INQUIRY INTO DRUG AND ALCOHOL TREATMENT

Organisation: South Eastern Sydney Local Health District

Date received: 7/03/2013

Submission from:

South East Sydney Local Health District

Prepared by:

Associate Professor Nicholas Lintzeris,

Director, Drug & Alcohol Services, SESLHD & Chief Addiction Medicine Specialist, MHDAO, NSW Health

To

NSW Legislative Council, General Purpose Standing Committee No. 2 Inquiry into drug and alcohol treatment

Terms of Reference

That the General Purpose Standing Committee No 2 inquire and report on the effectiveness of current drug and alcohol policies with respect to deterrence, treatment and rehabilitation, and in particular:

- 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
- 2. The level and adequacy of funding for drug and/or alcohol treatment services in NSW
- 3. The effectiveness of mandatory treatment on those with drug and/or alcohol addiction, including monitoring compliance with mandatory treatment requirements
- 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
- 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
- 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
- 7. The proposed reforms identified in the *Drug and Alcohol Treatment Amendment* (Rehabilitation of Persons with Severe Substance Dependence) Bill 2012

Introduction

This is a submission from South East Sydney Local Health District (SESLHD). SESLHD consists of ten Local Government Areas (LGAs) in metropolitan Sydney, and had a resident population of approximately 800,000 in 2006.

SESLHD provides a range of drug and alcohol specialist services across the region, including hospital based and community drug and alcohol services. Specialist D&A services are provided at Prince of Wales, The Women's, Sydney and Sydney Eye, St George and Sutherland Hospitals, the outpatient facility at Langton Centre (Surry Hills) outreach services across a range of community and primary care settings. St. Vincent's Hospital is also geographically located within the boundaries of SESLHD, and the two organisations provide a range of complementary D&A services.

Twelve non-government organisations also provide drug and alcohol treatment in the region. Two Medicare Locals, the Eastern Sydney Medicare Local and South East Sydney Medicare Local, have recently formed to co-ordinate primary health care in the region.

Background

Harms from alcohol and drug use are significant contributors to morbidity and mortality across Australia. The estimated burden of disease related to substance use in Australia is alcohol 4.3% (2.3 % net effect), illicit drugs 2.0% and tobacco 7.8%¹. The estimated costs of alcohol and other drug use in 2004/05 in Australia was \$55.2 billion, of which alcohol accounted for 27%, illicit drugs 15% and tobacco 56%², relating to healthcare, road accidents, loss of productivity and crime costs. Furthermore, these estimates exclude burden of disease arising from pharmaceutical drugs, particularly prescription opioid analgesics and benzodiazepines, such that the total impact may be considerably more.

Key considerations regarding people with drug and alcohol problems include the following issues:

- Drug and alcohol problems occur across a spectrum of severity, from mild to severe
 problems. Many people with mild substance use disorders, or those at-risk of developing
 harms through their use of alcohol or other drugs, may benefit from information and brief
 interventions provided by general health providers (in primary care, community and
 hospital settings). However those with persistent problems may require from more
 structured specialist D&A interventions (e.g. D&A counselling approaches)
- Addiction, or dependence is a chronic relapsing bio-psycho-social disorder that involves
 heavy and regular opioid use despite persistent interpersonal, health and legal problems,
 and is characterised by a loss of control over the use of the drug. The likelihood of an
 individual developing dependence is determined by a complex mix of risk and protective
 factors that are biological, psychological, social and cultural in nature.

- While substance use occurs across all social classes, people with significant substance
 use problems are often marginalised, of low socio-economic backgrounds and have low
 levels of health literacy. Indigenous people are over-represented in drug and alcohol
 treatment presentations.
- Given the chronic nature of dependence disorders, long-term changes in substance use and related improvements in health and social well-being are enhanced by engagement with long-term D&A treatment. Effective and evidence-based treatments are available for alcohol, opiate and other drug dependence disorders.

Responses to the Terms of Reference of the Inquiry

- 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

D&A treatment services are delivered by specialist health, NGO and primary care providers across a range of across a range of ambulatory, residential and hospital settings. The range of evidence-based treatment approaches for addiction to alcohol and other drugs available in NSW include:

- withdrawal services (outpatient, residential and inpatient),
- post-withdrawal services (counselling (including psycho-education, motivational interviewing, relapse prevention), case management and support, day programs and residential rehabilitation treatment),
- opiate (methadone and buprenorphine maintenance) substitution treatment
- other medication assisted treatment (e.g. naltrexone, acamprosate and disulfiram for alcohol, naltrexone for opioids)
- diversion programs, including MERIT and Adult Drug Court Programs
- specialist consultation services, including hospital-based Drug and Alcohol Consultation
 Liaison services, perinatal and infant services, specialist consultation services (e.g. comorbidity clinics)
- harm-reduction oriented interventions effective in reducing the harms from alcohol and other drugs to individuals and the community, including needle syringe programs, supervised injecting centres, wet houses and sobering-up services.

The evidence base for the safety, effectiveness and cost effectiveness of each of these approaches varies according to the patient population, and quality of services delivered. The evidence base for these interventions are summarised in a range of systematic reviews (e.g. Cochrane reviews), national clinical guidelines (e.g. National Alcohol Treatment Guidelines⁴, and the forthcoming National Clinical Guidelines for Medication Assisted Treatment of Opioid Dependence), and NSW Clinical Guidelines (including Withdrawal Services, Opioid Treatment Guidelines Psychosocial Services and Residential Rehabilitation Services). It is beyond the scope of this submission to review these in detail.

The safety and effectiveness of naltrexone treatment is highlighted in this Inquiry. Naltrexone is licensed in Australia as an oral tablet formulation (50mg) for the indication of treatment of alcohol dependence and for opioid dependence (subsided by the PBAC only for alcohol treatment). The mechanism by which naltrexone operates for alcohol (where it effectively reduces cravings and heavy drinking) is different than opioids, where it acts as an opioid antagonist to 'block' or reduce the effects of other opioids. Oral naltrexone treatment (50mg daily) is effective for a minority of opioid users (estimated at between 5-10% of patients participating in a series of Australian clinical trials from approximately one decade ago (referred to as the NEPOD trials⁵)). The limitation with oral naltrexone is that most patients discontinue its use, and relapse to opioid use, with some concerns of increased mortality with the resumption of heroin use. As such, there has been limited use of oral naltrexone for opioid dependence in Australian clinical practice. Nevertheless, oral naltrexone has a clinical role in highly motivated individuals with intensive monitoring and good psychosocial supports (e.g. impaired health professionals).

The problems of poor patient compliance with oral naltrexone have led to a number of long-acting naltrexone preparations having been developed. The most notable one is the depot intramuscular naltrexone preparation (Vivitrol®), licensed in the USA for the management of both alcohol and opioid dependence, and for which there is an evidence base of its efficacy for both alcohol and opioids.

It is unclear whether the pharmaceutical company (Alkermes Inc) has plans to license Vivitrol® in Australia. A/Prof Lintzeris has unsuccessfully applied for NHMRC research grant funding (on three occasions in 2008, 2009 and 2010) with Australian clinical and research colleagues to conduct randomised trials examining Vivitrol. NSW Health (MHDAO) has previously funded clinical researchers from SESIAHS and National Drug Alcohol Research Centre (UNSW) to conduct pilot research using Vivitrol for opioid dependence, however we were unable to secure supplies of the medication from the manufacturing company in the USA, Alkermes Inc, and as such the trial was not progressed.

The other approach has been the use of implantable naltrexone products, manufactured by a number of groups across Australia and internationally (including manufactures in China, Russia and UK). There is no naltrexone implant product licensed in Australia by the TGA (nor to our knowledge any regulatory body outside of Russia). A number of private doctors have used imported, unlicensed naltrexone implant products through the Special Access Scheme (Section A) of the TGA. The fact that there is no licensed naltrexone implant product available in Australia means that naltrexone implant products should not be used within NSW Health settings outside of clinical trial conditions.

The recent NHMRC review of long-acting naltrexone products came to the conclusion that the safety and evidence base for nattrexone implants is still emerging, and that nattexone implants should only be used in properly conducted trials, within appropriate ethical and regulatory frameworks, and not as part of routine clinical practice. The available evidence indicates that there may well be an important role for long-acting naltrexone products, although there are concerns regarding its safety, and it is by no means a panacea for opioid other drug use. Studies (and clinical experience) clearly indicate that a proportion of patients continue to use opioids (e.g. heroin, diverted pharmaceuticals such as oxycodone or buprenorphine) and other drugs (e.g. benzodiazepines, amphetamines) whilst in naltrexone treatment.

Conducting trials of unlicensed medications in Australia should only occur under the TGA CTN or CTX Schemes. This requires the submission of an Investigators Brochure (IB) for the medicinal product under investigation (detailing for example chemical and biological stability, preclinical and human safety data). Clinical trials of a medicinal product under the CTN or CTX scheme require a suitable IB. Prof Lintzeris is not aware of any naltrexone implant product for which a suitable IB is available (that would meet the requirements of Human Research Ethics Committee (CTN) or TGA (CTX)). This to date has been a significant barrier to conducting clinical trials of naltrexone implants in Australia.

The NHMRC review was conducted appropriately, and there is no reason to question the validity of its conclusions. Other peak bodies, such as the ANCD, professional groups (e.g. Royal Australian College Physicians) and consumer groups (e.g. NUAA) have independently published position papers with similar conclusions.

Ref: T13/7960 SESLHD Submission

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

The NSW Drug and Alcohol Budget in 2009/2010 was \$140 million ³. More recent funding enhancements include:

- a \$2.5 million per annum allocation to the NGO sector in 2012,
- enahncements to OTP sector to better co-ordinate specialist and community based programs,
- the recent Involuntary Drug and Alcohol Treatment Units (located in North Sydney and Orange).

NSW Health has led DA-CCP, a national project, endorsed by the Commonwealth and jursidictions that enables, for the first time, a population planning approach to D&A services. DA-CCP provides an estimate of the number and type of DA treatment services required per 100,000 population. DA-CCP is currently being tested, and it is expected to be launched later this year.

Until then, we can only surmise as to the degree of under-funding of D&A treatment services. The burden of disease froim drug and alcohol problems is 4.3% of the total burden of disease, yet the combined federal and state government funding for alcohol and drug treatment comprise only approximately 0.33% of health budgets. There is a clear disparity between expenditure on services and the need for services. Modelling studies regarding opioid substitution treatment suggest significant shortfalls (by at least 50% of treatment need) in the availability of methadone and buprenorphine treatment.

Specific gaps in treatment for people with drug and alcohol problems in SESLHD include:

- A lack of funding for hospital-based D&A Consultation Liaison (CL) Services, and Comorbidity services linking D&A Services with Mental Health, Maternal and Early Childhood, Pain and Primary Care services. These are described further in Section 4. The absence of secure funding base for CL and related services means that resources are necessarily diverted from other treatment services (e.g. counselling, withdrawal, opioid treatment), which creates shortages in these areas.
- A lack of services for people with particular treatment needs, such as those with cognitive impairment (e.g. acquired brain injury), homelessness, Aboriginal People, older persons (recognising the impending increase in older Australians with substance use problems)
- Need for expansion of diversion programs. The recently opened Adult Drug Court at
 Downing centre, a collaboration between Attorney General department and SESLHD,
 is the smallest of the Adult Drug Courts (at only 40 places), and it is expected that
 future expansion will be required to meet demand of this successful and cost effective
 treatment model.

- Infrastructure support in the D&A sector is severly lacking. There has been almost no development in Clinical Information Systems over the past decade, although at least now NSW Health is embarking upon the development of a Clinical Information System (CHOC) for NSW D&A Services. The failure to develop clinical information systems means that data regarding D&A services, patients presenting for treatment and outcomes of treatment are rudimentary. SESLHD D&A Services is the lead site in NSW for the implmenetation of the new Clinical Information system that will for the first time provide the basis for such data, enabling better planning and co-odination of services.
- Workforce development for the D&A sector is also under-resourced. To date, there is no recognisied clinical speciality for urses or allied health professionals in D&A. The medical speciality (Chapter of Addiction Medicine) remains small in number, partly due to the poor funding of D&A Services across Australia, and the failure to secure sustainable Medicare items for Fellows at the Commonwealth level. This makes private medical specialist practice in Addiction Medicine difficult outside of private inpatient hospital settings.
- 3. The effectiveness of mandatory treatment on those with drug and/or alcohol addiction, including monitoring compliance with mandatory treatment requirements Mandatory treatment refers to involuntary treatment, and should be clearly delineated from diversion programs where individuals consent to treatment as a part of a criminal justice diversion program (e.g. MERIT, Adult Drug Court). In NSW, the recent Involuntary D&A Treatment Act (2009) has established the new framework for involuntary treatment. It enables involuntary inpatient admission for alcohol or drug dependent patients who are endangering themselves or others from their substance use, who are unwilling to enter or complete D&A treatment voluntarily, and for whom treatment would likely benefit the person. The process requires referral by a medical practitioner (e.g. GP) or magistrate, certification by an Addiction Medicine specialist at one of the two IDAT units (North Sydney and Orange), and review by a magistrate. The orders enable detention for up to 3 months.

The effectiveness of involuntary treatment remains unclear. Whilst anecdotally such interventions can have positive effect on individual patients and their families, there have been no formal evaluations of the long-term effects of involuntary treatment in the D&A field. There is no provision for Community Based Orders (as per Mental health), although this is under consideration in NSW by MHDAO, and will require a passage of time and formal evaluation of the IDAT program to assess the need for such changes in legislation to enable Community Treatment Orders. It is premature to embark upon such changes without further evidence. We are unaware of any legislation mandating involuntary community D&A

treatment in Australia.

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

Patients with severe D&A problems often have a range of other physical, mental and cognitive impairments or co-morbidities. These can not only increase the intensity of treatment required and result in poorer treatment outcomes, but also can prevent some individuals from being able to access the required services. Effective treatment of patients with D&A problems almost always requires co-ordination across other parts of the health, welfare and social service systems (including child protection, violence prevention, housing, legal and vocational services).

Specific strategies are required to achieve effective co-ordination of services—such as conjoint positions (e.g. mental health and D&A co-morbidity workers), multidisciplinary teams (e.g. Addiction Medicine staff working in Pain Clinics, Perinatal D&A Services), hospital D&A consultation-liaison services, and systems that enhance shared care between specialist D&A and primary care services. Such approaches include integrated models of care (e.g. where patients accessing drug and alcohol services can have their mental health problems treated in the drug and alcohol setting and patients with mental health problems can have their drug and alcohol problems in a mental health setting), shared treatment and referral pathways, workforce development and clinical governance activities.

There needs to be continued emphasis upon strengthening links between the drug and alcohol sector and primary care sectors, and in enhancing the capacity of the primary health sector to manage patients with mild or moderate severity substance use disorders. This will be a key area for development as there is greater clarity regarding the arrangements for Medicare Locals and LHDs. SESLHD is working closely with its Medicare Locals (East Sydney ML and South East Sydney ML) to support GPs in the treatment of patients presenting to their practices with drug and alcohol issues and support better referral processes.

The complexity of patients with chronic co-morbid presentations highlights the need for co-ordination of care and treatment services over a long period of time across a range of settings — including primary and specialist services delivered in both the public and NGO sectors. It is therefore important to position drug and alcohol services alongside mainstream health services, and to establish systems that raise the profile of drug and alcohol services across all sectors of the health system.

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

The strategies employed to address D&A problems in any society reflect the nature of the D&A problems (patterns of use, harms), the nature of the health care system, and the economic and cultural conditions of the society. It is difficult to generalise regarding comparisons with the Swedish or UK models, as the models in these countries are also fluid. For example, whilst Sweden for many years had been characterised as restricting opioid substitution treatment, it now has markedly increased access to opioid substitution treatment using buprenorphine. Likewise, strategies used across the UK vary from district to district and it is difficult to generalise.

A/Prof Lintzeris, Director D&A Services at SESLHD (and Chief Addiction Medicine Specialist, MHDAO, NSW Health), worked for almost 5 years in the UK (based at the Maudsley Hospital and Institute of Psychiatry on a NHMRC Fellowship 2002-2006) and has worked as a consultant across a range of countries in Europe and Asia, and the World Health organisation. He is familiar with treatment services in many of these countries, and would be happy to discuss these issues with the Committee.

7. The proposed reforms identified in the *Drug and Alcohol Treatment Amendment* (Rehabilitation of Persons with Severe Substance Dependence) Bill 2012

The evidence base for the long-term effectiveness of involuntary treatment is limited and has not been established by controlled clinical trials. Under the previous NSW Act permitting detention of people with significant drug and alcohol problems, the 1912 Inebriates Act, homeless people and Aboriginal people were disproportionately over-represented in people detained under for involuntary drug and alcohol treatment^{13 14}. Any widening of powers of people able to refer under this act therefore requires very cautious consideration to ensure adherence to an ethical process based in good medical treatment of addictions. In particular, it would be inappropriate and unethical to use investigational and unlicensed treatment approaches (e.g. naltrexone implants) in patients who are not able to or unwilling to consent to such procedures. The UNODC discussion paper ⁷ on treating drug dependence neatly summarises the issues: 'drug dependence treatment without the consent of the patient should only be considered a short term option of last resort in some acute emergency situations and needs to follow the same ethical and scientific standards as voluntary based treatment. Human rights violations carried out in the name of 'treatment' are not compliant with this approach.' (pg iii)

References

- 1. Begg S, Vos T, Barker B, Stevenson C, Stanley L, Lopez AD. The burden of disease and injury in Australia 2003. Canberra: Australian Institute of Health and Welfare, 2007.
- 2. Collins D, Lapsley H. The costs of tobacco, alcohol and illicit drug abuse to Australian society in 2004/05. Canberra: Department of Health and Ageing, 2008.
- 3. MHDAO. Mental Health and Drug and Alcohol Office, 2012.
- 4. Haber PS, Lintzeris N, Proude E, Lopatko O. 2010. Treatment of Alcohol Problems. Australian Commonwealth Department of Health and Aged Care. Canberra.
- 5. Mattick RP, Digiusto E, Doran CM, O'Brien S,Shanahan M, Kimber J, Henderson N, Breen C, Shearer J, Gates J, Shakeshaft A and NEPOD Trial Investigators, 2001. National Evaluation of Pharmacotherapies for Opioid Dependence: Report of Results and Recommendations. National Drug and Alcohol Research Centre, Sydney.
- 6. Ritter, A., & Chalmers, J. (2009). Polygon: The many sldes to the Australian opioid pharmacotherapy maintenance system. ANCD Research Paper #18. Canberra: Australian National Council on Drugs.
- 7. Webb MB. Compulsory alcoholism treatment in New South Wales. *Medicine and Law* 2003;22(2):311-22.
- Legislative Council Standing Committee on Social Issues. Report on the Inebriates Act 1912.
 Sydney: NSW Parliamentary Library, 2004.
- United Nations Office on Drug Control. From coercion to cohesion: Treating drug dependence through health care, not punishment. Vienna: United Nations, 2010.