Submission to the

Education and Health Standing Committee

Inquiry into the Adequacy and Appropriateness of Prevention and Treatment Services for Alcohol and Illicit Drug Problems in WA

from

Fresh Start Recovery Programme
65 Townshend Road, Subiaco, WA

31 July 2009

Background

Social determinants of drug use

The Fresh Start Clinic typically greets 700 to 800 patients per year who present for detoxification, management and continuing support. In addition to this our workers provide continuing support for the 6000 patients already in our treatment program. Fresh Start Clinic is located in Subiaco. The map in Figure 1 shows the distribution of the postcodes of a sample of over 4,500 of our patients. The dark blue areas have the most users.

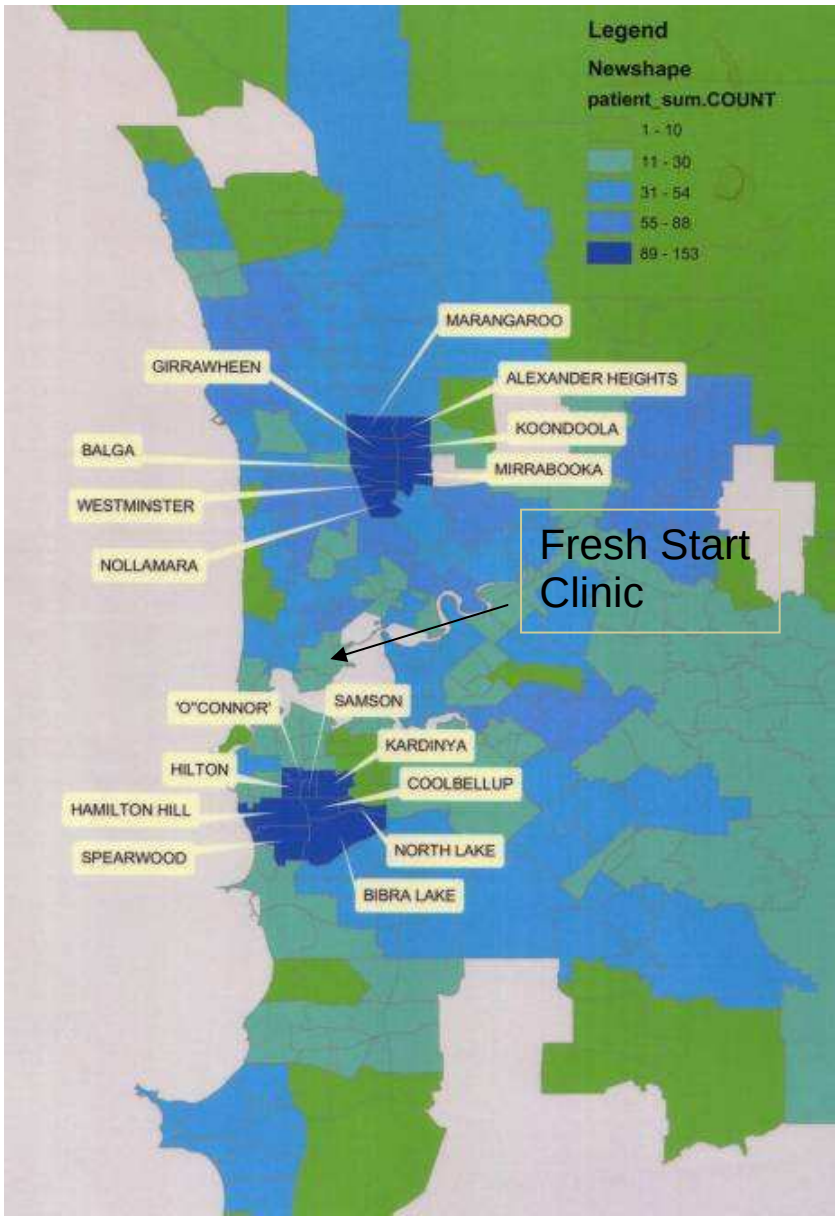

Figure 1: Location of Fresh Start Clinic

This data indicates that there are concentrations of higher prevalence of drug use. We believe that this exposes today's school-age children in those areas to a higher risk of developing addictions. Notwithstanding the different populations of the suburbs, resources for education of school-age children to discourage drug use should be increased in heavy use areas.

Mental, physical, family and economic consequences of drug use

Our experience is that drug use interferes with motivation, honesty, education, community, and mental health[1,2,3]. Within the West Australian setting, we note that those affected with the use of drugs are unable to join the normal part of a productive community with enormous costs to Australia. The U.S.

National Institute on Drug Abuse[4] reports that the income-producing ability for those that start using marijuana in their teenage years is 30% less than the rest of the community over a lifetime. Reduction in income may be attributable to cognitive impairment or other factors[5]. In the long tern the high use of marijuana and its association with other drugs as well as the fall off in education and motivation means that we have a large population of young people sitting on the couch each day watching daytime television and consuming drugs for one or two generations in a row.

The roles of family groups

The patients that we have been treating typically are affected by their family's influence as well as the community around them. Figure 1 shows the effects of government-subsidised housing and planning in relation to drug use in Perth. More importantly, the second-best strategy of having the country commit itself to harm minimisation has increased the number of government-subsidised opiate dependent patients (methadone, morphine, buprenorphine and others) from 1000[6] in 1985 to more than 50,000[7]. Families are enormously affected by the type of medication offered. If they were given another opiate and the patient's addiction is maintained the non-using family is relatively separated from the opiate dependent individual and their lifestyle and value system. In contrast to the harm minimisation approach that Australia has committed itself to the Fresh Start approach assumes that all individuals who wish to escape from opiate dependence should immediately be assisted. Twelve years' experience has defined that the majority of these individuals present with their families with the dream of reuniting the family. The approach of using naltrexone implants terminates the opiate dependence at least for six months or more and the patient has the experience of living in a non-opiate dependent world with his or her family. The most profound difference between maintaining opiate dependence and correcting it is the reaction of mothers and other family members who become committed to supporting the new drug-free lifestyle.

We need strong families because this changes how the community thinks. We need families to be engaged in drug abuse prevention alongside schools and other organisations. Drug abuse prevention may be more easily achieved if government policy is able to increase involvement of the family unit in drug prevention. Several publications explore this subject in more detail[8,9,10,11].

Early intervention

To achieve early intervention, we need early detection.

The average young person who commences their drug use in Perth, WA, starts smoking nicotine first and cannabis a short time later between the ages of 10 and 16. 50% of our patients' heroin use has commenced by the age of 18 and 80% of their heroin use by the age of 22[12]. This means that the government must consider developing early detection, early intervention programs as well as providing intensive help for the affected families of adolescents. This will mean a major investment in schools and organisations supporting adolescents. Britain has shown good leadership in drug detection in schools and such programs have not been supported by Australian policy. Over the last 10 years our community has adjusted to urine screening for employment in jobs where the lives of other people could be affected by drug use. Australia leads the OECD countries for drug use[13]. We hope that governments, education leaders, health professionals and the whole community can adjust to the concept of annual health checks for adolescents within our community. These health checks which may be facilitated by education or health leaders have the potential to reduce drug use and increase productivity for the families concerned and the whole community.

The National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD)[14] report found that the age of first use of heroin among its subjects was on average 20 ±5 years. The National Drug Strategy Household Survey 2007[15] reported a similar average age of first use of heroin of 21.2 between and 18.8 for cannabis (averages from 1995 to 2007; standard deviations were not reported). Data from the USA[16] shown in Figure 2 also has its peak near 18 years for cannabis. It can be seen from Figure 2 that 80% of first cannabis use starts between the ages of 12 and 22. It is reasonable to assume that the window of first heroin use is only a little different from that for cannabis. It is also a reasonable assumption that people who try cannabis will be more likely to try other illicit drugs such as heroin. The National Drug Strategy Household Survey 2007[15] found that 13% of 12- to 19-year-olds in Australia had tried at least one illicit drug. It also found that 5,900 14- to 19-year-olds had ever tried heroin including 5,300 who had used it recently – about 0.3% of the population in that age group.

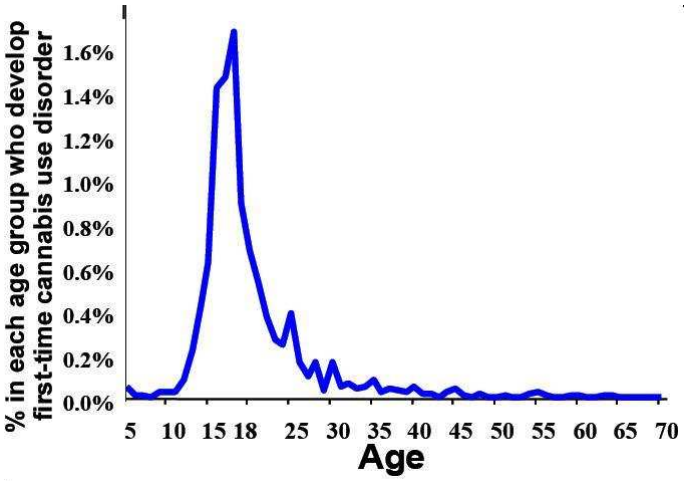

Figure 2 Age of first regular use of cannabis[16]

This data implies that a significant proportion of drug use starts at school age. The data resonates with our experience at Fresh Start Clinic[12]. It is our belief that there should be drug screening for school-age students so that early detection can lead to early intervention. We recommend screening be carried out by suitably qualified doctors in conjunction with school nurses. Initially this may well be marketed to families who adopt the principle of regular health checks for adolescents during a stressful period of growth where the health checks include mental health and drug use screening with a view to intensive support early rather than late.

The role of legislation

We believe that legislation should facilitate effective treatments. If the Department of Child Protection legislation could be extended to provide drug screening at puberty it would enable drug problems to be addressed at the time they are developing. This screening should be promoted through health promotion groups in an effective manner. It is not our belief that children should be punished or forced to go into treatment programs, but to monitor drug use in individuals who may test positive for illicit drugs would be beneficial so that early detection could enable early help being made available to children.

Drug policy in other countries

In the U.S., the widespread use of distributing needles for injection has been taken up less efficiently than in Australia. The result for Perth patients is that we are seeing about 1 in every 1000 patients who inject having HIV while in the U.S. and Canada many cities have up to 40% of their injecting population HIV positive. This aspect of harm minimisation is may well have contributed to this benefit that we enjoy in Australia.

In Russia, medications like methadone have been made illegal[17] because the treatments are known to prolong addiction.

The Swedish model[18] involves early detection and early intervention. In schools, police officers, social workers and school nurses work together to interview all students who show sudden changes in educational performance or family distress and drug screen them. This is followed for students who test positive for drugs with a compulsory intensive education programme consisting of six weeks of learning how to live, one year in a residential rehabilitation education programme and a second year during which they are allowed to go and live in any town except their home town. The intensive education program costs US$10,000 per month. In Sweden, harm reduction programs also have limited availability.

The two examples of Russia and Sweden are very different from Australia's policy and Fresh Start is not advocating that either should replace the current policy. However we feel that incorporating elements of these policies (such as making screening available for school-age students and an increased availability of abstinence programs) may be helpful to increase the available ways to reduce drug problems in Australia.

Recommended changes in drug policy

The Australian Commonwealth government provides full funding for opiate replacement services. For a variety of reasons, oral naltrexone, which has been available since the mid-1980s in most countries, is funded for heroin addicts in the UK, but not funded for heroin addicts in Australia. The Australian government has chosen to fund oral naltrexone for alcoholics only. Professor Hulse's work[19] has demonstrated in a randomised control trial that implant naltrexone is significantly more effective than oral naltrexone in preventing return to opiate dependence. The information from Britain, Professor Hulse's work and data from nine years' work in Perth needs to be re-evaluated by government in the light of the fact that there is a failure in duty of care when patients die from heroin overdose after leaving government institutions such as jails and detox units. These deaths are known to be preventable and this is demonstrated in Professor Hulse's work where he confirmed blood naltrexone levels above 2ng/ml for more than 160 days[20].

The 100% funding of opiate replacement programs and virtually no funding for non-addictive pharmacotherapies that have increasing evidential support will change over the coming years. Policy makers could facilitate this change occurring at a rapid rate in Western Australia in view of the enormous co-operation between our universities, industry and not-for-profits in WA.

Fresh Start Recovery Programme

Fresh Start Recovery Programme provides a range of medical treatments for people seeking to help from addiction to illicit drugs and alcohol. Other services include a GP clinic, hepatitis C therapy, counselling, chaplaincy, mental health care and residential rehabilitation facilities for recovering addicts and their families.

The two main treatment therapies at Fresh Start are naltrexone implants (for opiate, alcohol or amphetamine dependence) and flumazenil infusions (for benzodiazepine dependence). The majority of our patients are poly-drug users, which means that they often need to access a number of our services.

Around 80% of our patients who are injecting users are also infected with the hepatitis C virus and a large proportion present with a range of mental health problems. Consequently our treatment program takes into account issues relating to comorbidity.

Fresh Start aims to provide an alternative for drug addicts who haven't had success with other addiction programs. It is our belief that offering a choice of drug therapies increases the proportion of drug users who seek treatment.

All Fresh Start patients are presented with a bill for their treatment and a range of payment options. In practice, only a small percentage of patients make a full payment. Consequently, we are reliant upon Government funding as well as corporate and private donations to maintain our services.

About Fresh Start

Fresh Start Recovery Programme is the trading name for Australian Medical Procedures Research Foundation Limited, a not-for-profit company set up in 1996 to develop and improve medical procedures in the field of addiction medicine. It is a registered charity and deductible gift recipient with an independent Board. As well as treating patients, Fresh Start conducts research on drug treatments and collaborates with a number of academic institutions including The University of Western Australia in order to carry out clinical trials and further research.

Fresh Start uses a number of products manufactured by the local pharmaceutical and medical device company, Go Medical Industries Pty Ltd. The main product we purchase from Go Medical is the O'Neil Long-Acting Naltrexone Implant and the Springfusor infusion device. The Naltrexone Implant has not been registered by the TGA and is used for treating patients at serious risk of death under the TGA's Special Access Scheme. Go Medical has a long-standing relationship with Fresh Start as its principal shareholder is the founder of Fresh Start, Dr George O'Neil.

Our approach

Our experience is that medical treatments alone do not provide enough to enable the majority of drug users to stay drug-free in the long term. Therefore the services we provide all aim to support the patient in a process of whole life change.

Fresh Start's approach to helping people with addictions is sometimes known as the PHREE model:

- Physiology
- Housing
- Relationships
- Education
- Employment

Physiology

Our naltrexone and flumazenil programs treat the physical cravings of drug addiction. Our follow up and other medical services such as our GP Clinic and Hepatitis C program support the general health of patients.

Housing
Many drug users who come to Fresh Start depend on other users for a place to live. Once they start treatment this is not a suitable arrangement. The most suitable type of housing depends on the stage of recovery. We have a number of facilities and can also refer patients to other facilities.

Relationships
For many clients, rebuilding broken relationships is essential. We offer counselling, which aims to improve self-esteem and enable the client to start to form healthy relationships and rebuild broken relationships.

Education
Patients are offered the chance to engage in activities designed to enable them to live a normal lifestyle within the community. They are encouraged to enrol in TAFE and university courses. Many of the patients also choose to take part in a Christian version of 'The Twelve Steps'.

Employment
The ultimate aim of our program is that our clients will gain employment. Many have Community Service Orders and some do voluntary work which builds up their practical skills.

About the Clinic

Fresh Start Clinic is located in Subiaco, central to two areas of high drug use (Figure 1). In addition to the areas shown in Figure 1**Error! Reference source not found.**, almost half of the drug users who come to Fresh Start are from country areas of WA or from outside WA.

The clinic focuses on different treatments on different days of the week. Patients may see a doctor to be assessed and to be referred for treatment or other therapies. The addiction specialist and naltrexone treatment clinic operates on Wednesdays and Saturdays. Flumazenil infusions are typically started on Fridays. The hepatitis C treatment clinic takes place on Mondays and Tuesdays and the GP clinic is available on Mondays, Tuesdays, Thursdays and Fridays. Counselling, mental health services and chaplaincy are also available to patients on Mondays, Tuesdays, Thursdays and Fridays.

Residential Facilities

We also have several residential facilities appropriate to different stages of recovery. Our Medical House is an inpatient service providing supervised care for patients in withdrawal after receiving naltrexone implant treatment and for those receiving flumazenil infusions. We have a number of locations where our clients can be assessed before being transferred to one of our rehabilitation facilities or referred to another rehabilitation facility. Our main rehabilitation facility is located in Northam. We believe providing appropriate residential facilities helps prevent our clients slipping back into drug use.

Medical treatments

The medical treatments available at Fresh Start Recovery Programme include: oral naltrexone and naltrexone implants for patients dependent on opiates, alcohol, amphetamine-type stimulants or a combination of these; Suboxone for detoxification from opiates in preparation for an implant (used most frequently to detox from high doses of methadone); prescription of Antabuse for alcohol-dependent patients; Flumazenil infusions for detoxification from benzodiazepines; a GP clinic; and a successful shared-care hepatitis C treatment programme run jointly with Sir Charles Gairdner Hospital.

Naltrexone

Naltrexone is a drug that blocks the effects of opiates. When naltrexone is taken, it attaches to the opiate receptors in the brain. This stops opiate molecules being able to bind to the receptors and so the effects or 'high' associated with the opiate are eliminated.

Unlike other treatments for opiate dependence such as methadone and buprenorphine, naltrexone dose not produce a 'high' and does not cause dependence. It is considered an abstinence therapy, where methadone and buprenorphine are considered to be maintenance therapies.

Naltrexone is currently registered as an oral tablet (Revia® 50mg) for the treatment of opiate and alcohol dependence. It is also used off-label for amphetamine-type stimulants. Naltrexone is also registered in the USA as a 30-day injection (Vivitrol®) for alcohol dependence. Fresh Start also uses a sustained release implantable naltrexone formulation where appropriate known as the O'Neil Long Acting Naltrexone Implant.

Naltrexone tablets

Patients may choose to be treated using naltrexone tablets. There are risks associated with this type of treatment related the fact that naltrexone returns the opioid receptors in the brain to their normal levels of sensitivity. If a user skips a dose of naltrexone with the intention of using opiates there can be a tendency to overestimate the amount they can take without overdose. For this reason the risks of oral naltrexone are discussed with patients before commencing treatment. Our oral naltrexone and detox service was used mainly between 1997 and 2001. We treated around 3000 patients during that period, some more than once, totalling about 5800 detoxes. Research comparing naltrexone Rapid Opiate Detox (ROD) with conventional Clonidine detox between 1999 and 2000 showed that ROD patients had an 11% failure rate compared with 70% in conventional detox[12].

The Naltrexone Implant

The O'Neil Long Acting Naltrexone Implant was developed in 1999 because of problems associated with patients not taking oral naltrexone regularly. Since then, the implant has been used in almost 3000 patients including over 270 amphetamine patients and over 270 alcohol patients.

The implant is made of microspheres of naltrexone mixed with a special body-compatible polymer that gradually dissolves, compressed into pellets. Each implant consists of 10 pellets and patients are usually implanted with 2 to 3 implants. A picture of the implant is shown in Figure 3.

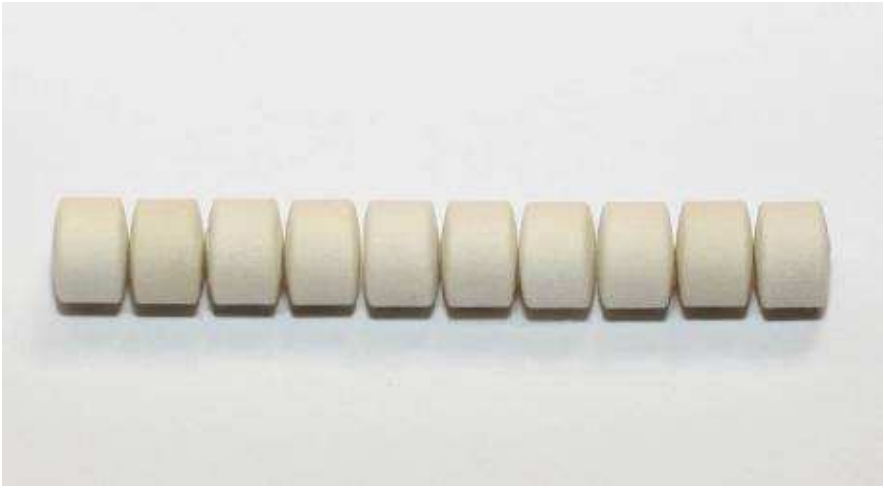

Figure 3: An O'Neil Long Acting Naltrexone Implant.

The implants are put under the skin through a small cut below the belt line. Two typical arrangements are shown in Figure 4. The cut is then closed with a few stitches or medical glue. The procedure is done under local anaesthetic.

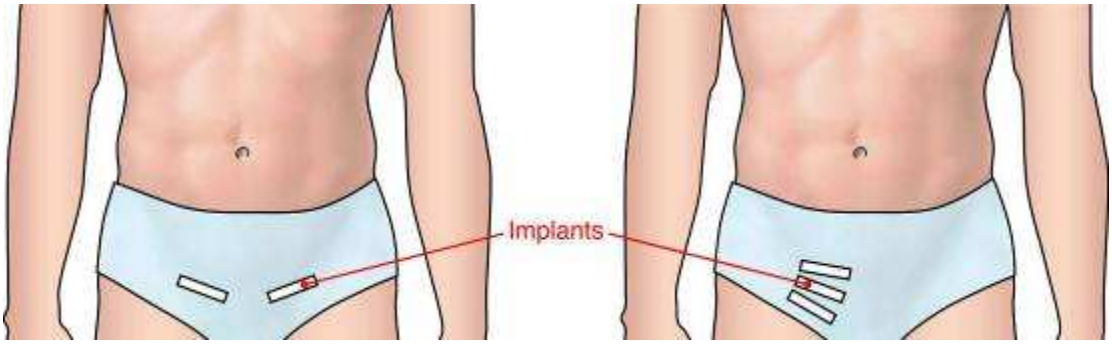

Figure 4: The implants are inserted into the subcutaneous tissue of the abdomen, below the belt line.

As the implant breaks down under the skin, naltrexone is released into the body. Naltrexone is released for approximately 3 to 6 months at levels high enough to have the desired effect and continues to release at lower levels for 6 to 12 months. The polymer continues to break down completely over 18 to 30 months[21].

Routes to treatment

The process of collating all the information for registering the O'Neil Long Acting Naltrexone Implant for use in Australia is currently underway. From 2001 to date around 45% of patients at Fresh Start Clinic have been treated with the implant under the Special Access Scheme (SAS) and the remainder under clinical trials. The SAS allows the use of unregistered drugs for the treatment of patients that are at a high risk of premature death. (The risk has been measured at approximately 13 times greater for opiate users than their peer group[22].)

Fresh Start has been the site of clinical trials (which will be used in the submission of TGA registration dossier) and is hoping that further clinical trials will take place at our Clinic. The trials will be sponsored by Go Medical, which manufactures the implant, and conducted by The University of Western Australia. It is estimated that the minimum time until the completion of all the required trials will be about 3 years.

Use of Naltrexone for the Treatment of Opiate Dependence

Opiates, including heroin, opium, morphine and codeine work by binding to the opioid receptors in the brain. The opioid receptors also detect the body's own naturally-occurring chemicals such as endorphins.

When a person regularly uses opiate drugs, the opioid receptors in the brain become much less sensitive. When naltrexone is taken, it attaches to the opiate receptors in the brain. This stops opiate molecules being able to bind to the receptors and so the effects or 'high' associated with the opiate are eliminated. It also allows the opioid receptors to recover to their former sensitivity.

Opiate Detoxification

Naltrexone (whether oral or implant) induces a rapid and uncomfortable detoxification for heroin users[23] so for this reason we tend to use light sedation for the first 24 to 48 hours.

Patients who are part of the naltrexone program will undergo detox as they come off opiates. This will be least severe for those who have managed to stop their opiates for 3 or 4 days beforehand. However this is not possible for many of our patients.

Heroin users can choose to switch to buprenorphine (Subutex) for the 3 or 4 days before they get their implant. However many prefer to simply get on and have their implant with a view to getting better as quickly as possible.

Methadone is more difficult to detox from and we ask users to go through a 2-week process of changing to Suboxone or Subutex (buprenorphine). Users are encouraged to stop their methadone on a Tuesday and arrive at the clinic early the next day. We will then usually start them on buprenorphine for approximately 10 days. Fresh Start will organise the first day of buprenorphine in the clinic if the methadone dose has been more than 40 mg/day. The highest dose of methadone that we have detoxed patients from is more than 500 mg/day. At the end of 10 days of buprenorphine we usually arrange three days off all drugs before inserting an implant. This means two reasonably 'gentle' detoxes.

Naltrexone for the Treatment of ATS Dependence

Amphetamine type stimulants (ATS) include amphetamines, methamphetamines, MDMA (ecstasy) and dexamphetamine. They work by increasing levels of serotonin, dopamine and norepinephrine in the brain.

While the effects of amphetamines are not directly related to the opiate system, the opiate system and the dopamine system are linked. Therefore increases in dopamine can be limited by blocking the opioid receptors using naltrexone. Research conducted by The Karolinska Institute in Sweden and

Fresh Start work supports the use of naltrexone in amphetamine patients. The Swedish work involved a trial of oral naltrexone with amphetamine-type drugs and the Fresh Start research investigated naltrexone implants mainly for methamphetamine users.

By using naltrexone, the changes in dopamine concentrations that come from using amphetamines can be reduced. By reducing dopamine, the motivation to use amphetamine and the feeling of reward obtained from using is decreased. The result is decreased cravings, decreased desire to use; and reduction in the 'feel' and 'like' of the drug[24].

Naltrexone for the Treatment of Alcohol Dependence

While the effects of alcohol are not directly related to the opiate system, the opioid receptors also detect the body's own naturally-occurring chemicals such as endorphins. This means the desire to use alcohol and the feeling of reward when it is used can be limited by blocking the opioid receptors using a drug such as naltrexone. However, naltrexone does not eliminate the feeling of drunkenness if alcohol is used. Therefore Fresh Start also recommends all patients who and are trying to stop drinking to take Antabuse.

Effectiveness of the Naltrexone implant program

Our patients typically experience 3 to 6 months free from cravings to use opiates after receiving naltrexone implants. Around half of them return for further implants. We have found that the patients who choose to take advantage of the other services provided at Fresh Start, including counselling, have the best success rate in staying clean long term.

Research has been done into the efficacy[25], biocompatibility[21,26] and safety[27] of the implant and the way the naltrexone is absorbed and moves through the body[20,28,29]. As part of the process of registration of the implant, research is ongoing at Fresh Start. Naltrexone implants have been found to be well-tolerated with few side effects and to have a measurable positive effect on recovery from addiction.

A clinical study recently completed in Norway[25] examined the efficacy of the naltrexone implant as compared to usual treatment. The study found that on average, over an 180 day period, subjects in the implant treatment group only used heroin on 17.9 days and opiates on 37 days, as compared with subject in the 'usual care' group who used heroin on average 64 day and opiates 97 days.
Two further clinical studies have been completed by UWA and are awaiting publication. These include a double blind, double-dummy randomised controlled trial of implant naltrexone vs oral naltrexone with follow up for 6 months and a pharmacokinetic study of naltrexone blood levels post-implant. Although efficacy results are yet to be published, 88% of patients in the active implant group had not used heroin at 6 months compared with 33% of patients in the placebo implant group (active oral naltrexone). In both studies, the implant was found to be well tolerated with generally only mild side effects often associated with oral naltrexone.

Opiates Research

A recent study[Error! Bookmark not defined.] comparing implant naltrexone to usual methods of care for opiate users showed that only 3 of 23 patients who completed 6 months of naltrexone implant treatment were still dependant on opiates, whereas 17 of 26 who completed 6 months of usual care were still dependant on opiates.

Another study done at The University of Western Australia comparing naltrexone implants with oral naltrexone showed that after 6 months, 85 % of people who had received a naltrexone implant had not gone back to using heroin regularly and 35 % of people receiving oral naltrexone had not gone back to regular heroin use. This study assumed that those patients who lost touch with the clinic relapsed back on to heroin.

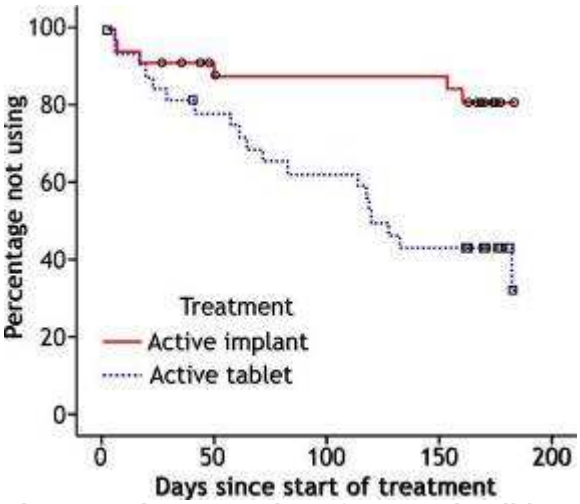

Figure 5: The proportion of users who did not return to regular heroin use on naltrexone implant (——) and oral naltrexone (----)

Amphetamine Research

A recent study conducted by Fresh Start's amphetamine research group, investigating the effectiveness of the implant in amphetamine patients, found that following implantation 65% of patients stopped using for a period of time (greater than 3 months) and 30% reduced or gained control over their amphetamine use.

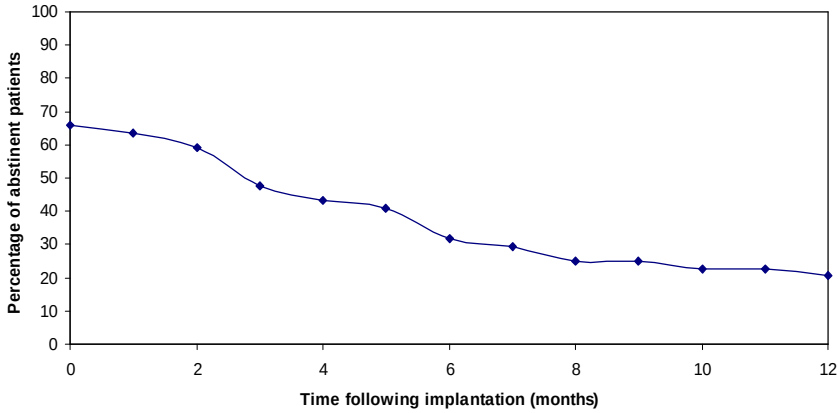

Figure 6: Abstinence in amphetamine dependent patients treated with naltrexone implants, conducted by Fresh Start

This data is supported by several large clinical trials conducted by the Karolinska Institute in Sweden using oral naltrexone. Their study showed that when compared with a placebo, oral naltrexone reduced patients 'wanting more', the 'feel of the drug' and the 'overall high' experienced for amphetamines. Their research also showed the number of consecutive negative urine tests was higher for patients treated with naltrexone (as compared with a placebo). At 24 weeks following the start of treatment approximately 35% of naltrexone patients had maintained negative urines for the duration of the study as compared with 7% in the placebo group.

Alcohol Research

The University of Western Australia and Fresh Start Recovery Programme are currently conducting research linked to the cost effectiveness of implanting patients with naltrexone, the health improvements of the patients and the burden on the public health system. As part of the research additional information is being gathered relating to the cessation of alcohol use, changes in drinking patterns and the satisfaction of patients with treatment.

Poly drug use

A majority of those seeking treatment at Fresh Start use several substances, typically including heroin, methamphetamine, prescription and illicit benzodiazepines (most common in females), binge drinking

and recreational cannabis. We treat the patient's addiction to their drug of choice and additional addictions which they are trying to cease may be treated concurrently. Although naltrexone does not block the highs associated with non-opioid drugs, research has found that the use of other drugs does reduce after the patient receives implant treatment. This unpublished data seems to show reduced poly drug use which in part should be attributed to the rehabilitation and other facilities available to the patients.

Figure 7 shows urine analysis results of patients who received naltrexone implants[30]. The graph shows that levels of other drug use reduced until about 110 days after treatment. As the effectiveness of the implant began to wear off, other drug use increased. Statistical analysis showed that the urine detected usage values for segment A on the graph in Figure 7 (the first 30 days) compared with segment B (81-110 days) and segment B compared with segment C (151-180 days) are significantly different for benzodiazepines, amphetamines and cannabis but not for opiates.
Table 1 shows the Fisher's Exact statistical reliability of the data.

Table 1

Segment of Figure 7		Benzodiazepines	Amphetamine	Heroin	Cannabis
A	1 - 30 days	58.3%	26.9%	5.0%	38.4%
B	81 - 110 days	26.1%	15.0%	0.6%	16.7%
	Fisher's Exact	P<0.0001	P = 0.0022	P = 0.0057	P<0.0001
C	151 - 180 days	43.5%	31.5%	2.2%	30.4%
	Fisher's Exact on increase	P = 0.0058	P = 0.0024	P = 0.2650 (not significant)	P = 0.012

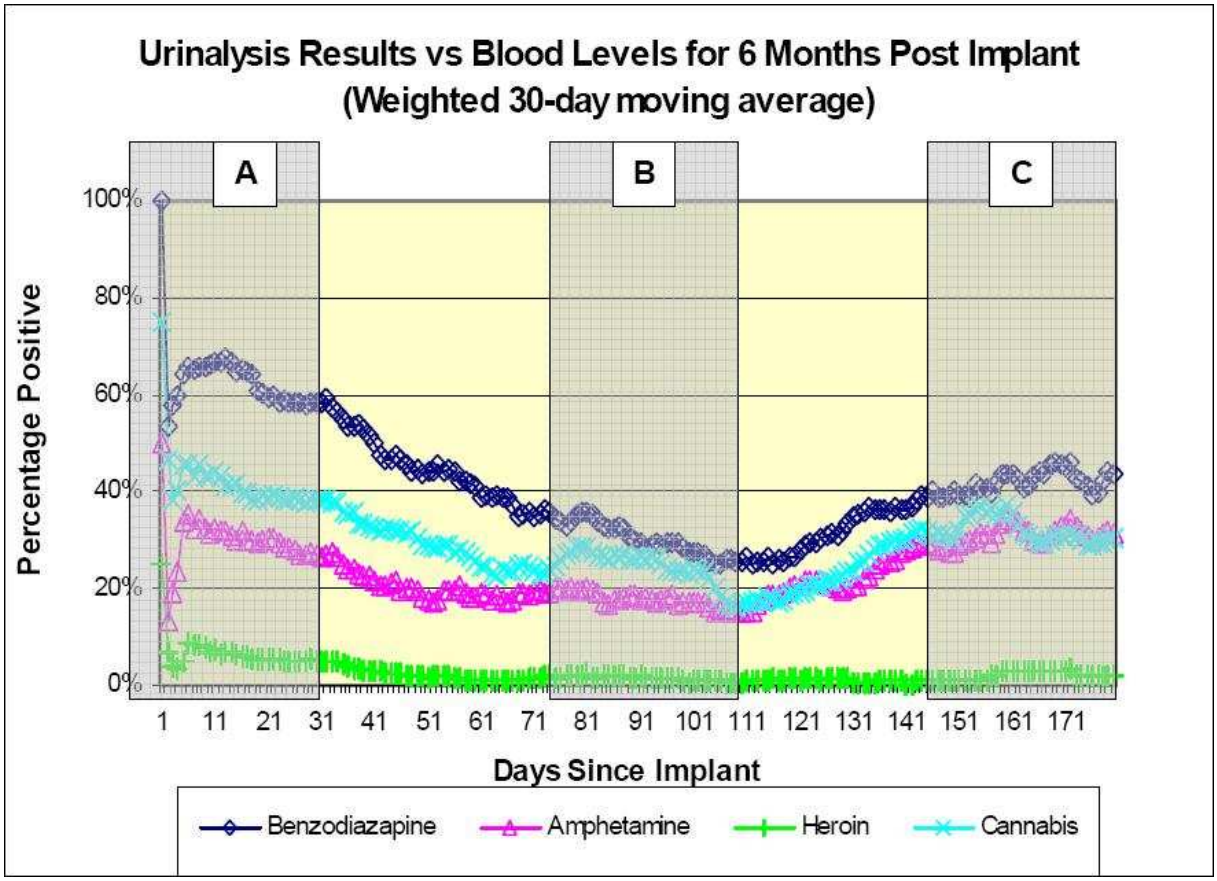

Figure 7: poly drug use after implant treatment

Naltrexone and Alternative Programs

Fresh Start aims to provide drug users with an alternative to other programs.

Australia has had an excellent reputation for opiate replacement programs (like the methadone and buprenorphine programs) which reduce crime and patient discomfort. But for many people, being put on to another opiate prolongs the addiction and continues to limit reintegration into society. Data from Scotland, UK[31], showed that patients are comfortable on methadone but that 3 years after the start of treatment only 3% are drug free.

NEPOD[14] data from 1999 found that the 7 day detox program has a 90% relapse rate at 30 days post treatment.

Scottish data on the success of non-medical rehabilitation programs[31] give a result of 33% of patients remaining drug free at 3 years post-treatment.

The research data shown in Figure 5 was measured at Fresh Start. An 85% success rate at 3 months after implant compares very well with other programs. Our patient data also suggests that at 3 years post implant 50% of patients have had no relapse and 90% are drug free. This data necessarily excludes any patients who have lost touch with the Clinic.

It is our belief that offering more than one system of medical treatment for addictions increases the proportion of drug users who seek treatment. Our clinic typically performs 700 to 800 naltrexone implant treatments per year, and sees up to 300 new patients per year, the majority of whom are resident in WA and the majority of whom are treated for opiate use. Data collected by the NOPSAD report of 2007[32] showed that there are just over 2800 clients were on methadone or buprenorphine programs in WA in a given month (average 2005-7). Many patients who come for treatment at Fresh Start for treatment tell us that they have been on opiate replacement programs in the past and have not had success in reducing their heroin use. Others come for treatment for their current methadone or buprenorphine use, both prescribed and illicit. We conclude from this experience that the majority of our clients have already made the decision that opiate replacement programs do not work for them and would not be willing to go back to them if the treatments at Fresh Start became unavailable. It is our hope that the availability of naltrexone implants will increase in other states so choices will be available to more drug users who have not had success with opiate replacement.

Cost-effectiveness of treatment

A study comparing implantable naltrexone with buprenorphine maintenance for opiate dependence[27] found that naltrexone treatments lasted for longer than average times that patients stayed registered on buprenorphine treatment (238 ±110 days versus 47 ±110 days). Fewer treatment episodes per patient were required (1.55 ±1.21 versus 3.46 ±3.99) but total retention in treatment programs was longer for naltrexone implants (371 ±285 days versus 162 ±245 days). The study concluded that naltrexone implants economised treatment resources without compromising on safety. Another study[33] found that naltrexone implant treatment could be extended to over 1 year of continuous coverage by giving a second implant procedure about 5 months after the first implant.

Heroin addicts in Perth use an average of $300 per day[34]. This amounts to $100,000 per year per addict. We estimate that our treatment cost of approximately $6000 per patient is a small cost compared to the amount of money these patients will have removed from the community each year. The investment of $6000 is a young person with another 60 years of life ahead of them is tiny compared with the potential productivity that is regained over the rest of their lives. It could be costed at $6000 divided over 60 years for the 50% of our patients who recover with one treatment ($100 per year)! It is certainly good value even for those who require many treatments. Our average number of treatments over 8 years is approximately 2.5 per person for the 3000 people treated so far.

Preventing overdoses and deaths

We have been unable to find out that any patients who were treated with naltrexone implants at Fresh Start died of overdose within the first four months after treatment.

A study[35] comparing mortality of patients on a methadone program with a naltrexone implant program found that the naltrexone patients had lower overall death rate than the methadone patients and that during an initial 14-day period of methadone treatment there was a peak in mortality of 94.47

deaths/1,000 person-years. In the naltrexone group, the rates overall were 3.76 deaths/1,000 person-years, compared with 5.83 deaths/1,000 person-years overall for the methadone group.
The rates compare with other published data for other care or for no care:

- Methadone (Australia): 5/1000 patient years[36]
- Street addicts untreated (Australia): 25/1000patient years[36]
- Post residential detox (UK & USA): 50/1000 patient years[36]

One reason that residential detox appears to increase death rates compared to no care may be that, similar to the risks of suddenly stopping oral naltrexone, in residential detox the patient's opioid receptors would tend to return to their former sensitivity meaning that a relapsing patient is prone to overestimating a safe heroin dose.

In addition a study[1] identified non-fatal overdoses in Fresh Start patients via WA Hospital Linked Data and ECHO Project EDIA data.

- 361 patients in the study
- 21 patient overdoses in the 6 months before treatment
- 0 opiate overdoses in the 6 months after treatment

The data is shown in Figure 8.

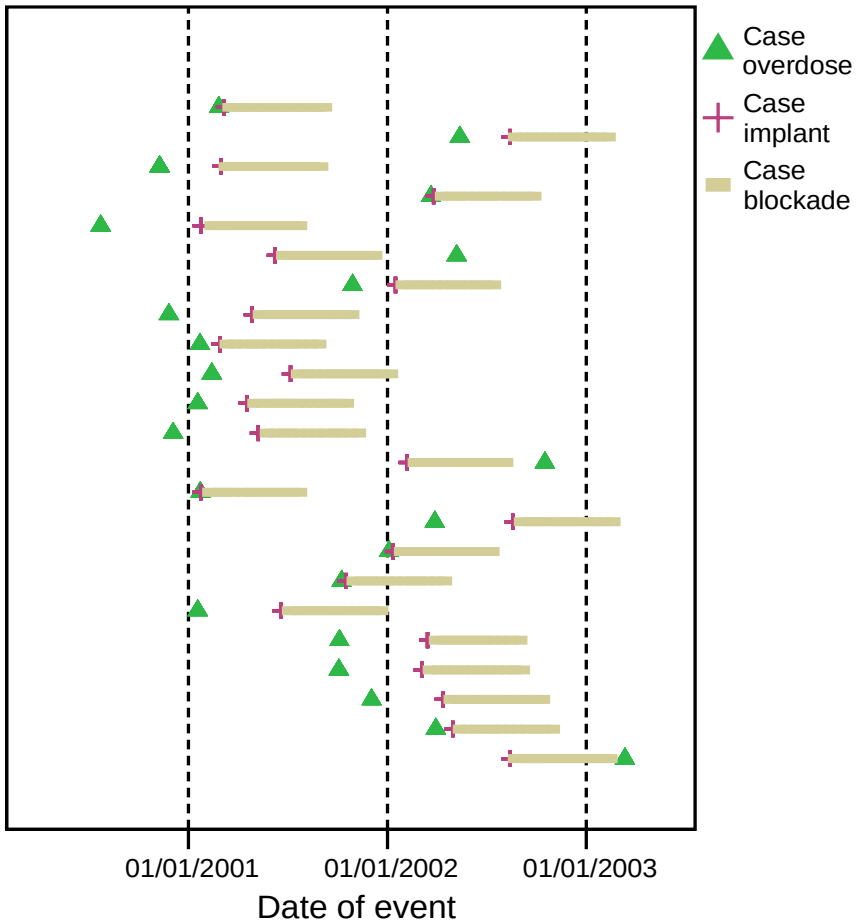

Figure 8: non-fatal overdoses ▲ in patients prior to, and during or after active naltrexone implant treatment phase +▬

Subcutaneous Flumazenil Treatment

Fresh Start Recovery Programme is currently using flumazenil to help with the withdrawal of patients from a range of benzodiazepines.

Flumazenil can be thought of as a benzodiazepine blocker analogous to the way that naltrexone blocks opiates. It was first used in the late 1980s and has since traded under a variety of names, including Mazicon, Romazicon and Flumazepil. Flumazenil reverses the effects of benzodiazepines.

Flumazenil's primary use with patients is generally to reverse the affects of sedation used in surgery or other medical procedures and to treat benzodiazepine overdose. It is usually administered as a single injection, with the dose and frequency being based on the patient's response. Flumazenil is one of the main drugs used in Australia for benzodiazepine overdose.

Flumazenil can prevent the brain feeling the effects of benzodiazepines. This means that for someone receiving a flumazenil infusion there will be little, if any, effect when taking benzodiazepines. It does not affect any other drugs that might be used, only drugs within the benzodiazepine family.

By using the flumazenil at a low dose and over a short period the receptors in the brain which detect benzodiazepines are thought to be reset, and the drug lessens the urge to take benzodiazepines. Additionally research at Fresh Start has demonstrated that it lessens the withdrawal symptoms and helps lower the feeling of anxiety and physical symptoms associated with withdrawal. After they have finished the infusion the receptors will be much more sensitive and the patient will be able to feel their body's own natural benzodiazepines again.

The dose of flumazenil is very low and is administered through a small, 26 gauge butterfly needle which is placed just under the skin in the abdominal area. The flumazenil is mixed with a small amount of saline and placed into a portable infusion device (see Figure 9). The device delivers the flumazenil in a continuous flow.

Figure 9: the O'Neil Springfusor, used for flumazenil infusion.

The amount that is given is set at the time of infusion and is monitored twice daily. The treatment requires several days placement in Fresh Start Medical House where the patient can be supervised. The site of infusion is examined as well as the level of withdrawal and overall health. The infusion usually lasts for a 96 hour period, but can be extended where required.

Effectiveness of the Flumazenil program

Currently, research is being conducted into the use of flumazenil for withdrawals from benzodiazepines both in Western Australia and Victoria by Professor Gary Hulse from UWA and Professor John Curry from St Vincent's Hospital in Melbourne. A range of pilot studies regarding subcutaneous flumazenil infusions have been published as a result of their research.

The findings have demonstrated excellent results with few adverse reactions. For the majority of patients there is substantial reduction of withdrawal symptoms, and generally well tolerated treatment. Patients that have undergone flumazenil treatment have expressed a high level of satisfaction with the treatment.

Research by Hood et al.[37] reported studies on benzodiazepine-dependent patients treated with a four-day flumazenil infusion. Patients with long-term benzodiazepine dependence who attended the Fresh Start Clinic for treatment were recruited for these studies. They found that no major complications or discomfort prompting study dropout were observed. Significant benzodiazepine abstinence occurred with flumazenil infusion despite high levels of initial dependence. Low-dose flumazenil infusion appears to be a safe and effective treatment resulting in withdrawal symptoms of lesser severity than any other cessation method currently available. The research also compared self-reported use of other drugs for 13 patients and found that flumazenil infusion reduced poly drug use in these patients (Figure 10). The authors of the research felt that the reduction in poly-drug use should be attributed to

the use of flumazenil combined with the post-treatment support and rehabilitation available to the patients.

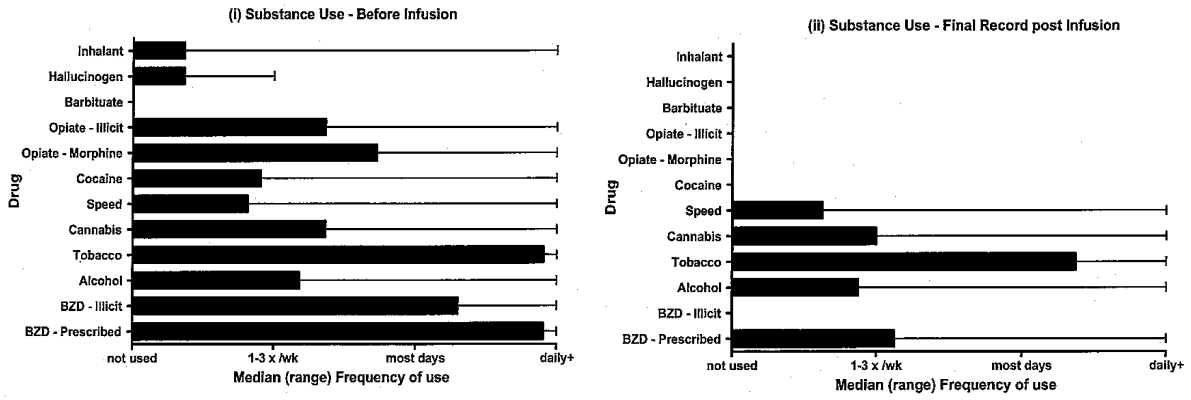

Figure 10 self-reported substance use in the four weeks prior to flumazenil infusion compared with two weeks post-infusion[37].

Hepatitis C treatment

Research has shown that regular use of intravenous drugs over a year will result in infection rates of hepatitis C of as high as 80% of users. This figure agrees with our experience. Treating hepatitis C is straightforward in theory but many intravenous drug users don't get offered treatment for it for a variety of reasons. However, Fresh Start, together with the Hepatology Department at Sir Charles Gairdner Hospital (SCGH), has a highly successful Shared Care treatment programme for hepatitis C and welcomes all drug users who come to Fresh Start for treatment to join it.

Patients who come for treatment with naltrexone at Fresh Start are routinely screened for hepatitis C. Those who have a positive test for the hepatitis C virus (HCV) are told about this result by the doctor at Fresh Start. They are provided with information and education about the disease by the doctor and nurse specialising in HCV and are given a choice about whether to go ahead with treatment. If the patient requests more information or HCV treatment, a full set of specialist blood tests are taken and the doctor checks that there are no reasons (for example, certain illnesses in the past) why they are not suitable for treatment. Then they will be seen by the visiting liver specialist from SCGH who will approve the prescription of HCV treatment for suitable patients.

Hepatitis C virus can be treated with a combination of the anti-viral drugs interferon and ribavirin. The HCV genotype of patients requesting treatment is tested and the length of time the patient continues to receive medications will depend on their HCV genotype, either 24 weeks or 48 weeks.

Patients are asked to come to the clinic every week for the first month of treatment and then every month until the end of the treatment. Their blood is tested and side effects of treatment are reviewed at each visit.

Effectiveness of the Hepatitis C program

A study done by the University of Western Australia, Sir Charles Gairdner Hospital and Fresh Start[38] on patients who were treated for hepatitis C in the HCV Shared Care programme at Fresh Start showed that 62% of them achieved an SVR after 6 months. This percentage is about the same as the results of hepatitis C treatment programmes for the general population (mainly non-drug users) at specialist out-patient liver clinics.

Recovery

Our patients go through several stages in recovery and their accommodation needs may change at each stage. In the first few days after starting treatment on either naltrexone or flumazenil we strongly recommend that our patients stay at our Medical House where they can receive supervision to ensure any adverse reactions to the treatment are safely dealt with. When the symptoms of withdrawal have lessened to a safe level we usually move the patients to our assessment houses and from there invite them to move to one of our rehabilitation facilities or refer them to another rehabilitation program as

appropriate. We believe providing appropriate residential facilities helps prevent our clients slipping back into drug use.

Medical House
A short term safe environment. Twenty-four hour care and medical assistance is available to those in the acute stages of detoxification and recovery.

Assessment Houses
A stable environment for our clients who are considering longer term residential options. Allows them to be supervised, medicated where necessary and assessed for further rehabilitation. We have houses for men, women and mothers with young children.

Rehabilitation
Patients staying at our Rehabilitation Centre at Northam are supervised with regards to prescriptions such as Antabuse. Northam is a longer term residential option for men and women with drug and alcohol problems. Many recovering patients from the metropolitan area find the location helpful in getting away from the habits and associations that make drug taking a way of life. Activities are tailored to education and training, relationships and rebuilding social structures and to spiritual healing. A Christian version of 'The Twelve Steps' is used. Fresh Start is also happy to refer patients to other rehabilitation facilities when appropriate.

Moving on
After around 6 months in rehabilitation our clients are usually ready to move to one of our houses designed for people in the later stages of recovery to assist them in finding independent accommodation and sustainable employment. Alternatively, if they have stable homes to move back to, they are encouraged to move back home.

Our other services

While medical treatments can be very successful in the treatment of alcohol and other drug dependence, they are most successful when used in combination with other therapies such as counselling. We recommend that all patients consider the other services available at Fresh Start to help improve the results of the treatment.

GP Clinic
While we encourage our patients to see their own doctor, all Fresh Start patients have access to our team of General Practitioners.

Mental Health Care
Fresh Start Recovery Programme offers a free Mental Health Nurse service for eligible patients, funded by the Commonwealth Government's Mental Health Nurse Incentive Program. Our mental health nurses are all accredited members of the Australian College of Mental Health Nurses.

Counselling
A free service for all Fresh Start patients and their families aimed at repairing broken relationships and reuniting family members. Our counsellors also discuss motivation with the patients. Typically a patient who presents for a naltrexone implant has protection against overdose as their main motivation for doing so. Our counsellors discuss the benefits of staying clean from drugs long term and of making life changes which can improve success in this endeavour.

Chaplaincy
Fresh Start has a team of chaplains who, upon request, provide Christian teaching and spiritual care for patients and their families. We never pressure patients to take part in these discussions. Nevertheless it is our experience that recovering drug users frequently wish to address their relationship with God after many years of feeling that drug use was 'sinful' yet being unable to commit to stopping it.

We also provide legal assistance; advocacy with Homeswest and the Department of Child Protection; help accessing education; and assistance finding employment. Our Traineeship Program provides employment for up to 15 recovering addicts every year.

Outstanding needs and gaps

The Clinic's needs

Staffing

Fresh Start currently has 71 paid 12 volunteer staff. In addition we employ up to 15 Trainees each year as part of our Employment and Training Program. These are recovering drug addicts who are paid a small allowance while being trained in various types of work within Fresh Start. This includes administration, maintenance and helping to run our residential and rehabilitation facilities as patient carers. Most of our trainees will go on to get jobs with other organisations and a few stay at Fresh Start, moving into fully paid work.

Our staff includes 5 doctors, two of whom can perform implant operations. All our doctors have part-time patient contact hours. The total number of hours available for implant operations per week is 26 and the total number of hours available for patient contact per week is 77. This is the equivalent of less than 2 full time doctors. Although we always have a doctor available by phone we strongly wish to increase the number of doctors at Fresh Start.

We also have an unmet need for more clinic staffing. If our staff were able to call every patient, every six months, to find out if they needed treatment and remind them to make an appointment, we feel that unnecessary deaths could be prevented.

We feel that our need staff in these two areas is partly due to lack of funds (and so being unable to offer attractive wages) and partly due to lack of applicants who are trained or experienced in abstinence programs or who wish to work in that area.

Funding

One of the decisions made by the directors of Fresh Start in June 1997 was to realise that the privilege of meeting heroin addicts who claimed that they wanted to cease heroin forever was that one should not confront them with a financial hurdle. Our policy of treating all patients whether they could pay or not has paid off. We believe that the stakeholders, including families, state and commonwealth governments, churches, shop-owners and all those in the community affected by addiction, should pay for the treatment. We are proud and grateful for the way in which stakeholders from all over the community have held our program together for 12 years. It is now time for the state and commonwealth governments to meet to review how we can get similar programs around Australia.

A naltrexone implant treatment costs $6000 and staying in our rehabilitation houses costs between $100 and $175 per week.

We are entitled to ask for the appropriate portion of the patient's Centrelink payments to be paid directly to us for accommodation. However, not all payments for accommodation are received. In the tax year 2008-9 $91,743 was received in payment for accommodation compared with an estimated cost of $2.68 million per year.

All patients are presented with a bill for their treatment and asked to pay as much as they can up front, followed by a regular direct debit or CentreCare payment. In practice, only a small percentage of patients are able to complete full payment. In the tax year 2008-9, $509,480 was received in payment for naltrexone implant compared with billed fees of $4,158,000.

Resource allocation

Fresh Start receives $8,000 annually from Subiaco City Council, $1,000,000 annually from the West Australian government (and in the recent financial year, an additional $500,000) and no funding from the Federal Government. These monies represent about 25% of our total costs.

Future government investment

We feel that since naltrexone implants are being used to successfully treat Australian citizens that their use should be funded by the Federal Government. Lack of funds is limiting the quality and availability of care.

National needs

Training of medical professionals

It is our experience that training for medical professionals includes good education on the running of harm reduction programs but not enough on abstinence programs or other programs that drug users need such as hepatitis C treatment programs.

Issues of early access

Our patients frequently present for treatment in crisis. Whether they have just seen a friend die of overdose, had a serious mental health episode, had an argument with loved ones or come to the point of despising themselves for crimes committed to fund drug use, treatment needs to made available immediately to prevent suicides and suicide attempts at the time of crisis. Fresh Start doctors' phone numbers are made available to patients so that they can call when they urgently need to have assurance that they can be treated. However we wish we could be available in this way to everyone who wishes to be treated and not just those who have already been in contact with Fresh Start before. To achieve this we need many more doctors on call.

Accessibility and the most appropriate ways to ensure integrated care

Australia has excellent harm-reduction programs for drug use including opiate replacement programs and resources to reduce needle-sharing. These programs are well-promoted but programs which promote abstinence from drug use are much less promoted. This seems to stem from an assumption that no drug user wishes to get clean. This does not agree with our experience. At different stages in a person's drug-use career their wishes and needs may change. We believe strongly that drug users need to be given choices and information.

We believe there is a need for information to be made available to drug users in the form of a booklet which would explain the different types of program available to them, both replacement- and abstinence-based, without making judgements about which is better.

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