

Analyzing Efficacy of Home Electronic Incarceration on Return-to-Custody Rates for Inmates During the COVID-19 Pandemic

(Technical Report)

The Inequitable Past of Clinical Trials and a Look Towards a Representative Future

(STS Paper)

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

The medical field has a dark history rife with the mistreatment and exploitation of underprivileged groups. Two of these demographics that are the subject of my research are the prisoner population and minority groups. The National Institute of Health (NIH) today heavily regulates research involving prisoners, but prior to this regulation, prisoners were subject to exploitative trials and studies that promised no purpose or benefit for the prisoner population itself; in the 1970s, one half of Phase I drug testing (not expected to be therapeutic) was conducted on prisoners (Reiter, 2009). The mistreatment of prisoners now primarily manifests itself as a lack of effective mental health support and resources, leading to mental health issues while in jail and negative outcomes post-release. Prior work on this topic has found that only 21% of individuals released from Albemarle-Charlottesville Regional Jail (ACRJ) with severe mental health issues received mental health resources upon release (O'Neill, 2020). My Technical Topic is building on prior work in this field by exploring pre- and post- COVID trends regarding prisoner mental health and will include a focus on the impact of therapeutic dosage on re-integration outcomes.

While clinical trials are no longer conducted coercively on the prisoner population, large issues still remain terms of diversity in trials. The participants in clinical trials have traditionally not been representative of our society as a whole, resulting in fewer positive outcomes for certain marginalized groups. One scathing example is in 2015 when black Americans were under-represented in multiple myeloma trials despite suffering from multiple myeloma at twice the rate as white Americans (Chen & Wong, 2018). My STS Topic will include a review of modern-day and historical underrepresentation, proposed barriers to trials for marginalized groups, policies in

place intended to increase representation, and innovative recommendations to eliminate barriers and promote equitable access to trials.

Technical Topic

In an era where society is learning to prioritize and destigmatize mental health, increased attention has fallen on the prisoner population. Many prisoners have pre-existing mental health issues which might play a part in their incarceration, and the prison environment of isolation and being separated from loved ones only exacerbates the issue. Prisoners have higher rates of major depression and psychosis and are at higher risk for suicide and self-harm than the non-prisoner population (Fazel et al., 2016). This systematic review of prisoner studies does a phenomenal job at addressing both the root causes and the symptoms of prisoner mental health issues. However, one method that this paper fails to identify is simply keeping people out of prison. A leader with ACRJ told our team that this is the most effective way to increase prisoner mental health. The COVID-19 pandemic increased prevalence of Home Electronic Incarceration (HEI) which allows non-violent inmates to serve their sentence in the comfort of their home, enabling them to care for their family and potentially remain employed; HEI is being utilized by ACRJ among other jails. Cleary (2021), when speaking with HEI participants from ACRJ, heard stories of overwhelming success including succeeding at work, feeling better mentally, and being protected from COVID-19.

My technical project is centered around a data analysis and review of the greater Albemarle County region of Virginia with various stakeholders involved. Data is provided to our team from ACRJ, Region Ten (a Charlottesville mental health service), the Blue Ridge Area Coalition for the Homeless (BRACH), and OAR Jefferson Area Community Corrections (OAR-JACC). ACRJ utilizes a Brief Jail Mental Health Screen (BJMHS) to identify and refer inmates

for further mental health analysis and support. Our methods for exploring this topic include interviews with influential individuals with the organizations listed, a document analysis of prior findings in this project and related projects, and an up-to-date data analysis tied to positive inmate outcomes. This project has been ongoing since 2007 and has evolved to a point such that every year's iteration builds on previous work to provide more confident analyses. With this combined dataset, trends can be explored related to BJMHS screen-in rates, linkage to R10, and the positive or negative outcomes seen as a result. Our group will also focus on pre- and post-COVID, researching if previously found trends still exist and trying to identify how the pandemic hindered or accelerated progress.

STS Topic

The issues inherent in modern clinical trials are largely the result of a troubled history of exploitation in the medical field. According to Bonevski et al. (2014) in a peer-reviewed systematic review of over 100 related studies, mistrust in medical research is one of the largest barriers for low response rates, especially for black Americans and Indigenous populations. The common theme among the barriers and solutions found is that research institutions need to allocate more funds towards resourcing and utilizing community partnerships, which I believe is an effective, easy to implement start to improve diversity in trials. Criteria for minority representation in clinical trials already exists, but is not being followed. The NIH Revitalization Act of 1993 requires that federally funded trials prioritize the inclusion of women and minorities and that this demographic information be included in publications for accountability; despite this, less than 2% of over 10,000 cancer trials examined after the passing of the NIH Revitalization Act met the stated criteria, with less than 5% even reporting inclusion of minorities (Oh et al., 2015). This peer-reviewed study supported in part by NIH grants states that

true inclusive research moving forward requires inclusivity in all walks of life prior. While this is a great sentiment and something society should strive for, that idea simply gives an alibi for the NIH and pharmaceutical companies to use for their blatant shortcomings.

When analyzing the underrepresentation of minority groups in clinical trials, the NIH might point to their policies and deflect blame for them not being followed. However, with this action, the NIH is not affording sufficient ethics of care to the groups in question. First developed by Carol Gilligan in 1977 and later elaborated on by Taylor (2020), the framework of ethics of care defines a system, or society, as a network of relationships of caring for one another. This framework provides a basis for how individuals might act seemingly irrationally, bounded by responsibility to others instead of traditional incentives. Taylor (2020) writes that less-visible groups are more likely to be those who act outside of traditional, expected norms. In the context of this topic, minority groups not responding to trial recruitment is a perfect example of this concept within the ethics of care framework. A greater ethics of care is owed to these people in understanding the context as to why this might be the case.

My methods for exploring this topic will include policy analysis of representation criteria, including from the NIH, an ethical analysis of attempts made in the past and whether or not they had the right interests in mind, and literature review of barriers, proposed solutions, and case studies related to this issue. One case study in particular that provides inspiration is the AIDS Coalition to Unleash Power (ACT UP). Nurith Aizenman (2019), long-time writer about national health policy for the Washington Post and NPR, tells the empowering story of AIDS patients' response to the FDA not providing experimental drug access to AIDS patients. Following direct protests, the FDA agreed to change their policy regarding access to experimental drugs, and the NIH and pharmaceutical companies began researching AIDS

treatments in parallel with research of a cure. If minorities continue to not be included in clinical studies for illnesses that disproportionately target them, it might take the power of the people to get the NIH and pharmaceutical companies to change their ways.

While addressing the history of clinical trials is necessary to understand the context of the situation at hand and structure how to move forward, getting caught in the atrocities of the past can also serve to redirect attention away from modern, promising discussions and solutions. Often cited as reasoning for distrust in the medical community, the Syphilis Study of Tuskegee (SST) has had lasting effects on the affected population in terms of medical distrust. According to the CDC, the US Public Health Service sponsored a study evaluating untreated syphilis in hundreds of black men in 1932 which continued to 1972, despite penicillin becoming a reliable syphilis treatment in the mid-1940s (*The Tuskegee Timeline*, 2021). While this spawned intense distrust of the medical community, especially within the black community, this barrier might be fading with time. According to Mays et al., (2012) while positively correlated, awareness of SST is likely not a key factor in determining low black American participation in HIV/AIDS trials, prevention, and intervention efforts. This study, surveying black and Latino Americans, found that older male black Americans were most likely to be aware of SST. Only 17.4% of the weighted sample said they had heard of SST. Mays et al. (2012) theorizes that what is symbolically represented by the SST is a larger barrier than SST itself. The medical community needs to acknowledge past atrocities, learn and move on from them, and rebuild trust with previously exploited communities. One modern method for trial recruitment that can ease this barrier is remote-based trials (as opposed to clinic-based). Stewart et al. (2022) found that in comparable randomized clinical trials, the remote-based study population on average was 11 years younger and 6% more female than clinic-based study populations. The white population

was also around 50%, compared to 85% white found in the clinic-based study. While the sample size in the study of Stewart et al. (2022) is small, the results are very promising and provide a path forward for increasing minority recruitment and rebuilding trust.

Conclusion

The research to improve prisoner mental health in the local community will serve as a template for communities around the world to alter their methodologies and adopt what works here in the Charlottesville community. Tangible progress has already arisen locally from this project in the form of the Behavioral Health Docket, which provides an alternative option to prison for those for which mental illness played a significant role in the crime committed (Hammel, 2022). Through research into clinical trials representation, I aim to build on preexisting work to provide an innovative systems engineering solution to generational barriers to participation in trials. The medical community has failed underprivileged groups in the past and needs a modern approach moving forward to help right those wrongs, or at least prevent them from occurring again.

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