Why effective consent presupposes autonomous authorisation: a counterorthodox argument

M Epstein

Effective consent is indeed a legal fiction

Since the late 1960s, the legal doctrine of consent has occasionally been subject to severe criticism from within the bioethical discourse. The criticism was often based on observations indicating that consents and refusals, which had been considered valid from legal or institutional points of view, had frequently failed to reflect genuinely autonomous decision making, hence genuinely autonomous choices.

This has led several critics to conclude that informed consent is a *legal fiction*. To clarify the concept, a legal fiction is a supposition of fact taken to be true by the courts of law, irrespective of whether it is true or not, and even though it might not be true (see “fiction” in *The Concise Dictionary of Law*).¹ What these critics probably meant to say was that the law deems any person who has given a legally valid consent to be genuinely task specifically autonomous, regardless of whether this is true or not and even though it might not be true. In other words, informed consent is a legal fiction, since it presupposes—that is, claims to reflect—genuine task specific autonomy, however baselessly.

It was precisely this potentially embarrassing conclusion that prompted Faden and Beauchamp (FB) to develop a brilliant and remarkably effective argument in defence of the legal doctrine of consent. In their seminal work, *A History and Theory of Informed Consent*, they indeed acknowledged that *effective consent* (the term they had specifically assigned to legally and institutionally valid consents and refusals) often fails to be compatible with *autonomous authorisation* (the term they had specifically assigned to genuine task specific autonomy). Indeed, they recognised that effective consent does not necessarily entail autonomous authorisation. They argued, however, that the former is not a legal fiction, since it does not presuppose the latter in the first place.² This argument will be referred to in the following as “the orthodox defence”, for the reason that it has been endorsed by

most scholars who have since been studying and teaching the legal doctrine of consent.^{3 4}

This paper endeavours to challenge this defence. It will show that FB made at least one, if not two, logical mistakes: 1) they wrongly assumed that from the fact that effective consent does not necessarily entail autonomous authorisation follows the logical conclusion that it does not presuppose it either, and/or 2) they mistook *meeting the requirements of effective consent*—being legally competent, being offered adequate disclosure, and being non-coerced (which does not necessarily entail autonomous authorisation)—for *effective consent* (which perhaps presupposes autonomous authorisation) and ignored the latter altogether.

The paper will argue that while meeting the requirements of effective consent neither reflects nor guarantees autonomous authorisation, effective consent—once it has been obtained—none the less presupposes autonomous authorisation. More specifically, its universal and most important legal implication—acceptance of full and exclusive responsibility for one’s decision—indicates that it does presuppose autonomous authorisation (actually, nothing less than absolutely autonomous authorisation) and that it is bound to be seen to be doing so by the contracting parties. In view of this inference, the paper will conclude that informed consent is indeed a legal fiction.

The author suggests that this conclusion might have some counterintuitive implications for the sociology, history, and perhaps even the morality, of the legal doctrine of consent and its supportive discourse. Unfortunately, this discussion exceeds the scope of one paper.

INFORMED CONSENT IN THE DOCK

Early critics in bioethics argued that the legal doctrine of consent had often been reduced—to use the words of Jonsen—to a “meager and formalistic” procedure, which does not go deeper than “a

mere ‘okay’ to an obscure request”.^{5–7} In fact, since the late 1960s, a growing body of evidence has been suggesting that “[the] chances are remote that the subject really understands what he has consented to”.⁸ Over 70 studies performed in a variety of clinical settings indicated that legally and institutionally valid consents and refusals had frequently failed to reflect genuinely autonomous decision making, and hence had failed to result in genuinely autonomous choices.⁹ Low socioeconomic status, poor education, old age, lengthy hospital stay, stress, language barriers, and misinterpretation of probabilistic data were found in these studies to be associated with such outcomes. These were typically complicated by poor, albeit otherwise legally or institutionally adequate, disclosure practices.^{10–16}

Such observations clearly reflect the critics’ understanding that the validation tests of consent and refusal have high sensitivity and low specificity in relation to their ability to identify genuine autonomy; in other words, they are prone to yield a high false positive rate. However, where does the root of the problem lie in relation to the latter allegation? Are the validation tests weak in relation to some *ideal conception of autonomy* a particular critic might have, or are they weak rather in relation to a *conception of autonomy which legally and institutionally valid consents and refusals arguably presuppose*?

Most bioethicists have endorsed the former option. Some argued that striving for fully informed consent is generally unfeasible and perhaps even undesirable.¹⁷ Many, however, including FB, argue that a fully informed consent ought to serve (and perhaps has served) at least as an ideal, albeit never fully attainable, a benchmark against which the moral adequacy of legal and institutional practices is to be evaluated.

Still within this context, many scholars endorsed an arguably more critical position. Jay Katz argued—for example, that the legal doctrine of “informed consent” bears a “name” that “promises much more than its construction in case law has delivered”. He maintained that the courts had made informed consent a “cruel hoax” and had allowed “the idea of informed consent...to wither on the vine”.¹⁸ Others argued along the same line that informed consent is a myth.^{19–22}

On the other hand, several critics argued explicitly that some forms of informed consent are legal fictions—for example, implied, opt out, and parental consent.^{23 24} Some went even further to argue that informed consent *in general* is a legal fiction.²⁵ Alan Stone also provided an explanation of the role of this

fiction, which he argued has little to do with respect for individual autonomy and freedom of choice.^{26 27}

It was precisely this allegation that prompted FB to develop an argument in defence of the legal doctrine of consent.

THE ORTHODOX DEFENCE

Faden and Beauchamp drew a distinction between two different concepts of informed consent. The first concept was designated *sense₁*, or *autonomous authorisation*. The authors defined this concept as:

an autonomous action by a subject or a patient that authorized a professional either to involve the subject in research or to initiate a medical plan for the patient (or both). ... an informed consent in *sense₁* is given if a patient or subject with (1) substantial understanding and (2) in substantial absence of control by others (3) intentionally (4) authorizes a professional (to do the intervention).²

By contrast, *sense₂* or *effective consent* was defined as a policy oriented kind of informed consent—that is, an authorisation from a patient or a subject that is “effective” in the sense that it “has been obtained through procedures that satisfy the rules and requirements defining a specific institutional practice in health care or in research”.²

Of course, autonomous authorisation and effective consent are not mutually exclusive. They may happen to be compatible with each other. However, neither necessarily entails the other, the former does not presuppose the latter, and what is more important—the latter does not presuppose the former either. Since the legal fiction argument depends on precisely the opposite premise, it is thus refuted.

According to FB, it is lamentable that autonomous authorisations are rarely obtained. However, effective consents could no longer be indicted for not being what they allegedly claim to be. Put differently, effective consent promises something that may perhaps be imperfect, but it misleads no one: it keeps its promise.

THE ORTHODOX ARGUMENT REFUTED

Since FB explicitly appeal to logic (“Our task in the following pages is the purely logical one of providing a conceptual analysis of informed consent”), let us consider the logic of two possible interpretations of their argument.² According to the first interpretation the argument takes the following form:

- (1) Autonomous authorisation does not necessarily entail effective consent, and
- (2) Effective consent does not necessarily entail autonomous authorisation, and
- (3) Autonomous authorisation does not presuppose effective consent. Therefore,
- (4) Effective consent does not presuppose autonomous authorisation.

Points 1–3 are certainly true. It is also easy to see that points 1 and 2 reflect symmetry: each provides a logical mirror image of the other. This does not, however, necessarily imply that points 3 and 4 maintain the same relation as well. Indeed, to say that point 4 follows from points 1–3 would be a formal fallacy—that is, a logically invalid conclusion.

Two legal examples might demonstrate this point. Let us replace autonomous authorisation with *innocence* and effective consent with *the legal presumption of innocence* (pertaining to persons who have not been convicted), and then follow the same line of argument:

- (1) Being innocent does not necessarily entail being presumed innocent, and
- (2) Being presumed innocent does not necessarily entail innocence, and
- (3) Being innocent does not presuppose being presumed innocent. Therefore,
- (4) Being presumed innocent does not presuppose innocence.

Now let us perform the same operation with *biological fatherhood* and *the legal presumption of biological fatherhood* (pertaining to the man who was the husband of a mother at the time of conception or birth):

- (1) Being the biological father does not necessarily entail being legally presumed to be the biological father, and
- (2) Being legally presumed to be the father does not necessarily entail being the biological father, and
- (3) Being the biological father does not presuppose being legally presumed to be the biological father. Therefore,
- (4) Being legally presumed to be the biological father does not presuppose being the biological father.

Clearly, in both cases points 1–3 are true, but the conclusion 4 is obviously false. In fact, the legal presumptions of innocence and fatherhood are classic instances of legal fiction.

According to the second interpretation, the conclusion 4 is not derived at all from considerations of symmetry; rather, it implies such symmetry. Of course, in order to argue so, one would need to prove, independently of points 1–3, that effective consent does not presuppose autonomous authorisation.

Such an argument could indeed be produced, if one took *effective consent* to be essentially identical to *meeting its conditions of validation*. In the assumption that they are indeed identical, it would be just logical to conclude that if the latter did not presuppose autonomous authorisation (which is undisputable), neither would the former. Indeed, FB distinguished between the specific conditions of validation—that is, “legal competence”, “adequate disclosure”, and “non-coercion”—and meeting them (being legally competent, being offered adequate disclosure, and being non-coerced), but they did not distinguish between the latter and effective consent.²

It is certainly true that meeting the requirements of effective consent may entail effective consent, as much as it is true that effective consent implies meeting its requirements. However, from this it does not follow that the former is identical to the latter, unless the latter is deemed to include the act of consent/refusal as well. For example, being an over 18 year old British national does not necessarily entail, and certainly does not presuppose, having an autonomous political opinion. By contrast, taking part in the general election, which implies that these conditions of eligibility have been met, does presuppose (perhaps wrongly) having an autonomous political opinion. In fact, the very legitimacy of democracy rests on this presupposition. Equally, the mere fact that meeting the requirements of effective consent does not presuppose autonomous authorisation should not be accepted as sufficient indication as to what effective consent presupposes or not.

THE COUNTERORTHODOX ARGUMENT

In meeting the requirements of effective consent, a person will acquire full authority to consent to or refuse a particular, otherwise lawful, intervention. This full task specific authority will presuppose full task specific autonomy. Certainly, authority may also be shared. In such cases, the effective consent or refusal will presuppose full task specific autonomy of the party as a whole. Although this is the most frequently mentioned legal implication of effective consent, it is certainly not the only one. Nor is it arguably the most important one.

In giving effective consent, the person universally acquires full and exclusive responsibility for her own decision. She exempts any other party from responsibility for her own decision. This is true regardless of whatever the indemnity arrangements are. Thus in case of mishap, she could blame herself only for having given consent; of course, provided that the other party has fully met the terms of the contract. The same applies to "effective refusal". Moreover, a person who is deemed to be legally competent will acquire full and exclusive responsibility even in relation to unlawful decisions.

All in all, the doctrine of consent turns out to be a legal instrument for privatising responsibilities. Yet, full and exclusive responsibility (or blame), hence effective consent, presupposes absolute autonomy, let alone autonomous authorisation. Moreover, it must be seen to be doing so by the contracting parties.

In light of this conclusion, it is now worthwhile to discuss what the conditions of validation of effective consent presuppose individually. A detailed discussion warrants an additional paper. For the purpose of the current argument, however, each one of these conditions must be considered in brief.

Competence

Legal competence to consent or refuse is established in different ways, depending on the situation. Relatively rigorous standards are normatively applied only in cases where competence or incompetence is being challenged. Since these standards reflect notions of subabsolute task specific competence, meeting them does not necessarily entail absolute competence. Still, effective consents or refusals obtained by person who have met these standards will presuppose absolute task specific competence. Arguing to the contrary would not be compatible with the fact that such consents and refusals entail full and exclusive responsibility for one's decisions.

The same holds true for the standard applied in the normal case—"the presumption of competence". In biomedical settings, it means that health professionals must work in the assumption that "every adult has the capacity to decide whether to consent, or refuse, a proposed medical intervention..."²⁸ Needless to say, this presumption does not necessarily entail competence—absolute or subabsolute. And yet, an effective consent obtained by a person presumed competent will presuppose absolute competence for the same reason as discussed above.

Adequate disclosure

Despite the fact that disclosure under the requirements of any contract rarely contains *all* the relevant information that could, in principle, be provided by the parties, the contract presupposes that it does. Information that is lawfully excluded from the disclosure is deemed to be simply irrelevant. The point is that extracontractual information may often have a crucial, if not exclusive, role in the parties' decision making. Moreover, despite its relevance, it may sometimes be inaccessible, misleading, or incomprehensible. None the less, once effective consent has been obtained, it will presuppose that this kind of information has been fully accessible and transparent and that the contracting parties have assimilated it competently.

Voluntariness and freedom from coercion

Most commonly, each party to the contract is presumed to be free from coercion. In some cases, particular forms of coercion must be actively excluded. Occasionally, the parties may also be asked to sign a declaration stating that their decision was made in the absence of coercion and based on free will. Of course, neither the presumption nor the exclusion nor the declaration necessarily entails absolute freedom. However, full and exclusive responsibility (and hence effective consent) indeed presupposes absolute freedom.

CONCLUSION

Although meeting the requirements of effective consent does not necessarily entail autonomous authorisation, its common legal implication—the acquisition of full and exclusive responsibility—indicates that it presupposes autonomous authorisation. This means that effective consent is bound to be a legal fiction.

Embarrassing as this conclusion might at first seem, its implications are not inevitably critical. In fact, one could defend effective consent *qua* legal fiction as an efficient tool capable of both containing paternalism as well as keeping any legal investigation of the facts within manageable bounds.

Of course, such arguments must also presuppose that 1) the false positive rate of genuine autonomy, which is implicit in the legal fiction, is reasonably low, that 2) even if the rate was high, persons would just benefit from it, that 3) even if they did not benefit from it, at least it would entail no great damage for them, that 4) even if it entailed such damage, it would be no one else's fault, and, at any rate, that 5) even if a third party could be blamed for causing either the high false positive rate, or the

damage it may entail or both, this party could not possibly gain anything from such actions.

However, if these presumptions were refuted, the defence of effective consent *qua* legal fiction would turn out to be deficient and perhaps even misleading. This would have to prompt a serious inquiry into the moral implications of this legal fiction, the role it plays within the legal, institutional, and economic spheres of contemporary society, and its history. Such inquiry, which is beyond the scope of this paper, would also have to explore the role played by orthodox bioethics in concealing the fictitious nature of effective consent.

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Correspondence to: Dr M Epstein, Queen Mary University of London, School of Medicine and Dentistry, Institute for Health Sciences, Unit for Human Science and Medical Ethics, 40 New Road, London E1 2AX, UK; m.epstein@qmul.ac.uk

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