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Reconciling Competence and Consent in Opioid-Dependence Research: The Value of Vulnerability Rhetoric

Michael O. S. Afolabi and
Duquesne University

Stephen O. Sodeke
Tuskegee University National Center for Bioethics in Research and Health Care

Central to addiction is a complex interplay between the erosion of the will to refrain from harmful behavior such as psychotropic drug use and how changes in human brain neurocircuitry continuously orient people toward pursuing the given behavior. In the addictive state, therefore, personal desires and habits increasingly denude and/or limit rational control of behavior and choices. Since autonomy with its undercurrent of competence and attendant garb of accountability requires mental stability (Afolabi 2015a), it is morally difficult for addicts to voluntarily consent to addiction research. Steel and colleagues (2017) partly acknowledge this idea in the context of opioid-dependent research, but their proposal attempts to frame the issues beyond this conceptual locale. For supervised injectable opioid assisted treatment (siOAT), they argue that the quandaries are better engaged using the language of inequities and the literature on “third-world” nonexploitation. However, this has a limited scope largely because it engages only a part of the series of distinct events that generate and are associated with the problem ab initio.

Genetic, epigenetic, neurodevelopmental, behavioral phenotypes, and sociocultural factors facilitate the pre-addiction state (Volkow and Morales 2015; Egervari et al. 2017). Personal choices made during exposure to the drug of addiction, the functional purpose that the drug serves (if any), and the extent to which an individual fancies the drug influence the progression of pre-addiction to the addictive state and how that individual behaves following the onset of addiction. Thus, contextual vulnerabilities in utero and post utero determine who may and who may not become addicted to psychoactive drugs and, to a larger extent, their postaddiction behavior.

Although individual differences in vulnerability exist in highly homogeneous populations and only a subset of those exposed to addictive substances develops addiction (Egervari et al. 2017), socioeconomic and geographic contexts may place a vulnerable person in the “wrong” place where drugs of addiction such as heroin and morphine are readily available. For example, specific stressors such as loss of a parent, parental divorce, death of a child, and emotional and sexual abuse are generally associated with predisposition to and craving

Address correspondence to Michael O. S. Afolabi, PhD, International Journal of Ethics Education, Center for Healthcare Ethics, Duquesne University, Pittsburgh, PA 15282, USA. curiousmaikl@yahoo.com.

ORCID

Michael O. S. Afolabi, <http://orcid.org/0000-0002-5243-4850>

for drug use as a coping mechanism (Sinha 2008; Heilig et al. 2016). In addition, living in a drug-infested community facilitates access to drugs of abuse, normalizes the use of such drugs (in the absence of countering ethical systems and values), and increases the possibility that people trapped within such communities will turn to drugs when the factorial recipes combine. Although people in poorer socioeconomic niches have fewer resources to deal with the background factors that spur addiction, the neuroplastic nature of the brain steers the transition of both rich and poor opiate users to become addicts. This neurobiological phenomenon ultimately diminishes the cognitive competence of some of these drug-dependent people. Although Steel and colleagues (2017) argue that the literature on nonexploitation is relevant in engaging the dynamics of opiate dependence, such a perspective seems most relevant in cases of induced addiction where specific groups are targeted with addictive drugs as part of the economic nexus of the international illicit drug trade (Afolabi and Umukoro 2016). Since the practice transcends national and municipal boundaries, this again underscores the limits of Steel and colleagues' position on the relevance of applying third-world literature on the issue.

Diminished competence is a critical component that defines vulnerability in the research context and that makes it ethically problematic for individuals so affected to give valid consent in research (Afolabi 2012). The non-competent capacity of opioid addicts to consent in clinical research is partly reflected in the high suicidal proclivity observed in this group. Indeed, up to 40% of patients who seek addiction therapy have a history of attempted suicide (Yuodelis–Flores and Ries 2015). Hence, opiate addicts need one or more of at least four types of “treatments”: continuous access to the drug (to avoid unpleasant withdrawal symptoms), treatment via buprenorphine, methadone, or naltrexone, treatment for its psychiatric-related sequelae including suicide and depression, and treatment for its infectious disease dimensions such as hepatitis B, hepatitis C, and HIV.

Although siOAT enables recalcitrant opiate addiction cases to find reprieve, it still technically belongs to one of the aforementioned “treatment” options or needs. Consequently, how opiate-dependent individuals align their particular needs with trials that grant access to siOAT will be dependent on their personal perception, the degree of their mental stability, the presence of alternative channels of accessing opioids, and how sincerely such individuals desire “cure” from their addiction. These situational dynamics create a context of uncertainty such that some of the addicts are mentally competent, some only appear competent, some are momentarily competent, and others are clearly not competent. These analyses echo the notion that addiction hardly puts people in a primitive state of being impervious to the currents of reason and reflection to the extent that they lose their status as free moral agents in a Kantian sense (Afolabi and Umukoro 2016). It also underlines Morán-Sánchez and colleagues' (2016) observation that some addicts possess decision-making capacity, at least when they are not experiencing cognitive impairment and acute withdrawal. Since these conceptual dynamics offer little pragmatic help in terms of specifics, the attendant uncertainty implies that many addicts have a shifting capacity for rational decision making in relation to drug use.

The *telos* of health care entails fostering medical good at the social and individual planes. Opioid-dependent addicts need medical help, and siOAT is believed to be a cost-effective

means of treatment when conventional interventions fail. Steel and colleagues (2017) note that when opioid-dependent persons who have medical access to the drug choose to participate in siOAT research, they are acting against addictive compulsions. Yet this position assumes that every opioid addict understands the range of options he or she has prior to being offered the opportunity to participate in siOAT research, as well as when such opportunities specifically arise. Hence, it ignores the uncertainty that surrounds the different levels of mental competence that such individuals may have, how each of these may influence their rational choices, and the personal, unstated motivations behind the choices of such individuals. This conundrum underscores how problematic it is to relegate the connection between voluntary consent and competence in the context of opioid-dependence research to the margins.

Opioid dependence begins with a noncompulsive choice that may be fully autonomous, facilitated by socioeconomic or situational contexts. As this “choice” acquires a tinge of compulsiveness in the complicated nature–nurture course of an individual’s experience, other choices may become available, including treatment and research sources of drug access. This demonstrates how behavior in a single individual can be voluntary, chosen, and compulsive simultaneously (Henden, Melberg, and Røgeberg 2013) and at different times. Seen through the lens of neurobiological, socioeconomic, and other contextual vulnerabilities, addiction becomes a dysfunctional consequence of the dynamic relational nexus that exists between individuals and their different environmental variables. Addiction in general or the opioid-dependent kind in particular is, therefore, foundationally sociorelational. Eijk and Uusitalo (2016) recently argued that this perspective is crucial for developing more ethical treatment and prevention policies. In the context of siOAT research, a sociorelational lens nuances voluntary consent since its underlying idea of competence is mired in uncertainty that can only be specified on a case-by-case basis. As such, some research participants may have the mental capacity to give consent while others may not. The latter view is partly supported by the idea that it is much harder for addicts than for nonaddicts to refrain from the drugs of their compulsive dependence, and even when they have some capacity to abstain, external help is often needed to achieve that purpose (Henden, Melberg, and Røgeberg 2013). This view runs counter and contrary to Steel and colleagues’ (2017) position and echoes Racine and Rousseau–Lesage’s (2017) stance, which favors a dynamic concept of voluntary action laced with different levels of voluntariness that respond to both internal pressures and external environmental impulses.

In the absence of an all-or-nothing approach to the mental stability that can morally justify voluntary consent vis-à-vis clinical research on SIOAT and other opioid trials, of what use is the requirement for consent as demanded by the Nuremberg Code? Against the background of the uncertainty associated with this issue, one possible approach is excluding opioid-dependent people from clinical research or appointing suitable surrogates, as some bioethicists increasingly suggest. Another approach entails developing new tools such as scales that can capture different levels of voluntariness (Racine and Rousseau–Lesage 2017) and using such scales as the basis for determining how particular opioid-dependent individuals satisfy Principle 1 of the Nuremberg Code.

Some bioethicists argue that the state of vulnerability implies supportive action and the obligation to show some degree of solidarity to vulnerable persons (Afolabi 2015b), hence, its rhetoric—when applied to the issue of consent and competence in addiction research—underscores the need to see opioid-dependent individuals essentially as persons in need of help rather than fully autonomous, eligible research participants. If different sets of vulnerabilities shape how psychotropic drugs—used as existential coping mechanisms, recreational aids, or functional aids—progress into compulsions, then there is an additional help that addicted people need. Specifically, this relates to the development of a diagnostic enhancement window as a form of therapeutic index that may help halt the progression of addiction in vulnerable populations (Afolabi and Umukoro 2016). This will also help such individuals retain their cognitive competence and hence their voluntary capacity to consent to research involving psychoactive drugs such as siOAT.

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