

A Puzzling Anomaly: Decision-Making Capacity and Research on Addiction

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Abstract and Keywords

Any ethical inquiry into addiction research is faced with the preliminary challenge that the term “addiction” is itself a matter of scientific and ethical controversy. Accordingly, the chapter begins with a brief history of the term “addiction.” The chapter then turns to ethical issues surrounding consent and decision-making capacity viewed from the perspective of the current opioid epidemic. One concern is the neglect of the cyclical nature of addiction and the implications of this for the validity of current psychometric instruments used to evaluate decision-making capacity in addiction. Another is the apparent discrepancy—possibly an ethical double standard—in the manner in which society and addiction researchers view the mental capacity and vulnerability of individuals who suffer from severe addiction. On the whole, the main ethical concern of the chapter is the puzzling lack of clinical research on decision-making capacity in research on addiction.

Keywords: addiction, vulnerability, harm reduction, decision-making capacity, opioid epidemic

1. Introduction

Ethical debates associated with current theories and treatment interventions for addiction tend to carry over into ethical concerns with research on addiction. Such concerns include the nature and definition of “addiction” and the consequences of this for informed consent and decision-making capacity (“mental capacity” or “mental competence”), a key ingredient of consent. These are the primary areas of interest in the present chapter, which is admittedly selective and will offer an ethical assessment of its own. The aim is to advance current debates rather than reiterate them.

The chapter will engage the ethics of addiction from the vantage point of the current opioid epidemic, now a major public health emergency in many North American jurisdictions (Jones et al. 2018, 21). The defining feature of that epidemic is said to be “an unprecedented increase in morbidity and mortality associated with the use of opioid pain relievers” (Kolodny et al. 2015, 559). While the opioid epidemic now includes the abuse of

psychoactive drugs other than opioids (Eibl et al. 2019), it is usually in the context of opioid addiction that such abuses occur. The rather sinister manner in which questions of scientific fraud, deception, conflict of interest, and disinformation are implicated in the opioid epidemic helps to remind us that clinical research on addiction never occurs in a sociopolitical or economic vacuum (Keefe 2017; Van Zee 2009). This greatly complicates discussion of the ethics of addiction research, where sociopolitical conditions are sometimes paramount and explicit (Yan and Kuo 2019) and at other times apparently absent (Walker et al. 2005).

One problem that arises in facing the conceptual and clinical challenges involved is the cyclical nature of addiction and the implications of this for the validity of current psychometric instruments used to evaluate decision-making capacity. A related concern is the apparent discrepancy—possibly an ethical double standard—in the manner in which society and addiction researchers sometimes view the decision-making capacity and vulnerability of individuals who suffer from severe opioid addiction. Lack of appreciation of the complex history of the term “addiction” is an important impediment to progress in addressing such questions.

2. Early and Current History of the Term “Addiction”

Etymologically, the term “addiction” derives from Roman law, where it was used in sentencing, in effect, to state or decree that an individual is *bound* by a sentence: *ad+dicere*, “to speak,” “to declare” (Lemon 2018, ix, 7; Maddux and Desmon 2000, 661). Addiction in this context is also often understood to involve a commitment, a voluntary choice, to give oneself up and surrender to one’s sentence, which may also be understood as a form of devotional attachment: “*Addictus* is thus one assigned by decree, made over, bound, or—in one such mode of commitment—devoted” (Lemon 2018, ix). In this context, one is expected to be loyal and devoted to one’s legal obligations and therefore willingly submit and surrender to one’s sentence. By the time we reach the early modern period (roughly 1400–1800) the range of things to which one may be addicted expands to include addiction to God, study, love, and friendship (pp. ix–xi). Theologian John Calvin, for example, invokes his followers to seek and choose to be addicted to God (“Addict ye”), though he also warns that in the process there is a risk of losing oneself in improper attachments (p. 32).

Viewed in this light, addiction is a form of zealous attachment and surrender to a person or cause (pp. 7, 24, 30). Although the risk of incurring compromised agency and losing oneself is considered to be inherent in all addictions, it is nevertheless recognized that addiction is often a positive thing, a “ravishing” experience, and “a form of devotion at once laudable, difficult, extraordinary, even heroic” (p. ix). It is possible to distinguish addiction as devotion and addiction as compulsion in this context, where the latter is sometimes more aligned with medical discourse on disease and compulsion and the former, simply life in general (Lemon 2018, x; Maddux and Desmon 2000, 661). The relevant

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point is that “the relationship between these two understandings of addiction is not solely oppositional,” though both may lead to “an overthrow of the will” (Lemon 2018, x).

Thus, agency and “agentive selfhood” may be compromised in addiction. But this may be viewed as a good or a bad thing depending on the addiction in question and the context. In other words, addiction is not necessarily a bad thing, even though it may involve a loss of self and even enslavement to a thing or person. Loyalty and devotion of some sort is the good side of the coin. Consider, for example, the social endorsement and (at times) obligation to engage in so-called health drinking in early modern England—a social practice in which individuals are called upon to demonstrate their loyalty, commitment, and devotion to the community by consuming alcohol together (Lemon 2018, 136–138). It is sometimes considered praiseworthy and an act of loyalty toward the community, although it is also recognized to have negative consequences when drinking turns into a compulsion and “loss of self.” Addiction also plays a central role in William Shakespeare’s *Othello* (pp. 23–50, 103–136). Othello is certainly wrong and guilty of murdering Desdemona. But was he really “capable” of doing otherwise, and isn’t it ultimately on account of his love, devotion, and loyalty to her that he does so? Something for which he might otherwise be praised? We are *torn*, and this perhaps is because addiction is a paradoxical and ambiguous concept that can at times defy unilateral, consistent praise or condemnation.

To sum up, the complex entanglement between positive and negative evaluations of addictive practices and behaviors during the early modern period is important to bear in mind in our current era, when addiction is so often judged to be a negative thing, as if there were something fixed and irrevocably bad in the nature of the phenomenon itself. We seem to have forgotten that there is much that is positive in some cases of addiction and that the surrender and loss of selfhood can be justified or excused when there is a higher calling or when it is a consequence of loyal commitment and devotion. The history of addiction in the early modern period teaches us that addiction is a paradoxical human phenomenon that offers rich possibilities for positive action and development, though these are inextricably bound and inseparable from risks that may lead to negative outcomes. This provides a helpful contrast to current discourse on addiction, which is often paralyzed with the oversimplifications imposed by the adoption of false dichotomies, especially the view that the term “addiction” refers to a phenomenon that is exclusively either good or bad.

At present, the scientific community appears to be sharply divided over the use of the term “addiction.” Some insist it is “a perfectly acceptable word ... used by the American Society of Addiction Medicine ... and the oldest journal in the field, simply known as *Addiction*” (Maddux and Desmon 2000, 662; O’Brien, Volkow, and Li 2006, 764). Others disagree. An example of this disagreement is the notable fact that the term is absent from the current edition of the *Diagnostic and Statistical Manual of Mental Disorders*, DSM-5, which explicitly states that “the word addiction is not applied as a diagnostic term in this classification, although it is in common usage in many countries to describe severe problems related to compulsive and habitual use of substances” (American Psychiatric Association 2013, 485). Reasons are provided for the exclusion: “the word is omitted from the

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official DSM-5 substance use disorder diagnostic terminology because of its uncertain definition and its potentially negative connotation” (American Psychiatric Association 2013, 485). The finality and assurance with which these reasons are stated belie the fact that the decision to exclude the term ultimately came down to a single vote: “a vote was taken at one of the last meetings of the committee, and the word ‘dependence’ won over ‘addiction’ by a single vote” (O’Brien, Volkow, and Li 2006, 764).

First, consider the charge of negative connotations. Certainly, it is hard to deny that the term “addiction” is often used with intended or accidental negative connotations, especially when it is used to label people by their illness, as in the term “addict”—an expression which for many people conjures up a picture of a derelict, dishonest, immoral, and selfish individual (Broyles et al. 2014, 218). However, the same can also be said of allegedly more neutral alternative terms like “substance abuse” (Botticelli and Koh 2016; Wakeman 2013). The other reason provided for the exclusion of the term “addiction” in DSM-5 is its allegedly “uncertain definition” (American Psychiatric Association 2013, 485). However, this seems rather disingenuous as there are respectable testable scientific theories that provide clear, operationally defined, evidence-based definitions of the term (Leshner 1997; Volkow, Koob, and McLellan 2016). For example, publications by the National Institute on Drug Abuse tie the terms “addiction” and “dependence” to different brain systems and mechanisms (National Institute on Drug Abuse 2007). “Addiction” is defined as “a state in which an organism engages in compulsive behavior even when faced with negative consequences” (National Institute on Drug Abuse 2007, sec. II, 5). It is hard to describe this definition of “addiction” as “uncertain.”

Underlying the controversy about the clinical status of “addiction” as a diagnostic term is an important issue that arises in the prescription use of opioids for chronic pain. In this case, the belief that “addiction” is the same as “dependence” is said to be a misconception “that leads some clinicians to avoid prescribing opioids to patients who would benefit from them and many patients to be afraid of taking opioids as prescribed” (Volkow and McLellan 2016, 1254). Omitting the word “addiction” from the DSM may surreptitiously help to downplay the risk of “addiction” that is involved in prescribing opioids for the treatment of pain since the word “addiction” is not even available to suggest the kind of “compulsive” behavior and loss of control that is of concern. In contrast, professional medical organizations tied to pain medicine often insist on the need for the term (Rosenblum et al. 2008, 7). This is not a trivial observation in the context of the aggressive and misleading marketing of the prescription opioid OxyContin in the years that preceded the opioid epidemic, “where there was a systematic effort to minimize the risk of addiction in the use of opioids in the treatment of non-cancer-related pain” (Van Zee 2009, 223). Using opioids to treat non-cancer pain is now judged to be “questionable” (Volkow and McLellan 2016, 1253), a practice with “no strong evidence based foundation” (Kissin 2013, 513). The term “addiction” is central to this debate.

3. Research on Decision-Making Capacity and Addiction

Issues of consent and decision-making capacity figure centrally in discussions of clinical research on treatment interventions undertaken in the context of opioid addiction and the opioid epidemic. A singular feature of such research is the provision of opioid drugs to individuals seeking treatment for opioid addiction, for example, methadone (a full agonist) or buprenorphine (a partial agonist), sometimes even the very same kind of opioids to which they are addicted, like heroin (a full agonist). Opioid agonist therapies of this sort are offered as treatment to opioid-addicted individuals (Metrebian et al. 2015; Perneger et al. 1998; Steel, Marchand, and Oviedo-Joekes 2017; Strang et al. 2010). This has generated ethical controversy. Some critics argue that there are circumstances where addiction can interfere with valid consent because decision-making capacity may be impaired (Charland 2002, 2017; Elliott 2002; Henden 2013, 2016; Sprumont 2002). Others apparently disagree (Carter and Hall 2008a, 2008b; Foddy and Savulescu 2006; Levy 2006, 2016; Pickard 2012; Steel, Marchand, and Oviedo-Joekes 2017; Uusitalo and Broers 2016).

Note that while it is sometimes technically important to distinguish between “opiate” drugs, which are entirely or partially derived from the opium poppy (*Papaver somniferum*), and synthetic pharmaceutically manufactured “opioids,” it is the fact that the same receptor systems are targeted (delta, kappa, and mu) that really counts; and speaking of opioids in general is often acceptable (Wang 2018). Alternate terms like “maintenance therapy,” “substitution therapy,” and “replacement therapy” are also commonly used to describe opioid agonist therapy, even though their application is not always consistent. “Medically assisted treatment” has been said to be the ethically preferable term because it clearly implies that pharmacotherapy is an adjunct to treatment and not a “replacement addiction” or a case of simply “substituting one drug for another,” which may increase stigma and devalue pharmacological treatment for addiction (Wakeman 2017, 1). Nevertheless, for reasons of clinical precision, the expression “opioid agonist therapy” will be the term employed in the discussion that follows since it is ethical questions concerning this specific form of medically assisted treatment that are of immediate interest.

Generally, opioid agonist therapy is intended to prevent opioid withdrawal and relapse by maintaining the individual on a less harmful kind and/or dose of opioid drug than the one they habitually use, at a dose unlikely to induce intoxication (Bond and Witton 2017). Sometimes additional drugs, for example, benzodiazepines, are prescribed to accompany opioid agonists (Eibl et al. 2019). Ideally, opioid agonist therapies should be accompanied by interventions designed to address underlying personal and socioeconomic factors in a comprehensive harm reduction and health promotion envelope. Consent is required for participation in treatment and clinical research of this type. Admittedly, these therapies

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target the brain, though it is now well recognized that addiction is “not *just* a brain disease” (Leshner 1997, 46, italics added).

Typically, the clinical population involved in this kind of research consists of individuals diagnosed with severe opioid addiction. In DSM-5 the relevant diagnostic category is “Opioid Use Disorder,” specified to be severe (American Psychiatric Association 2013, 541–546). Many of these individuals will be diagnosed with comorbid mental disorders, like anxiety and depression. Unfavorable personal and socioeconomic circumstances also tend to be the norm for this population, which both complicates and aggravates their addiction—as well as their recovery. Repeated treatment failure is a common additional criterion for subjects selected for research in this context.

This clinical profile is typical of many individuals enrolled in research studies undertaken in response to the challenges posed by the opioid epidemic, as well as similar studies undertaken before that crisis. Intuitively, this would appear to be a very vulnerable population of research participants (Charland 2002, 38; Steel, Marchand, and Oviedo-Joekes 2017, 33). In the current opioid epidemic, these chronic, treatment-refractory users are some of the people most at risk of accidental overdose, although naive users are increasingly in peril, especially when the opioids they purchase include dangerous doses of undeclared additional compounds.

Informed consent standardly requires that any choice to undergo medical treatment or to participate in research must be informed, voluntary, and capable (Faden and Beauchamp 1986, ix). This last requirement is referred to as “decision-making capacity” and sometimes “mental competence” (Charland 2015, 1). According to one influential theory, capacity is comprised of four abilities: understanding, appreciation, reasoning, and choice (Grisso and Appelbaum 1998, 52–58; but see also Kim 2010). Weighing the potential risks and benefits of a decision requires values, so some scholars stipulate that capacity also requires a minimally stable set of values, or conception of the good (Buchanan and Brock 1989, 24–25). The outcome of a capacity assessment is typically a yes or no determination that a subject is or is not capable to make a putative decision at a particular time and place, though the factors that enter into such an assessment are more nuanced and complex and require interpretation. Note that decision-making capacity in this context must be distinguished from legal competence to stand trial, which focuses on the mental ability of a defendant to interact with their attorney and engage in court proceedings (Roesch 2016).

Since the mid-1990s a growing number of clinical studies have investigated the decision-making capacity of treatment and research subjects diagnosed with mental disorders to provide informed consent (Appelbaum 2006; Carpenter et al. 2000; Owen et al. 2009, 2015; Szmukler 2009). *Prima facie* worries about the capacity of individuals to provide valid consent in disorders like major depression and anorexia nervosa have been taken seriously and systematically investigated (Appelbaum et al. 1999; Elliott 1997; Elzakkars et al. 2018; Hindmarch, Hotopf, and Owen 2013; Rudnick 2002; Tan et al. 2006). Typically, this research is carried out using the MacArthur Competence Assessment Tool-Treat-

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ment (MacCAT-T) (Grisso and Appelbaum 1998; Grisso, Appelbaum, and Hill-Fotouhi 1997) or the very similar MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum and Grisso 2001). The MacCAT-T is often said to be the accepted gold standard in the area, or at least “the single most widely used instrument for formal assessment of capacity to consent to research” (Morán-Sánchez et al. 2016, 2).

Results achieved by administering the MacCAT-T vary from case to case and are typically rather nuanced. One reason is that “patients may perform quite well on one ability while performing very poorly on another” (Grisso and Appelbaum 1998, 121). Importantly, “the MacCAT-T does not yield a ‘Total’ MacCAT-T rating because it would have little empirical meaning” (Grisso and Appelbaum 1998, 121). There is no absolute fixed cutoff point or threshold for capacity or lack of it, and so determinations of capacity can vary with raters and circumstances. Indeed, “combining the ratings to suggest that the patient has overall ‘average’ ability would ignore the fact that poor ability in one area may be a critical deficit for purposes of judgments about competence” (Grisso and Appelbaum 1998, 121). There are other factors that usually also need to be considered in making an overall determination of capacity, such as obtaining a psychiatric history, conducting a mental status assessment, and perhaps employing other neurocognitive tests and measures (Grisso and Appelbaum 1998, 90–91). Generalizations across different studies for different, or even the same, population(s) in this domain must therefore be approached with great caution.

The authors of the MacCAT-T also tell us that preservation and promotion of autonomy are central to the assessment process.

From a principled perspective, given the importance of the value of autonomy, it is always desirable to aid patients in retaining the right to make their own decisions. From a practical point of view the likelihood of successful treatment outcome is often enhanced by maintaining the patients motivation and commitment to treatment, which is more likely if the patient is involved in making the treatment decision. (Grisso and Appelbaum 1998, 92)

It is now widely recognized that a diagnosis of mental disorder does not in itself automatically imply incapacity to consent to treatment or to participate in research, even when the disorder in question is severe: “no diagnosis carries with it a conclusive presumption of a patient’s incompetence” (Grisso and Appelbaum 1998, 68). This is a major finding of research on decision-making capacity. However, this does not mean that there are no known risk factors for inquiring into the capacity of patients to consent to treatment or to participate in research (Grisso and Appelbaum 1998, 66–76). Indeed, there can be situations where “*doubts exist* about decision-making and a capacity *assessment may be required* to resolve that doubt” (Grisso and Appelbaum 1998, 67, italics added). The question in such cases is whether there are legitimate reasons to doubt capacity.

4. An Anomaly in Research on Decision-Making Capacity

There exists an intriguing anomaly in research on decision-making capacity where addiction is concerned. There has been substantial clinical research in which the MacCAT-T and MacCAT-CR have been employed to investigate decision-making capacity to consent to research on mental disorders like depression, schizophrenia, and anorexia nervosa. But there exist no comparable studies for addiction.

The only exception to this rule is a very recent clinical study which employs the MacCAT-CR in relation to addiction (Morán-Sánchez et al. 2016). It is a cross-sectional study that involves a comparison between 53 subjects with a DSM-5 diagnosis of substance use disorder (SUD) and 50 non-psychiatric subjects. No mention is made of whether the subjects in question are diagnosed with “mild,” “moderate,” or “severe” SUD (American Psychiatric Association 2013, 484). This is crucial since the present discussion is only concerned with “severe” addiction and not addiction in general.

The aim of the study is to challenge commentators who “describe loss of control and compulsive behavior” in addiction in “absolute terms” (Morán-Sánchez et al. 2016, 2). They directly allude to Charland (2002) in that regard. In particular, the authors wish to refute the claim that “people with SUD fail to satisfy the required standards for competent voluntary consent and that we should assume that addicts are incompetent to consent to trials unless proven otherwise” (Morán-Sánchez et al. 2016, 2). In contrast, the authors claim to provide evidence that “a large proportion of addicted individuals with SUD had decisional capacity for consent to research” (Morán-Sánchez et al. 2016, 9). The authors found no statistically significant differences between the two groups, and they state “most people diagnosed of the SUD group were able to provide consent to research” (Morán-Sánchez et al. 2016, 5)—“most,” but not all, and this is key.

This innovative study represents a valuable and much needed addition to research on decision-making capacity in addiction. Indeed, it appears to be the only such study to date. Unfortunately, the particular thesis that it aims to refute is largely beside the point since no one has ever suggested that *all* persons diagnosed with addictions lack decision-making capacity in absolute terms. What has been suggested is that there are good grounds to *doubt*, and therefore inquire into, the decision-making capacity of a very small and specific clinical population of individuals who are considered for heroin prescription trials of a specific sort (Charland 2017). In this case the research subjects are individuals with severe treatment-refractory addiction to opiates, who are in dire psychosocial circumstances and suffer from comorbid mental disorders (Perneger et al. 1998).

What needs to be stressed is that this particular clinical population has never been properly clinically investigated for decision-making capacity using up-to-date instruments like the MacCAT-T or MacCAT-CR. Consequently, intuitive ostensible clinical pronouncements in the area remain woefully unsupported by the available evidence (Charland 2003; Racine and Barning 2019). Thus, there exists no satisfactory *direct* evidence for an evi-

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dence-based approach to ethics in this area. Yet despite this paucity of evidence, many influential addiction researchers appear ready to insist that there are no special problems with capacity to consent to research in cases where research involves the administration of drugs of abuse to persons diagnosed with addictions to those drugs (Hall, Carter, and Morley 2003a; Heyman 2017; Ling 2002; O'Brien 2002; Pickard 2012). The only exception to this rule are episodes of intoxication and withdrawal that can indeed impair capacity, a fact that is well recognized (Carter and Hall 2008b, 218) but even so merits further study (Aldridge and Charles 2008).

In opposition to this stance, it can be argued that there are legitimate reasons to *doubt* the decision-making capacity of some individuals with severe addictions to consent to treatment or research of this sort—not only in the case of special research populations of severely addicted individuals who might receive their drug of choice but also perhaps in other cases and circumstances of severe addiction. One argument is that if indeed addiction is defined by compulsive drug seeking and consumption, and often “truly uncontrollable,” behaviors (Leshner 2001, 77), then by definition there is good reason to *initially* doubt whether persons in opioid agonist trials truly have the capacity to consent to treatments when they are offered their drug of choice (Charland 2002, 40). A second argument is that severely addicted individuals often lack a stable set of values and preferences to guide their decision-making, which is reason to doubt the capacity and accountability of many of the choices they make (p. 42). Admittedly, saying that based on such doubts we should unilaterally suspend the presumption of capacity of severely addicted individuals (p. 45) may be unhelpful rhetoric and hyperbole, though in context this is only really meant to be a practical affirmation of the consequences of legitimate clinical doubt, about a very specific clinical population, rather than an a priori arbitrary principled stance (p. 43).

To be fair, this is an area where there are also intriguing counterexamples. There is some clinical evidence, and some anecdotal evidence, which suggests that persons with severe heroin addiction sometimes do “say no” to offers of free clinical heroin, although whether they go on to seek heroin from alternate sources right after is an unsettled question (Dehue 2002; Hall, Carter, and Morley 2003a; Levy 2016). The alleged counterevidence is therefore insufficient to rule out the soundness of the initial doubts about capacity that are of concern. Clinical trials designed to assess decision-making capacity over time are required. It is perfectly conceivable that even a severely addicted individual may, under some circumstances, delay immediate gratification for a good of questionable quality (prescription heroin) and instead seek a good of better quality (illegal heroin). Note also that the fact that individuals may recover and “mature out” of their addiction (Pickard 2012) by no means implies that they never experienced compulsions to seek and use drugs that proved to be irresistible at the time (Charland 2012, 51)—nor that some may have died as a result of such compulsions before they could “mature out.” Moreover, arguing that doubts about capacity like these can be ignored for now on the basis of unverified predictions that “people who are heroin dependent will not prove to differ remarkably from people with no disorders or people with other disorders” is not a satisfactory response (Hall, Carter, and Morley 2003b, 1175). It is worth noting that sometimes, para-

doxically, harm reduction practitioners report that they “see their clients both as autonomous and competent to take decisions, and as helpless and in thrall to the power of drugs” (Andersen and Järvinen 2007, 248).

5. The Drug Dealer’s Point of View

Addiction researchers and practitioners embroiled in the opioid epidemic approach the issue of consent and capacity from the vantage point of improving the health interventions available to persons who are severely addicted to drugs, in this case primarily opioids. The flip side of this vision is drug dealers—less neutrally, “pushers”—who also seek to provide opioids to persons with severe addictions to those drugs but instead seek to exploit vulnerabilities in their clients’ decision-making capacity in a manner that is meant both to undermine and to exploit their autonomy. The contrast is revealing.

Good ethnographic data on the lives of drug dealers are available (Bourgeois 2003), although research in the area is notoriously beset with complex theoretical and ethical problems (Sandberg and Copes 2013). It is clear that drug dealers often view their clients as capable of making choices. However, whether or not they also consider those clients to have the requisite decision-making capacity to make those choices is much harder to discern. There are data that can be invoked to initially reflect on and hopefully eventually study this question. But some speculation and liberty of interpretation are required if we are to make any progress.

One especially rich source of evidence on how dealers interact with their clients is the “county lines” drug supply model in the United Kingdom. This is a “market trend” that employs a highly mobile drug distribution system in which drug dealers travel from urban hubs to rural settings, both to sell drugs and to exploit local vulnerable populations through coercion and manipulation (Moyle 2019). Often, dealers set up “outposts” in the homes of enlisted locals after “cuckooing” them to the point where “victims become imprisoned in their own homes” (Spicer, Moyle, and Coomber 2019, 9). A distinct feature of research on the “county lines” model is the ubiquitous reference to the “vulnerability” of the population that dealers seek to “exploit,” many of whom are said to be “dependent” on, or “addicted” to, “street heroin” or “crack” (Coomber and Moyle 2017; Robinson, McLean, and Densley 2019). Some researchers observe that “the notion of vulnerability may contradict life experiences in which involvement in criminality or exploitative labor may *otherwise* be understood as demonstrating a certain level of autonomy” (Moyle 2019, 752, italics added). Yet they also maintain that “[d]ue to the lack of alternatives for sustaining daily heroin and crack repertoires in local drug markets, we might therefore anticipate drug dependent populations to continue to gravitate toward such opportunities,” and some groups “*persistently* engage in county lines labor” (p. 752, italics added).

Severe addiction to street heroin is by no means the only vulnerability that dealers seek to exploit in the “county lines” model. But it does provide an interesting evidence base from which to extrapolate and infer what drug dealers might believe and assume about their clients’ autonomy and decision-making capacity, at least in this circumstance. What

follows is admittedly speculative. However, the exercise seems worthwhile since it helps to shed light on the manner in which assumptions about vulnerability can vary in addiction research concerned with roughly the same clinical population, namely, persons who are severely addicted to opioids, in this case, street heroin.

One can surmise that, statistically, drug dealers know very well that demand for their drugs will continue to be robust—all things being equal—despite the fact they also know that many users will accidentally die as a result of overdose from those drugs. Economically, dealers bet on the assumption that new and current users will continue to buy and use drugs, even though they also know that some of those clients cannot properly appreciate and weigh the risks and consequences of doing so. Drug dealers thus choose to view their clients as vulnerable rather than as fully autonomous. Their aim is to exploit that vulnerability for personal gain.

Dealers know from experience that, despite the fact that their clients have agency and make choices to delay or avoid drug use, many still return on a *predictable* basis anyway, because *on the whole* they lack the capacity to make informed decisions about their drug use (Sripada 2019). Ironically, drug dealers capitalize on facts about the decision-making capacity of drug users that many addiction researchers and philosophical commentators appear determined to overlook or deny. Dealers know that “for some addicts, at some times, in some contexts, there appear to be compulsions that make it practically impossible for those individuals to successfully curb or control their drug use for a period of time” (Charland 2002, 51). What is especially interesting about the dealer’s point of view in matters of consent and capacity is the insight that incapacity in addiction is not solely tied to clearly delimited momentary episodes of intoxication or withdrawal—as addiction researchers typically assume—but is really a *process* that is subject to cycles and sudden triggers and about-faces. Dealers know that their clients are ambivalent and why, though they bet on their clients’ decisions to use drugs, rather than abstain from them.

6. Agency, Choice, and Decision-Making Capacity

Notwithstanding this, it must certainly be admitted that, at some level, individuals who are struggling with opioid addiction do exercise their *agency* and make a *choice* when they seek and use opioids and other drugs of abuse (Freckelton 2002). But are they truly able to properly weigh the risks and benefits of their drug use? It is important to appreciate in this context that the fact that a particular decision, or choice, is made and agency is manifest does not automatically entail that the choice, or decision, is capable. Capacity requires an additional justification of its own, for which there are established standardized measures, as stated. Moreover, in this context the terms “choice” and “decision” are often interchangeable, although there exists controversy about exactly whether and how to distinguish them (Abend 2018). Oddly, in so far as they involve clinical research on individuals with a substance dependence diagnosis, clinical studies in choice theory require that those subjects be judged to have decision-making capacity. But choice theories them-

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selves never seem to inquire into decision-making capacity as an important research topic of its own. This is puzzling.

Choice theories of addiction are often contrasted with the medical, or “brain disease,” model of addiction. According to some versions of choice theory, “recovery from addiction is better predicted by a model in which addicts choose to use drugs rather than one in which they are compelled to do so by a disease” (Pickard, Ahmed, and Foddy 2015, 1). The essential point is that “addicts respond to incentives and use drugs for reasons, and so addictive behavior must be understood as choice” (Pickard, Ahmed, and Foddy 2015, 1). In other words, “addiction is not compulsive drug use, but it also is not rational drug use” (Heyman 2013, 1). Addiction is “suboptimal behavior” explainable by empirically established principles such as “the matching law, melioration, and hyperbolic discounting,” the details of which need not detain us here (Heyman 2013, 1). Thus, addiction may be destructive, but it is still a matter of voluntary choice. Proponents of choice theories often argue that the medical, or disease, model of addiction should be abandoned because “it does not fit the facts” and fails to capture “what the research shows” (Heyman, 2013, 1).

Choice theories constitute an important contribution to the understanding of addiction. But the relation between such theories and the “medical” model need not detain us. The relevant point is that choice theories of addiction completely overlook the concept of decision-making capacity and that choice does not in itself imply capacity. Specifically, choice theories do not address the question whether a voluntary choice, whether it is rational or irrational, is capable or not. To repeat: choice does not imply capacity, which in turn means that capacity cannot be assumed just because choice occurs. A crucial observation is that in many models of decision-making capacity, a choice may be deemed capable while at the same time being deemed irrational, for example, the refusal of life-saving transfusion due to religious doctrinal reasons and values (Charland 2001). This kind of distinction seems impossible to make in choice theories, where the relationship between choice, informed consent, and decision-making capacity remains obscure.

So, while “addicts” obviously manifest *agency* and make *choices* in their quest to seek and use drugs, this does not in itself settle the question of whether they have the *decision-making capacity* to do so. Decision-making capacity is a further determination (Charland 2012, 50–51). This is perhaps one of the most important areas of misunderstanding in the ethics of addiction research, much of which is written as if the concept of decision capacity did not exist as a distinct research topic. The same is true of discussions that are framed in terms of the folk psychological concept of “free will” (Baumeister 2017). The fact that a choice is thought to be “free” does not in itself settle the question of whether it is capable. Appropriate studies must be conducted (Racine and Barned 2019).

Finally, choice theories also face the challenge of forcible addiction, which bears on the question of vulnerability. Persons can become addicted to drugs like opiates without choice and without consenting to the administration of those drugs. Indeed, “opioids in particular are an effective coercion tool for traffickers because they numb both emotional

and physical pain; clinicians have noted clear links between the current US opioid epidemic and trafficking” (Chon, 2016; Stoklosa, Stoklosa, and MacGibbon 2017, 26).

7. Fluctuating and Permanent Impairments in Decision-Making Capacity

These last remarks again point to an issue that is insufficiently appreciated in addiction research, namely, that addiction is often a highly cyclical disorder where craving, drug seeking, drug use, and intoxication follow each other in quick succession, sometimes merely a matter of hours. Consequently, it is a disorder with “fluctuating capacity” (National Bioethics Advisory Commission 1998, 32; Presidential Commission for the Study of Bioethical Issues 2014, 3–7). Strangely, this feature has commanded little attention in the clinical ethics literature on decision-making capacity and addiction. Typically, the observation is limited to an acknowledgment of the fact that capacity may be impaired during episodes of intoxication and withdrawal (Carter and Hall 2008b, 221)—as if capacity between such episodes of incapacity were always stable and could not be subject to additional impairments of its own. Clearly, the issue merits further investigation (Biros 2018; Sripada, 2019).

One way to view the issue of fluctuating capacity in the kind of severe opioid addiction we are concerned with is to situate momentary assessments of capacity at fixed times in the context of the natural course of the condition, which is typically governed by a regular frequency of cycles of drug craving, drug seeking, use, and withdrawal. The cycles can be relatively frequent. For example, in one study 52 percent of cocaine users reported injecting up to three to eight times a day, while 66 percent of heroin users reported using at intervals of one to two times a day (Leri et al. 2004, 42). Low injection frequencies certainly occur, but so can higher ones. The point is that for some users the presence of idiosyncratic triggers causing low-intensity craving combined with generally higher frequency of use might compromise or even impair capacity in between episodes of acute intoxication and withdrawal. The question certainly seems worthy of further study. Moreover, without such evidence it seems premature to assume that, apart from episodes of intoxication and withdrawal, subjects are fully mentally capable to regulate their drug use throughout the drug cycle. Sudden and unexpected triggers can notoriously precipitate additional use between such episodes and even relapse in sobriety. Finally, in addition to evidence of possible (often likely) fluctuations in capacity between intoxication and withdrawal, there is evidence that “once addicted, the individual has moved into a different state of being ... as if a threshold has been crossed” (Leshner 2001, 75–80).

The finding that disinhibition in some substance use disorders is subject to “state” fluctuations based on environmental and psychological triggers means that some individuals may be subject to “accidental” impairments in capacity between episodes of intoxication and withdrawal, and therefore relapse, in the presence of sudden unexpected triggers (Jones et al. 2013). If so, a capacity assessment that an individual is capable to consent to or refuse administration of a drug of abuse at one time cannot be assumed to carry over

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from that moment forward. The fact that overdose deaths or accidents can occur at any time during the addictive cycle should occasion doubts about the capacity of persons with severe addictions between moments of intoxication and withdrawal. In such cases, accountability is problematic (Elliott 1991). The development of prognostic predictive models for fatal and non-fatal opioid overdose accidents is likely to have important implications for how to think about capacity in this domain (Glanz et al. 2018).

Therefore, the possibility that there may be occurrences of impaired decision-making capacity in the addictive cycle that lie between times of intoxication and withdrawal must be added to our conception of the fluctuations in capacity that are characteristic of opioid and other similar addictions. Certainly, there are basic fluctuations due to reversals or discounting in preferences, or values, that lie at the theoretical center of choice theories of addiction and the contingency management therapies designed to treat them. But there are also more intermittent kinds of fluctuations. This second class of fluctuations has not been sufficiently studied in research on consent and capacity in addiction, though it has been identified as a distinct research topic (Charland 2002, 44; Pickard 2012, 40–49). They have to do with affective factors like values and emotions, rather than understanding (Charland 1998, 2006; Hermann et al. 2016; Tan et al. 2006). Taken together, these kinds of fluctuation help explain why ambivalence is sometimes thought to be the hallmark of addiction (Elster 1999, 74–79) and why some leading researchers even state that “addiction is ambivalent drug use” (Heyman 2013, 4).

Aside from these kinds of fluctuations, some authors speak of *permanent* impairments in capacity that may arise due to chronic use and abuse of opioids when associated with chronic pain (Yan and Kuo 2019). Indeed, in contrast to addiction specialists and philosophical commentators on addiction science, who almost invariably tend to lean on the side of autonomy in matters that pertain to consent and capacity when it comes to the prescription of opioids, some pain specialists urge us to acknowledge the fact that “dependence and addiction [to opioids] affect judgment, and arguably make it impossible for the dependent or addicted individual to make rational decisions about opioids” (Ballantyne and Fleisher 2010, 366). In such cases, “while the assumption of a patient’s incompetence may be a violation of the patient’s autonomy, and may represent unjustified paternalism ... it acknowledges that both pain and opioids can at times compromise an individual’s ability to fully understand opioid limitations” (Ballantyne and Fleisher 2010, 366).

Therefore, there exist cases where there are good clinical reasons to doubt the decision-making capacity of some individuals to whom opioids are or may be prescribed. This kind of evidence must be incorporated into the existing literature on the ethics of opioid agonist therapies, which typically fails to consider research on opioid prescribing in the context of chronic pain. In sum, while it is clearly unethical to treat opioid-addicted individuals as if they automatically lack the capacity to consent to their drug of choice, it is equally unethical to ignore risks that suggest we should doubt their capacity to consent in

some circumstances—and assess them for capacity with an open mind, paying careful attention to their overall clinical profile (Nassif and Decatur 2019).

Understandably, addiction researchers may feel trepidation when confronted with the possibility that significantly more of their research subjects may require individual clinical capacity assessments using standardized psychometric instruments like the MacCAT-T and MacCAT-CR (which on average can take 15–20 minutes to administer). When we incorporate the likelihood of idiosyncratic triggers together with the cyclical character of severe addiction into the assessment process, findings of incapacity may rise. All of this may seem overly cumbersome and time-consuming to researchers, something that could potentially slow recruitment for addiction research.

One possible solution to these problems is substitute decision-making (Charland 2002, 44). But while it is an ethical possibility worth mentioning, resorting to substitute decision-making in such cases may not seem an attractive solution to researchers because it is impractical, and time is of the essence. Yet there might be modifications to this practice where, depending on the jurisdiction in question, legal guardianship might be provided in more systematic ways in order to protect subjects as a group and ensure accountability of the consent process (Sprumont 2002). This moreover is perfectly compatible with the promotion of autonomy and educational measures to include it in the consent process. That said, determinations of incapacity must be ethically respected for what they are, and research subjects who are deemed to be lacking in capacity must be accorded special attention in the consent process.

8. Vulnerability, Harm Reduction, and the Opioid Epidemic

The time has come to tie these clinical and ethical concerns about capacity and the kind of opioid agonist therapies discussed with assumptions surrounding vulnerability in other types of harm reduction initiatives undertaken in the context of the opioid epidemic, for example, needle exchanges, clean injection facilities, provision of naloxone kits, socioeconomic counseling and assistance, and so on.

Harm reduction in the context of the opioid epidemic is sometimes said to arise from “the need to provide ... people who use drugs with options that help minimize risks from continuing to use drugs and of harming themselves or others—especially the harms associated with involvement with their nation’s criminal justice systems” (Drucker et al. 2016, 241). A key premise of this type of harm reduction approach is that “allowing people to suffer or die from preventable causes of drug use as well as punitive drug policies is not an option” (Drucker et al. 2016, 241). It is common to view harm reduction approaches as “an important alternative to abstinence-based treatment,” which in some jurisdictions “dominates the field of addiction” (Drucker et al. 2016, 241).

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Harm reduction is sometimes directly tied to “vulnerability,” which may operate at the level of the individual, the community, and society (Ezard 2001). At the same time, it is sometimes said that harm reduction embraces the assumption that “a drug user is a sovereign citizen and member of a community, not a deviant individual or only an object of measures” (Stafford 2007, 88). A “sovereign citizen” is said to be “someone who has autonomy over their life ... an active rather than a passive entity, capable of making choices over his/her own life, taking responsibility for these choices, and playing an important role in prevention, treatment, and the recovery process” (Stafford 2007, 89). How exactly to understand the nature and scope of agency in these contexts is a heated political question with important clinical and ethical ramifications (Gowan, Whetstone, and Andic 2012).

Could there be a discrepancy—potentially, an ethical double standard—in the manner in which the decision-making capacity and vulnerability of individuals who suffer from severe opioid addiction are viewed by different stakeholders in the harm reduction community? Paternalistic interference appears to be discouraged and shunned when the concern is with prospective subjects for medically assisted agonist therapies of the sort discussed. In this case, the promotion and defense of autonomy appear to trump any worries that prospective treatment or research subjects might be vulnerable with respect to the consent process, although we do paternalistically exclude subjects from the consent process when they are intoxicated or undergoing withdrawal. However, in the case of other harm reduction interventions, there appears to be a clear recognition that prospective subjects are truly vulnerable and need to be helped because they cannot be relied on to help themselves. Note that these are not usually cases of strict paternalism, which involves *interfering* with an individual’s autonomy, but rather attempts to influence a person’s autonomy, by altering the range of possible choices they may have (Dworkin 2017).

Whether this second option amounts to indirectly “interfering” with autonomy is not clear. It could plausibly be argued that we indirectly seek to interfere with a person’s autonomy when we actively intend to influence their autonomy by encouraging them to use clean needles and make such needles readily available or when we invite them to use medically manufactured and prescribed opioids, and even at times make such drugs freely available, in order to steer addicted subjects away from dangerous adulterated opioid compounds that are likely to cause overdose.

Obviously, persons diagnosed with addictions are not all equally vulnerable, in all respects, all of the time. And adequate comparative studies of vulnerability with respect of harm reduction interventions in the opioid epidemic pose significant theoretical challenges. Evidently, this is not a simple either-or issue, another false dichotomy in the ethical debates in research on addiction (Charland 2012; Racine, Sattler, and Escande 2017). Rather, the point of the question is to suggest there may be a tension in the manner in which society and the harm reduction community choose to view vulnerability in addiction. In some cases, the assumption appears to be that because persons with severe substance-related disorders cannot sufficiently help or protect themselves from the risks and harms of addiction, society must step in and help them in that regard, while at the same

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time encouraging autonomy and more responsible behaviors. However, in other cases, clinical and ethical worries about the capacity and possible vulnerability of subjects to consent to medically assisted therapies are either downplayed or ignored on the basis that they are derived from ill-founded paternalistic assumptions that are ethically incompatible with the alleged autonomy of those subjects (Carter and Hall 2008a).

Readers can decide for themselves whether such worries are well founded or not. But that there is little direct clinically relevant evidence on decision-making capacity in addiction to pass judgment on this issue at the present time seems indisputable. Recall the massive campaign of deception, disinformation, fraud, and misguided practice guidelines associated with the early years of the North American opioid epidemic (Van Zee 2009). In such a historical context, is it not worth asking the question whether clinical practitioners and researchers may have exaggerated the decision-making capacity and autonomy of addicted subjects to consent to opioids, just as they began prescribing opioids for non-cancer pain and were simultaneously taught and encouraged to downplay the risks of addiction? After all, the history of psychiatry provides ample evidence that conceptions of autonomy can vary over time and across different jurisdictions, just as thresholds for legal competence and clinical decision-making capacity can be socially set higher or lower, as the case may be (Charland and Musto 2021).

Indeed, clinical practice guidelines have now been substantially altered in many jurisdictions since the opioid epidemic began (Jones et al. 2018). What is puzzling is that assumptions surrounding consent and decision-making capacity in addiction research do not appear to have changed despite rapid increases in mortality (National Institute on Drug Abuse 2019). The argument of the present chapter is that the issue is ethically concerning since there is so little direct evidence on the matter and it is important for understanding the causes of the opioid epidemic, which in turn informs thinking about solutions. We may wish and probably should endeavor to treat persons with severe addictions as if they were fully autonomous agents, but that does not make them so. Recall that the legal presumption of capacity to consent is just that: a *presumption*. The argument of this chapter is that there are sound, evidence-based reasons to doubt and investigate capacity in some cases of severe, chronic addiction that have not been sufficiently discussed in the relevant research literature. We should also be mindful that standards to assess decision-making capacity are historically and socially conditioned and therefore not immutable.

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