NEW SOUTH WALES STATE CORONER

Names of Deceased:	**Mr James Unicomb** **Mr Michael Poole** **Ms Grace Yates**
File Number:	**1357/05, 516/08, 2915/10**
Hearing Dates:	**20th August – 24th August 2012**
Location of Inquest:	**NSW State Coroner's Court, Glebe**
Date of Finding:	**27th September 2012**
Coroner:	**NSW State Coroner, Magistrate Jerram**

Representations:

Ms Gail Furness SC instructed by Ms Alana McCarthy of the *Crown Solicitor's Office* appeared to assist the Coroner.

Other parties represented were Dr Donald Tan, Dr Jassim Daood, Dr Rhaman Shinwari, Lauren Tancred and Ms Yates partner and father.

These three deaths were investigated in one inquest because of the possibility of there being a common link, each death following, or at some time after treatment at the Psych n Soul Clinic ('the Clinic') in Ultimo, Sydney.

The inquest was held over five days, from August 20 to 24. I was assisted by Ms Gail Furness, now SC, of Counsel, and Ms Alana McCarthy from the Crown Solicitor's Office. Other parties represented were Dr Donald Tan, Dr Jassim Daood, Dr Rhaman Shinwari, Lauren Tancred and Ms Yates' partner and father.

THE FACTS

James Unicomb

On September 7 2005, James Unicomb, then aged 22 presented at the Clinic (owned and managed by Ross Colquhoun, a psychologist) with his mother for the insertion of a naltrexone implant. James had a history of opiate use and was on the methadone programme. He was attended by Dr Tan, the medical officer at the Clinic for that day. Dr Tan had not seen James before. Dr Tan took a history ofJames' drug use, and satisfied himself after speaking to James and by doing a naloxone test that he had last used heroin about 24 hours previously. Dr Tan believed that it was safe to administer naltrexone 24 hours after opiate use.

Dr Tan then made a small incision in James' lower abdomen and inserted one pellet of naltrexone under the skin and stitched the incision. The implant that James was given was intended to have an effect for about 12 weeks, and should have been replaced on December 7, 2005.

There is no record that James was told this, and Dr Tan did not explain the information given to James on forms which he had to sign. James' parents had earlier received information from the Clinic that the implants lasted an average of 24 weeks.

James never returned to the Clinic, either to have the stitches removed, blood tests done or for the insertion of a replacement implant. In early November the implant site was red and inflamed, and James was prescribed an antibiotic by a local doctor, which resolved the inflammation. He did have an appointment for replacement of the implant on December 7, but it was postponed because he had just begun work.

On the morning of December 10, 2005, having spent the evening before taking drugs at a friend's house, he was found deceased. Toxicology results indicated morphine, codeine, diazepam, and very low levels of methadone, methamphetamine and marijuana in his system, but naltrexone was not detected at autopsy.

The Post Mortem Report by forensic pathologist Dr Dianne Little gave as his cause of death, 'acute toxicity due to multiple drugs'.

Michael Poole

Michael Poole had a long history of depression, and of methadone use. Aged 48, he twice attended the Clinic in February 2008 for a pre-treatment assessment for Rapid Opioid Detoxification ('ROD'). He was assessed by both Ross Colquhoun and Dr Daood on February 20. Dr Daood, like Dr Tan, worked from time to time as a medical officer at the Clinic. Both Ross Colquhoun and Dr Daood were told that Michael had a history of depression, which is a contra-indicator for ROD according to the NSW Health Guidelines.

Ross Colquhoun appears to have filled out the assessment questionnaire, in which there are a considerable number of errors (including that Michael had been on anti-depressants for 6 months, whereas in fact he had been taking them for 14 years). It was arranged that Michael would attend the Clinic for treatment on March 7. Michael advised Ross Colquhoun a week before by email, that he would need to stay overnight at the Clinic as he had no other accommodation option in Sydney.

On March 7, Michael was noted by Dr Daood on attendance, as having detoxed from methadone and heroin (Michael had never used heroin and told Dr Daood so, though Dr Daood later told the Court that 'they usually use it and never tell the truth'). Following the procedure, Michael was delirious, anxious and delusional at least until mid afternoon. He was supervised only by a registered nurse, Philippe Jacquot. Michael stayed overnight at the Clinic and, early on March 8, was coherent if 'wobbly' (according to Mr Jacquot) and was driven by Ross Colquhoun to a boarding house in Randwick, and left outside that building.

On March 10, police were called to the boarding house because Michael was reportedly confused and disoriented and had been so for the last one or two days. He was admitted to Prince of Wales Hospital, where it was recorded that he said he had taken methadone, some benzodiazepines and other medications since discharge from the Clinic. He denied having sniffed WD 40, a can of which was found in his room, of which he reportedly smelled. CT scans taken revealed a widespread subarachnoid haemorrhage and a dissecting aneurysm of the thoracic aorta. Despite treatment, he deteriorated and died on March 29.

The Post Mortem Report by forensic pathologist Dr Rianie Janse Van Vuuren gave as his cause of death, 'ruptured berry aneurysm and its consequences'. Differing opinions were heard on the possible effects of Rapid Opioid Detoxification Treatment leading to aneurysm to which I shall come shortly.

Grace Yates

Grace Yates had a heroin dependence and had been on the methadone programme for four years. She was 24 years of age and had a young child. Grace was determined to break herself of her drug dependence for the sake of her child. On September 27, 2010 she was referred to a cardiologist by her general practitioner for an ECG prior to Rapid Opioid Detoxification as advised by Ross Colquhoun.

That ECG showed that she had a prolonged QTc interval of 0.445msec. Grace rang Ross Colquhoun with this information, and was told to come to the Clinic on the following day where she could have a further ECG performed. She never did attend the specialist appointment with a cardiologist. A prolonged QTc is a relative contra-indicator to Rapid Opioid Detoxification Treatment.

According to David Anjoul, Grace's partner, on September 28 they both presented at the Clinic for treatment, and signed the consent forms without either reading them, or having them explained and the risks outlined. Ross Colquhoun organised a further ECG for Grace , which showed a more prolonged QTc interval of 0.470 m sec.

Despite this alarming result, Grace was admitted and the Rapid Opioid Detoxification procedure commenced. She was given naltrexone at about 10.30 am, and then developed opioid withdrawal symptoms which continued throughout the morning. At about midday, she fell over but appeared to have suffered no injury or harm.

There was no registered nurse on duty in the afternoon. Daniel Macri, who was studying nursing at the time, left the Clinic at 4.45 pm before the arrival of the night nurse, Ms Tancred, a registered nurse, came to work just after 5 pm. 'Handover' thus had to be made by telephone. Shortly after 5.20 pm, Grace was heard to gasp and groan and was found to be non-responsive.

Attempts were made to resuscitate her for about 8 minutes before ambulance officers arrived. She was admitted to Royal Prince Alfred Hospital, her implant removed and urinalysis performed, revealing the presence of methamphetamine in her system.

She never regained consciousness, suffered further cardiac arrest, and tragically, died on November 30, 2010. The Post Mortem Report by forensic pathologist Dr Stephen Wills gave as her cause of her death as 'Acute bronchopneumonia in an individual with severe hypoxic-ischaemic encephalopathy'.

THE ISSUES

Was the implant placed in James Unicomb faulty and why was it not found at autopsy?

What were the circumstances of Michael Poole's discharge?

Was the treatment of Grace Yates including the assessment that she was suitable for the treatment appropriate, was the staffing adequate, and were the records properly kept?

What was the cause of death of Michael Poole and of Grace Yates, and were all or any of the deaths directly related to procedures and treatment given to them by the Clinic?

THE WITNESSES

Dr Tan was the medical officer who treated James Unicomb at the Clinic on 7 September 2005. Dr Tan is General Practitioner and knew naltrexone implants were experimental. He said there were no protocols in place in 2005 regarding implants, but that he believed it was only necessary for the patient not to have had heroin in the 24 hours prior to implant. He admitted he had not explained the risks or procedures to James, despite his signature attesting to having done so on the consent form. Rather, he seems to have treated the forms as irrelevant and unimportant.

Mr Jacquot worked at the Clinic casually at the time of Michael Poole's treatment. He had had no experience in drug and alcohol treatment, and was given no induction or training at the Clinic, only being shown policy manuals after Michael died. He gave evidence that he had always had concerns about patients being discharged while still withdrawing or upset, and thought that they all should have stayed overnight after treatment. He was given no mentoring or supervision and no help.

In the case of Michael, the treating doctor, Dr Daood had left about 3pm, no other nurse was available and Mr Jacquot had offered to stay overnight with him having already worked a shift from 8 am to 5 pm. He recalled Michael as having been quite settled overnight, and seeming ready for discharge in the morning, but did not know that Michael had no support person and was going to a boarding house. In fact, he said that Ross Colquhoun had told him he (Michael) was going to his Aunt's. He had thought it strange that Ross Colquhoun drove Michael.

Dr Daood provided medical treatment occasionally at the Clinic between 2004 and 2008, having received full Australian registration as a medical practitioner in 2004. In assessing Michael, he said he was aware of his depression, and that it was a relative contra-indicator to Rapid Opioid Detoxification, but only if it was current, severe and the patient was on medication. He claimed that Michael showed no signs of current depression, was not on medication (despite opioids and methadone being detected in Michael's toxicological tests) and was an appropriate candidate, he believed, for

Rapid Opioid Detoxification.Under questioning about Michael's denial of being a heroin user, he said, 'They usually use it and never tell you the truth'. Dr Daood said that he stayed at the Clinic until 7pm, and checked on Michael's condition prior to discharge in the morning, contrary to Mr Jacquot's claim. Dr Daood had never seen the NSW Health Guidelines for Rapid Opioid Detoxification.

Dr Shinwari was the medical practitioner who treated Grace Yates at the Clinic. His professional conduct in relation to her treatment is currently under investigation by the Health Care Complaints Commission (' the HCCC'). Dr Shinwari objected to giving evidence under s 61 of the *Coroners Act 2009* and was not required to give evidence about his treatment of Grace Yates.

Ross Colquhoun also objected to giving evidence under s 61 of the *Coroners Act 2009* and was not required to give evidence in relation to his treatment of James Unicomb, Michael Poole and Grace Yates but gave evidence regarding his qualifications and current work, including evidence that the Clinic currently provides treatment in the form of naltrexone implants.. The Psychology Tribunal has determined that his registration be conditional, including that he practice under supervision and only practice Rapid Opioid Detoxification on premises licensed to perform Rapid Opioid Detoxification. The Clinic is not licensed to perform Rapid Opioid Detoxification and was not licensed at the time of Grace's treatment. Ross Colquhoun has applied for the Clinic to be licensed to perform Rapid Opioid Detoxification.

Daniel Shaw, a registered nurse who worked only 6 shifts altogether at the Clinic , his final shift being the day Grace Yates was admitted, said he had never seen a Policy and Procedure Manual and could not remember the consent forms. Mr Shaw saw Grace incur the fall in the morning, and reported it to Dr Shinwari, but strongly denied that Dr Shinwari told him to make hourly observations. There was a document in evidence which indicated that Dr Shinwari had suggested the recording of hourly observations. Mr Shaw had only been called to work that morning, and said he was available only from 8am till 1pm. When he left, Grace was stable and in the sole charge of Mr Macri.

Mr Macri also worked for the last time on 29 September 2010, the day of Grace's collapse. Although since registered as a nurse, he had not completed his studies at that time. He was adamant that Dr Shinwari left in the early afternoon and did not tell him to make hourly observations, and he was unhappy about being left in sole charge of 3 patients. Mr Macri had never seen a Rapid Opioid Detoxification Policy Manual. He did leave before his replacement arrived that afternoon, and handed over to Ms Tancred only by telephone.

Ms Tancred also, had never been shown a Policy Manual, though she did recall signing 'a white folder'. Her training in Rapid Opioid Detoxification was merely 'on-the-job' by another nurse and whichever medical practitioner attended on her shift. Ms Tancred said that when she commenced working at the Clinic Mr Macri had mentioned to her to do observations whenever possible, but without any specific guidance as to timing of observations.

Her experience was that 4 hourly was the norm. Grace had seemed stable enough initially and Ms Tancred spent most of her time time attending to the other two patients who were recovering but unwell. When Grace began to collapse and gasp, she called for the oxygen mask but felt quite inadequate to deal with Grace's condition. Despite her nursing training including resuscitation, she had never actually had to perform CPR nor had any training at the Clinic in the resuscitation equipment including the defibrillator.

Expert Witnesses

Professor John Saunders, the primary expert and independent witness, is a consultant physician in internal medicine and addiction medicine, and a former chair of a Commonwealth Expert Advisory Committee on a clinical trial of naltrexone implant treatment. He provided a written opinion on the treatment of each of the three, as well as an overall written opinion, and then gave oral evidence for a considerable time. In relation to Rapid Opioid Detoxification, he explained that Rapid Opioid Detoxification is a procedure which aims to accelerate the opioid detoxification process by the administration of an opioid antagonist such as naloxone or naltrexone and has a much shorter phase than the norm.

He stated that such treatments are suitable, at most, for a small minority of patients, the most successful and evidence-based for heroin dependence still being methadone or buprenorphine under supervision and for an extended time, typically some years. Rapid Opioid Detoxification, in his opinion, can be fatal if not adequately managed with suitable pre-procedure medication and close post-procedure observation and medical treatment often for several days.

Expert opinion in relation to Rapid Opioid Detoxification

Professor Saunders' opinion was that the medical assessment at the Clinic was grossly inadequate. He had not seen any evidence that alternative options for treatment had been discussed with either of Michael Poole or Grace Yates or that the seriousness of the withdrawal symptoms had been explained.

The staffing of the Clinic was wholly inadequate. There ought to have been a ratio of 2 registered nurses to each patient throughout, or at least 1 to 1. A urine drug screen at the time of admission, followed by a naloxone challenge would have been the safest approach to ensure that no withdrawal syndrome was precipitated.

Expert opinion in relation to James Unicomb

In relation to James Unicomb, Dr Saunders pointed out that at the time of his implant in 2005, the evidence as to the effectiveness of naltrexone implants was non-existent, while methadone maintenance was strongly supported. James, in his opinion, would have been better treated by methadone given his long history of heroin addiction.

The inflammation aroundJames' implant site in November 2005 may have been a result of James trying to remove the implant in order to re-use heroin.
In fact, there having been no evidence of an implant found at autopsy, that hypothesis becomes more likely, the possibility of it having been removed by James before the overdose which led to his death. He described Dr Tan's medical assessment as patchy and incomplete and his lack of records as surprising.
It is clear that there is no direct link between James' death and the implant.
However the efficacy of the implant will never be known as these implants have not been approved by the Therapeutic Goods Association. .

Expert opinion in relation to Michael Poole

In relation to Michael Poole, Professor Saunders thought it possible that Rapid Opioid Detoxification treatment could have caused or aggravated an initial haemorrhage from a cerebral aneurysm. Michael had many contra indications for treatment by Rapid Opioid Detoxification including a history of depression and no immediate home support in Sydney. Accordingly, he was not an appropriate patient for Rapid Opioid Detoxification from the outset.

His dependence on codeine should have been managed in the Professor's opinion by methadone, but he was given no alternative by Ross Colqhoun. Again, his medical assessment, in his case by Dr Daood, was 'scanty in the extreme' and did not remotely approach the standard expected for the assessment of a patient for Rapid Opioid Detoxification Treatment.

No physical examination was recorded, his observations during after care were far too infrequent and inadequate, and he was knowingly discharged by Ross Colqhoun to a boarding house with no supervision or assistance. That discharge was of very serious consequence as Michael still delirious, was highly vulnerable to a range of accidents and health problems without any appropriate help. He ought to have been managed in a medical ward, or a high dependency unit, with potential lifesaving benefit.

Given that the cause of death given after autopsy by the forensic pathologist was

1) subarachnoid haemorrhage due to a ruptured berry aneurysm of the R internal carotid artery and

2) dissecting aneurysm of the thoracic aorta,

Professor Saunders remained of the view that the Rapid Opioid Detoxification Treatment could have resulted in or aggravated either or both of those conditions.

Expert opinion in relation to Grace Yates

In relation to Grace Yates, Professor Saunders was emphatic that the cause of death was indeed ischaemic/hypoxic encephalopathy, caused by cardio-respiratory arrest following Rapid Opioid Detoxification Treatment. Grace was a long-term heroin user who had been on methadone for more than two years.

The Rapid Opioid Detoxification Treatment recommended to her by Ross Colqhoun seems to have been put as her only option, whereas Professor Saunders states that it had the effect of her discontinuing a solidly evidence-based mainstream treatment (methadone) in favour of a niche treatment with a minimal evidence-base. Medically, she was assessed by Dr Shinwari quite inadequately.

An ECG ordered by her general practitioner had already shown a prolonged QTc interval of 0.445 msce. A further ECG arranged by Ross Colqhoun showed the QTc interval to have lengthened to 0.470 msec. That ECG abnormality although a relative contra-indication to ROD, does not seem to have been given consideration in assessing Grace's suitability. It is recognised as leading to cardiac arrhythmias which can be severe and even fatal. The treatment should have been given only after careful medical testing and consideration, and on the balance of evidence that it was necessary. She was a high risk patient.

As well as the medical treatment, Grace's nursing care after the procedure was below standard. She was not adequately monitored and observed. There was no qualified nurse present in the Clinic for the whole afternoon and Mr Macri left before his replacement arrived. It also appears that no medical practitioner was present from early afternoon.

Professor Saunders completed his written report on Grace by saying,
"Had (she) been treated in a high dependency unit, as is appropriate for patients undergoing Rapid Opioid Detoxification-naltrexone treatment, the monitoring that occurs would have identified the arrest as soon as it had occurred (and would be expected to identify deterioration in cardiac or respiratory function before such an event). In this case, resuscitation measures would have commenced promptly and the outcome would likely have been very different."It should also be noted that on the date of Grace's death, September 29, 2010, the Clinic was not licensed to perform Rapid Opioid Detoxification even though Ross Colquhoun knew the Clinic needed to be licensed.

Further expert evidence

Further expert evidence was given by Professor Dan, a neurosurgeon, about the management of cerebral aneurysm and subarachnoid haemorrhage, in the matter of Michael Poole. He accepted Professor Saunders' opinion that periods of hypertension are common in Rapid Opioid Detoxification, and explained that hypertension causes an aneurysm to rupture. He confirmed therefore that Michael Poole's given cause of death may well have been the result ultimately of hypertension during the withdrawal period.

The Court also admitted a report from Dr Caplehorn, an emergency physician specialising in addiction medicine, in which he gives his opinion that Rapid Opioid Detoxification most likely had no role in Michael's death. I accept that neither Professor Saunders nor Dr Caplehorn express a definite view that Rapid Opioid Detoxification either did or did not play a role. Professor Saunders having been subjected to lengthy questioning, and exhibiting a high degree of expertise, is to be preferred although he too considers it only a possibility.

DISCIPLINARY PROCEDURES ELSEWHERE

As Counsel Assisting made clear in her opening address, there have been a number of disciplinary cases completed involving personnel at the Clinic, some of whom were summonsed to give evidence at this inquest.

Dr Tan was found guilty of unsatisfactory professional conduct in November 2009 in relation to the Rapid Opioid Detoxification Treatment of a patient in 2006. He was found not to have taken an adequate drug use history as part of his medical assessment, to have administered naltrexone when he either knew or should have known that the patient had used opioids in the 24 hours before treatment, and to have allowed discharge of the patient while still delusional. The conditions that were placed on his practice, including that he not perform Rapid Opioid Detoxification.

Mr Jacquot was found guilty by the Nursing and Midwifery Professional Standards Committee of NSW in April 2011 of unsatisfactory professional conduct in relation to his care of Michael Poole after Rapid Opioid Detoxification Treatment in March 2008. He was found to have not carried out adequate observations and his record keeping was inadequate.

Ross Colquhoun had his registration as a psychologist suspended by the Psychology Council in November 2010 in respect of his treatment of Michael Poole. He appealed that decision, and in November 2011, the Tribunal determined that his registration be conditional on his practising only under supervision and only using Rapid Opioid Detoxification on premises licensed accordingly. The suspension was revoked.

In July 2012 a differently constituted Psychology Tribunal heard a complaint against by the Health Care Complaints Commission concerning his treatment of Michael Poole. That Tribunal made findings of fact that he failed adequately to assess Michael's suitability for Rapid Opioid Detoxification, treated Michael notwithstanding his known depression (a contra-indicator) failed to provide necessary information to the patient and to maintain proper clinical records and discharged him knowing that he would not be adequately supported. The outcome of those most recent proceedings involving Ross Colquhoun are not yet complete.

I am satisfied on the evidence before me that I may make the same findings as the Nursing and Midwifery Professional Standards Committee of NSW in relation to Mr Jacquot and of the Psychology Tribunal in relation to Ross Colquhoun.

CONCLUSIONS

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, James Unicomb because of his severe and long term addiction (despite his strong family support), Michael Poole because of his depression and virtually total lack of outside support in Sydney, and Grace Yates because of her cardiac risk.

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

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

James Unicomb's death cannot be directly connected with his procedure at the clinic, but the lack of alternatives and follow –up, strongly suggest as Professor Saunders believed, that he would have been better to have remained on methadone in a much longer-term programme, known at the time to have been more effective than any other in counter acting dependence.

Michael Poole also should not have been considered suitable for reasons previously given. But had he been provided with careful medical and nursing care after the procedure, and on discharge strong support ensured, he may not have died as he did.

The death of Grace Yates must be directly attributed to the poor assessment by the Clinic, the decision to provide the treatment despite her ECG results, the lack of proper after care during the withdrawal process, and the failure of the Clinic to ensure that staff were properly trained and experienced in emergency procedures.

I am aware that Ross Colquhoun and Dr Shinwari await a decision from the Health Care Complaints Commission as whether their respective professional conduct in relation to their treatment of Grace Yates will be the subject of a complaint.. I do not criticise the nurses generally, as such inadequacies as they displayed were mainly due to their having been employed (or contracted) at a low level of experience and/or training, presumably for financial reasons.

I have been told during these proceedings that Mr Jacquot was found to have been guilty of unsatisfactory professional conduct in his care of Michael Poole. Although I do not seek to quibble with the Nursing and Midwifery Professional Standards Committee, in fairness it should also be said that he voluntarily stayed overnight with Michael, after completing a day shift and despite not having been called in for the night, and that he had been concerned generally about the lack of supervision and nursing for patients after the Rapid Opioid Detoxification procedures.

FORMAL FINDINGS FOR MR JAMES FRANCIS UNICOMB

James Francis Unicomb died between 11.30pm, December 9, 2005 and 12.14pm December 10, 2005 at 31 Brushwood Place, Hornsby in the State of New South Wales of acute toxicity due to multiple drugs which were self-administered.

FORMAL FINDINGS FOR MR MICHAEL POOLE

Michael Poole died on March 29, 2008 at the Intensive Care Unit of the Prince of Wales Hospital, Randwick in the State of New South Wales of a ruptured berry aneurysum and it's consequences, and bronchopneumonia, three weeks after receiving Rapid Opioid Dextoxification Treatment.

FORMAL FINDINGS FOR MS GRACE YATES

Grace Yates died on November 30, 2010, at the Royal Prince Alfred Hospital, Camperdown, in the State of New South Wales of acute bronchopneumonia following a severe hypoxic-ischaemic encephalopathy caused by cardio-respiratory arrest following Rapid Opioid Detoxification Treatment.

RECOMMENDATIONS

To the Health Care Complaints Commission:

1.

That these findings be forwarded to the Health Care Complaints Commission for consideration of proceedings being taken against Dr Jassim Daood.

2.

That I strongly endorse the statements and recommendations of the Australian National Council on Drugs in it's position , Statement on Naltrexone Sustained Release Preparations (Injectible & Implants) of March 2012, annexed hereto and Exhibit 14 in these proceedings.

Magistrate Mary Jerram **27 September 2012**

NSW State Coroner **Chambers, Glebe**

AUSTRALIAN NATIONAL COUNCIL ON DRUGS

ANCD POSITION STATEMENT

Naltrexone Sustained Release Preparations (Injectible & Implants)

March 2012

In response to the ongoing debate regarding the use of Naltrexone implants to treat opioid dependence, the Australian National Council on Drugs, as the principal advisory body to the Federal Government on drug and alcohol policy and programs, has released the following statement and fact sheet:

The Australian National Council on Drugs:

I. Supports increased access to, and availability of scientifically accepted evidence based treatments for people with drug and alcohol related problems;

II. Supports the trialling and development of innovative treatments for people with drug and alcohol related problems when accompanied by appropriate ethical and evaluation frameworks;

III. Believes it is vital that a comprehensive range of treatments be provided to meet the individual needs and circumstances of people trying to address their drug and alcohol related problems;

IV. Believes that only pharmacological treatments that are registered as safe and efficacious should be available for routine use;

V. Believes that for pharmacological treatments that do not have Therapeutic Goods Administration (TGA) approval, such as sustained release naltrexone preparations, formal registration processes through the approved clinical trial procedures should be followed;

VI. Believes that ongoing use of the TGA Special Access Scheme for sustained release naltrexone preparations circumvents formal processes to ascertain quality, safety and efficacy of pharmacological treatment products and is therefore inappropriate;

VII. Recommends that further independent clinical trials on the safety and efficacy of sustained release naltrexone preparations as a pharmacological treatment for drug dependence be conducted as soon as possible;

VIII. Believes that there needs to be full and informed consent from any clients prior to their engagement in any form of treatment for drug and alcohol dependence and related problems;

IX. Believes that given the very limited Australian data and evidence on the efficacy and safety of sustained release naltrexone preparations, their authorised use through the TGA Special Access Scheme is ethically problematic as it puts patients at risk of unknown harms, for an unknown benefit;

X. Recommends that the TGA and the Department of Health & Ageing resolve the ongoing use of the Special Access Scheme for the use of naltrexone implants and any other sustained release naltrexone preparations that are utilised via this scheme.

AUSTRALIAN NATIONAL COUNCIL ON DRUGS

Fact Sheet:

- Naltrexone is an opiate antagonist which blocks opioid receptors, and as a result people on naltrexone who take opioids, such as heroin, are unlikely to experience the effects of those opioids;
- Oral naltrexone tablets were approved for prescription use for relapse prevention in opioid dependence in Australia in 1998;
- The effectiveness of oral naltrexone among oplate users is significantly reduced by non-compliance, as people are able to stop taking their tablets to regain the effects of any opioid use;
- In response to this non-compliance, longer-acting, sustained release injectable naltrexone and naltrexone implants have been developed in a number of countries, including Australia;
- A naltrexone implant is a surgically implanted device that provides a slow release of naltrexone over a period of time, effective for 3-6 months;
- Injectible sustained release naltrexone, which is effective for 4 weeks, was approved for the treatment of opioid dependence in the USA in October 2010;
- Previous studies on oral naltrexone have reported increases in the risk of overdose post treatment due to a decreased tolerance for opioids;
- Research regarding whether naltrexone implants and other sustained release preparations can lead to the same risk of overdose or other problems related to their surgical insertion is unclear;
- Despite the strong theoretical background for naltrexone implants, evidence for their safety and efficacy sufficient for registration in Australia has not been presented;
- Despite this lack of Therapeutic Good Administration (TGA) approval for use in humans, naltrexone implants have been inserted in thousands of people in Australia over the last decade;
- Clinicians have been able to obtain and utilise the implants under the TGA Special Access Scheme (SAS), which allows the use of unapproved therapeutic goods for people for whom death is otherwise likely.

Further information:

Bell J, J Kimber, et al. (2003). *Clinical Guidelines and Procedures for the Use of Naltrexone in the Management of Opioid Dependence*. Australian Government Department of Health and Ageing, Publications Production Unit.

Lobmaier P, H Korner, et al. (2008). "Sustained-Release Naltrexone For Opioid Dependence." *Cochrane Database of Systematic Reviews* 2008 (3).

NHMRC (2010). *Naltrexone implant treatment for opioid dependence: Literature review*. Available at http:/www.nhmrc.gov.au/your-health/naltrexone-implants.

ANCD

AUSTRALIAN NATIONAL COUNCIL ON DRUGS

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