Consenting to consent

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Both ethicists and lawyers accept that a provider – be it a researcher or a clinician – should provide sufficient information for a reasonable person to make an informed decision about whether they wish to go ahead with the proposed intervention or treatment.¹ They are bound to do so both because they have an ethical responsibility to preserve the individual's autonomous decision making, and, in many countries, because the law obliges them to. In this month's issue of the JME, three articles tackle ethical issues relating to consent in different contexts. Overarching these analyses is the pragmatic question of whether the process of taking consent in itself might alter the outcomes, and whether, in doing so, it can undermine the initial therapeutic or research goal – so creating another ethical question of what to prioritise.

Psilocybin (a serotonergic psychedelic) is entering Phase III trials to evaluate its effect on treatment resistant depression and cancer related depression and anxiety; earlier trials have shown sustained symptom reduction in these populations. Smith and Sisti examine whether a form of enhanced consent is ethically required for these drugs.² They explore how to adequately consent for 'therapeutic touch' (eg, holding someone's hand) in a future altered state; the rare but significant mental health risks including trauma re-exposure; and the potential for a personality change given the intense experiences which many subjects have reported. They illustrate the potential for personality change with an example regarding the spiritual experiences which can occur with serotonergic psychedelics, and suggest that *'agnostic or atheist patients may take the development of a newfound sense of spirituality or belief in God to be a loss if it is incongruent with their prior values or if it is disruptive to relationships with others'*. They note the difficulty in adequately consenting a patient for such a new sense of spirituality: *'they (the atheist patient) might acknowledge that others have deep encounters as if connecting to God or 'deep' reality but assume that they themselves would not take such encounters as real.'* They argue that taking time to enable the patient to understand this possibility is an important aspect of consenting for such treatment, particularly since personality change

might occur after a single treatment, and so there is not time to gradually evaluate the effect the drug is having, and withdraw or stop. What has not yet been addressed is whether patients might be suggestible during this process, and whether consenting individuals for such spiritual events might in itself alter the experience they have; further research could examine the effects of different consent procedures.

Smith and Sisti propose that enhanced consent should take place over what is now called 'preparatory sessions' before the treatment has actually been decided upon. They note that because some of the experiences are inarticulable the patient can never be truly informed when they agree to undertake the treatment. They address this by making parallels with other experiences we undertake without knowing what they will really be like until we have experienced them for ourselves: starting a new relationship for example. We start a relationship believing it will be good for us, but accepting that much is unknown. A patient may not be able to fully imagine everything that they will experience with psilocybin, or exactly how they will be after the treatment, but there is enough information that participants to date have had 'profoundly positive feelings about the experience' to enable the consent process to be ethically sound. What is not known on an individual level is balanced by what is known at a population one. In fact, they argue that so long as phase III trials are positive, there is an ethical imperative to proceed to using psilocybin in mainstream psychiatry, with the enhanced consent process that they describe.

Silverio *et al*'s paper examines the duties of a researcher to report non-recent (historic) childhood sexual abuse.³ It was written in response to an ethics committee's suggestion that researchers investigating experiences of pregnancy and childbirth in those who had survived childhood sexual abuse would need to report it. It illustrates the difficulty with trying to obtain informed consent for sensitive qualitative interviews; the authors review the ethical and legal obligations that a researcher has to their participant and to the population in undertaking such research.

They note that while a participant may feel some distress at recounting traumatic

experience, *'research-based exchanges can even be cathartic due to offering a non-judgmental 'safe space' in which participants may achieve validation and find a voice'*. Going into the interview, therefore, the participant needs to feel confident that they are speaking in a trusting, confidential environment. This would be negated if (as the ethics committee that Silverio went to suggested) the researcher had a duty to report historic childhood sexual abuse: either researchers would need to consent the participant to the potential breach of confidentiality in advance (in which case recruiting might become more difficult, and those that were recruited would potentially speak less openly), or they would need to breach the element of trust built between the participant and researcher, which can be particularly damaging to someone who has previously been abused.

The authors reviewed several legal jurisdictions, and concluded that in the UK – and even in countries where there are some mandatory reporting laws – researchers would not be legally obliged to report disclosures of historic abuse against the wishes of the participants. They recommend that, in the event of a public interest disclosure occurring (for example relating that a perpetrator might pose a current risk to vulnerable people) a safety risk should be assessed by an independent agency on an anonymous basis.

Silverio *et al* emphasise that Researchers and Research Ethics committees have a responsibility to review and understand legal obligations in their country before they undertake or review research which may unearth historical crimes; to not do so might lead to the research itself becoming re-traumatising and unethical. Researchers should also be prepared to offer participants guidance to external support and reporting should they wish it. The primary ethical responsibility of the researcher lies with the participant; maintaining trust with them is paramount.

Gabrielli *et al* examine issues with the increasingly prevalent practice of audio and/or video recording in the operating room, which is done to improve patient safety, surgical training, and accountability.⁴ The authors analyse the European and American legal frameworks, examining how the differences in them

are dependent on the cultural contexts in which they have been developed. They highlight the importance of not '*applying a foreign paradigm to a very different culture*' when developing guidance for other regions. They examine the ethical issues of both the act of recording (including preparatory procedures such as consent) and the consequences and responsibilities that emerge from VR (for example who owns the recordings, and who has the right to edit or delete them). They highlight the difficulties in adequately consenting a patient (or surgeon) in an age when technology and communication methods are developing rapidly: while anonymity might be intended and promised, retrospective identification at a later date, while unlikely, might be possible. If the consent process covers every imaginable future possible risk it might reduce

participation and undermine the benefits both to that particular patient and to the population.

In all of these examples, it is critical that trust between the clinician/researcher and the participant is established and maintained. One way of doing this is to ensure that the clinician/ researcher communicates their intent to inform the patient about all reasonably predictable outcomes, but also explains the uncertainty that is inherent in predicting the future; that they understand the consent process and its limitations. The authors in this issue have illustrated important examples of this.

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