The concise argument: the importance of consent and choice

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When Beauchamp and Childress articulated the necessary and sufficient conditions for informed consent, they might have thought that would be the final word on what informed consent is.[1] It's emphasis in the Belmont Report,[2] the Nuremberg Code,[3] the Helsinki Declaration[4] and numerous codes of professional ethics seems more than sufficient for emphasising its importance. Nonetheless, its place as the central issue for medical ethics appears undiminished and Pubmed lists 6192 publications with 'Informed Consent' in the title since 1979.

One view of this is that medical ethics has channelled too much intellectual effort into consent, perhaps at the expense of other important ethical issues. Papers in this issue of the *Journal of Medical Ethics* suggest that the discussion of consent continues because of the need to consider what it means in new contexts, how it can be a challenge in some contexts, how it is related to tough theoretical issues about the value of choice and autonomy and how it can blend into other debates.

The development of biobanking and the challenges it presents about which variant of consent should apply have been discussed in the JME before. One option is for consent to be 'broad', meaning that when consent is given for the collection of tissue the 'type' of future secondary uses are specified but not the specific research studies, on the basis that the potential benefits are significant, the risks low and the costs of gaining consent for every use of tissue significant. Hofmann has argued against broad consent on the basis that being 'informed' is a crucial aspect of informed consent and respecting autonomy.[5] The debate about how consent should be conceptualised for biobanking continues in this issue of the JME. Manson develops a series of objections[6] to 'meta-consent', a version of consent that Ploug and Holm claim respects the autonomy of donors and is feasible for biobanking and the secondary use of data more generally.[7] The idea is that individuals can decide whether they want their consent or refusal to be 'broad' or to be asked 'dynamically' about each new study that falls within the category of research that they have given 'broad' consent to. On the face of it, this appears to be a solution that respects autonomy more fully and is sensitive to the meaning that individuals attach to donating their tissue, hence the idea of it being 'meta' consent.

Manson objects to meta-consent for the following reasons: researchers don't have a moral obligation to facilitate meta-consent and that there are costs and practical problems in providing meta-consent. While Ploug and Holm are likely to be correct that some individuals will prefer a greater say about the secondary studies their tissue or information is used for, Manson argues that it doesn't follow that researchers must accommodate this preference, particularly if 'broad consent' is thought to be specific enough. He argues that the costs of meta-consent are likely to be significant, perhaps as significant as they would be for dynamic consent and that the autonomy promoting argument goes beyond what we ordinarily think of as required for respecting autonomy.

Ploug and Holm respond that the ongoing use of tissue and data from individuals who have donated to a biobank mean that researchers have a long term relationship with donors and that they therefore have additional moral duties to those individuals.[8] That, and the changing nature of research mean that for Ploug and Holm meta-consent is a better model than broad consent, even if it produces additional costs for research. It would appear that which model of consent fits biobanks and other secondary research best turns on deeper issues about how we understand the value of choice, autonomy and the relationships between those seeking and giving consent.

Wilkinson explores the relationship between the value of choice and equity in his paper on public health and obesity.[9] He draws a distinction between people only being able to choose between poor options and people making poor choices between options. He claims that, in general, public health initiatives that aim at reducing obesity via regulation reduce choice and thereby work by reducing the ability to make poor choices. From this observation he argues that those who make an equity case for public health regulation should demonstrate that some people are choosing badly (from a public health perspective), otherwise acting to influence choice is unlikely to promote equity. He claims that these conditions are not met in the case of obesity regulations and they therefore tend not to promote equity. Fenton responds by applying pressure to Wilkinson's claim that preventive regulations reduce the options that people can choose from and that this tends not to promote equity.[10] She observes that the harmfulness of reducing a choice depends on the nature of that choice, for example regulations that improve health by stopping a risky form of employment such as mining are a more significant restriction of choice (and freedom) than legislation that removes the choice of consuming foods made with trans fats.

There's more to be said about the value of choice in the context of public health interventions, but as is the case with the debate about broad consent for biobanking, the positions we defend often embody important assumptions about the value of choice and its relationship to important ethical concepts such as equity, as well as to autonomy.

What we should do when the prospects for meaningful choice are limited is explored in a paper by Bruni.[11] He describes a number of insights for proxy consent from a study that evaluated functional MRI for prognosis with patients who have suffered a severe brain injury. These are patients who cannot consent nor make choices, so a substitute decision maker is often involved to either consent on behalf of the patient (if that's a possibility in that jurisdiction) or to provide an informed view about the choice the patient might have made if they had been able to. The discussion centres on strategies for avoiding the therapeutic misconception and ensuring that the context and timing of a discussion about a study such as this enable a substitute decision maker to make a meaningful and informed choice.

Enrolment in a study, particularly one that is unlikely to result in a medical benefit to a patient, ordinarily requires consent of some kind. However,

decisions such as whether a Do Not Resuscitate (DNR) order is medically indicated involve weighing the potential for causing harm against the potential for benefit and there is an ongoing debate about whether consent should be required for DNRs. Asua *et al* consider a number of arguments in favour of using 'Informed Dissent' for such decisions.[12] The idea is that rather than actively seeking the agreement of the patient or a substitute decision maker, they are informed about the reasons why a DNR should be applied and they then might object to this decision. When viewed from one perspective it might be objected that in the event that a dissent resulted in the DNR not be made, that this is in effect equivalent to informed consent, because the logic of that concept implies that 'but for' the consent, something would not have happened. What Asua *et al* appear to be emphasising is that a DNR should primarily be viewed as a clinical judgement about when treatment is warranted given the foreseeable harms and the possibility of benefit and that recasting this as 'dissent' emphasises the nature of this judgement.

This issue of the JME explores a number of other important ethical issues, but as is often the case with medical ethics, choice, consent and autonomy feature prominently in many of our debates.

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