WHEN ALL IS EXPERIMENTAL: MARSHALING ETHICS AESTHETICS THROUGH AUTONOMY FORMULATIONS IN URBAN U.S. EMERGENCY MEDICINE RESEARCH

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Introduction

Bioethics regards autonomy, the capacity for an individual to make their own decisions, as a cornerstone of ethical biomedical research. Ideally, researchers realize autonomy through informed consent, a practice wherein they communicate study details to potential subjects, enabling potential subjects to make enlightened decisions regarding their own participation in research. Emergency medicine, however, frequently does not sustain the conditions requisite to consent potential subjects due to fleeting therapeutic intervention windows and incapacitated patients, challenging models of autonomy oriented around the individual. Faced with conditions that preclude consent, how do clinician-scientists perform biomedical research in a manner they and the regulatory authorities overseeing their research deem ethically acceptable? What are the loci of disagreements about what constitutes ethical research? Between 1981 and 1996, the U.S. Food and Drug Administration placed a legal moratorium on research without consent, yielding pushback from emergency medicine clinicians who claimed that the consequential lack of research ironically rendered most usual practice experimental. In 1996, the Food and Drug Administration released 21 CFR 50.24, an amendment to federal policy which permits exception from informed consent (EFIC) research given that certain community engagement procedures (technically termed Community Consultation and Public Disclosure) presuppose experimental interventions. The use of such community engagement procedures in lieu of informed consent begs an investigation of functional overlap and its ethical implications: How do emergency medicine clinician-scientists calibrate the ethical and political utility of EFIC community engagement practices with the ethical and political utility of informed consent? How do such calibrations configure clinician-scientists' rationalization of research without consent?

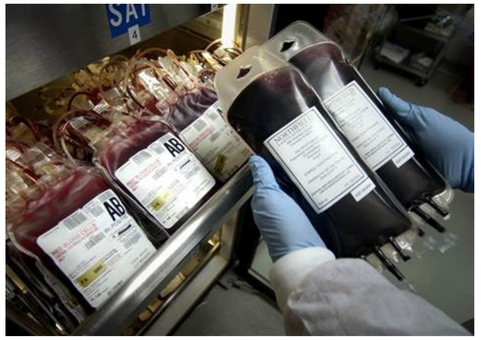

Image 1. A Northfield Laboratories technician holds bags of Polyheme, a partial blood-substitute that was used in an EFIC clinical trial that became the crux of national discourse about 21 CFR 50.24

Source: http://www.nbcnews.com/id/11625520/ns/health-health_care/t/ethicists-blast-study-testing-fake-blood/#.XWB8D3t7jPY

Methods

Over the summer of 2019, I conducted nearly 30 interviews with clinician scientists from major U.S. academic hospitals who conduct EFIC research. Interview participants were stratified by role within the research team (e.g., clinical investigator, clinical coordinator), amount of experience conducting EFIC research, clinical trial(s) worked on, and trial site(s). I sampled purposively for maximum variation.

I used qualitative data coding techniques to reveal key themes about participants' attitudes toward and experiences with community consultation and public disclosure.

Results

Given that preserving autonomy is politically and ethically valorized as a pillar of legitimate research, emergency medicine clinician scientists are motivated to preserve vestiges of it in settings which preclude informed consent (the primary mechanism for realizing autonomy in ordinary circumstances). Using CC and PD mechanisms mandated by EFIC research regulation, Emergency medicine clinician scientists assert that particular communities (defined on the basis of geography or disease) may provide substituted judgment about the appropriateness of proposed studies for the individuals who end up enrolled. Clinician scientists frame this substituted judgment as salient to decision making on a 'If they could decide for themselves I think they'd choose X' rather than 'best interest' basis, challenging contemporary models of ethical substituted judgment which err in favor of 'best interest' surrogacy. The use of surrogate decision making in conditions which preclude informed consent evinces the overwhelming impetus to preserve autonomy. Whether or not any substituted judgment or preservation of autonomy is needed ethically is highly contested among clinician scientists, while its political imperative is agreed upon.

An 'I think they'd choose X' model of autonomy:

When you talk to patients who've been through a stroke or a trauma, their answer was often like, I would have tried anything to not end up in the way that I ended up. I wish I had been participating in a trial or glad that my family put me in a trial or whatever. When you talk to the family members – like I felt like when they were asked to make a decision, I felt really uncomfortable making that decision because what if something bad happened to my loved one? Which if you use EFIC, you're actually closer perhaps to the patient's perspective than their surrogates. Right? And that – I think that's kind of remarkable. Right? Like based on this overwhelming feeling of, again, of the – and this is probably a severity issue. Right? Because the patients who have more mild injury, but couldn't make a decision at the time, maybe they would feel differently. But the ones who are more severely impaired felt like they would have tried anything and their families were more reluctant. EFIC, I think, would have satisfied the patients' desires better than the surrogate. And that's not usually what we think of it. Right? First it should be the patient, then their loved one and if all else fails, then EFIC. But maybe EFIC is closer to the patient than the surrogate – at least in the acute brain injury setting . . . I think the survivor population is really the key here, because I think they can understand this. ~ Participant 58

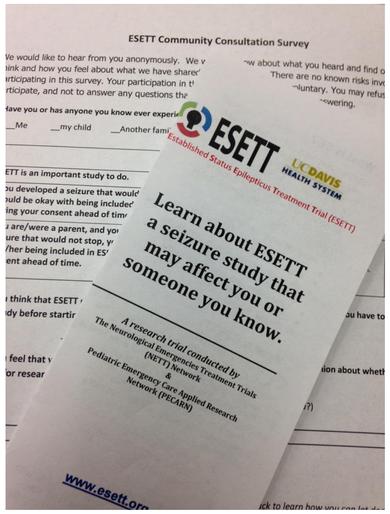

Image 2 (left). Materials including a pamphlet and survey used during a community consultation session for the EFIC clinical trial, ESETT.

Source: https://twitter.com/hashtag/esett

Image 3 (bottom). An opt-out bracelet for the EFIC clinical trial, RAMPART. Opt-out is not mandated by 21 CFR 50.24, but is almost always used in EFIC studies. One clinician I interviewed calls opt-out a "regulatory band-aid" to cover bases in case of community backlash.

Source: https://www.mercurynews.com/2009/01/26/bay-area-doctors-study-ways-to-stop-seizures/

Discussion

Clinical/scientific actors marshal commensuration, a sociolinguistic process for realizing equivalencies, to achieve ethics aesthetics in previously uncharted domains. As the condition underpinning commensuration, clinician scientists reformulate autonomy in relation to various social collectivities rather than individuals. Commensuration thus enables two disparate practices for realizing autonomy to achieve ethical equivalence and consequently assume the stead of one another when indicated by clinical environs in combination with social demands. This equivalency evinces biomedicine's reductive tendencies; perfunctory engagements between clinician-scientists and lay collectives, undertaken in the ethical stead of informed consent, render nuances of public receptivity to research illegible. Additionally, equivalency obfuscates the intermittently oppressive research participation experiences of actors for whom autonomy does not figure as the primary metric of ethicality.

Further Directions

A cross-cultural version of this project which explores the American emergency medicine context in juxtaposition to a nation (e.g., Sweden, Australia) which is geographically detached from the historical legacy of biomedical research abuses that drive American policy and ethics, and maintains a collectivist culture which deprioritizes autonomy could elucidate the ways in which biomedical history and national values (e.g., autonomy) articulate with clinical decision making, research operations, and perceived ethical and scientific imperatives.

Acknowledgments

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Image 4. https://jamanetwork.com/collections/5621/emergency-medicine

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