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Leslie Francis

S.J. Quinney College of Law, University of Utah, leslie.francis@law.utah.edu

John Francis

University of Utah

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Justice and Research on Controlled Substances with HIVC Persons

Leslie Francis and John Francis, University of Utah

Andreae and colleagues (2016) argue in defense of research involving the use of controlled substances for pain and other symptom control in HIVC patients by raising and defusing selected ethical and legal concerns about this research. While we do not dispute the importance of the research, we are concerned that their discussion construes the research and concomitant issues it raises too narrowly, particularly with respect to data use and confidentiality. In this brief comment, we note and briefly explore five additional issues about data collection and use with HIVC populations that, we believe, are critical to building a case for research with HIVC patients: data availability, data protection, risks of stigmatizing inferences about individuals, potential mismatches between research participants and research beneficiaries, and standards for interventional versus non-interventional research. We begin with two background observations, about the HIVC population and the nature of the research examined by Andreae and colleagues.

The demographics of the HIVC population pose issues of justice. It is well known in the United States that African-Americans are the racial group most affected by HIV. According to recent Centers for Disease Control and Prevention (CDC) statistics (<http://www.cdc.gov/hiv/group/raciaethnic/africanamericans>), African-Americans account for an estimated 44% of new HIV infections although they are only 12% of the population; the rate of new infections among African American males in 2010 was 7 times that of white males and twice that of Latino males. For African-American women, rates of new infections are 20 times that of whites and 5 times those of Latinos. Estimates are that one in 16 African-American men and 1 in 32 African-American women will be diagnosed with HIV at some point during their lives. Lower percentages of African Americans are linked to care, remain in care, receive appropriate prescriptions of antiretroviral therapy, and achieve viral suppression. These factors, together with the increased prevalence of other sexually transmitted diseases (STDs), unawareness of HIV status, and missed opportunities for treatment as prevention, contribute to increased burdens of disease in this population. Perhaps less well known in the United States are European data that HIV disproportionately affects migrants; in many West European countries more than half of new HIV diagnoses were in this population (European Centre for Disease Prevention and Control 2013).

Second, the research model that Andreae and colleagues discuss is primarily interventional, most likely randomized controlled trials evaluating the safety and efficacy of controlled substances in selected patient

populations. While such trials have been considered the gold standard, their prominence has recently been questioned. Issues include enrollment barriers, bias in study design or analysis, unwillingness to be randomized and other ethical or practical questions about randomization, whether study populations and conditions mirror real-world conditions such as adherence, endpoint selection, and inability to detect low-frequency events. All of these issues are likely to be present in research with HIVC populations, given the demographics just presented (West et al. 2008). Donnell and colleagues (2013), for example, recommend considering adherence in designing studies of pre-exposure prophylaxis for HIV.

It may therefore be important to consider possibilities for types of research other than clinical trials of prohibited drugs or drugs of uncertain legal status. New statistical techniques of data analysis are enabling research using existing patient records that controls more effectively for selection bias (West et al. 2008). Data analyses in the 24 U.S. jurisdictions now allowing medical cannabis might provide evidence of safety and efficacy of cannabis use in HIV patients, to take one example. There are also possibilities of building on the extensive efforts to study methods for increasing willingness to be tested for HIV or to stay in HIV treatment. Results from such research might help build the case for federal support of the drug trials considered by Andreae and colleagues. Our suggestion here is that researchers should consider creative methods to avoid the more direct legal challenges of concern to Andreae and colleagues. The goal is to devise strategies that are within the legally available world to build the case for testing proscribed drugs for treating serious pain. But there are barriers and ethical concerns here as well, to which we now turn.

1. **Data availability.** In addition to the HIV population demographics that suggest that many are unaware of their status or not in care—so data may simply not be available—there may be special legal constraints on data involving treatment of patients using a controlled substance. The Substance Abuse and Mental Health Services Act (SAMHSA) part 2 regulation imposes stringent consent requirements on disclosure of information about patients treated in substance abuse facilities receiving federal funds; it also imposes special requirements on research use of this data. These restrictions may make it more difficult to conduct research on HIV patients treated for substance abuse in these facilities.
2. **Data protection.** As Andreae and colleagues indicate, the level of legal protection afforded by certificates of confidentiality is uncertain (Check et al. 2014). Deaths from abuse of opioids—both legal and illegal—are recognized as an important public health problem in the United States today (National Institute on Drug Abuse [NIDA] 2014)

Drug use, drug diversion, and drug sales are an area of particular interest to police and prosecutors. Despite emphasis on the importance of education and public health efforts (NIDA 2014), efforts at investigation, mandated treatment, and even prosecution may be expected to intensify as well (Levulis 2015). Wolf et al. (2015) document the importance of clarifying confidentiality protection; enhanced protections are especially critical for doubly sensitive data such as information about patients who both are HIV positive and use controlled substances.

3. Risks of stigmatizing inferences. Particularly when data sets are combined, novel and unanticipated inferences may appear. These inferences appear from a constellation of factors: that if a person has characteristics a-1 to a-n, the person also has characteristic a-nC1. To be sure, these inferences are likely to be probabilistic and with different levels of confidence. Nonetheless, if the inferred characteristic is troublesome, it may be stigmatizing. Importantly, these risks of stigma for individuals may arise even from research with de-identified data, without efforts to re-identify individuals in the data, and regardless of whether the individual about whom the inference was drawn was in the original data set. A poignant example from the history of HIV is inferences that were drawn about Haitians from data about original disease incidence (Capo' 2013). Researchers should recognize the possibility of these risks of stigma, the possibility that they might reduce willingness to participate, and take steps to communicate research in ways that mitigate these risks.
4. Mismatches between participants and beneficiaries of research. When people permit data to be used in research, or when data about them are used without consent, they contribute to an overall public good. As a matter of minimal fairness it is reasonable to think that they should not be shut out from receiving the benefits of the good to which they contribute (Francis and Francis 2014). Given the demographic characteristics of the population with HIV—including the demographics of those who remain unaware of their status or who are not consistently in care—along with other data about racial and ethnic disparities in access to care more generally, such unfair mismatches are a genuine possibility with any HIV research. Where the research involves additional risks, such as research with HIV-positive people who also use controlled substances, attention to these fairness concerns is imperative.
5. Interventional versus non-interventional research standards. Debates about whether the standards for protecting individuals in interventional research should differ from those appropriate to protecting individuals in non-interventional research are ongoing. The recent Common Rule NPRM, 80 Fed. Reg. 53933 (Sept. 8, 2015), proposes adding as a new

category of exempt research secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given and applicable privacy protections are in place including heightened protections for sensitive information. The uncertainty surrounding certificates of confidentiality suggests that risks may be attendant on this strategy, however.

Building the case for research improving pain management in HIV patients is an urgent matter. Interventional research with controlled substances may need to be complemented with other research strategies, given existing legal risks and barriers. These complementary strategies— along with the research discussed by Andreae and colleagues—require attention to the additional barriers we have explored in this comment. Ethical questions about this research must not be framed primarily as a binary choice between liberty and the need to solve a critical social problem. Considerations of justice must be at the fore, most notably risks to participants such as individuals newly infected with HIV who are among the most vulnerable of populations in the United States, in Europe, and elsewhere. Addressing these considerations of justice requires longer term strategies such a research on pain control in less vulnerable populations, non-interventional research, or other research methodologies that although not gold standard may still produce findings of value. Even partial or imperfect results may help build the case for reforming public policies that govern experimentation with controlled substances. There is value in the adoption of a risk-averse approach to research on controlled substances with HIV-infected patients so that these doubly vulnerable patients are not placed in legal harm's way.

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