

PUBLIC STATEMENT ON CONTINUED USE OF NALTREXONE IMPLANTS

19 October 2012

The Australian Injecting & Illicit Drug Users League (AIVL) has welcomed a recent coronial inquest into the deaths of three people in NSW associated with naltrexone implants and the media coverage earlier this week and today that has followed the report's release. Unfortunately however, we also believe the recommendations of the inquiry do not go anywhere near far enough in addressing the seriousness of the apparent medical negligence issues and fundamental human rights abuses at the heart of these 3 cases.

AIVL believes there must be an immediate review and change to the availability of the naltrexone implants; currently accessed through the Therapeutic Goods Association (TGA) 'Special Access Scheme' Category A, which allows the supply of an unregistered medicine if the person is suffering from a life-threatening condition and where there is a lack of alternative treatments. Neither of these fundamental conditions applies in the case of opioid dependency but the TGA has allowed the SAS approval to be continually and routinely used despite the mounting evidence of adverse health outcomes and deaths associated with the use of naltrexone implants. Doctors using Category A of the SAS are also required to inform their patients that the product is unregistered. Anecdotal reports from patients suggest this requirement does not appear to have been met in the majority of cases, if ever.

AIVL is the national peak organisation that advocates for, and represents, people who use or have used illicit drugs (PWID) including people with opioid dependence. AIVL promotes the health and human rights of people who use or have used illicit drugs, and believes they should be treated with dignity and respect both as human beings and as consumers of health and social services.

The New South Wales Coroners report (released: 27th September 2012) has investigated the deaths of 3 people that were indirectly or directly attributable to naltrexone implants administered at Psych n Soul Clinic in Sydney. Naltrexone is an opioid antagonist which works by both pushing opiates off the body's receptors if present, and also by blocking them; thereby preventing any pleasurable effect if people use opioids. Once implanted naltrexone implants (if the patient has not already detoxed from opioids), cause a rapid opioid detoxification; resulting in an almost immediate onset of severe withdrawal symptoms.

Expert testimonies by independent witnesses in the inquiry were extremely damning. Currently there are safer, less expensive, more effective and evidence-based medications already approved through the standard regulatory TGA process for opioid dependence including methadone and buprenorphine. None of the 3 patients who died after receiving naltrexone

implants at the Psych n Soul Clinic in Sydney were made aware of these other treatment options that were available to them. The seriousness (such as potential fatalities) of the withdrawal symptoms was also not explained and medical assessments of clients were described as lacking and “scanty in the extreme”.

Conclusions by the NSW Coroner included:

“Not one of the three deceased were entirely suitable for the (highly expensive) treatment recommended and administered to each by the Clinic. Each, though clearly motivated to find a solution to their various dependencies, had contra-indications to such treatment.”

“The medical and nursing staffing of the Clinic was extremely inadequate. Assessments, records and observations were cursory, and nursing staff were given almost no training and no supervision. It appears that a patient only had to present at the Clinic to be enthusiastically recommended for Rapid Opioid Detoxification no matter what their history or situation, without alternatives being discussed or considered or any information given on the risks involved.”

“The Clinic appears to have been run on a minimal expense basis, with patient care and staff skills very low in priority. Ross Colquhoun and the medical staff seem to have ignored the need for training or policy and protocol adherence, and the professional literature on the treatment widely available and disseminated. Their lack of after care for Michael Poole and Grace Yates was abysmal.”

Given all the above its both shocking and disgraceful that naltrexone implants can still be easily accessed and there is little to no responsibility for the health and well-being of people seeking treatment for opioid dependence in the states and territories where these devices are being used. Naltrexone implants are an experimental treatment that has been repeatedly shown to have serious safety, efficacy and ethical problems.

This is not a complex health policy or clinical regulatory issue. Matters of safety, efficacy and ethics are ‘bread and butter’ issues for the TGA and by extension, the Australian Government. If any other section of the Australian population were being routinely subjected to such harmful experimentation – being treated, quite literally as human guinea pigs, there would quite rightly be public outrage. With naltrexone implants however, it appears that some Australians are more equally than others and that the lives of people seeking treatment for opioid dependence are expendable.

Annie Madden
Executive Officer

Australian Injecting & Illicit Drug Users League (AIVL)

Email: anniem@aivl.org.au

Phone: +612 62791600

Fax: +612 62791610

Mobile: 0414 628 136

Website: www.aivl.org.au

Postal:

GPO Box 1552

Canberra ACT 2601

AUSTRALIA

AIVL Address:

Level 2, Sydney Building

112-116 Alinga Street

Canberra ACT 2600

AUSTRALIA