

**Submission
No 33**

INQUIRY INTO DRUG AND ALCOHOL TREATMENT

Organisation: NSW Users & AIDS Association Inc

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SUBMISSION to

INQUIRY INTO DRUG AND ALCOHOL TREATMENT NSW

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NUAA | 345 Crown St | 02 83547300

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Contact Details:

Sione Crawford; Director – Programs & services

Jeffrey Wegener; Policy & Advocacy Coordinator

Summary:

NSW Users & AIDS Association (NUAA) is a peer-based consumer organisation that works with people most affected by the proposed changes to the Drug and Alcohol Bill: those who are drug dependent.

Submission outline

This submission will consider the *“Inquiry into Drug and Alcohol Treatment”* Terms of Reference points one to seven in turn.

In responding to these points we will frequently refer to the community of people affected by drug dependence or who wish to access drug treatment. It is generally accepted by the medical and healthcare sector that drug dependence is best managed as a chronic, recurring health issue. NUAA maintains that people affected by drug dependence should be treated the same as any other person with a chronic health or medical issue. That is, with respect and dignity and with a concern for their welfare, health and human rights when engaging with the health system as well as an understanding that long term issues sometimes require evidence based long-term solutions and not quick or easy fixes.

It is also important to note that drug use and drug dependence occurs along a continuum. While there are some people who are particularly marginalised and visible and may appear to conform to stereotypes of drug dependence such as street-based and high risk drug use there are also many people who do not fit that stereotype and who have a different relationship to their drug use / drug dependence. There are many people, for instance, who work full time and have a career but who also have issues with drug dependence. Drug treatment must be flexible enough to respond to the needs and capacities of individuals placed along the continuum of drug use/dependence.

Involuntary treatment that waives the rights of anyone to a fair trial, presumption of innocence, natural justice (including not being accused of a crime that has not yet been committed) and the rule of law should not be passed into law. The Bill that is considered in point 7 of the Terms of Reference seems to be moving us towards just such a scenario.

NUAA objects strongly to such a path being taken in NSW and will speak to the complexity of drug treatment and drug dependence in this submission.

Introduction

The NSW Users & AIDS Association (NUAA) would like to thank the New South Wales Government and General Purpose Standing Committee No. 2 for the opportunity to make a submission to the *Inquiry into Drug and Alcohol Treatment* and to the *Drug and Alcohol Treatment Amendment (Rehabilitation of Persons with Severe Substance Dependence) Bill 2012*.

The New South Wales Users & AIDS Association (NUAA) is the not-for-profit state wide community controlled organisation representing and working closely with people who use drug illicitly and are engaged in drug treatment. NUAA has a particular focus on those most affected by hepatitis C; people who inject, people with a history of injecting drug use and people engaged in drug treatment or who have drug dependency issues. NUAA was formed in 1989 in the face of a growing HIV epidemic.

NUAA provides community controlled peer education, peer support, community development, information and advocacy to our constituents, their friends and allies. NUAA has often led the way in developing innovative approaches and responses and has contributed to Australia having one of the lowest HIV rates amongst people who inject in the world. NUAA is a valued partner in the NSW with a range of partnerships for HIV, Viral Hepatitis and STIs as outlined in the State's strategies.

NUAA has a vibrant and focused policy program that is responsible for ensuring that the voice of the affected community is considered and included in policy development that impacts upon our community.

This submission will be concerned with the drug treatment aspect of this inquiry as NUAA has expertise in this area rather than the area of alcohol treatment.

With this in mind we can turn to the Terms of Reference and the submission proper.

- 1. The delivery and effectiveness of treatment services for those addicted to drugs and/or alcohol, including Naltrexone treatment, with reference to the welfare and health of individuals dependent on illicit drugs and the impact on their families, carers and the community having regard for:**
 - a. The need for appropriate human research, ethics and Therapeutic Goods Administration approval for use of new treatments in clinical trials**
 - b. The current body of evidence and recommendations of the National Health and Medical Research Council**

The NSW Drug Treatment Landscape

Drug treatment sits within an overall policy of Harm Minimisation in NSW. Harm Minimisation consists of three components that together comprise the policy response to drug use. These are:

- **Supply Reduction** – interdiction of illicit drugs, and the criminal and justice system responses to illicit drugs
- **Harm Reduction** – the frontline response to prevention of harms associated with drug use, such the Needle and Syringe Program aimed at reducing the incidence of blood-borne viruses such as HIV and Hepatitis C
- **Demand Reduction** - the provision of services such as rehabilitation centres and detoxification services designed to reduce the use of and demand for illicit drugs.

While much of the subject matter of this submission will be concerned with the demand reduction component of Harm Minimisation, it is important to note that all three components impact on one another. A person with drug dependence may be in contact with all of these responses at one time or another. They are not mutually exclusive responses and they are designed to support one another.

There are a range of treatment options already available in NSW:

- Residential and out-patient rehabilitation centres
- Therapeutic communities
- In-patient and out-patient detoxification services
- The NSW Opioid Treatment Program (OTP) – which itself has components including public clinics, private clinics, GP prescribers and community pharmacy pharmacotherapy dosing, and a range of treatment options including methadone, Buprenorphine (Subutex) and Buprenorphine/Naloxone (Suboxone)
- Amphetamine -Type Substance substitution program trials and cognitive behavioural therapeutic treatment programs
- Cannabis Clinics

A complex and complete range of treatments are needed to respond to individuals at different places along the continuum of drug dependence. For instance, this year a person may need to undergo a detoxification at a public centre, but next year may require a substitution treatment program. When we talk about drug treatment we are above all talking about people's lives and all the complexity and change over time that entails. This complexity must be reflected by ensuring that a range of treatment options are available that can be tailored to a person's needs. Central to the delivery of treatment is that it is client centred. Changes to treatment modalities require consumer consultation and input.

The drug dependence treatment picture can be complex but sometimes so too are the lives of individuals engaged in treatment. Sometimes the lives for people living with drug dependence as a marginalised person can be so challenging for the person or for their

family and friends that they offer a “cure” or a “magic bullet” can be enticing. Our experience and research evidence shows that there is really no such thing as a magic bullet but there is a strong and growing body of evidence for many of the treatments that already exist in NSW, such as methadone maintenance as well as others overseas such as the hydromorphone and heroin assisted treatment

Stigma and Discrimination

Across NSW, there are issues and challenges with the way existing services are sometimes delivered. Stigma and discrimination are two of the key issues faced by people with a drug dependence which can impact greatly on the efficacy of drug treatment services.

OTP clients for example are stigmatised because of the close association between substitution treatment and illicit drug use:

“Stigma and discrimination are routine aspects of the daily lives of people who use illicit drugs resulting in poor treatment, no treatment or abusive treatment at the hands of health, legal and social services”¹

The patient’s view of much treatment is of an overly punitive and often confusingly regulated system. Stigma and discrimination can function in either subtle or obvious ways and it is the case that service providers are not always aware they are engaging in it.²

It (stigma and discrimination) might manifest as always being served last when picking up doses in a chemist setting or it might manifest as service providers sharing confidential information in a way they would not with other patients.³ These events all have the effect of stigmatising an already marginalised group who do not access health services as much as other groups, and serve to drive people away from treatment rather than towards it.

Health care workers require workforce development and training in anti stigma and discrimination practice if we are to make the most effective use of the health system for people who use drugs and need to access the treatment system.

Naltrexone Implants – Please see:

- **NUAA Briefing Document Appendix 1**
- **AIVL Statement Appendix 2**

¹ Madden & Cavaleri in ANCD (2009) *Polygon*: 59

² Hopwood M, Treloar C. The 3D Project: Diagnosis, Disclosure, Discrimination & Living with Hepatitis C National Centre in HIV Social Research, **2003**

³ Hopwood M, Treloar C. The 3D Project: Diagnosis, Disclosure, Discrimination & Living with Hepatitis C National Centre in HIV Social Research, **2003**

(a) The need for appropriate human research, ethics and Therapeutic Goods Administration approval for use of new treatments in clinical trials

The lives of Australians are protected by the Therapeutic Goods Administration (TGA). The role of the TGA is to administer the *Therapeutic Goods Act 1989*. This legislation provides a framework for a risk management approach that allows the Australian community to have timely access to therapeutic goods which are safe, effective and of a high quality.

The TGA has a Special Access Scheme, (SAS) this scheme refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

Patients are grouped into two categories under the scheme:

- Category A patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- Category B patients are all other patients that do not fit the Category A definition.

It is due to the TGA, SAS that the use of Naltrexone implants has been possible in the past. The idea that all people dependent on drugs or opioids are likely to die within a matter of months is simply not tenable. While there are unfortunate instances of overdose still from illicit use of opioids, there are treatments and options available in NSW that offer safer options to the overwhelming majority of opioid users. Indeed, the ageing population of people who use drugs both here and overseas shows that most users in fact are living longer healthier lives. This is due to evidence based harm reduction interventions and quality drug treatment services.

That a surgical and drug related experimental procedure such as naltrexone implants can be performed regularly on a vulnerable group of people, with often dire outcomes, such as those exposed by the recent Coronial report in Sydney indicates that this group are not treated with the respect and dignity that any person should expect to be treated with by our health system.

We wonder if diabetics or patients rights groups, for instance, would countenance an invasive, highly risky and experimental surgical procedure as “treatment” for diabetes when safer and proven options exist to treat the condition. It is unlikely such a treatment would be developed let alone trialled.

We reiterate here that while Oral Naltrexone may be of some use for some patients, Naltrexone implants remain a potentially dangerous treatment with negligible advantages over the treatments already available in NSW.

b. The current body of evidence and recommendations of the National Health and Medical Research Council

NHMRC Naltrexone Literature Review 2010

In 2010 the National Health and Medical Research Centre (NHMRC) reviewed current literature for the effectiveness of naltrexone implants for the treatment of opioid dependence. The review concluded that evidence is currently at an early stage and as such, naltrexone implants remain an experimental product and should only be used within a research setting.

In the same literature review, the NHMRC found that oral naltrexone treatment, alone or in association with psychosocial therapy is somewhat effective in limiting heroin use but that this effect declined over time. No clear benefit was shown in terms of retention in treatment, side effects or relapse at follow up.⁴

The NHMRC concludes that there is not yet enough evidence to judge the efficacy of naltrexone implant therapy and recommends more research.⁵

Informed consent and human research

The NHMRC and Consumer Health Forum (CHF) *Statement on Consumer and Community Participation in Health and Medical Research (2001)* says,

“Research is a powerful tool, and those who control health and medical research have considerable influence over the health care system and a profound effect on the lives of all health consumers and their families.

Lisa Power, a Health Advocacy Manager for the Terence Higgins Trust in London argues that fully informed consent is about the dignity and empowerment of all test subjects and the genuine involvement of patients in health research.⁶

*Those who are to benefit (or suffer) from the decisions made by researchers, policy makers and health care administrators **should be an integral part of the decision-making process.**”⁷ (emphasis added)*

This decision- making and consent process should include a meaningful partnership with consumers and a genuine consultation with consumers to establish whether consumers and

⁴ NHMRC Literature Review: Naltrexone Implants for Opioid Dependence (2010)

⁵ NHMRC Literature Review: Naltrexone Implants for Opioid Dependence (2010)

⁶ Power L (1998) Trial subjects must be fully involved in design and approval of trials, BMJ, 316:1000-01.

⁷ NHMRC & CHF (2001) ‘Statement on Consumer and Community Participation in Health and Medical Research

“those who are to benefit (or suffer) from the decisions made by researchers [and] policy makers”⁸ even consider the trial of naltrexone implants an acceptable research priority.

A meaningful partnership with consumers should include consultation with NUAA and its members. As an organisation with twenty five years experience representing and advocating for people with a history of drug use or engagement with drug treatment, NUAA is well placed to be involved in such consultations. NUAA is able to access and consult those most affected by any new treatment, as well as provide policy and advocacy advice from our organisation.

2. The level and adequacy of funding for drug and/or alcohol treatment services in NSW

NUAA welcomes an investigation into the level and adequacy of funding for drug treatment services in NSW.

NUAA supports a broad array of evidence based treatment modalities for people who are drug dependent and who want to engage in treatment. As we have previously stated, in Section 1, a drug treatment framework with a range of options is required to respond effectively to the diverse needs of the diverse range of people who wish to access drug treatment in NSW.

The drug treatment landscape in NSW encompasses detoxification services, a range of rehabilitation services, the Opioid Treatment Program, an Amphetamine Substitution trial and cognitive behavioural therapy, Cannabis Clinics, GPs and private clinics.

Service provision is undertaken by a similarly wide range of providers including Government services, Non-Government Organisations, private enterprise, GPs and community pharmacies.

The Opioid Treatment Program; Efficacy of Medications; Cost Benefit; and Cost Burden

Methadone and Buprenorphine

OTP is one of the key drug treatment responses in NSW. The OTP offers substitution treatment for opioid dependence using the following pharmacotherapy medications

- Methadone
- Buprenorphine (Trade name: Subutex)
- Buprenorphine / Naloxone combination (Trade Name: Suboxone).

⁸ NHMRC & CHF (2001) ‘Statement on Consumer and Community Participation in Health and Medical Research

Methadone was introduced into Australia in the 1970s but did not have a major role in heroin treatment until the 1980s when new funds were provided to support methadone maintenance programs in the context of the upsurge in HIV.⁹ Methadone was introduced and is an evidence based response to harm reduction as well as a medical response to opioid dependence.

Methadone was the only maintenance medication for opioid dependence until 2001, when Buprenorphine gained PBS approval. Buprenorphine is a partial opiate agonist, which provides less risk of opioid overdose and has utility as a detoxification medication.

The combination product Buprenorphine/ Naloxone (Suboxone) was developed to discourage diversion. The presence of naloxone makes the product unappealing to inject as the naloxone, which is inactive when taken orally, brings about “precipitated withdrawal” (immediate withdrawal symptoms) when injected. Suboxone was made available in 2006.

Efficacy and cost benefit of pharmacotherapy

Methadone is a highly effective treatment for opioid dependence with a strong evidence base for this effectiveness. Over 20 years of research shows that methadone reduces heroin use, reduces criminal activity, and improves health and psychosocial functioning.¹⁰

In addition, both methadone and buprenorphine are highly cost effective relative to other treatments such as detoxification alone or residential rehabilitation.¹¹

Cost-benefit research has demonstrated that the costs associated with providing methadone maintenance are significantly lower than the accrued societal economic benefits. Estimated across more than 20 studies, the ratio of economic benefits to costs range from 2:1 to 38:1¹²

OTP provision modalities

In NSW the OTP is provided in three key settings:

- public clinics funded and run by Local Health Districts,
- private clinics operating as private enterprises under Ministry of Health guidelines
- private prescribers, including Addiction specialists and GPs, who generally refer patients to community pharmacy for medication dispensing.

Public clinics provide free prescribing and dispensing of pharmacotherapy, while private clinics and community pharmacy dosing charge dispensing fees to the patient. In both public

⁹ ANCD (2009) ‘Polygon: the many sides to the Australian Opioid pharmacotherapy maintenance system’

¹⁰ ANCD (2009) ‘Polygon: the many sides to the Australian Opioid pharmacotherapy maintenance system’

¹¹ Moore, Ritter and Caulkins(2007) A cost effectiveness comparison of three policy options for reducing heroin dependency. *Drug and Alcohol review*, 26(4): 269-378

¹² ANCD (2009) ‘Polygon: the many sides to the Australian Opioid pharmacotherapy maintenance system’

and private clinic settings generally only pharmacotherapy prescribing and dosing is provided, not access to any other healthcare.

The OTP is regulated and not responsive to the needs of individuals. While unsupervised dosing, in the form of take-away doses, is crucial for those who work and for those with family responsibilities, it can sometimes be a “privilege”, not a “right” in the eyes of many service providers. Withholding of take away doses as a punishment for missing doses or other forms of “misbehaviour” is not uncommon.

This highlights the fact that people engaged in drug treatment are not treated with the same respect or dignity that people managing any other chronic disease would be accorded.

A diabetic is not expected to collect treatment daily for instance and would certainly not have medication withheld if they made a mistake with their medication or missed a dose of medication. The stigmatisation of people with the condition of drug dependency is not only accepted by many healthcare workers, it is encouraged by the structural conditions¹³ and historical evolution of the Opioid Treatment Program in NSW.

The cost burden of OTP and dispensing fees

There is a significant cost burden of Methadone and Buprenorphine treatment that is borne by the patients themselves. The private clinic and community pharmacy dosing settings require the patient to make co-payments for their daily medication costs. In NSW this can range from around \$30 per week for clients of community pharmacies through to \$80 per week for the most expensive treatment options at private clinics. For people on Centrelink benefits this constitutes a very high proportion of their income each week.

The ANCD research paper *Polygon: the many sides to the Australian opioid pharmacotherapy maintenance system* estimates that 80 percent of clients pay dispensing fees in Australia and that for someone on a Disability Support Pension a weekly dispensing fee of \$70 equates to a third of their income. This is before rent, food and bills are taken into account.¹⁴

This is a significant barrier for those most vulnerable and close to poverty. That there is little opportunity for people in these situations to access discounted or waived dispensing fees is one of the major issues for the drug treatment system in NSW.

The only option is to apply for a temporary “respite” place at a public clinic. This allows the client a short period of free dosing at the public clinic before being returned to their private dispensing clinic or chemist once again. These are limited to one per month for each public clinic however.

¹³ Rance J, Newland J, Hopwood M, Treloar C. The politics of place(ment): problematising the provision of hepatitis C treatment within opiate substitution clinics. *Social science & medicine* **2012** Jan;74(2):245-53.

¹⁴ ANCD (2009) ‘Polygon: the many sides to the Australian Opioid pharmacotherapy maintenance system’

It is clear that although the Opioid Treatment Program offers an effective long term treatment option, significant barriers exist for people wanting to access this treatment. Given the clear efficacy of this treatment for people with an opioid dependence, NUAA encourages the committee to investigate the adequacy of funding provision for public clinics and private options and to investigate options for ameliorating these high dispensing fees, at least for those most in need of the assistance.

Other substitution treatment options

Given the proven efficacy of methadone and increasingly for buprenorphine opioid substitution treatment NUAA would encourage other substitution options such as injectable treatments and hydromorphone and heroin assisted treatment be investigated and trialed. Evidence for these programs can be found from countries such as Switzerland, Netherlands, Germany and the UK. Currently there are very few options for substitution treatment for drugs other than opioids. An ongoing trial for Amphetamine-Type Substance (ATS) substitution has been underway in NSW for some time and this should be examined and options for ATS treatment also investigated and funded based on evidence of success or potential for success.

Detoxification and Rehabilitation services

A range of rehabilitation approaches exist in NSW, from Twelve Step and abstinence based models to SMART recovery and Cognitive Behavioural Therapy based approaches. A great number of Government and Non-Government services do excellent work across NSW.

Detoxification services

“Detox” services are generally either inpatient or outpatient services. Not all detoxification services offer medicated detoxification service. Ambulatory detox is available at some OTP clinics. In this instance a client attends an OTP clinic or chemist daily to receive a gradually reducing dose. Addiction Medicine Specialists will often oversee this treatment as they would an inpatient, but these detox services are also available through GPs if they are willing.

Accessing these services is not always straightforward, with processes differing in each local Health District. In NUAA’s *Users News #70* Dr. Nadine Ezard, St Vincent’s Hospital Drug and Alcohol Director stated that unifying intake systems across the state is a priority to ensure adequate access is provided.

In most jurisdictions clients are asked to call back each day for an update on whether a place has been made available. This is a considerable barrier and fails to make the most of a person’s decision to enter treatment. The motivation that encouraged the initial contact needs to be capitalised on. It is not clear how many people are lost to drug treatment in this way as statistics are usually collected around treatment provision only.

“Rehab” Services

Rehabilitation approaches vary across different services but generally the aim at these services is ongoing and permanent abstinence from all drugs (and alcohol). In NSW there is also one harm reduction based residential service that aims to stabilise people onto an opioid substitution dose rather than complete abstinence.

Rehabs are usually inpatient and run very strictly, with punishments for infractions against an agreed code of conduct.

Therapeutic Communities are usually designed to “graduate” a person through different stages of responsibility and this responsibility and conduct is usually agreed by the entire community and people are held responsible to the entire community.

A mix of services for the individual

A range and mix of services are required to effectively meet the demands of the wide range of people who access or wish to access drug treatment. Drug dependence and use exists along a continuum of experience and in this context one size cannot fit all. Any review of funding should look at the efficiency of service provision and its ability to meet the needs of its consumers.

Above all drug treatment must be flexible enough to be tailored to the needs of the individual accessing the treatment.

The continuum of drug dependence is complex and the needs and capacity of each patient changes depending on where they are on this continuum at any given time. Drug treatment should be able to offer options for each person based on their location along this continuum and recognise and be able to respond to the fact that this will change for each individual over time.

Although drug dependence is considered a chronic condition by professionals and addiction specialists, people with drug dependence are not treated with the same basic courtesy and respect that most people being managed through a chronic disease management model are accorded. This inequity must be addressed.

The government must outline a framework for effective drug treatment service provision that rewards drug treatment services that;

- operate from a firm and effective evidence base,
- treat people with chronic drug dependence issues in line with other chronic disease management programs
- involve consumers as active participants in their treatment and care plans
- treat people with respect and dignity
- are responsive to the changing needs and capacities of the individual over time
- involve their consumers in the development of their services

It bears repeating that these are not demands which lie outside the generally accepted approach to other forms of health and disease management models. At the heart of the inequities between drug treatment and other treatments is the issue of stigma and discrimination, as we outlined in Section 1. Treatment for drug dependency is linked to the stigma attached to illicit drug use. Ongoing staff training and workforce development by consumer groups such as NUAA and AIVL could be mandated for services as part of their Quality Improvement plans.

Like any publically funded program, drug treatment should be accountable and aim to give value for money. The crucial part of this formula is defining a positive outcome or positive measure of success. A successful outcome from treatment may be very different for different people engaged in treatment at a different stage in their life journey or continuum. It is not too dramatic to say that for some people; simply continuing to live is a dramatically successful outcome. For others being able to travel for work is a positive outcome, while for others it may be reducing from a pharmacotherapy dose. Again we reiterate that what is important is that the affected individual or community participate in defining what comprises positive outcome and successful drug treatment.

On an individual level this may be as simple as involvement in defining a meaningful treatment careplan for the next two years, while on a policy level NUAA and consumers should be engaged in defining broad outcome measures that are used to assess treatment service success.

3. The effectiveness of mandatory treatment on those with drug and/or alcohol addiction, including monitoring compliance with mandatory treatment requirements

Mandatory treatment in NSW

Mandatory treatment of drug dependence is defined by the very lack of choice which NUAA has promoted throughout this submission. Mandatory treatment in this context refers to coercing individuals into drug treatment either directly or via diversion from the criminal justice system into a treatment setting.

In NSW currently mandatory treatment includes:

- MERIT – Magistrate’s Early Referral Into Treatment
- NSW Drug Court and NSW Youth Drug Court
- Involuntary Drug & Alcohol Treatment Unit

MERIT: Operates at Local Court level as an option to divert an individual from further engagement in the criminal justice system if they undergo drug treatment. Although clients must be willing to undergo drug treatment, it is coercive in that the alternative is further engagement in the criminal justice system and possible criminal record

NSW Drug Court: a person may have their trial referred to the NSW drug court from another District Court, if they agree and if a number of conditions are met. Generally the offence must be related to drug dependency and carry a prison sentence. It is coercive in the sense that once engaged in the court, the individual must attend mandated drug treatment or face prison.

IDAT: The IDAT is a recently constituted Compulsory Treatment unit which is aimed at treating people who are judged to be engaged in immediately life-threatening drug or alcohol use and who do not have the cognitive ability at the time of commitment to prolong their own life.

Mandatory Drug Treatment facilities in Asia

Mandatory drug treatment is relatively common in SE Asia. In a number of countries including China people who use drugs are routinely arrested and sent to mandatory drug treatment centre which are run by custodial staff, with little involvement from health care staff. The “treatment” consists of sanction rather than of therapy and relapse rates after release are often very high.¹⁵

Of particular concern is any idea that NSW would move further down the road toward the harsh models of mandatory treatment such as these.

All mandatory treatment however is problematic because it:

- Denies access to natural justice
- Can deny application of informed consent
- Often applies to some of the most vulnerable people in society and has the capacity to breach their human rights
- Is not as effective treatment undertaken voluntarily

Although the systems for mandatory and compulsory drug treatment vary across NSW, Australia and the region it is clear that,

“There is no evidence that these centres represent a favourable or effective environment for the treatment of drug dependence.”¹⁶

NUAA agrees with the joint statement issued by a broad range of United Nations agencies, including the UN Office on Drug Control (UNODC), the World Health Organisation (WHO); UNHCR; UNICEF; UNAIDS; UNESCO and more which states quite clearly that:

“all health care interventions, including drug dependence treatment, should be carried out on a voluntary basis, with informed consent.”¹⁷

¹⁵ WHO (2009) ,”Assessment of compulsory drug treatment of people in Cambodia, China, Malaysia and Vietnam.:

¹⁶ UNAIDS, (2012) ”Joint statement: Compulsory drug detention and rehabilitation centres”

¹⁷ UNAIDS, (2012) ”Joint statement: Compulsory drug detention and rehabilitation centres”

This opinion is based on human rights grounds and the strong evidence base that treating drug dependence as a health condition is the most effective response to achieve positive outcomes for the individual.¹⁸

The statement goes on to recommend scaling down mandatory treatment and states that building capacity for voluntary, evidence informed and community-based approaches are positive steps for those countries looking to scale down their mandatory drug treatment.¹⁹ Drug treatment in NSW should be looking towards achieving this capacity as well rather than moving towards further mandatory treatment.

As we have outlined in our responses to the Terms of Reference so far, a treatment mix that offers a range of treatment initiatives and is able to respond effectively and flexibly to patients who are at different points along the continuum of drug dependence. Central to this is the need for choice and voluntary involvement in treatment. Mandatory drug treatment runs counter to these principles

Expert Opinion on Mandatory Drug treatment.

In a submission to the Chapter of Addiction Medicine, Dr Alex Wodak outlines a number of points to show the weaknesses and ineffectiveness of mandatory drug treatment; the relatively high cost and the inherent inequity in linking a drug treatment to criminal justice systems:

(i) The only times when compulsory treatment is used in medicine are when an individual's capacity is impaired by cognitive impairment or mental illness;

(ii) Cognitive impairment is managed well by Guardianship Tribunals and mental illness by Mental Health Acts;

(iii) These approaches can be and are used very successfully for people with alcohol and drug problems just as they are for people with other sorts of problems;

(iv) Compulsory treatment is not more effective than voluntary treatment but it is more expensive, reduces the civil liberties of people with alcohol and drug problems and has a history of being abused by authorities;

(v) Severely intoxicated persons can be at short - term risk to themselves and others. Short term (< 72 hours?) compulsory care may be justifiable;

(vi) Alcohol and drug treatment in Australia is currently poorly funded by any objective measure - funding an expensive and not particularly effective intervention such as compulsory treatment would put further strain on an already limited budget for a condition which affects many families in Australia;

¹⁸ UNAIDS, (2012) "Joint statement: Compulsory drug detention and rehabilitation centres"

¹⁹ UNAIDS, (2012) "Joint statement: Compulsory drug detention and rehabilitation centres"

(vii) The need for compulsory treatment in mental health and the lack of need for compulsory treatment for people with alcohol and drug problems is another reason why mental health and the alcohol and drug field do not fit well together;

(viii) Compulsory treatment in the alcohol and drug field is much more likely to be invoked for people of low socio-economic status than for people of high socio-economic status;

(ix) If the voluntary treatment sector is forced to contract as funding is shifted to involuntary treatment, a perverse incentive is created for people to develop even more severe problems in order to qualify for assistance;

(x) Expensive and cost ineffective involuntary treatment for a small number of possibly intractable people is likely to be at the expense of less expensive, and more likely more cost effective voluntary treatment for a larger number of people with less severe and more tractable problems;

(xi) If evidence emerges in future that compulsory treatment is more effective, safer and more cost effective than voluntary treatment, then policy should be revised;

(xii) Diversion from the criminal justice system to alcohol and drug treatment should be supported provided that the offender (a) can choose between these options; and (b) has a similar choice of options within voluntary treatment of comparable quality as community members who are not under the control of the criminal justice system.²⁰

Mandatory drug treatment is unnecessary in NSW

Dr Wodak states that drug treatment options in NSW are ‘poorly funded by any objective measure’. NUAA agrees that before implementing new, unproven models that fly in the face of most international and local opinion and evidence, current voluntary treatment options that have a strong evidence base should be given every opportunity to succeed first. This includes providing adequate funding in general but also better funding for those services that succeed by following a human rights and patient rights model that supports treatment choice for clients and works from this strong evidence base.

4. The adequacy of integrated services to treat co-morbid conditions for those with drug and/or alcohol addiction, including mental health, chronic pain and other health problems

NUAA is pleased that the committee will be investigating this important area. A person is said to have a co-morbid condition or co—occurring health issue when at least two and sometimes more health issues affect a person at once. It is a particularly important consideration when the conditions are both serious and/or affect one another to increase the impact of each condition on the patient.

²⁰ (Wodak.A.,2013,submission to Chapter of Addiction Medicine draft article cited by emailwith author’s permission to the author of this piece 2013)

Diagnosis of co-occurring health issues

Co-occurring health issues can develop independently of one another or one may be the consequence of the other. It is important for treatment providers to unravel this knot and work through with the patient an approach to treating both or all issues,

At the heart of why co-occurring health issues are difficult to manage is the specialisation of medical and health expertise. A treatment provider that specialises in drug treatment may not have the expertise to deal with the co-occurring issue and the service that can deal with the other issue may not be able to treat the drug dependence issue.

Diagnosis of the co-occurring conditions may not even occur accurately if the patient is not aware of all issues affecting themselves and the treatment or service provider is not aware of the co-occurring condition.

This can be exacerbated for people who are being treated for drug dependence in NSW as often drug treatment clinics are less concerned with overall holistic health and concerned primarily with the drug treatment issue alone. This is the case with many public and private OTP clinics in NSW. Many people on OTP see a specialist for their drug treatment and a GP for everything else and prefer not to mix the two. The reasons for this can include a fear that

Partnerships and treatment plans

Genuine partnerships both between treating services and between the services and the patient are important to endure clear and accurate information sharing to best treat the client. Informed consent, treatment plans, which, when undertaken in genuine partnership can be a guide to a patient journey that benefits the patient across all their conditions.

Co-occurring conditions of particular consideration include:

- Drug dependence and mental health issues
- Drug dependence and chronic pain and pain management
- Drug dependence and Hepatitis C

Drug dependence and mental health

Mental health and drug dependence have been linked in the health bureaucracy in NSW for some time. The Mental Health / Drug and Alcohol Office (MHDAO) at the NSW Ministry of Health is an example of this traditional linkage. This, like the combining of drug and alcohol issues under one banner is not always helpful as there are quite distinct health issues for people from each community.

NUAA rejects any notion that drug dependence in itself is a mental health issue, although we recognise that people who present with co-occurring drug dependence and mental health issues face particular barriers, due to heavily stigmatised nature of both these diagnosis.

Despite the fact that mental health and drug dependence issues have these traditional linkages those with co-occurring issues sometimes fall into the “too-hard basket” for both drug treatment and mental health workers. Service providers, some of whom are unsure about the impact of the co-occurring issue outside their area of expertise also recognise that people with these co-occurring issues “fall between the cracks” in this system.²¹

Drug dependence and Chronic Pain Management

Pain Management is an important issue, not least because alongside an ageing population generally, the population of drug dependent people is also ageing. Chronic pain is more likely as ageing occurs.

Research conducted by AIVL cited people routinely being accused of “drug-seeking” behaviour by healthcare workers when medical intervention and pain relief was required legitimately.

“The issue of access to pain relief and pain management was identified by the majority of respondents in the sample as a major concern. Several respondents reported horror stories about unfortunate friends and associates who had been denied pain relief when in genuine distress. They commented on the seemingly arbitrary withholding of pain medication by hospital staff and the need for clear policies to guide the fair and humane provision of analgesic drugs in hospital environments.”²²

Drug Dependence and Hepatitis C Treatment

The burden of hepatitis C in NSW is borne by people with a history of injecting drug use, as it is in most developed countries.²³ Hepatitis C is now a treatable chronic condition, with advances in its treatment meaning that more and more people are able to undertake treatment successfully.

Unfortunately the link between hepatitis C and drug dependence and injection is such that stigma and discrimination is a major barrier to people undergoing hepatitis C assessment and treatment.²⁴

²¹ Holt, Treloar, Bath et al (2007) Barriers and incentives to treatment for Illicit Drug Users with Mental Health Comorbidities and complex vulnerabilities

²² AIVL (2012) *Double Jeopardy: Older Injecting Opioid Users in Australia*

²³ Shepard CW, Finelli L, Alter MJ. Global epidemiology of hepatitis C virus infection. *The Lancet infectious diseases* **2005** Sep;5(9):558-67.

²⁴ Hopwood M, Treloar C. The 3D Project: Diagnosis, Disclosure, Discrimination & Living with Hepatitis C National Centre in HIV Social Research, **2003**

Efforts to increase the rate of hepatitis C treatment uptake have included developing guidelines that allow people who are still using illicitly to undergo treatment; offering hepatitis C treatment and peer support in OTP pharmacotherapy clinics across NSW in the NUAA and Kirby Institute Ethical Treatment of Hepatitis C in Opioid Settings (ETHOS) research project partnership.²⁵

Integrated Treatment Services

With the exception of one health centre that offers a broad range of low-threshold services for people who are drug dependent, NSW does not offer primary care health centres, which are commonplace in Canada, the UK and around the world, where a person dependent on drugs can obtain pharmacotherapy treatment and other healthcare easily. Both public and private clinics in NSW are dedicated to providing pharmacotherapy, but do not have the mandate or scope to offer comprehensive healthcare or integrated treatment for people with issues of drug dependence.

Treatment careplans are not routinely developed in partnership with patients on the OTP and case workers either do not exist or have high workloads. As a result pathways through treatment and referrals to other specialists for co-occurring health issues are not easily available.

There are exceptions to this of course. The ETHOS project co-locates hepatitis C treatment delivery at places where it is most efficient for many drug dependent people and it is an example of partnerships between service providers that can work to effectively manage co-occurring health issues.

A better standard of integration across the drug treatment landscape is needed to effectively offer patients opportunities to work through co-occurring or co-morbid health issues.

5. The funding and effectiveness of drug and alcohol education programs, including student and family access to information regarding the legal deterrents, adverse health and social impacts and the addictive potential of drugs and/or alcohol.

Drug education programs and information campaigns are often highly visible. NUAA notes that often public campaigns play upon stereotypical views of drug users or simplistic views of drugs and drug use and reminds the committee that inaccurate campaigns may be counter-productive.

To ensure value for money and effectiveness such campaigns and programs and campaigns should be evidence-based and should always be developed in partnership with the community at whom the education is aimed.

To ensure meaningful partnerships with this community NUAA encourages:

²⁵ Rance & Treloar (2012) Integrating Treatment; Key findings from a qualitative evaluation of the ETHOS study

- involving a consumer organisation and involving members the affected community at an early stage of planning
- further consultation of the affected community through focus groups and interviews at all stages
- a consideration of the impact of campaigns that stereotype or demonise people who are dependent on drugs on the affected community or the subject of the stereotypes
- a rounded approach to drug education including harm reduction messages when necessary and appropriate

Information and education are a form of protection for people. It should assist people to:

- Clearly understand risk practices
- Understand their own capacity for avoiding these risks
- Know where to go for more information, including harm reduction information.

Peer Education

NUAA has a strong peer education program and promotes peer education as an important approach in many circumstances.

Peers well resourced with correct information are a powerful force. Utilising community development and health promotion approaches and evidence based education is a strategy that empowers as well as educates the target community.

6. The strategies and models for responding to drug and/or alcohol addiction in other jurisdictions in Australia and overseas, including Sweden and the United Kingdom

NSW Context

Before considering the wholesale or partial adoption of a drug treatment system developed in another jurisdiction or nation, it is important to be clear on the local context. NSW has issues that are unique to our state and must be taken into account.

These issues include:

- *Cultural mix.* NSW has a very broad range of cultures and backgrounds amongst its citizens. These backgrounds can play a role in our responses to systems. Drug treatment must be accessible and effective for all our residents.
- *Indigenous Peoples.* NSW should be proud of our original inhabitants, the Aboriginal peoples of this area. A complex history, including the failure of governments for decades, has culminated in the situation today where Aboriginal people are over-represented in many of our most vulnerable groupings, including that of people who are drug and/or alcohol dependent. It is crucial that any system should be be

effective and welcoming for Aboriginal people. Aboriginal people should be afforded the opportunity for self-determination at all levels.

- *Distance*: NSW is a very large land area and people in rural, remote or regional NSW face particular problems of access to services, both in terms of distance and travel time and availability of services.
- *Historical development*: Every area develops differently and this includes the face or drug use and drug dependence in NSW. Types of drugs used and methods of use impact on what services should be available.

Sweden

Sweden's policy aims for a 'drug-free society'²⁶. A zero-tolerance foundation means that heavy enforcement against drug users is undertaken. Penalties for drug use and possession (not only trafficking) include imprisonment for up to ten years. At the same time they have rolled back needle and syringe programs, with only two available and opioid substitution treatment is made very difficult to access. Instead coerced abstinence – based treatment is the focus.

This is very clearly a punitive drug policy with drug use quite clearly placed in the criminal justice, rather than health system. We have already looked at the evidence against mandatory treatment and the evidence for effectiveness of voluntary treatment.

Much work has been undertaken around Sweden's drug policy model. The United Nation's Office of Drug Control (UNODC) 2007 report on Sweden was laudatory, citing lower prevalence of drug use amongst as evidence for its success.²⁷ The fact is that if lower prevalence of drug use is the goal, there are many ways to get to that goal. For instance, the Netherlands, has a famously tolerant approach to drug use (notwithstanding it's recent tightening of some rules) and yet drug use prevalence in the Netherlands is lower than Sweden's.²⁸

Unfortunately there are a range of other measures that should be taken into consideration when considering the success or otherwise of a policy. There are two in particular that show Sweden may in fact be killing its citizens in the name of its drug-free society.

- *Drug related deaths*. Since 1994 drug related deaths have risen from just under 200 to over 400 in 2008.²⁹
- *HIV rates* amongst people who inject drugs have doubled since between the mid-90s and 2008.³⁰
- *Problem drug use* as defined by the European monitoring Centre for Drugs and Drug Addiction (EMCDDA) has not decreased since the mid – 90s³¹

²⁶ Maria Larsson, Stockholm 2008; <http://www.government.se/sb/d/8018/a/110658>

²⁷ UNODC (2007) Sweden's Successful drug policy: A review of the evidence

²⁸ <http://www.drugfoundation.org.nz/mythbusters/swedish-model>

²⁹ <http://www.emcdda.europa.eu/publications/country-overviews/se#drd>

³⁰ <http://www.emcdda.europa.eu/publications/country-overviews/se>

These measures can be linked causally to Sweden’s drug policy just as the prevalence data can be. Clearly prevalence is not everything and clearly their policy is not effective in these areas. The issue is that problematic and risky drug use practices are what cause the most harms. Rolling back harm reduction and substitution treatment impact on this because people have less education and information around harm reduction “for today” and less access to life-saving treatments. There are a group of people who will not be dissuaded by laws and won’t be able to achieve abstinence. Policies such as Sweden’s effectively throw these people onto the junkpile.

Far from being a land of massages for drug users, Sweden has shown that poor drug policy can kill people.

United Kingdom

For the last five years the UK has followed a drug policy widely known as “recovery” or “new recovery.” The use of the term “recovery” is widely used in Mental Health sector and it’s meaning there is slightly different to the meaning in the context of the UK recovery.

The UK Recovery Foundation defines recovery as including principles such as:

- There are many pathways to recovery and recovery exists on a continuum of improved health & wellbeing
- Recovery ...does not seek to be prescriptive
- Recovery challenges all discrimination
- Recovery embraces harm reduction (and abstinence)³²

However, the UK government has used the term recovery with abstinence-based treatment and has conflated it with economic rationalism as well:

*“no longer will addicts be parked on methadone...without an **expectation** of their lives changing. We must ensure all those on a substitute prescription engage in recovery-driven support to maximise their chances of being free from any dependency...”*

“We are exploring how to incentivise such changes by introducing a payment by result (PbR) model for treatment providers. This will shift the focus of providers from process to output to delivering tangible personal and social outcomes as well as clear value for public money”³³

This may appear to be reasonable the problem is that once again drug dependent people are being talked about and not included in the discussion. As the organisation who

³¹ <http://www.emcdda.europa.eu/publications/country-overviews/se>

³² http://www.ukrf.org.uk/index.php?option=com_content&view=article&id=88&Itemid=130

³³ <http://www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/recovery-roadmap?view=Binary>

represents this group in NSW NUAA would hope very much that any inclusion of UK recovery approaches in NSW drug policy be considered carefully and that organisations like NUAA should be involved in developing policy.

An overview of the UK recovery model by Dr. Eliot Alber of the (International Network of People who Use Drugs (INPUD) shows:

- *The indicator of success that treatment services will use in the new model (public outcomes model) is the number of people leaving services. Ultimately payment will be made for full recovery only. The arbiter of success is getting people off the program- Payments to services are the same.*
- *Under this payment by results system local borough will only receive full funding if they maintain steady levels of client existing over a 12 month period.*
- *The insistence of abstinence as the only real incidence of a satisfactory or successful engagement with health services.*
- *There have been some publications since the original Recovery Roadmap document which seem to disavow some of the more extreme measures mentioned prior*
- *Because of this new ideological position taken on, many people will be discouraged from entering into OST. For many who know that OST provide a “crucial life raft of stability,” the new agenda destroys this as well as implying the notion of having to jump, or be pushed off ASAP.*
- *The new agenda rejects OST as an endpoint. But for many people all they want to be stable and be treated with the normal degree of dignity and respect that most patients receive from health services.³⁴*

A phenomena emerging alongside the recovery agenda in the UK has been the increase in the number of people willingly submitting to rapid detoxification. This seems to increase the propensity for cross-addiction and relapse.³⁵

Discussion

As we have stated many times, treatment for drug dependence is a complex situation. There is no doubt that drug treatment services could always deliver better outcomes, **but these outcomes must be defined by the patient through a partnership with their treatment provider.** People who are drug dependent are agents and must be allowed the opportunity to exercise that agency in terms of making decisions about their treatment future. Neither the Swedish model nor the emerging version of Recovery in UK offer this.

³⁴ Albers, Eliot. (2012), Drink and Drugs News, UK

³⁵ Neale et al (2012), *Drug and Alcohol Dependence*

The subtext in all discussion that places abstinence as the primary end goal of a drug policy is that a person who is not abstinent is somehow not complete or not legitimate. We contend that a person who is dependent on drugs is fully capable of being a whole person worthy of respect and worthy of having their decisions about their health issues taken seriously and being respected.

Abstinence is simply not a realistic goal for many people, but there are many other realistic goals along an improved health and lifestyle continuum. By all means put in place options treatment journey plans that end in abstinence but these must not be forced upon anyone.

If a pharmacotherapy can enable a person to work, raise a family and travel, why would it be considered a positive step along their life journey to take that away from them?

Fundamental to much of these discussions is an assumption that being drug dependent is completely debilitating. This may be true for some people sometimes without medication, but so too is suffering any major chronic illness such as diabetes, without medication. Why is it considered acceptable to consider removing medications from a person who needs them? An evidence based clinical approach to mental health would never consider forcing someone off their medication. Making the judgement on need should never be left to the government or even to a clinician alone. The consumer must be involved and must be considered as a full partner with considerable agency.

We must accept that drug dependence and use is a health issue and should be treated that way. Outcomes that are beneficial for both society and the individual should be the priority. Once those are agreed and in place, then it is hard to argue that public money is not being spent well.

7. The proposed reforms identified in the *Drug and Alcohol Treatment Amendment Bill 2012*

The proposed reforms in *Drug and Alcohol Treatment Amendment Bill 2012* are not generally supported by NUAA.

Involuntary treatment for people with “severe” substance dependence.

As stated, involuntary treatment already exists for the very small number of people whose drug or alcohol use is so problematic as to warrant it. This unit has only just been opened. It would be worth waiting for the evaluation of this unit before amending legislation related to the issue.

Applying involuntary treatment any more widely than IDAT is a breach of any number of human rights, including the right to natural justice and the rule of law. *“Removing the risk of the person committing an offence due to the person’s substance dependence”* is particularly troubling. That anyone might be restrained and have a surgical procedure forced on them

because a doctor thinks they *might* commit a crime sometime in the future is horrifying. It creates a class of person against whom it is considered acceptable to:

- Disfigure by surgery
- Risk their life with a proven dangerous drug
- Presume to be guilty before an offence is even committed let alone after an offence
- Detain indefinitely for months

This is beyond an Orwellian nightmare vision.

The instrument by which the treatment is to be undertaken (naltrexone implant) is not only ineffective it is provably dangerous. Coroners and previous users alike have spoken out against naltrexone implants. (see Appendix 1)

Schedule 1 [29] (b)

“ a dependent person must not have in his or her possession objects that are able to be used by the dependent person or any other person in assisting abuse of a substance, that could be detrimental to the rehabilitation process of the dependent person, or any other person being treated at the treatment centre, or could be detrimental to the good order of the treatment centre (proposed section 20A (2)),

This section clearly prohibits items such as syringes from the possession of a person deemed dependent. This flies in the face of 25 years of blood-borne virus prevention work in NSW, where we lead the world in HIV prevalence amongst people who inject drugs.

Effective HIV and other blood-borne virus prevention is clearly predicated on allowing harm reduction initiatives such as the needle and syringe program. Banning equipment that is considered a health initiative and which demonstrably saves lives and money³⁶, regardless of the setting, is potentially negligent.

It would put not only individual lives at risk but put at risk 25 years of public health gains.

Summary

The overarching principle which NUAA submits should be applied to any of the points in the Committee Terms of Reference and to the *Drug and Alcohol Treatment Amendment Bill 2012* is that people who are dependent on drugs should have the same rights as any other citizen or health system client.

Treatment should be solidly evidence based and people should be genuinely partnered with on developing a treatment journey care plan that establishes realistic, beneficial goals for that person.

³⁶ NCHECR, UNSW (2002) Return on investment in Needle & Syringe Programs in Australia

Treatment should never be undertaken purely to fit legislation or to fit into an activity based funding model alone. The reality is that all areas of government should be publically accountable, but that accountability is not simply economic but can also encompass the way citizens in general and those most vulnerable are treated.

NUAA would welcome the opportunity to address the General Committee No. 2 at any stage of its inquiry.

Thank you for the opportunity to submit our perspective and for taking the time to consider it.

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APPENDIX 1:



NSW USERS & AIDS ASSOCIATION INC

BRIEFING PAPER

NALTREXONE IMPLANTS

October 2012

Introduction

The NSW Users & AIDS Association's (NUAA) is the not-for-profit state wide community controlled organisation representing and working with people who use drugs illicitly. NUAA has a particular focus on those most affected by hepatitis C; people who inject, people with a history of injecting drug use and people engaged in drug treatment. NUAA was formed in 1989 in the face of a growing HIV epidemic.

NUAA provides community controlled peer education, peer support, community development, information and advocacy to our constituents, their friends and allies. NUAA has often led the way in developing innovative approaches and responses and has contributed to Australia having one of the lowest HIV rates amongst people who inject in the world. NUAA is a valued partner in the NSW partnerships for HIV, Viral Hepatitis and STIs as outlined in the State's strategies.

NUAA has a vibrant and focused policy program that is responsible for ensuring that the voice of the affected community is considered and included in policy development that impacts upon our community.

This paper is written on behalf of NUAA, our members and constituents who are affected by drug treatment policies in NSW and in particular in this instance the use of naltrexone implants. The paper outlines:

- What naltrexone is,
- what a naltrexone implant is,
- safety of naltrexone implants,
- efficacy of naltrexone implants,
- treatment for opioid dependence
- the Therapeutic Goods Administration and
- conclusion.

What is naltrexone?

Naltrexone is a drug used in the management of alcohol and opioid dependence. Opioids are a class of drug that relieve pain and can create a sense of well-being. While heroin is the most well known opioid in relation to dependence, other opioids include methadone, buprenorphine, opium and the common pain-relievers morphine and codeine.

When taken, naltrexone attaches to the opiate receptors in the brain and blocks them. This means that if someone tries to use any kind of opiate while they are on naltrexone, they will feel no euphoric effect from the opiate. The rationale for using naltrexone is that if a person does not experience any positive effect, they will stop using opioids.³⁷

We know that drug dependence is a complex issue and that a range of treatment options that have been approved and evidence based need to be available to those that require it. While naltrexone itself may be for some a useful tool, this will not be the case for others. Presented as the magic cure for opioid dependency, the simplistic hope that naltrexone, by reducing positive desired affects of opioids will reduce or stop opioid use is questionable.

What is a naltrexone implant?

³⁷ Australian Government National Health and Medical Research Council: <http://www.nhmrc.gov.au/your-health/naltrexone-implants>



Naltrexone implants are inserted through a one cm incision in the lower abdomen. The implants consist of one pellet in the case of a three month implant and twenty pellets in the case of 10 month implant and are inserted 3-4mm under the skin. Naltrexone implants have not been approved for human use in Australia due to a lack of results from clinical trials demonstrating their pharmaceutical quality, safety and efficacy.

How safe are naltrexone implants?

In 2011 the National Health and Medical Research Centre (NHMRC) reviewed current literature for the effectiveness of naltrexone implants for the treatment of opioid dependence. The review concluded that evidence is currently at an early stage and as such, naltrexone implants remain an experimental product and should only be used within a research setting. Until the relevant data are available and validated, the efficacy of the treatment, alone or in comparison to best practice, cannot be determined. NHMRC's position on naltrexone implants is that further research on adverse effects is required before a statement on safety can be confidently made.

The relentless ongoing practice of using naltrexone implants in Australia and here in NSW has resulted in deaths. This is because overdose can occur when people who have had the implants inserted use opioids that are indeed able to bind to the opioid receptors in the brain. This is because the ability of the implant to block the receptors reduces over time. This can be exacerbated when a person uses a larger quantity of opioids in an attempt to "override" the implant. This highlights that just because the implant can prevent the affect of opioids, it does not mean that a person will stop seeking it. As has been stated opioid dependence as with any dependence is complex.

There is evidence that demonstrates clearly the dangers associated with naltrexone implants for example:

- In Queensland concerns were raised in 2001 about naltrexone implants and the practice of Dr. Reece who was subsequently instructed to cease operating by the Medical Board of Queensland. It is stated that there was a minimum of 24 deaths among almost 850 patients treated by Dr Reece since July 1998.³⁸
- A study undertaken by Associate Professor Nicholas Lintzeris et al showed over a 12 month period twelve unplanned admissions to hospital occurred following having naltrexone implants 12 cases were identified: eight were definitely or probably related to naltrexone implants or the implantation procedure (rapid detoxification). Of these, six patients had severe opiate withdrawal and dehydration, with an average hospital stay of 2.3 days. One patient had an infection at the implant site, and one an underlying anxiety disorder requiring psychiatric admission. Three patients had analgesia complications, and one had unrelated cardiac arrhythmia.
- An article from 2007 showed that a review of Australian coronial records, there were five deaths involving implantable naltrexone between 2000 and 2004. One man died from acute narcotism with a naltrexone implant in place and a blood naltrexone level of 0.3 mg/L. A woman died of combined drug effect (including naltrexone) accompanied by severe pain from a naltrexone implant site. These cases indicate that patients can die from opioid

³⁸ Media Awareness Project, 31st May 2001, <http://www.mapinc.org/drugnews/v01/n997/a10.html>

overdose with a naltrexone implant and blood naltrexone levels higher than reported blockade levels.³⁹

A range of other concerns have been documented about the use of naltrexone implants these include:

- While the pharmacology of naltrexone blocks the effect of opiates, many people simply switch to other drugs in order to achieve desired affect
- There have been cases also of post operative infection, and other side effects from the implant procedure. There have been cases of self-removal of implants, or attempted self – removal. With one of the recent Sydney Coronial Inquest cases there was inflammation around the implant site of one person who died and this may have occurred because of their attempt to remove the implant.
- There have also been numerous reports into cases of depression, severe anxiety and other psychological distress from people who have had naltrexone implants. The following quote captures how people can feel, *“This implant has made me feel super depressed... nobody has told me you can’t feel good with a revia (naltrexone implant)”*⁴⁰
- In Russia where naltrexone implants are used there have been reports of increased suicide rates⁴¹
- An abundance of anecdotal evidence documents the emotional toil of living with a naltrexone implant where for some the only option is to remove the implant themselves causing great pain, damage and infection.

What is the efficacy of naltrexone implants?

The evidence shows that the efficacy of naltrexone implants is highly questionable:

- While naltrexone implants may act to stop the effect of opiate substance, other drugs can be used to their normal effect level.
- Naltrexone advocate Dr. George O’Neill claims that naltrexone implants are 100% effective. It is highly unlikely that any treatment is 100% effective in the mid to long term. This analysis clearly does not take into account the three deaths highlighted in the Coronial Inquest and the very many others that have been related to naltrexone implant treatment.
- The most committed of patients using the best treatments may relapse over time, or people may use other drugs to compensate. For example during the heroin shortage in the last decade the incidence of methamphetamine use has increased.

The fact remains that there is little to no clinical evidence to show the efficacy of naltrexone implants as a long-term solution.

Better options

³⁹ Amy E Gibson, Louisa J Degenhardt and Wayne D Hall, [Opioid overdose deaths can occur in patients with naltrexone implants](#) Med J Aust 2007; 186 (3): 152-153.

⁴⁰ anon, <http://www.Bluelight.ru>

⁴¹ 2010, Holt E. Russian injected drug use soars in face of political inertia. *The Lancet* 2010; 376(9734): 13-14

Currently the only treatment options available to people who are opioid dependent are methadone and buprenorphine. In other countries a fuller range of pharmacotherapy options are available that are safe, efficient and evidence based. NUAA supports choice of treatments that suit individual need. We do not however support naltrexone implants as a safe option for people who are opioid dependent.

We know that some people have concerns about using pharmacotherapy based treatments, such as methadone and buprenorphine and some who do not like abstinence based models. However, the fact remains that there is now a large body of evidence to support Opioid Substitution Treatment (OST) particularly if used over a longer period. It has shown to give gains in health and general life stability. OST has become a “gold standard” and there exists a body of evidence around its use.

The Coroner in the recent Sydney cases states that the people who died were entirely unsuitable for naltrexone implant treatment:

“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.”

Professor Saunders, an Addiction Medicine Specialist and Chair of a Commonwealth Advisory Committee on a clinical trial of naltrexone gave evidence at the Coronial Inquest and concluded that such *“treatments are suitable, at the most, for a small minority of patients, and the most successful and evidence –based treatments still is methadone”*.

The attraction of naltrexone implants is that it promises a quick and simple solution. For people with terrible and extended experiences of detoxification, the promise of a solution to quickly “fix” a complex issue is undoubtedly alluring. The “quick fix” offer of naltrexone implants is dangerous as it unrealistic and problematic.

The Therapeutic Goods Association

The lives of Australians are protected by the Therapeutic Goods Association, (TGA). The role of the TGA is to administer the *Therapeutic Goods Act 1989*. This legislation provides a framework for a risk management approach that allows the Australian community to have timely access to therapeutic goods which are consistently safe, effective and of high quality. The TGA works with consumers, health professionals, industry and its international counterparts in order to effectively regulate increasingly complex products resulting from rapid scientific developments.

The TGA has a Special Access Scheme, (SAS) this scheme refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Patients are grouped into two categories under the scheme:

- Category A patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- Category B patients are all other patients that do not fit the Category A definition.

It is due to the TGA, SAS that the use of naltrexone implants is possible. NUAA calls for the TGA to act to take control of naltrexone implants and undertake an immediate review.

Conclusion

It is clear that the use of naltrexone implants is unethical and unsafe.

We understand that the use of illicit drugs and drug dependence is challenging, society seeks a magic bullet yet, here in 2012 drug use continues and people become drug dependent. It is a fact of life that can never be changed.

What we as a society together can change is to eradicate the stigma and discrimination that people who use drugs especially those that are drug dependent experience. We have to question why it is that the lives of people who use drugs are not valued by society. If the outcomes that have been evidenced from the use of naltrexone implants were found in children, older Australians or people living with cancer the use of naltrexone implants would be banned. Why is it then that the lives of Australians' who are drug dependent are not afforded the same value?

Permitting the further use of naltrexone implants would be irresponsible at best and the cause of more unnecessary deaths at worst. Naltrexone implants are an experimental product and their use must be looked on with extreme caution. Until such time that there exists clear evidence of their safety and efficacy they should not be used.



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 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 abysmal."

Given all the above it's 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 equal than others and that the lives of people seeking treatment for opioid dependence are expendable.