

Off-label prescription of ketamine for treatment-resistant depression (11HDC01072, 9 July 2013)

Psychiatrist ~ Public hospital ~ District health board ~ Ketamine ~ Treatment-resistant depression ~ Informed consent ~ Research ~ Experimental procedure ~ Off-label prescribing ~ Professional guidelines ~ Peer consultation ~ Documentation ~ Policy

In 2010 and 2011, a psychiatrist treated 11 patients with intramuscular injections of ketamine. Each patient had treatment-resistant depression (TRD). The psychiatrist is employed by a university and holds a clinical position with a District Health Board.

Ketamine is approved for use in New Zealand only as an anaesthetic. The unapproved use of an approved medicine is termed “off label” and is subject to practice guidelines.

It is important that innovation is able to flourish in the health and disability sectors. However, it is even more important that consumers are fully engaged in their treatment and fully informed as to their options and choices, and properly consent to their treatment course.

Six patients gave only verbal consent to the treatment following some discussion about the use of ketamine. Those patients also received written information. Later an information/consent sheet on the use of ketamine in treating depression was created. The five patients who were subsequently treated with ketamine for TRD signed that information/consent sheet. The information/consent sheet was subsequently modified to include a sentence to the effect that the use of ketamine in this way was off label.

No individual patient complained about either the informed consent process or the provision of ketamine. It was accepted that the patients involved in this case were provided with the information they needed, and their decisions were made on an informed basis. Nonetheless, a more explicit discussion of the fact that this was off-label prescribing, and the anticipated end point of the treatment, and careful recording of that discussion, should have occurred for all patients.

The Code requires informed consent in writing if the consumer is to participate in research or if the procedure is experimental. Consideration of this matter centred on whether the prescription of ketamine in these circumstances could be categorised as clinical research or as an experimental procedure and, in addition, whether the relevant practice guidelines were complied with.

The controversy surrounding these events demonstrates that different minds may form different views as to whether or not a particular treatment amounts to research, or is experimental. The psychiatrist formed the view that the extant research provided a sufficient base on which to treat patients with ketamine. It was accepted that this position was not unreasonable, and was thus open to the psychiatrist.

The evidence did not, on the balance of probabilities, support a finding that research was being undertaken, and did not, on the balance of probabilities, support a finding that the treatment, although uncommon, was experimental.

However, the psychiatrist's research interests in this area undoubtedly informed his use of ketamine. These interests were generally known, and thus it was not beyond the realms of possibility that his treatment of patients with ketamine would raise questions as to whether or not research was being undertaken.

Although it would go too far to suggest that there was ambiguity in the psychiatrist's actions, there was insufficient formality in relation to what was clearly an uncommon approach to treatment of patients with TRD. Aspects of the record-keeping processes adopted should have been better and in the future the psychiatrist and his colleagues must adopt a more disciplined approach to the recording of consultations with peers when approaching the question of whether a treatment is experimental and whether it also constitutes research.

In April 2010 there was no requirement that the psychiatrist advise the DHB of his intention to prescribe this off-label medication. The DHB should have had in place a requirement that management be informed about the proposed prescribing of medication in a manner not previously known to have been prescribed in New Zealand. It was suboptimal for the DHB to adopt a "hands off" system of oversight. Also, In contrast to a number of other DHBs at the time of these events, the DHB did not have a policy in place regarding off-label prescribing. The policy that was subsequently developed by the DHB was not sufficiently specific to make the DHB's expectations clear and it was recommended that the DHB review the policy.

Recommendations were made that the DHB and all New Zealand DHBs ensure they have in place appropriate policies on off-label prescribing and policies and protocols that set out what is required of staff members in relation to their clinical and research activities.