

Highlights from this issue

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Should we be free to self-medicate?

In this month's feature article, Jessica Flannigan presents a challenge to our commitment to respecting patient autonomy, arguing that prescription drug laws that enable doctors to control access to medications violate what she calls a patient's rights to self-medication (*see page 579*, Editor's choice). She makes the bold point that the prescription drug system has bad consequences and it privileges regulators' and physicians' judgments about a patient's health over the patient's judgment about her overall well being, as well as violating patient autonomy. She points out that the doctrine of informed consent already affords patients the right to refuse medical treatment, and patients may not have treatments forced on them against their wishes. To do so is now regarded as unacceptably paternalistic, and an infringement of individual autonomy. Flannigan argues that the same thinking should apply to decisions about medication. Where a patient wishes to take a particular drug, she should not be prevented from doing so if the choice is informed and competent. Restricting access to medications via the prescription system is a paternalistic violation of patient autonomy. Just as we allow patients to make their own choices about which treatments to refuse, so we should allow them to choose which drugs they will take. The current system should, in Flannigan's view, be replaced by non-prohibitive policies that enable patients to access whichever available medicines patients wish while promoting informed consumer choices by making expert advice readily available.

Using the example of different approaches to managing diabetes, Flannigan teases out what she calls the 'puzzle of self-medication'. She presents two cases of risky patient choices for comparison: the case of Debbie, who is advised by her doctor to manage her diabetes by taking insulin, but she *refuses* this treatment, preferring to control her condition through diet and exercise; and the case of Danny, who is advised to use diet and exercise to control his diabetes, but who *wants* to use insulin instead. Debbie

is legally permitted to pursue her chosen approach and cannot be injected against her will, whereas Danny is prevented from pursuing his if his doctor refuses him a prescription. 'If patients are entitled to make refusal decisions without coercive or deceptive interference', Flannigan asks, 'then why are they not similarly entitled to make treatment decisions more generally?' If we are committed to respecting informed, autonomous patient choices, then this would suggest that we should treat both cases alike, and prevent neither Debbie nor Danny from pursuing the treatment they prefer. This does not entail a requirement that the government actually provide patients with pharmaceuticals, Flannigan argues, only that they do not bar a patient's way to accessing what is available to others.

Flannigan presents three arguments in support of the doctrine of informed consent, which she draws on as her three arguments against prescription requirements. She demonstrates how consequentialist, epistemic, and deontic considerations justify the doctrine of informed consent. She suggests that the doctrine of informed consent leads to better patient outcomes, that patients are better placed to know what is best for them, and that patients have 'the sole authority to make self-regarding treatment decisions even if it is not in their overall interest to do so'.

James Stacey Taylor offers a response (*see page 587*) in which he argues that the moral value of autonomy is not independent of the moral value of well-being, but that this does not undermine Flannigan's argument. Rather, it should lead us to move away from focusing on the moral value of autonomy to justify the doctrine of informed consent, and instead focus on the moral value of well-being. We should then draw on empirical studies of the *effects* of drug access policies on patient well-being to determine how to regulate, rather than resting our policy on 'conceptual arguments concerning the nature of autonomy and how one should morally respond to its value'. Only in this way, he argues, can we decide whether to continue with prescription requirements.

In a second response, Nir Eyal finds Flannigan's arguments partially

unconvincing (*see page 589*). He argues that while Flannigan does make the case for non-coercion in the specific area of drug access, she is wrong to say that it is an historical fact that drug prescription requirements prove counterproductive—for some drugs, he states, prescription requirements do in fact promote overall welfare by a large margin (as in the case of opioids). Finally, he argues against Flannigan's stance on the value of autonomy in its own right, holding that 'just because we have the right to govern ourselves doesn't mean, without further argument, that we should have the right to access anything we please to put in our bodies'.

Our third commentator, Adrienne Martin, highlights a number of problems with Flannigan's proposal and examines how opponents of her stance might make their case (*see page 588*). One is the risk of increases in uninformed and reckless drug use and thereby a risk of harm to people other than the self-medicating individual. Another concern is the possibility of an increase in administrative costs brought in by the need for competence-confirmation and the policing of pharmaceutical advertising.

In reply, Flannigan concurs with our commentators that there is a need for further research into the benefits or otherwise of loosening controls on access to drugs, and is pleased to note their measured and partial support for liberalising the system (*see page 591*). However even given this, she maintains that the burden of proof should shift, and patient autonomy ought to be promoted further, with restrictions on access becoming the exception rather than the norm. She concludes, 'when patients' rights profoundly expanded in the twentieth century, medicine became more ethical as a result. A right of self-medication is the next step'. This issue also contains discussions on a number of other interesting topics, of which we highlight a few below.

A range of contexts for consent: sexuality and the dementia patient, data linkage and vaccination surveillance

Three papers this month consider other issues around autonomy, focusing on

consent. The first explores some of the issues raised by sexual relationships between dementia patients living in aged care facilities (*see page 609*). Laura Tarzia argues that 'the formation of relationships, physical intimacy and the expression of sexuality is a basic human right and a normal and healthy part of ageing' and that given this, extends to those older people in aged care facilities, including dementia sufferers. There are issues that do need careful attention, such as capacity and consent, but the complexity of these issues is not such that the right to sexual expression of residents should be negated.

Questions of consent are examined by Jesia Berry *et al* in a randomized controlled trial to compare opt-in and opt-out parental consent for childhood vaccine safety surveillance (*see page 619*). Berry *et al* conclude that the opt-in approach resulted in low participation and a biased sample that would render any subsequent data linkage unfeasible, while the opt-out approach achieved high participation and a representative sample. On this basis, they suggest that the waiver of consent afforded under current privacy regulations for data linkage studies meeting all appropriate criteria should be granted by ethics committees and supported by data custodians.

Finally, Marcia Marinho da Silva looks briefly at informed consent for record linkage (*see page 639*). In a systematic review of consent procedures, she concludes that, in general, individuals tend to consent to the use of their data for record linkage, with exceptions in specific populations or minorities. Alternative consent models emerge as beneficial, particularly those that adopt a variety of procedures aiming to protect privacy by including accountability, strong security measures and transparency policies with regards to the purposes for which information is used.

Neuroenhancers, addiction and research ethics

David Shaw responds to the assertions of Heinz *et al* in a recent paper in this journal,¹ in which they suggested that proponents of cognitive enhancement make two unjustified assumptions: that cognitive enhancing drugs will be safe, and that research into cognitive enhancement does not pose particular ethical problems (*see page 605*). Shaw argues that these assumptions, far from being unjustified, are in fact correct. While accepting that neuroenhancement does raise a number of ethical issues, he argues that research and safety in this context are not uniquely difficult. One

of Heinz *et al*'s main concerns is the potentially addictive nature of cognitive enhancers, which speaks against research into their use. Shaw disagrees, countering 'one cannot assume that the risk of neuroenhancers outweighs any potential benefit; if we can safely drink coffee, then we may well be able to safely consume more powerful neuroenhancers too'.

Medical training

Finally, this month's issue includes a range of papers covering aspects of medical training. Two papers consider processes for decision making in complex cases that may have a moral dimension. Cody de Boer explores the implementation of a structured, multi-professional medical ethical decision making approach in a Neonatal Intensive Care Unit, (*see page 596*) while Mirjam Plantinga evaluates a Dutch training program designed to train healthcare professionals to be moral case deliberation facilitators (*see page 630*). In a third paper in this area, Robert Card looks at conscientious objection by medical students (*see page 602*).

REFERENCE

1. Heinz A, Kipke R, Heilmann H, *et al*. Cognitive neuroenhancement: false assumptions in the ethical debate. *J Med Ethics* 2012;**38**:372–5.