedure is] risk free." Four clinics referenced licensure by COFEPRIS (FDA's counterpart), yet there is no indication of rigorous regulatory oversight by this agency. On the basis of marketing claims and lack of oversight, direct-to-consumer marketing of SCTs raises significant ethical concerns including safety, efficacy, quality control and informed consent. The primary concern is the likelihood that misleading SCT marketing claims expose vulnerable patients to unjustifiable risk without quantifiable benefit. This practice also raises broader questions regarding legal recourse in the event of injury, as well as transnational regulatory and health policy. These findings suggest collaborative efforts by regulatory agencies, researchers, and policymakers in the U.S. and Mexico are necessary in order to ensure adequate oversight and patient safety.



Alexandra (Alex) Corwin Aguilar, OD, JD, is a defense attorney at Montgomery & Andrews Law Firm, Santa Fe, NM. She received a BA in biology from Grinnell College and an OD and JD from University of California, Berkeley. Her legal practice has focused on health law and medical negligence defense. She received the Jurisprudence Award for Legal Issues in Biomedical Ethics from the University of California Berkeley School of Law. Alex plans to focus on bioethics advocacy, health policy, justice, and access to health care.

Miguel Dorante

Capstone Mentors: Martin McKneally, MD, PhD

Professor Emeritus of Surgery, University of Toronto, Department of Surgery and Joint Centre for Bioethics; Visiting Professor of Surgery, Harvard Medical School

Christine Mitchell, RN, MS, MTS

Executive Director, Center for Bioethics, Director, Master of Bioethics Capstone Program, Lecturer on Global Health and Social Medicine, Harvard Medical School

Faculty Advisor: Anthony Breu, MD

Teaching Faculty, Center for Bioethics, and Assistant Professor of Medicine, Harvard Medical School at the Brigham and Women's Hospital and VA Boston Healthcare System

Cross-Cutting Themes in Surgical Ethics: A case-based curriculum

This capstone focused on surgeons' ethical duties to their patients, highlighting the complexities of the surgeon-patient relationship from preoperative assessment through postoperative care. Given the potential for ethical challenges to arise in the course of surgical care, education in surgical ethics is critical and requires both the practical application of medical knowledge and the theoretical application of surgical ethical analysis. However, there is a dearth of surgical ethics education to medical students, residents, and attending surgeons. This capstone project sought to address this unmet need by developing case-based surgical ethics curriculum materials geared towards resident and faculty surgeons through a Surgical Ethics Working (SEWing) Group at the Center for Bioethics. The project explored the fields of cardiothoracic surgery, urology, and plastic surgery, covering cases of total anomalous venous return, gender confirmation surgery, and facial vascularized composite allotransplantation. The SEWing Group invited providers of these procedures to the Center for Bioethics for discussions about cross-cutting themes including surgical innovation, learning curves, adverse events and errors, informed consent, and allocation of resources. Through this project, the SEWing Group developed a framework for creating ethics teaching cases in surgery. The framework incorporated medical facts, pertinent contextual evidence around the case, and patient narrative for ethical analysis from a surgeon's perspective. With this framework, the SEWing Group developed four in-depth cases to be used as training material. The SEWing Group is now working to share this experience and knowledge through academic scholarship in surgical journals.



Miguel Dorante, BS, is a medical student at Boston University School of Medicine. He received a BS in biomedical engineering with a minor in philosophy from Johns Hopkins University. Miguel believes that bioethics is a necessary and complimentary field to his interests in reconstructive plastic surgery. After graduating, he will return to medical school and apply to plastic and reconstructive surgery residency programs. His interests are in vascularized composite allotransplantation and organ donation, gender confirmation surgery, and craniomaxillofacial reconstruction.

Gabrielle Dressler

Capstone Mentors: Lachlan Forrow, MD

Faculty Associate, Center for Bioethics, and Associate Professor of Medicine, Harvard Medical School; Director of Ethics Programs, Beth Israel Deaconess Medical Center

Areej El-Jawahri, MD

Associate Director, Cancer Center Survivorship Program, and Director, Bone Marrow Transplant Survivorship Program, Massachusetts General Hospital; Instructor in Medicine, Harvard Medical School

Faculty Advisor: J. Wesley Boyd, MD, PhD

Teaching Faculty, Center for Bioethics, and Associate Professor of Psychiatry, Harvard Medical School; Codirector of Human Rights and Asylum Clinic, Cambridge Health Alliance

Validation of a Prognostic Awareness Questionnaire for Patients with Advanced Cancer

When faced with a life-altering cancer diagnosis, patients must often make very difficult decisions regarding their overall goals of treatment. Patients' understanding of their disease process and prognosis have been shown to factor heavily into such medical decisions. However, there is no effective instrument to assess cancer patients' perceptions of their illness and treatment goals. The purpose of this capstone project was to evaluate the content validity and readability of a prognostic awareness questionnaire developed by oncologists, psychiatrists, psychologists, and palliative care clinicians from the Cancer Outcomes Research Program (CORe) and Division of Palliative Care and Geriatric Medicine at Massachusetts General Hospital (MGH). Work with this research team, led by Areej El-Jawahri, MD, involved administering the questionnaire to patients with advanced cancer during their infusion appointments at MGH, conducting cognitive interviews upon survey completion, analyzing audio recordings of participant responses, determining their understanding of individual survey items, and ultimately creating a refined version of the questionnaire for future use. In addition to this empirical work, the project also included an ethical analysis of prognostic awareness questionnaires as clinical tools under the guidance of capstone mentor Lachlan Forrow, MD.



Gabrielle Dressler, BA, is a research assistant for the Division of Palliative Care and Geriatric Medicine at Massachusetts General Hospital. She received a BA in English and Russian literature from Columbia University and subsequently completed the Harvard Extension School Premedical Program. Gaby's interests include the ethical and legal questions surrounding end-of-life care and narrative medicine. She will attend medical school in the fall.

Rhian Evans

Capstone Mentors: Robert Green, MD, MPH

Professor of Medicine, Harvard Medical School; Director, G2P Research, Division of Genetics, Brigham and Women's Hospital; Associate Member, Broad Institute of Harvard and MIT

Kurt Christensen, PhD

Instructor in Medicine, Brigham and Women's Hospital

Faculty Advisor: Aaron S. Kesselheim, MD, JD, MPH

Teaching Faculty, Center for Bioethics, and Associate Professor of Medicine, Harvard Medical School; Associate Physician, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital

Determining Clinical Utility in Whole Genome Sequencing of Healthy Adults

There are high hopes for genomic sequencing and its place in the future of medicine and health care, but it is not yet known whether whole genome sequencing (WGS) in healthy individuals for screening purposes will be clinically useful. As a result, the ethical basis for use of WGS in this context, particularly at a population level, is unclear. It is unknown whether the potential benefits, such as clinical utility, outweigh the potential harms of negative psychosocial outcomes and economic impact. Authoritative evidence on both sides is lacking, with evidence about clinical utility noticeably absent. This capstone project began to address this unmet need by conducting a secondary analysis of data gathered in the MedSeq Project, a pilot randomized trial that assessed the impact of disclosing risk information gained from WGS to patients and physicians. This project asked what short-term clinical utility WGS provides to healthy primary care patients. It assessed clinical utility using four outcomes, adapted from those proposed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) initiative: (1) diagnostic thinking/health information impact, (2) patient outcome impact, (3) familial and social impact, and (4) perceived utility. This project also included a subanalysis to explore whether return of 'high risk' results yielded greater clinical utility than 'low risk' results. Preliminary results are inconclusive for positive findings of clinical utility by randomization status. However, the findings suggest that greater clinical utility is found in patients who are classified as high risk than those classified as low risk. This finding is interesting, particularly because it has been found that 'high risk' findings are more common within the population than previously assumed. While limited in its scope and by its sample size, this study has helped to clarify important areas of focus for future studies, which may expand upon and provide further insight into determining the clinical utility of WGS as a screening tool in healthy adults.



Rhian Louise Evans, LLB, MA, is a medical student at Barts and The London School of Medicine and Dentistry. She received her LLB in law from Nottingham University, and her MA in medical ethics and law from King's College London. She completed the Sherwin B. Nuland Summer Institute in Bioethics at Yale University, and was awarded the Institute of Medical Ethics Intercalated Scholarship. In the fall she will return to medical school where she will begin her clinical years.

Ariel Henig

Capstone Mentor: Elaine Meyer, PhD, RN

Faculty Associate, Center for Bioethics, and Associate Professor of Psychology, Harvard Medical School; Senior Attending Psychologist, Boston Children's Hospital

Faculty Advisor: Louise King, MD, JD

Director, Reproductive Ethics, Center for Bioethics, and Assistant Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School; Chief, Division of Minimally Invasive Gynecologic Surgery, Beth Israel Deaconess Medical Center

Whether, When, and How Anesthesia Residents Solicit Patients' Questions During Informed Consent

Anesthesiologists often obtain informed consent from patients right before surgery. However, patients' inadequate understanding of information may limit their ability to fully participate in the informed consent process. Soliciting and answering patients' questions is vital to meeting the needs of patients, upholding the integrity of the informed consent process, and applying the ethical principle of respect for patient autonomy. When and how residents solicit patients' questions may affect the ability of their patients to participate in the informed consent process.

This capstone project used analysis of video tapes to determine whether, when, and how clinical anesthesia residents solicited patients' questions through simulated informed consent encounters. The case involved a 52-year-old standardized patient awaiting emergency surgery for a perforated gastric ulcer. Results showed that the majority of residents solicited patients' questions, though one fourth of the residents did not engage in question solicitation. Results also demonstrated considerable variability in quality and timing of question solicitation. These findings suggest that there is room for improvement with respect to the solicitation of patients' questions during the preoperative anesthesia informed consent process. Anesthesia residents may benefit from educational and practical opportunities to incorporate question-asking within the informed consent conversation (as compared to at the end) and ensure that patients have more than sufficient opportunity to ask questions. Meeting the informational and decisional needs of the patient during the informed consent process, through repeated and welcoming solicitation of questions, should be emphasized.



Ariel Henig, BA, majored in neuroscience at Swarthmore College and is certified as an emergency medical technician. Ariel's research interests include bioethical issues related to women's health and ethics education. Her capstone project was accepted to the 2018 Research Forum of the Academy of Communication in Healthcare, and she was awarded one of ten scholarships allocated by the conference to cover the cost of attendance. Ariel was also a member of the winning team of the 2018 Global Mental Health Hackathon at Harvard. Following the completion of her MBE, she plans to attend medical school.

Gali Katznelson

Capstone Mentors: Carmel Shachar, JD, MPH

Executive Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

I. Glenn Cohen, JD

Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, and Professor of Law, Harvard Law School

Faculty Advisor: Eric G. Campbell, PhD

Director of Research Ethics, Center for Bioethics, and Professor of Medicine, Harvard Medical School; Core Faculty, Mongan Institute for Health Policy, Massachusetts General Hospital

Exploring the Wild West: Smartphone mental health apps in clinical settings

There are thousands of smartphone applications (apps) available for download that are intended to help individuals manage or improve their mental health, yet the U.S. Food and Drug Administration does not regulate the majority of these apps. Some health apps have posed risks to consumers, such as misinformation and data breaches. The purpose of this qualitative study was: 1) to assess trends in the support of smartphone mental health apps by clinicians, 2) to identify concerns regarding such technologies, and 3) to assess attitudes toward existing and potential regulations and guidelines. Interviews were conducted between January and March 2018 with mental healthcare professionals (13 clinical psychologists and 9 psychiatrists) and analyzed using a thematic coding method. Findings revealed that 14 participants (64%) supported patients in using various smartphone apps as adjuncts to clinical care. Though participants were mostly optimistic about the future implementation of smartphone apps into mental health care delivery, they raised varied concerns regarding evidence standards, privacy and security standards, depersonalization of mental health care delivery, use without a professional, self-diagnosis, the rapid pace of innovation, a disconnect between app developers and the clinical community, and screen effects. Most participants were not aware of, nor reliant upon guidelines that could help them implement apps into their clinical workflow and were eager for more direction, though not necessarily in the form of further regulations.



Gali Katznelson, B.Arts Sc., received a bachelor's degree in arts & science from McMaster University. This year, she served as a student fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and wrote about on various ethical issues for the Center's blog, "Bill of Health." She is particularly interested in the ethics of emerging health care technologies. Gali plans to attend medical school in Canada.

Armenouhi Kazaryan

Capstone Mentor: David Sontag, JD, MBE

Teaching Faculty, Center for Bioethics, and Faculty, Harvard/MIT Health Sciences and Technology; Deputy General Counsel, Beth Israel Deaconess Medical Center

Faculty Advisor: Patrick Smith, PhD

Teaching Faculty, Center for Bioethics, and Lecturer on Global Health and Social Medicine, Harvard Medical School; Associate Professor of Philosophical Theology and Ethics, Gordon-Conwell Theological Seminary

Organizational Bioethics: An ethics needs assessment at Lahey Hospital and Medical Center

Since The Joint Commission announced its expansion of patient rights and standards in 1995, hospitals across the U.S. have been expected to assure their commitment to ethical organizational practice. Given the role of hospital ethics committees, this study focused on assessing staff understanding and utilization of ethics services offered by the Ethics Section at Lahey Hospital and Medical Center (LHMC). The primary aim of this study was threefold: (1) to identify areas of ethical concern, (2) to assess gaps in ethics knowledge and/or service utilization, and (3) to provide insight/recommendations as to how the LHMC Ethics Section might improve upon its current ethics practices and services. In collaboration with the LHMC Ethics Section co-chairs, primary data was collected through quantitative and qualitative survey questionnaires and interviews. Two versions of the survey were distributed to 51 chief hospital administrators and clinicians; an administrative version was distributed among key medical administrators and a clinical version of the survey was distributed to heads of clinical departments. Nine qualitative interviews were also conducted with members of the LHMC Ethics Section and other administrative leaders. As a preliminary finding, three methodologically significant ethical considerations were found to help foster the process of developing a valuable and comprehensive ethics needs assessment; (1) understanding an organization's culture and climate in relation to its ethics and defined mission (i.e. knowledge of the audience), (2) collaborating with organizational insiders to create an effective and appropriate survey (i.e. know what questions to ask), and (3) thinking carefully about semantics when developing an ethics survey (i.e. know how to ask questions). As an ongoing study, final recommendations will be provided when a significant number of key stakeholders have expressed their thoughts and experiences with ethics services at LHMC.



Armenouhi (Amy) Kazaryan, MPhil, received a BA in anthropology from UC Berkeley and an MPhil in medical anthropology from the University of Oxford. Given her experience in Western and non-Western medical interventions, she is interested in reconciling epistemologically different ethical frameworks, particularly through an ethics of care approach which focuses on the rights and welfare of vulnerable patient populations in both clinical care and research settings, as well as in relation to organizational ethics. Her future goals involve ethics-oriented policy development for health care institutions within the public and private sectors.

Sarah Kelly

Capstone Mentor: Stephen F. O'Neill, LICSW, BCD, JD

Teaching Faculty, Center for Bioethics, Harvard Medical School; Associate Director, Ethics Support Service, Beth Israel Deaconess Medical Center

Faculty Advisor: J. Wesley Boyd, MD, PhD

Teaching Faculty, Center for Bioethics, and Associate Professor of Psychiatry, Harvard Medical School; Codirector of Human Rights and Asylum Clinic, Cambridge Health Alliance

Transparency and Support around Medical Error: Does practice live up to policy?

Medical error is one of the leading causes of death in Western nations. To combat this problem, there have been recent public policy and legal reforms in the United Kingdom aiming to engender a culture of openness and transparency that better addresses and learns from incidents of medical error. For example, in 2014, the Health and Social Care Act introduced a statutory duty of candour mandating disclosure and apology for any incident that causes moderate physical or psychological harm. Other professional policies emphasize that health care organizations themselves have a duty to support their staff in reporting and learning from adverse incidents. However, there have been no concurrent educational or institutional changes to support these statutory and professional obligations. Current practice around institutional handling of medical error continues to fall short of professed policy and legal standards, as was borne out in the case of Hadiza Bawa-Garba. Following an incident in 2011, Dr. Bawa-Garba—a trainee paediatrician—was convicted of gross negligence manslaughter in November 2015 and erased from the UK medical register in January 2018 despite strong consensus among the medical community that her conduct did not meet negligence standards and the error was primarily due to systemic failings. This capstone project examined how the handling of the Bawa-Garba case demonstrated the significant gap that remains between policy and practice, with particular focus on how blame continues to be centred on individuals, rather than institutions. Capstone fieldwork was also undertaken at Beth Israel Deaconess Medical Center to gain familiarity with the work of their ethics program and staff to develop a culture of respect and transparency. Attention focused on how an institutional model of encouraging and supporting transparency might translate to the UK and provide a means of supporting clinicians and patients following incidents of medical error.



Sarah Kelly, BSc, is a medical student at the University of Edinburgh, Scotland. She received an intercalated bachelor of science degree from King's College London in medical ethics and law. Sarah's interests include end-of-life care, psychiatric ethics, and justice in health care. She was the winner of the Institute of Medical Ethics Intercalated Scholarship and serves as secretary of the UK Medical Student Ethics Council. Sarah plans to return for her fourth year at Edinburgh Medical School.

Marisa Levinson

Capstone Mentor: Brenden Abel, JD

Teaching Faculty, Center for Bioethics, Harvard Medical School; Legislative and Regulatory Affairs Counsel, Massachusetts Medical Society

Christine Mitchell, RN, MS, MTS

Executive Director, Center for Bioethics, Director, Master of Bioethics Capstone Program, Lecturer on Global Health and Social Medicine, Harvard Medical School

A Push for Supervised Injection Facilities in Massachusetts: Identifying barriers to implementation of novel opioid use disorder treatment

A supervised injection facility (SIF) is a place where individuals may use their own injection drugs under the supervision of clinicians. SIF staff provide clean needles; medical care, such as the opioid-reversal agent naloxone for overdoses; and information and referrals for treatment. There are approximately 100 authorized SIFs in at least sixty-six cities in nine countries worldwide, though none are currently legally operating in the United States. SIFs function as an integral piece of a harm-reduction strategy by lowering the incidence of fatal and nonfatal overdoses, reducing the transmission of infectious disease, and bridging those who use SIFs into health care and addiction treatment programs. In the face of an opioid epidemic that claimed roughly 2,000 lives in Massachusetts in 2017, there exists a moral obligation to reduce harm. Informed by interviews with key leaders in the Boston addiction treatment community, this capstone project focused on gaining an understanding of the current harm reduction and treatment options available to persons in Massachusetts with opioid use disorders and identifying barriers to opening a pilot SIF in the Commonwealth. This work highlighted that public opinion often runs counter to scientific evidence, and stigma from the community has played a large role in the pushback against SIFs. As such, bioethics has a role in revealing and eliminating harmful bias and barriers to health care for vulnerable populations. Work with SIF advocates at the Massachusetts Medical Society to assemble a critical interpretive literature review of the current research has identified a lack of data on clinicians' attitudes towards SIFs in the United States. Support from trusted physicians and nurses in the community will be crucial in weakening stigma, and eventually, in opening and staffing a SIF.



Marisa Levinson, RN, BSN, received her BSN from the University of San Francisco. She is a registered nurse at Massachusetts General Hospital, where she works on an adult inpatient general medicine unit. Marisa is a member of Mass General's Optimum Care (ethics) Committee. Through her work caring for a growing number of patients with substance use disorders, she has become especially interested in exploring the ethics of opioid use and misuse. She hopes to continue her work related to the opioid epidemic while integrating clinical ethics into bedside nursing practice.

Dylan Marashi

Capstone Mentor: Christine Mitchell, RN, MS, MTS

Executive Director, Center for Bioethics; Director, Master of Bioethics Capstone Program, Lecturer on Global Health and Social Medicine, Harvard Medical School

Faculty Advisor: Patrick Smith, PhD

Teaching Faculty, Center for Bioethics, and Lecturer on Global Health and Social Medicine Harvard Medical School; Associate Professor of Philosophical Theology and Ethics at Gordon-Conwell Theological Seminary

Harvard Medical School Bioethics Journal, Issue 3

Bioethics has emerged as a new field of inquiry and action focused on the ethics concerning health, illness, and medicine. Clinicians, researchers, lawyers, and philosophers have each made significant contributions. And yet, bioethics is still in the process of defining itself and being defined. As the field continues to develop and establish a professional presence, the Harvard Medical School Bioethics Journal aims to document and support the academic and research foundations of the field of bioethics. Like other media domains, this journal has involved a multidisciplinary team and group of content experts to write and review manuscripts. However, its free access, online presence, and international outlook aim to move the field beyond its American beginnings. The balance between academic rigor and wide-readability represents an important and critical tension of the Harvard Medical School Bioethics Journal. Bioethics should not only serve bioethicists but also the diverse perspectives and interests of those outside of bioethics. It is difficult to relate ethics to local contexts while also avoiding dangerous misunderstandings and oversimplifications. This is a necessary project in bioethics, to which this edition of the HMS Bioethics Journal can make a modest contribution.



Dylan Marashi, BS, received a BS from Seattle Pacific University with a concentration in biochemistry. His independent research and fieldwork has explored the ethical and legal issues surrounding genetics, including reproductive autonomy, personalized medicine and the return of incidental findings in research. As he prepares and submits his medical school applications, he will be teaching medical ethics to pre-medical students studying abroad in Budapest, Hungary.

Alison Parmar

*Capstone Mentor and Faculty Advisor: Christine Mitchell, RN, MS, MTS
Executive Director, Center for Bioethics; Director, Master of Bioethics Capstone Program,
Lecturer on Global Health and Social Medicine, Harvard Medical School*

Disaster Ethics: Resource allocation

The goal of this capstone project was to examine differing views on decision making during a crisis to help inform comprehensive disaster planning for hospitals, while increasing engagement in the topic and generating awareness of disaster planning.

One aspect of disaster planning is developing a framework to support decisions about resource allocation that may arise from either a patient surge or a resource shortage. This process is often referred to as “crisis standards of care”, and the Commonwealth of Massachusetts is actively engaged in this topic. In the most extreme situations, a hospital must be prepared to face questions related to re-allocation of resources (taking a resource from one patient and giving it to another). This aspect of disaster planning is fraught with difficult decisions, however both the fields of emergency preparedness and ethics provide frameworks for facing such difficult decisions; therefore the combined knowledge offers an opportunity to develop the necessary plans.

This project accepted the premise that crisis standards of care and resource reallocation are a critical aspect of emergency planning. This work will inform future discussions investigating the feasibility of implementing operational changes that may be contrary to individual clinicians’ diverse ethical beliefs, as measured by a series of scenario-based workshops and a survey of Massachusetts General Hospital clinicians.



Alison Parmar, JD, received a BA in sociology from the University of Massachusetts at Amherst and a JD with a focus in health care administration from New England School of Law. She is currently the senior administrative manager with the Center for Disaster Medicine at Massachusetts General Hospital. Ali has a thorough understanding of the legal system to ensure the Mass General program is developed within the framework of the evolving regulations in the healthcare industry. She looks forward to leading new advances in the exploration of disaster ethics.

Jay Pravda

Capstone Mentor: Melissa Abraham, PhD

Assistant Professor of Psychology, Harvard Medical School; Director, Research Ethics Consultation Unit, Division of Clinical Research, Massachusetts General Hospital

Faculty Advisor: Rebecca Li, PhD

Teaching Faculty, Center for Bioethics, and Instructor in Medicine, Harvard Medical School; Executive Director, Vivli

Conceptual Evolution of the Therapeutic Misconception

Informed consent is at the center of human subjects research because it provides participants with the necessary information to make an autonomous and voluntary decision regarding study participation. Despite having read and signed an informed consent form, research suggests that some study participants are not fully aware of the implications of study participation. The failure to appreciate the difference between the goals of clinical research and ordinary clinical care is called the Therapeutic Misconception (TM). The presence of the TM implies that study participants are not providing fully autonomous consent for their participation, which poses a challenge to the ethical basis of study participation. Three categories of TM have been identified and include; (1) an erroneous expectation of benefit (TM1); (2) a failure to understand the imperatives of clinical trials (TM2); and (3) a failure to grasp that clinical studies are undertaken to produce generalizable knowledge in order to help future patients (TM3). Interventions aimed at addressing the TM have met with limited success. This capstone project tracked the conceptual evolution of the TM from its early recognition in 1982 until the present and identified the various interventions employed to address the TM, reported to be present in fifty to 100 percent of study participants.



Jay Pravda, MD, MPH, earned an MD at the University of Puerto Rico School of Medicine and an MPH at the Harvard T.H. Chan School of Public Health. He completed a residency in medicine at San Juan City Hospital and an allergy/clinical immunology fellowship at the Mayo Clinic. He is the CEO of Therashock, LLC, a drug development company that is repurposing an FDA-approved drug to treat sepsis and septic shock. Jay plans to use his training in bioethics to aid in the development of treatments for diseases with unmet needs, and to function as a freelance bioethicist so that he may address important ethical issues from an independent perspective.

Courtney Sarkin

*Capstone Mentor: Elizabeth Schwartz, MPH
Community Health Coordinator, Komen New England*

*Faculty Advisor: Judith A. Johnson, JD
Teaching Faculty, Center for Bioethics, Harvard Medical School, and Lecturer on Anaesthesia,
Boston Children's Hospital*

Queering Bioethics: Why integrating cultural humility into medical education matters

The interplay between culture, identity, and health has an impact on health outcomes. In the health care setting a variety of provider-driven cultural biases reinforce the marginalization of LGBTQ+ patients, especially those with intersectional self-definition. This marginalization is compounded by health conditions, such as breast cancer, that are described as inherently abnormal. Further, cultural understandings of health, illness, and disease invoke moral judgments. This confluence shapes beliefs about breast cancer risk and response to/by LGBTQ+ patients. In seeking to influence the nature of care of LGBTQ+ patients, medical education has developed cross-cultural communication strategies involving cultural competency standards, yet these have limited clinicians' abilities to examine their own cultural standpoints that influence the care of LGBTQ+ patients. This project examined how an alternative model of cultural humility, which motivates clinicians to examine their own cultural biases and assumptions, as well as the power imbalances inherent in the patient-provider relationship, could enable a queering of medical education. This queering would involve changing the structure of how LGBTQ+ individuals' health is understood, both by centering and privileging the voices of LGBTQ+ patients and examining how the provider-patient interaction is shaped by sociocultural context. To work toward the elimination of LGBTQ+ health and breast cancer disparities, clinicians have an ethical responsibility to engage with cultural humility. Further, in a commitment to social justice, bioethics should actively pursue cultural humility as an integral aspect of bioethical inquiry. The queering of both bioethics and medical education is essential for: 1) actively creating space for patients to become part of the ethical conversation around healthcare and 2) alleviation of health and breast cancer disparities.



Courtney Sarkin, BA, received BAs in molecular and cell biology, legal studies, and gender studies from University of California, Berkeley. She most recently worked as a legislative aide for California State Senator Carol Liu. As a Rose Hills Fellow at UC Berkeley, she conducted independent research on the healthcare experiences of lesbian and trans* breast cancer patients and survivors. As an incoming health services research, policy, and administration PhD candidate at the University of Minnesota, Courtney hopes to continue advancing social justice and closing gaps in health disparities by addressing ethical, legal, and social complexities created when identities intersect within the medical field, specifically in cancer care.

Samar Shahid

Capstone Mentor: Sharon Shriver, PhD

Director of Programs, PRIM&R, Public Responsibility in Medicine and Research

Faculty Advisor: Rebecca Li, PhD

*Teaching Faculty, Center for Bioethics, and Instructor in Medicine, Harvard Medical School;
Executive Director, Vivli*

Creating Accessible Educational Tools for Institutional Review Boards

Research Ethics Snapshots is a resource designed by Public Responsibility in Medicine and Research (PRIM&R) to provide institutional review boards (IRBs) with opportunities for short educational sessions at IRB meetings, and to help IRB members stay up-to-date on current regulations while tackling important ethical issues. Research ethics snapshots are one-page guidelines about emerging and unsettled issues in bioethics designed to aid discussion among members of IRBs reviewing proposed research involving human subjects. They serve as educational tools that introduce a bioethical challenge, provide some background information with and a mini case study concerning the relevant topic, and offer a set of questions designed to promote discussion and practical application.

The goal of this capstone was to work with PRIM&R to create two research ethics snapshots—one on obtaining assent in research with children, and another on conflicts of interest regarding academic-industry partnerships. To create these snapshots, this capstone targeted select subject areas that are current and relevant to IRBs. The challenge was to identify topics that were complex enough to generate thoughtful discussion, but that could also be condensed into a one-page format useful for a focused, brief educational session. These snapshots provide an example of an ethically challenging case that IRB members might face, suggest questions they should raise that identify the key ethical dilemmas, and provide links to additional material for further reference. After drafting the snapshots, each was reviewed by two subject matter experts for their feedback and to ensure validity and coherence. The final versions of the snapshots developed through this work are accessible through the *Knowledge Center* on the PRIM&R website for IRB staff and members.



Samar Shahid, BS, received a BS in biology with a minor in sociology from the University at Albany. She researched *tui na* (traditional Chinese medicine) at Chengdu University of Traditional Chinese Medicine, in China. Samar was previously a lead clinical research coordinator at Columbia University Medical Center in the Department of Obstetrics and Gynecology. She has worked on NIH research studies for maternal-fetal medicine where she interacted with vulnerable populations. Her interest in bioethics stems from her passion to ensure quality and integrity within research. Samar plans to return to the research setting, incorporating research ethics into practice.

Elizabeth Siliski

Capstone Mentor: Christine Mitchell, RN, MS, MTS

Executive Director, Center for Bioethics, Director, Master of Bioethics Capstone Program, Lecturer on Global Health and Social Medicine, Harvard Medical School

Faculty Advisor: Judith A. Johnson, JD

Teaching Faculty, Center for Bioethics, Harvard Medical School, and Lecturer on Anaesthesia, Boston Children's Hospital

Harvard Medical School Bioethics Journal, Issue 2

Bioethics has emerged as a new field of inquiry and action focused on the ethics concerning health, illness, and medicine. Clinicians, researchers, lawyers, and philosophers have each made significant contributions. And yet, bioethics is still in the process of defining itself and being defined. As the field continues to develop and establish a professional presence, the Harvard Medical School Bioethics Journal aims to document and support the academic and research foundations of the field of bioethics. Like other media domains, this journal has involved a multidisciplinary team and group of content experts to write and review manuscripts. However, its free access, online presence, and international outlook aim to move the field beyond its American beginnings. The balance between academic rigor and wide-readability represents an important and critical tension of the Harvard Medical School Bioethics Journal. Bioethics should not only serve bioethicists but also the diverse perspectives and interests of those outside of bioethics. It is difficult to relate ethics to local contexts while also avoiding dangerous misunderstandings and oversimplifications. This is a necessary project in bioethics, to which this edition of the HMS Bioethics Journal can make a modest contribution.



Elizabeth Siliski, RN, BSN, CCRN, works as nurse in the Surgical Intensive Care Unit (SICU) at Massachusetts General Hospital. She received her BS in neuroscience and behavioral biology from Emory University and later completed an accelerated bachelors of nursing at the MGH Institute of Health Professions. Beth coordinates her unit's ethics rounds and is a member of the MGH Optimum Care Committee (OCC). She is interested in the process of ethics consultation, caregiver moral distress, and the ethics of death and dying. Following graduation, Beth will continue to work in the SICU while orienting to the role of OCC ethics consultant.

Genevieve Simpson

Capstone Mentor: Joseph T. Giacino, PhD

Teaching Faculty, Center for Bioethics, and Associate Professor of Physical Medicine and Rehabilitation, Harvard Medical School; Director, Rehabilitation Neuropsychology, Spaulding Rehabilitation Hospital

Faculty Advisor: Laura Specker Sullivan, PhD

Research Fellow, Center for Bioethics, Harvard Medical School

Navigating Health Care Challenges After Severe Acquired Brain Injury

Severe acquired brain injury is a catastrophic event that leads to significant clinical, ethical, and socioeconomic challenges for patients and their families. These challenges are compounded by restrictive language around eligibility criteria in regulatory policies among federal and commercial payers, which often hinder admission to inpatient rehabilitation programs and access to long-term services and supports. This capstone project was initiated to obtain a first-person account of the variety of challenges faced by patients and family caregivers across the first year post-injury, as they navigate the U.S. health care system. The larger project, of which this is a part, will have three phases and in total is expected to span 24-36 months. Phase I—the focus of the capstone—consisted of developing investigational and regulatory materials to enable data collection in Phase II. Preparatory activities included completion of a detailed literature review, interviewing brain injury specialists and researchers, and establishing a collaborative agreement with neuroethicist, Dr. Joseph J. Fins, to assist with the design of the project. Additionally, meetings were arranged with personnel from the Quality Assurance, Compliance, and Public Relations Departments at Massachusetts General Hospital and Spaulding Rehabilitation Hospital, to ensure adherence to institutional, legal, and regulatory policies. Finally, the institutional review board application (with the protocol summary and consent forms) was prepared, and structured interview forms for use with caregivers and providers were developed. During Phase II, structured interviews will be conducted with up to five patients and their families, along with their care providers, to capture real-time personal experiences encountered by both participant groups, from the Neuro-ICU, through post-acute care settings, to community reentry. Phase III will provide quantitative analysis of interview data to inform educational materials tailored to consumer and professional audiences



Genevieve Emma Simpson, BSc, MPhil, received a BSc in neuroscience from the University of Bristol and an MPhil by research in chemical engineering and biotechnology from the University of Cambridge. She is interested in ethical dilemmas posed by clinical research, clinical practice and the use of innovative technologies. Upon return to the UK, Genevieve hopes to continue with bioethical enquiry and Alzheimer's research. She will also continue to grow her small London-based digital health start-up.

Shivam Singh

Capstone Mentor: K. Babu Krishnamurthy, MD, MBE

Director of Epilepsy and Ethics Associate, Steward Medical Group; Lecturer in Neurology, Harvard Medical School

Faculty Advisor: Eric G. Campbell, PhD

Director of Research Ethics, Center for Bioethics, and Professor of Medicine, Harvard Medical School; Core Faculty, Mongan Institute for Health Policy, Massachusetts General Hospital

Ethics Consultation Teaching Tools for Health Care Providers

Ethics consultations are helpful in resolving ethical dilemmas, reducing moral distress and costs, and navigating conflicts between patients, families, and care providers. This project considered whether further education for health care providers would increase the number of consultation requests, possibly providing additional benefits. The objective of this project was to develop teaching tools to: 1) promote awareness of the availability of ethics consultations, 2) educate and inform providers about situations where consultations may be useful, and 3) reduce the time from patient's admission to date of request for ethics consultation. The most frequent reasons for ethics consultations were identified from a literature review and from research previously conducted at Boston Medical Center (BMC). The results of the capstone study showed that the most frequent consult requests from the literature were: withdrawing/withholding therapy, conflict resolution, code status, appropriateness of treatment, and patient autonomy. The most frequent consult requests from BMC were concerns about decision-maker choice, futility or inappropriateness of non-beneficial treatment, withdrawing/withholding life-sustaining treatment, moral distress, and goals of care. This data has informed development of a teaching module on the common reasons for obtaining ethics consults, mechanisms to obtain ethics consultants, and a representative case highlighting potential ethical issues that might generate consult requests. It has also led to the development of an employee badge card to facilitate ethics consultation. Future plans include validating common reasons for calling consultations using the Beth Israel Deaconess Medical Center consult database, using the teaching module for incoming interns and residents, and collecting pre- and post-implementation data on numbers of consultations called, and on time from admission to consult request.



Shivam Singh, BSc, received his BSc with an honours specialization in genetics at the University of Western Ontario in London, Canada. His research work focused on using polymorphisms to predict outcomes of delayed graft function in post-renal transplant patients. He was the recipient of the 2016 DUROP research-funding award at Western University and served on the executive leadership board of the HMS Medical Genetics Interest Group for 2017-2018. He is interested in various topics in bioethics including gene-editing and patient access in genomics, medically assisted dying, and global health and human rights. He plans to attend medical school following the completion of the program.

Zaev Suskin

Capstone Mentor: Laura Specker Sullivan, PhD

Research Fellow, Center for Bioethics, Harvard Medical School

Faculty Advisor: Robert Truog, MD, MA

Director, Center for Bioethics, Frances Glessner Professor of Medical Ethics, Professor of Anaesthesia and Pediatrics, Harvard Medical School at Boston Children's Hospital

Ensuring the Qualitative Development of Deep Brain Stimulation

Deep brain stimulation (DBS) is a neurosurgical procedure in which electrodes are implanted in order to target, measure, and modulate specific brain activities. Although most often used to treat movement disorders, DBS has gained traction for therapeutic use in neuropsychiatric illnesses and neuroenhancement. However, the development of DBS has largely ignored nonclinical and qualitative information about how the device is used. This information is critical so that ethical and technical development of DBS hardware, software, and procedures may incorporate 'lived experiences' of patients and caregivers. This is crucial in the context of increasing use of DBS, concerns about pertinent side-effects, phasing out of qualitative information by closed-loop developments, limited sources of device production in the U.S., and broad lack of FDA oversight. The purpose of this capstone project was to determine the amount and type of qualitative research on DBS available and to ascertain its content regarding non-clinical perspectives. A systematic literature review identified 505 publications and 22,452 participants from whom qualitative data had been obtained. However, of those, only eighty-six studies (seventeen percent) and 5,179 participants (twenty-three percent) fulfilled inclusion criteria. Overall, the review showed that studies of DBS existed for thirty-two illnesses and were conducted in thirty-six countries. Only twenty-four percent of these studies were conducted in the U.S and had stagnated in the last five years. Data was additionally limited by short length of follow-up (seventy-four percent did not go beyond one year), limited non-clinical assessment (only nine percent left room for unique input), and lack of caregiver input (only one percent). Further investigation of the implications of these results and end-user narratives are forthcoming.



Zaev David Suskin, BA, is a fourth year medical student at Georgetown University, where he plans to matriculate to a neurosurgical residency. He earned a BA at Vanderbilt University, where he triple-majored in philosophy, psychology (cognitive neuroscience), and medicine, health, & society. He received the Scholl Fellowship at the Pellegrino Center for Clinical Bioethics in 2016. His primary bioethical interests are in neuroethics, particularly the use of functional neurosurgery for psychiatric illnesses, evolutionary morality, and neurolaw.

Robert Torrance

Capstone Mentor: Robert Tasker, MD, MA, DCH, FRCPC, FRCPC, FHEA

Professor of Neurology, Harvard Medical School; Senior Associate in Critical Care Medicine; Director, Pediatric NeuroCritical Care Program, Boston Children's Hospital

Faculty Advisor: Robert Truog, MD, MA

Director, Center for Bioethics, Frances Glessner Professor of Medical Ethics, Professor of Anaesthesia and Pediatrics, Harvard Medical School at Boston Children's Hospital

Sudden Unexpected Death In Epilepsy (SUDEP): Should all epilepsy patients be informed of the risk?

Sudden and unexpected death in epilepsy (SUDEP) cannot be prevented, and for this reason it is argued that the risk (1/1000 adults and 1/4500 children) should not be disclosed because the information may cause significant distress with no discernible gain. However, the American Academy of Neurology recommends disclosure of SUDEP to all patients with epilepsy. This capstone focused on the ethics of SUDEP disclosure. This project used a systematic literature search of the MEDLINE database for articles about SUDEP disclosure in epilepsy with subsequent collation and analysis of the ethical content. Thirteen of an initial 1,389 articles identified met the inclusion/exclusion criteria for detailed inspection and were critically reviewed. Nine of these studies had surveyed physicians, patients, and relatives to seek views about SUDEP disclosure. The data revealed that 77.6 percent of patients/relatives (n=232) supported disclosure. However, of 2,166 physicians surveyed, only 14.6 percent counselled more than fifty percent of epileptic patients about SUDEP. The discrepancy between the preferences of patients/relatives and the practice of physicians identified in this study suggests that SUDEP disclosure should be more frequent. Yet informing all patients about SUDEP, regardless of their desire for information, is problematic. First, since SUDEP is unpreventable, the patient's right not to know about SUDEP may supersede their right to this information. Second, patients and relatives often wanted to know about SUDEP in the mistaken belief that they could affect outcome, which questions the value of the finding that the majority of patients and relatives support disclosure. Third, since some patients would not want to know about SUDEP, providing this information to prepare relatives for such an event is in conflict with the dictum 'patients come first.' In summary, the findings indicate that increased disclosure of SUDEP to carefully identified patients is needed. In addition, until there is evidence that SUDEP can be prevented, universal disclosure should not be the ethical standard.



Robert Torrance, MBChB, is a physician from the UK, with degrees in psychology from University of York and medicine from University of Aberdeen. He has completed his foundation training as a junior doctor at Aintree University Hospital in Liverpool, and part A of membership to the Royal College of Surgeons. Robert's research focus has been on the ethical issues that arise from neurological/psychiatric illness. In addition, he has undertaken clinical research in various surgical subspecialties. After graduation, he will pursue a PhD in global health ethics.

Mike Trentalange

Capstone Mentor: Rebecca Weintraub Brendel, MD, JD

Director, Master of Bioethics Degree Program, and Assistant Professor of Psychiatry, Harvard Medical School; Director of Law and Ethics, Center for Law, Brain, and Behavior, and Associate Psychiatrist, Massachusetts General Hospital

Faculty Advisor: Patrick Smith, PhD

Teaching Faculty, Center for Bioethics, and Lecturer on Global Health and Social Medicine, Harvard Medical School; Associate Professor of Philosophical Theology and Ethics at Gordon-Conwell Theological Seminary

Do Organizational Ethics Codes Give Rise to Civil Liability?

Medical ethics codes date to the fifth century B.C.E. and the Hippocratic admonition to “first do no harm” as the foundation of the ethical principle of non-maleficence. The English physician Thomas Percival devised the first modern code of medical ethics, based upon what later became identified as the principle of beneficence. Today, codes of ethics serve several important functions. The adoption of a code of ethics signals the emergence or independence of a profession. It assists individual members of the profession in moral decision making. Codes provide assurance to the general public that those bound by its terms recognize duties and aspirations separate and distinct from pecuniary self interest. Finally, ethical codes provide a basis for discipline and self-regulation.

Enacting specific provisions of any particular code of ethics can be substantively controversial and consensus can be difficult to achieve. External factors may complicate efforts to reach consensus. Fear of litigation can have a chilling effect on mandating specific conduct in a code of ethics. Members may be reluctant to enact standards which may later be used against them. This capstone looked at whether such fears are justified. Using Westlaw and Lexis and key cite and key word searches, decisional law in U.S. state and federal courts was examined to locate cases in which attempts had been made to use medical ethical codes as a basis for civil liability. The results support the conclusion that concerns about potential liability are exaggerated and unfounded and that exposure to civil liability should not preclude the enactment of demanding ethical standards.



Mike Trentalange, JD, received a BA in philosophy from University of Florida and a JD from Stetson University College of Law. Mike is board certified as a specialist in civil trial law by the Florida Bar and the National Board of Trial Advocacy. He is an attorney and managing shareholder at Trentalange & Kelley, P.A. He has served as lead counsel in more than 1,000 cases involving product liability, medical malpractice, and civil rights claims. His interests include medical error reduction and critical race praxis in bioethics. Mike will act as lead trial counsel in several wrongful death cases against R.J. Reynolds Tobacco Company this fall.

Farhad Udwadia

Capstone Mentor: Ameet Sarpatwari, JD, PhD

Instructor in Medicine, Harvard Medical School; Associate Epidemiologist and Assistant Director, Program on Regulation, Therapeutics, and Law (PORTAL), Brigham and Women's Hospital

Faculty Advisor: Bizu Gelaye, PhD, MPH

Teaching Faculty, Center for Bioethics, and Lecturer on Global Health and Social Medicine, Harvard Medical School, Research Scientist, Harvard T.H. Chan School of Public Health

An Ethical Analysis of for Involuntary Treatment for Opioid Use Disorders

Supply-side interventions such as prescription drug monitoring programs, “pill mill” laws, and dispensing limits have done little to quell the burgeoning opioid crisis. An increasingly popular demand-side alternative to these measures is court-mandated involuntary commitment and treatment. Massachusetts General Law, Ch. 123, §35 allows physicians, spouses, relatives, and police officers to petition a court to involuntarily commit and treat a person with “a likelihood of serious harm” due to their alcohol or drug abuse. This capstone explored the ethical underpinnings of this law. Beginning with the origins and evolution of the opioid crisis, with particular focus on attempted policy interventions and their impact, the procedural and substantive standards of Section 35 were highlighted. The application of the law in practice, including the frequency with which it has been invoked, by whom, and to what end was evaluated in order to inform an ethical critique of the law. Specifically, the project argued that the infringement of autonomy and privacy associated with involuntary commitment and treatment under Section 35 is not currently justified on the grounds of a lack of evidence of benefits and a risk of significant harm. Equitable concerns raised by the different standards of care provided across existing facilities used under the Section 35 pathway compounded this argument. Based on this analysis, the capstone provides recommendations as to the minimum necessary steps that Massachusetts must take to mitigate these ethical shortcomings, specifically, providing the gold standard of medication assisted treatment, ensuring clean and safe living conditions, restricting use of this pathway to a ‘last resort’ under a more stringent evidentiary risk standard, and committing to the timely release of outcomes data.

Farhad R. Udwadia, BA, received his BA in economics from McGill University. His research work has focused on the Indian health care system and the treatment of neurofibromatosis in developing countries. He is interested in ethical challenges in medical decision making, organ transplantation, and in addiction rehabilitation. He received the Maclean Murray Scholarship for academic excellence, served as the editor-in-chief of the *McGill Journal of Economics*, and received the Moyse Travelling Scholarship to attend the master of bioethics program. Farhad plans to attend medical school after the completion of his master’s degree and will continue the research he began while at the Center.



Hillary Weiner

Capstone Mentor: Stephen D. Brown, MD

Associate Professor of Radiology, Harvard Medical School; Director, Institute of Professional and Ethical Practice

Faculty Advisor: Robert Truog, MD, MA

Director, Center for Bioethics, Frances Glessner Professor of Medical Ethics, Professor of Anaesthesia and Pediatrics, Harvard Medical School at Boston Children's Hospital

Acknowledging Physician Biases, Values, and Opinions within Patient Counseling and Outcomes

This capstone project focused on creating an online learning program to help participants identify and understand how various physician biases may influence patient counseling and decision-making. The target audience is trainees in obstetrics and gynecology and students of bioethics. The first segment of this program described how the patient-physician relationship and related methods of counseling have evolved from directive, paternalistic counseling toward that which emphasizes patient autonomy, and shows how shared decision making has emerged as the endorsed standard for balancing patients' values and preferences with physicians' expertise and experience. When counseling patients, physicians have numerous obligations: providing and interpreting medically relevant information; discussing the range of ethically permissible options; eliciting patients' preferences; and helping patients construct their health-related values. In the second segment, the program examines the power that physicians have to influence patients' decisions within the context of various counseling models. It depicts how value neutrality, which is held by many as an ideal, may be quite difficult to achieve in practice. Physicians' biases may emanate from their personal demographic characteristics, professional specialty orientation, or institutional affiliation. Biases, preferences, and values may emerge in their tone, word choice, ordering of treatment options, or in how they frame risks or benefits. These factors are particularly challenging because they may influence patients in ways that neither the patient, nor the physician are aware of. The third segment utilized simulated video recordings of realistic physician-patient interactions to explore the dynamic interplay of biases within the context of various counseling practices. Video clips are integrated with additional supplementary readings, analysis, reflections, and discussion. The goal is to inform viewers, while simultaneously encouraging self-elucidation of the learner's own biases and implementation of this knowledge to their own clinical practice and career.



Hillary Weiner, BS, previously worked as a research technician for the University of Michigan Medical School Central Biorepository. She majored in biopsychology, cognition, and neuroscience at the University of Michigan. She completed an EMT-B national course and certification in the United States and volunteered as an emergency first responder abroad. Hillary's current research focuses on the quality of end-of-life care and physician assisted suicide. She is particularly interested in bioethics related to women's rights and reproductive ethics. In the future, she hopes to focus on the issue of maternal mortality in the United States. She was recently accepted at the University of Michigan Medical School and will begin her studies this August.

Notes

Acknowledgements

Capstone Mentors

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Stephen Brown, MD	Candace Nelson, ScD
Alexandra Cist, MD	Stephen P. O'Neill, LICSW, BCD, JD
Areej El-Jawahri, MD	Nancy Oriol, MD
Lachlan Forrow, MD	Ameet Sarpatwari, PhD, JD
Charlene Galarneau, PhD	Elizabeth Schwartz, MPH
Joseph Giacino, PhD	Carmel Shachar, JD, MPH
Robert Green, MD, MPH	Sharon Shriver, PhD
Aaron Kesselheim, MD, JD, MPH	David Sontag, JD, MBE
Louise King, MD, JD	Laura Specker Sullivan, PhD
K. Babu Krishnamurthy, MD, MBE	Robert Tasker, MA, MD, MBBS, DCH, FRCPC, FRCP, FHEA
Melissa Lopes, JD	Rainelle Walker-White, BS
Wendy McHugh, RN, MS	

Capstone Seminar Faculty

Christine Mitchell, RN, MS, MTS, FAAN, Capstone Program Director
Amy Marcus, MBE
Jolion McGreevy, MD, MPH, MBE
Stephen F. O'Neill, LICSW, BCD, JD
Sheleagh Somers, MSW, LICSW
David Sontag, JD, MBE

Master of Bioethics Leadership

Rebecca Brendel, MD, JD, Master's Program Director
Brooke Tempesta, MA, Master's Program Manager

Center for Bioethics Staff

Angela Alberti, Communications Specialist
Paula Atkeson, Staff Assistant
Laura Gallant, Staff Assistant
Blair Kahn, Center and Program Coordinator

Center for Bioethics Leadership



Robert D. Truog, MD
Director



Christine Mitchell, RN, MS, MTS, FAAN
Executive Director



Rebecca Brendel, MD, JD
Director of the Master's Degree Program



Mildred Solomon, EdD
Director of Fellowship in Bioethics

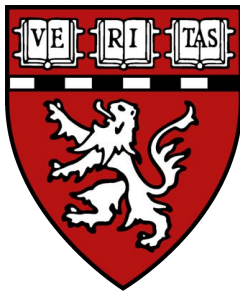


Edward Hundert, MD
Associate Director



Lisa Bastille, MS
Program and Financial Administrator

#HarvardBioethics



**Harvard Medical School
Center for Bioethics**
641 Huntington Ave.
Boston, MA 02115



617-432-2570



bioethics@hms.harvard.edu



@HMSBioethics



@HMSBioethics



Harvard Medical School Center for Bioethics