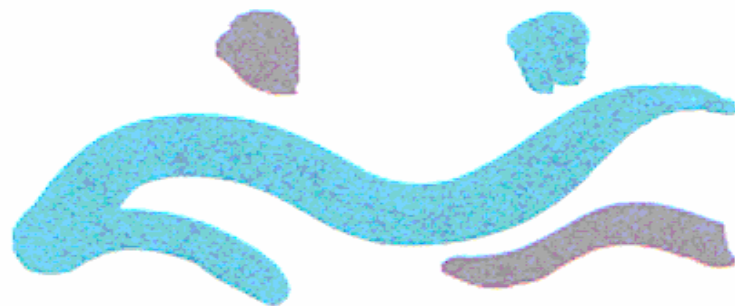


**A Study to Develop a Model for a
Community Detoxification Team using
Lofexidine**



**Clondalkin
Drug Task Force**

**By
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EXECUTIVE SUMMARY

This study was prompted by the growing interest in and demand for non-opiate alternatives to methadone detoxification, such as the $\alpha 2$ -adrenergic agonist lofexidine.

Lofexidine acts centrally to suppress the opiate withdrawal syndrome and offers a non-opiate, rapid withdrawal treatment from opiates, without the risk of dependency. The study aims to identify an appropriate alternative model for a Community Detoxification Team for implementation in Clondalkin, an urban area where there are high levels of opiate misuse.

The review of the relevant literature provided a conceptual and practical base of knowledge to inform the study. The review found that lofexidine can be used safely in a community setting and therefore could provide a viable, safe alternative to methadone.

Qualitative research techniques were employed to illicit key informants' experiences and views of lofexidine detoxification. 20 people participated in two focus groups, while 11 participated in individual semi-structured interviews. Interviews were transcribed and analysis aided by the use of the Nud*ist 4 software package.

The findings of this study support the need for the provision of alternative treatment options to drug misuser. In general, lofexidine was found to be suitable mainly for younger users with a short history of opiate dependence. Motivation, family and social supports together with the availability of counselling were identified as important factors in determining a positive outcome from lofexidine detoxification.

The study recommends that a Community Detoxification Team, using lofexidine, be established on a pilot basis. The team should consist of a Co-ordinator, Drugs Worker, Nurse and General Practitioner. It is proposed that the community detoxification programme will take place over a four-week period and an integrated care pathway has been identified. Areas of further research were also discussed.

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CHPATER ONE

INTRODUCTION

1.1 Introduction

The aim of this study is to identify an appropriate alternative model for a Community Detoxification Team for implementation in Clondalkin, an urban area where there are high levels of opiate misuse.

Drug misuse, particularly opiate misuse, remains one of the major social problems facing Irish society today. A recent capture recapture study of the prevalence of opiate use in Ireland 2000-2001 (Kelly et al, 2003) showed an overall prevalence of opiate¹ use of 5.6/1,000 population. Males aged 25-34 years had a higher national prevalence (13.7 and 14.7/1,000 pop for 2000 and 2001) compared with the remaining males and females of all ages.

Dependence on opioid¹ drugs is a major health and social issue in most societies. Although the prevalence of opioid use is low, the burden of disease is substantial. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2003) indicates that in the European Union around two percent of the general population has ever used opioids for non-medical purposes. The burden to the individual user and the community of opioid dependence arises from mortality (National Institutes of Health, 1997), which is most marked in the 15 to 34 year age group (Hall, 1998), transmission of HIV and hepatitis C, health care costs, crime and law enforcement costs, as well as the less tangible costs of family disruption and lost productivity (Mark, 2001).

¹ Opiates/ Opioids: the terms refer to a group of alkaloids derived from the opium poppy with the capacity to reduce pain and produce a sense of well being (euphoria), and, in higher doses, stupor, coma, and respiratory depression. The terms include both natural and synthetic opioids such as, heroin and methadone

Treatment is central to the reduction of the harms incurred by individuals and the community from opioid dependence. In fact, there is strong evidence to show that treatment programmes are able to confer important benefits on drug misusers, their families and the wider community and society (United Nations International Drug Control Programme, 2003). Treatment can be defined in general terms as the provision of one or more structured interventions designed to manage health and other problems as a consequence of drug misuse and to improve or maximise personal and social functioning.

Managed withdrawal, or detoxification, is not in itself a treatment for dependence (Mattick, 1996). Rates of completion of withdrawal tend to be low, and rates of relapse to opioid use following detoxification are high (Broers et al, 2000; Gossop et al, 1989), but withdrawal remains a required first step for many forms of longer-term treatment (Kleber et al, 1982). It may also represent the end point of an extensive period of substitution treatment such as methadone² maintenance. As such, the availability of managed withdrawal is essential to an effective and comprehensive treatment system.

1.2 Overview and Objectives of Study

The aim of this study is to identify an appropriate alternative model for a Community Detoxification Team for implementation in Clondalkin, an urban area where there are high levels of opiate misuse. Currently the most widely used treatment modality for detoxification involves suppression of withdrawal from opiates with methadone and gradual reduction of the methadone dose over a period of time, usually twelve to fourteen weeks. I propose to carry out this study by researching key informants' experiences of lofexidine detoxification. Lofexidine is a non-opioid α 2-adrenergic agonist, which has been found to suppress the chemicals which produce the acute withdrawal symptoms drug misusers experience when they are undergoing detoxification from opiates.

The objectives of the study include:

² Methadone is a synthetic opiate drug, which when given in an adequate dose to opiate dependent individuals it reduces the desire to use heroin and other opiates, eliminates opioid withdrawal, and blocks the euphoric effects of the other opioid drugs

1. To document the nature and extent of existing non-methadone based detoxification services using the α 2-adrenergic agonist lofexidine;
2. To identify a range of models of good practice at local, national and international level;
3. To identify appropriate protocols in which a Community Detoxification Team should operate; and
4. To identify an appropriate operational model for a Community Detoxification Team, taking account of the current structure of health care delivery in Ireland

The research achieves these aims and objectives through qualitative research methods, in which 20 people participated in two focus groups, while 11 participated in individual semi-structured interviews.

1.3 Organisation of Study

Chapter Two outlines the writings, theories and concepts that are considered most appropriate to the study area. The chapter reviews the relevant literature pertaining to the concepts of addiction and drug treatment together with the elements of a comprehensive drug treatment system. It discusses the various pharmacotherapies available for opiate detoxification; in particular it reviews the literature in respect of the non-opioid α 2-adrenergic agonist, lofexidine. It also reviews the substance abuse treatment literature to identify patient and treatment process variables that have been shown to be important in determining outcome from addiction treatment efforts.

Chapter Three elucidates the research methods, collection and analysis of the data, ethical and practical research considerations and limitations of the methods used.

Chapter Four discusses the findings, which have been categorised in line with the coding system used in the analysis. The chapter analytically explores the findings, making connections and interpretations to the literature review. Finally, Chapter

Five outlines the recommendations and conclusion as drawn from the completed study.

1.4 The Irish Context

According to the Department of Health & Children (1991) 'of its nature, the treatment, care and management of the drug misuser does not lend itself to any one solution approach'. Thus the provision of services aimed at the achievement of a drug free society only, or harm reduction solely, are inappropriate. There is a need to make available to the drug misuser a range of possible approaches and the means of access to the services most appropriate to his / her immediate needs and capabilities. A fundamental consideration in this respect is to ensure that services available are attractive and accessible in order to encourage drug misusers to avail of them and to motivate them to continue with treatment.

Although many treatment modalities have been used, the pharmacotherapeutic approach, using methadone maintenance therapy is the mainstay of treatment in the Irish setting (Sinclair et al, 2001). Methadone is the most widespread substitution treatment available in the European Union. Despite the dominance of methadone, however, its status has been challenged over the last number of years with many European countries now providing alternatives to it (EMCDDA, 2000). There are certain disadvantages associated with methadone therapy, including (a) the risk of fatal respiratory depression in overdose, because of its full agonist properties (b) the inconvenience of daily dosing and daily attendance at clinics, which makes it unattractive to some patients and (c) the risk of diversion of take-away doses (Mattick et al, 1998). Countries such as the United Kingdom (Neeleman et al, 1997) and Germany (Heinemann, 1998) have identified a significant problem associated with methadone related deaths.

In Ireland there is very little published information that documents clients' satisfaction with treatment services. O'Connor (2002) examined patient satisfaction with the pharmaceutical aspect of methadone treatment services provided in Ireland between July 1998 and March 1999. According to the author, respondents were pleased to have access to treatment services, secure free treatment and experienced

improved standard of care. The clients expressed dissatisfaction with several issues. According to respondents there was lack of choice with respect to substitution drugs. The respondents also reported that the services provided at drug treatment facilities were limited with respect to opening hours and social and personal support. The respondents also reported problems with exposure to fellow clients that continued to use street opiates and attended methadone treatment services

Farrell (1994) identifies that ambivalence to the use of a drug of dependence to treat opioid dependence, government restrictions on prescription of methadone, and consumer dislike of the protracted nature of methadone withdrawal have culminated in the need for non opiate based drug treatment. Also, it is reported that the Pharmaceutical Society of Ireland has proposed that the use of non-opioid alternatives to methadone (such as lofexidine) should be considered for use in the management of opioid dependence in the future (Sinclair et al, 2001).

In April 2001, the Irish Government approved the National Drugs Strategy, 2001-2008, in which the need to progress towards a more fully integrated and holistic treatment service was identified. It goes on to say that the expansion in the range of available treatment types is an important component to the attainment of this goal. The consultation process for developing the Strategy highlighted that the use of methadone may be ‘inhibiting the use of alternative treatment types’ (Department of Tourism, Sport and Recreation, 2001). Lofexidine was identified in the Strategy as an alternative treatment type that could be considered although it states that ‘as with all substitutes, their applicability to the treatment of heroin misuse in an Irish context should be rigorously evaluated and closely monitored’.

The National Advisory Committee in Drugs (NACD)³ monitors the developments in the whole range of treatment approaches and, as such, became aware of the increased interest in the use of non-opiate based approaches to the management of withdrawal from opiates such as heroin and methadone. In response the NACD commissioned a review to evaluate the usefulness of lofexidine in the overall management of opiate dependence syndrome in the Irish setting. According to Dr

³ The NACD was established in response to the drug problem by Minister Eoin Ryan TD in July 2000, to advise the Government on problem drug use in Ireland in relation to prevalence, prevention consequences and treatment based on the analysis and interpretation of research findings

Desmond Corrigan, NCAD Chairperson, ‘we are confident that the experience of using this aid (lofexidine) to withdrawal will be of enormous benefit to those wishing to intervene with clients seeking to explore the drug free treatment options available to them’ (NACD, 2003).

In light of the aforementioned issues coupled with the fact that the Clondalkin Drug Task Force in its consultation process for its Area Action Plan 2001 identified the limited capacity of existing detoxification services in the Clondalkin area to respond to the need for non-methadone based treatment. It was felt that a review of both the literature and key informants’ experiences of lofexidine should be carried out in order to identify an appropriate model for community based detoxification.

1.5 Irish Drug Policy

Treatment service provision for problem drug misusers in Ireland until the mid-1980s was centralised, specialist and ideologically tending towards abstinence models of intervention. However, in the context of continuing heroin use and its accompanying public health risks, all these features of policy and service provision changed gradually over the next decade. (Butler, 2002)

The Irish drug scene (which effectively was the Dublin drug scene) had almost no heroin and very little intravenous drug use of any kind prior to 1979. Research in the 1960s and 1970s on the use of illicit drugs in Ireland found only evidence of amphetamine (Walsh, 1996), cannabis, and LSD use (Masterson, 1970; Nevin et al, 1971). Policy responses included the formation of the Garda Drug Squad, the establishment of the National Advisory and Treatment Centre for Drug Abuse and the enactment of the Misuse of Drugs Act 1977. The National Advisory and Treatment Centre for Drug Abuse was established in Jervis Street hospital in 1969. Two years later, in 1971, methadone was introduced as a standardised therapeutic approach for the treatment of those dependent on opiates. In 1973, the Coolmine Therapeutic Community was also established, “derived from the American concept-based programmes using the experience of former addicts in the provision of highly structured residential services” (Butler, 1991).

The drug scene changed dramatically with the beginning in 1979 of what local epidemiologists referred to as the 'opiate epidemic' (Dean et al, 1985) involving the large-scale use of heroin in areas of socio-economic deprivation in Dublin. This new wave of drug use saw the emergence of a 'needle culture' for the first time in Ireland, as intravenous drug use became the norm. What became clear, with the wisdom of hindsight, was that policies and structures that had been set in place in the earlier and more innocent days of illicit drug use in Ireland were seriously deficient in the face of the problems associated with intravenous heroin use (Butler, 1991)

In response a number of Government Committees were established to report on the drug problem. However, most of the subsequent action focussed on legislative changes to reduce the supply of drugs. Little was implemented in the field of demand or harm reduction⁴ and treatment services remained predominately abstinence focussed.

The onset of HIV and AIDS in the early 1980's began to influence the type of services being offered to injecting drug misusers. A report of the National Aids Strategy Committee (Department of Health, 1992) stated that "all the indications are that the majority of people affected at present (by HIV/AIDS) are from deprived urban areas and many have experienced social and economic disadvantage. Statistics have shown that intravenous drug use is the main source of transmission of the virus; 60% of positive tests are drug related."

The problem was also examined on a geographic basis, highlighting the Dublin Inner City area as having particular problems. Recommendations focused on establishing satellite clinics that would treat drug misusers for HIV/AIDS in their own communities. This corresponded with the Government Drug Strategy (Department of Health, 1991) which aimed to establish Community Drug Teams, increase greater participation of General Practitioners (GPs) in managing drug misusers in their practice, link people into appropriate services through referral and use outreach strategies to target drug misusers not in contact with services.

⁴ Harm reduction refers to a set of practical strategies that reduce the negative consequences of drug use, incorporating a spectrum of strategies from safer use, to managed use to abstinence

The services were primarily involved in harm reduction and HIV prevention through the distribution of clean needles and 'works', and the prescription of methadone. Action was forced by public health concerns that the fear of infectious disease, then found in a defined population, would spread to the general population. Professional bodies in contact with drug users on a daily basis exerted power and influence in the evolution of policy aimed not at tackling drug addiction but in reducing injecting behaviour, associated crime and risk of HIV. Without much debate, Ireland experienced an ideological shift from total abstinence (Coolmine Therapeutic Model) to harm reduction (methadone maintenance model). Butler (1991, 1996) suggests that because the rationale for the shift in policy focus was primarily due to fears of HIV transmission from intravenous drug users into the general population, rather than a result of a radical ideological shift, not only did changes in service provision occur slowly, but they were marked by conflict and ambivalence in service delivery.

Despite these measures, by the mid, 1990s, the drug problem particularly in Dublin was still growing. The literature identifies a further shift in drug policy that occurred at this time. Farrell et al (1996) described this policy shift as a move from a HIV generated response to a broader concern about all aspects of drug misuse with a particular concern about the links between drug misuse and crime, and community safety and community well being. Central to this policy shift was the belief that the rate of drug-related crime may be lowered by bringing problematic drug users into treatment. Consequently, government policy (and funding) was directed to the expansion of treatment service provision. The extent to which heroin use became endemic in Dublin and the way in which treatment policy responded may be illustrated through a brief reference to the city's treatment statistics.

- i. In 1979, the Jervis Street clinic treated 55 heroin users; this figure rose to 213 in 1980 (Butler, 1991).
- ii. In 1990, the newly established Dublin Drug Treatment Reporting System (O'Hare & O'Brien, 1992) reported that 2037 opiate users were being treated in an expanding treatment system.
- iii. By December 2000, there were 4936 residents of the Eastern Regional Health Authority registered for methadone treatment on the central

methadone treatment list (Department of Tourism, Sport and Recreation, 2001).

Since 1996 the Irish Government's drugs strategy has been underpinned by the findings, recommendations and policies established by the two reports of the Ministerial Task Force on Measures to Reduce the Demand for Drugs (1996, 1997). Since then the overall aim of the Irish Government's drugs strategy has been to provide an effective, integrated response to the problems posed by drug misuse and to work in partnership with communities most affected by the drugs problem in tackling the issues raised (Moran et al, 2001). Four basic principles underpinned the Government's strategy at that time:

- it is recognised that an effective strategy must encompass a range of responses, which not only address the consequences of drug misuse, but also attack its causes;
- the response to the drug problem must take account of the different levels of drug misuse, which are being experienced around the country. While illicit drug use is a nation-wide phenomenon (particularly the use of drugs such as cannabis and ecstasy), heroin abuse, in view of its public health implications and close association with crime, is currently seen as the most pressing aspect of the problem. A more targeted response is required, therefore, in the areas experiencing the highest levels of heroin abuse;
- the need for all agencies, which have a role in responding to the drug problem, to work together so as to ensure that their individual contributions form part of an overall coherent and integrated approach; and
- the need to tap the depth of experience and knowledge which community groups and voluntary organisations can bring to a response to the drug problem. It is recognised that there is considerable knowledge and experience among communities in the areas experiencing the highest levels of use. These communities, therefore, must have an opportunity to participate in the design and delivery of the response to the problem in their areas (Flood, 1999).

New structures were also introduced to direct and co-ordinate drug policy. The operational implementation of approaches to drugs issues was devolved from the

National Co-ordinating Committee on Drug Abuse to a more structured sectoral approach involving:

- A Cabinet Committee on Social Inclusion – to confer political leadership to drugs policy and to resolve inter-organisational barriers to effective responses;
- An Inter-Departmental Group (IDG) – to address policy issues and review progress;
- A National Drugs Strategy Team – to operate on a cross-departmental basis and ensure effective coordination, to identify and consider policy issues before being referred to the IDG and co-operate with and over see the work of the Local Drug Task Forces; and
- Local Drug Task Forces (LDTF) – were set up in areas identified as having the highest levels of drug misuse. The LDTF's contribute to national drug policy aims and objectives by developing and implementing area action plans which co-ordinate existing or planned drug services and addresses any gaps in those services. The LDTF's provide a mechanism that enables local communities to participate in developing an integrated response to the context and consequences of drug misuse in their local area. The Government allocated £10 million to support the implementation of over 200 separate projects in the initial plans which were prepared in 1997. A further £15 million was allocated in 2000 to develop updated plans.

A comprehensive review of the National Drug Strategy was initiated by the Government in 2000 which resulted in the current National Drug Strategy 2001-2008. The overall strategic objective for the Strategy is 'to significantly reduce the harm caused to individuals and society by the misuse of drugs through a concerted focus on supply reduction, prevention, treatment and research' (National Drug Strategy 2001-2008, 2001) The new Strategy endorsed the Irish Government's existing approach to tackling the drugs issue. The four 'pillars' of the new Strategy - supply reduction, prevention, treatment and research - focus on the same four issues as in the Government's previous Drugs Strategy highlighted above. One hundred individual actions together with key performance indicators were developed under the four pillars which are designed to build on the existing approach and drive the

new strategy forward. The new National Drugs Strategy, however, seeks to strengthen the strategy and sharpen its focus, by:

- welcoming the Government's positioning of the National Drugs Strategy within the wider Social Inclusion policy and the strong commitment to areas of disadvantage in the NDP 2000 - 2006. The Review Team recognises that the best prospects for communities affected by the drugs problem, in the longer term, rest with a Social Inclusion strategy which delivers much improved living standards to areas of disadvantage throughout the country; and
- acquiring all state agencies involved in delivering the National Drugs Strategy to specify annual targets in terms of outputs and desired outcomes for their respective programmes and initiatives.

1.6 The Clondalkin Drug Task Force

The Clondalkin Drug Task Force brings together a range of statutory, community and voluntary representatives to design and implement an integrated, holistic strategy that seeks to address the context and consequences of problem drug use in the Clondalkin area. Clondalkin has a population of approximately 55,705, with a high percentage of young people, 30.9% under 15 years in 1996 (Clondalkin Partnership, 2000). Unemployment for the area lies at 19% compared to a national figure of 15%, local authority housing predominates in certain areas, and early school leaving presents as a persistent problem (Clondalkin Partnership, 2000).

To date the only estimate of the prevalence of opiate use in Clondalkin can be found in a study carried out by Comiskey in 1996. Minimum prevalence estimates of opiate use among males aged 15- 24 years by location of residence was identified in the study. In Clondalkin, the minimum prevalence estimate for this cohort was 50.2/1000 or 5.02% of the population. Since Clondalkin has a population of 55,705 (Census, 1996) this would give an estimated population of male drug users aged 15-24 years as 2,796. Clondalkin was identified as having the third highest estimated level of opiate use among this cohort. One must remember that there exists a paucity of information on the estimated prevalence of opiate use among other drug using populations, such as females, in Clondalkin.

To date the Task Force has developed two Area Action Plans. The first plan '1997-1999' received an allocation of approximately €1.2 million and supported a total of 49 projects under the four pillars of Education, Treatment, Supply and Research, 16 of which have been mainstreamed. The current plan '2001 – 2003' received €1.5 million.

In developing its second Area Action Plan the Clondalkin Drug Task Force undertook a comprehensive needs assessment in relation to the local drug issue. This needs assessment used a combination of several quantitative and qualitative data collection techniques in order to assess the nature and extent of health and social problems associated with drug misuse in the area together with the ability of the community to respond to those problems. The UNDCP (2003) describes needs

assessment as a systematic exploration of the current status of a single individual or a group with drug misuse problems and of the changes that they and others consider necessary to improve their health and social status. One of the key issues identified during the process was the limited capacity of existing detoxification services to respond to the need for non-methadone based treatment.

1.7 Summary

Treatment is central to the reduction of the harms incurred by individuals and the community from opiate dependence. Irish Drug Policy has played an important role in the development and provision of drug treatment services. The pharmacotherapeutic approach, using methadone maintenance therapy is the mainstay of drug treatment in the Irish setting. A number of issues have arisen in recent years which have challenged the status of methadone therapy. These include the risk of fatal respiratory depression in overdose, because of its full agonist properties together with the risk of diversion of take-away doses. Dissatisfaction has also been expressed by service users in the lack of choice with respect to substitution drugs. Thus, in recent years there has been a growing interest in and demand for non-opiate alternatives to methadone detoxification, such as the α 2-adrenergic agonist lofexidine. The following chapter identifies the main theories and concepts relevant to the development of a non-opiate based community detoxification team.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter examines the literature available on the topic of addiction and drug treatment. It discusses the elements of a comprehensive drug treatment system and identifies the various pharmacotherapies available for opiate detoxification. In particular it reviews the literature on the non-opioid α 2-adrenergic agonist, lofexidine. It also reviews the substance abuse treatment literature to identify patient and treatment process variables that have been shown to be important in determining outcome from addiction treatment efforts.

2.2 Addiction

Addiction or a dependence syndrome is described as a cluster of physiological, behavioural and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value (World Health Organisation, 1992). A central descriptive characteristic of the dependence syndrome is the desire, often strong and sometimes overpowering, to take psychoactive drugs.

According to the WHO (1992), a definite diagnosis of addiction is usually made if three or more of the following have been experienced or exhibited at some time during the previous year:

1. A strong desire or sense of compulsion to take the substance.
2. Difficulties in controlling substance taking behaviour in terms of its onset, termination, or levels of use.
3. A physiological withdrawal state when substance use has ceased or been reduced.

4. Evidence of tolerance, such that increases of the psychoactive drugs are required in order to achieve effects originally produced by lower doses.
5. Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects.
6. Persisting with substance use despite clear evidence of overtly harmful consequences.

According to the UNDCP (2002) the evidence is compelling that, at the present state of knowledge, addiction is best considered a chronic relapsing condition. It is true that not all cases of addiction are chronic and some who meet diagnostic criteria for substance dependence recover completely without treatment. However, many of those who develop addiction disorders suffer multiple relapses following treatments and are thought to retain a continuing vulnerability to relapse for years or perhaps a lifetime. The available research is quite clear on the following points:

- Education does not correct drug dependence: it is not simply a problem of lack of knowledge.
- Consequences of drug use (e.g. hangovers, loss of job, arrest, etc.) appear to be important stimuli leading to entry into drug abuse treatment.
- Very few addicted individuals are able to profit from a corrections-oriented approach by itself. Relapse rates are over 70 per cent from all forms of criminal justice interventions.
- Addiction is not simply a matter of becoming stabilized and getting the drugs out of one's system. Relapse rates following detoxifications are approximately the same as those following incarceration.

Based on these findings, drug abuse is best treated by combinations of continuing outpatient therapy, medications and monitoring, with the goal of retaining drug abusers in that treatment/monitoring regimen to maximise and maintain the full benefits of treatment.

2.3 Social and Economic Costs of Drug Abuse

Problems of substance dependence produce dramatic costs to all societies in terms of lost productivity, transmission of infectious diseases, family and social disorder, crime and, of course, excessive utilization of health care (UNDCP, 2003). These drug-related problems not only reduce the safety and quality of daily life, they are also a source of substantial expense. For example, according to results from a study released by the Home Office (2002), the annual economic costs of drug abuse in the United Kingdom are between £3.7 billion (or US\$ 5.6 billion) and £6.8 billion (or US\$10.3 billion). Most of these costs fall upon the criminal justice system as a result of drug-related criminality in the form of organized crime, burglaries and robberies and violence. Other social costs are borne by the health system (about £235 million (US\$338 million) in 2001 on primary care services, accident and emergency admissions and drug abuse treatment), the workplace, schools and families (total social costs were estimated at £10.9 billion (US\$16.5 billion) to £18.8 billion (US\$28.4 billion)). It is estimated that 99 per cent of the costs are associated with problem drug abusers. As the study estimated that there are 280,000 problem drug users in the United Kingdom, each problem drug user could cost about £30,000 (US\$45,000) a year.

A review of research by Yates (1999) concluded that “studies are nearly unanimous in finding that subsequent to treatment for drug abuse there is a reduction in the utilisation of general health care services”. Also, Cartwright et al (1991) reviewed research showing that there was a four-to-one return on the investment of tax dollars for law abiding citizens for treatment programmes” and “the crime-reduction impact estimated here represents only a portion of the potential savings attributable to drug abuse treatment”.

Studies to estimate the healthcare or other social costs of drug abuse have not been carried out in Ireland. Nor are estimates available on the economic costs to society from drug use. Accepting that the “social costs” incurred by drug use can be defined and interpreted variously, and that no research has been undertaken in Ireland with the specific aim of estimating such costs, a number of research findings can be drawn

upon to illustrate evidence of significant costs to individuals, families and communities as a result of drug use.

As might be expected, this evidence arises primarily from research on a range of social problems associated mainly with disadvantaged communities. Numerous researchers have documented the perceived negative impact of high levels of drug misuse on communities where drug use is concentrated (O'Higgins 1999; Corcoran 1998). Residents of estates where drug use is concentrated consistently draw attention to the destructive effect of drug use and drug trafficking on community life. Furthermore, they are acutely aware of the negative way in which their community is perceived by outsiders. Mayock (2000), in a qualitative study of drug use by young people in a Dublin inner-city community, noted that respondents made constant reference to the area's drug problem. Furthermore, these young people expressed resentment of outside representations of their neighbourhood. They were particularly critical of the negative effects of disparaging media reports of drug problems in their community, which they felt exaggerated the issue. Many clearly felt stigmatised by virtue of living in a locality where drug use and associated activities are concentrated.

There is relatively little research available pertaining to the consequences of drug problems for individual families. For example, there is no available estimate of the number of individuals affected by familial drug use. However, the issue of how children are affected by drug misuse has emerged as an issue of critical concern. Hogan (1997), in an exploratory study of the social and psychological needs of children of drug using parents, found that the majority of children whose parent(s) were heroin users were experiencing difficulties at school. Key workers interviewed for the purpose of the research expressed concern about the quality and consistency of care-giving by drug using parents.

2.4 Drug Treatment

Treatment can be defined in general terms as the provision of one or more structured interventions designed to manage health and other problems as a consequence of drug abuse and to improve or maximise personal and social functioning. According to the WHO's Expert Committee on Drug Dependence (1998), the term "treatment" refers to "the process that begins when psychoactive substance abusers come into contact with a health provider or any other community service, and may continue through a succession of specific interventions until the highest attainable level of health and well-being is reached". O'Brien et al (2000) defines drug treatment as 'any activity which is targeted directly at people who have problems with their drug use and which aims to ameliorate the psychological, medical or social state of individuals who seek help for their drug problems'.

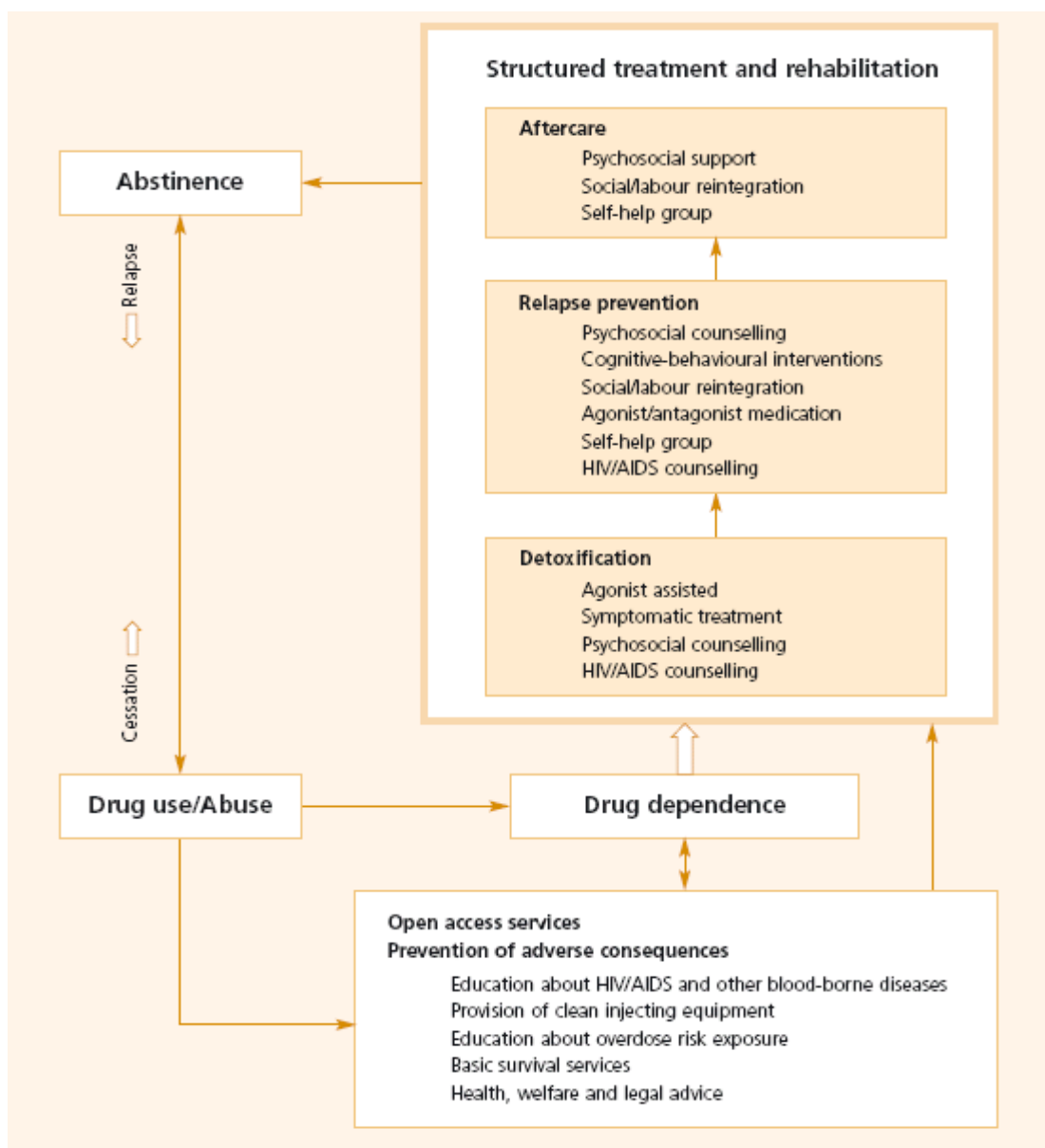
According to the UNDCP (2002) "treatment and rehabilitation are seen as a comprehensive approach to identification, assistance, health care and social integration of persons presenting problems caused by any psychoactive substance misuse". The Expert Committee (WHO, 1998) suggests that treatment should have three broad objectives:

1. to reduce dependence on psychoactive substances
2. to reduce the morbidity and mortality caused by, or associated with, the use of psychoactive substances; and
3. to ensure that users are able to maximise their physical, mental and social abilities and their access to services and opportunities, and to achieve full social integration.

2.4.1 Elements of a Comprehensive Treatment System

Various terms and labels are used to describe treatments and referral and support services for drug abuse. These can be grouped under the headings of ‘open access’ services and ‘structured treatments’. Figure 1, shown below, gives a schematic diagram of the services and care processes involved in a comprehensive drug treatment system.

Figure 1: Drug Treatment System and Care Process



2.4.1.1 Open Access Services

Open access services are important elements of an integrated treatment response. Those services do not provide formal treatment as such, but act as important points of first contact for people who have drug-related problems and for those concerned about the drug use of another (for example, parents, siblings, spouses and friends). They are provided by both statutory and community/ voluntary agencies, and can provide the following services:

- "Drop-in" (that is, non-appointment-based) service for accessing information and advice (health care, legal issues, housing, employment, training etc.);
- Community outreach and advice; blood-borne virus prevention services, including education, counselling and syringe and needle exchange; and overdose prevention education;
- Appointment-based general counselling service;
- Telephone help-lines for anonymous, confidential advice;
- Onward referral information and advocacy;
- Self-help groups for individuals and family members (for example, Narcotics Anonymous).
- Family support groups; and
- General community aftercare and support services.

One cannot overemphasise the importance of open access services. Some drug abusers may be reluctant to resort to specialised drug dependence services, and open access resources can be a critical place of first contact for them. Specialised open access services, play an invaluable role in minimising the adverse consequences of drug abuse and as entry points to the treatment system (UNDCP, 2002). Particularly, those services that provide information and specific interventions to prevent overdose and the acquisition and transmission of blood-borne infection.

2.4.1.2 Structured Treatments

Structured treatment characterises services that are based on a formal assessment, the development, monitoring and review of individual plans for client care and a programme of medical treatment and/or counselling services. Figure 1, shows that the main components of structured treatments include:

- **Detoxification** - Medical detoxification is the initial and acute stage of drug treatment. The main goal of detoxification programmes is to achieve withdrawal in as safe and as comfortable a manner as possible. Various medications have been shown to be effective in opioid detoxification, including true agonists⁵ such as methadone, partial agonists such as buprenorphine and other non-opioid drugs that are called α 2-adrenergic agonists (lofexidine or clonidine). Detoxification will be discussed in more detail later in this chapter.
- **Relapse Prevention/ Rehabilitation** - The rehabilitation or relapse prevention phase of treatment is oriented to the needs of persons who have either completed a formal detoxification or who have dependence but no formal withdrawal symptoms requiring access to the previous phase of treatment. According to the UNDCP (2003) 'relapse prevention or rehabilitation programmes are designed to change the behaviour of clients to enable them to regain control of their urge to use substances'. Goals of this phase of treatment are to prevent a return to active substance abuse, to assist the patient in developing control over urges to abuse drugs and to assist the patient in regaining or attaining improved personal health and social functioning.

Both psychosocial and pharmacological interventions are involved in this phase of treatment. Interventions can include such diverse elements as medications for psychiatric disorders; medications to relieve drug craving; substitution pharmacotherapies to attract and rehabilitate patients; group and individual counselling and therapy sessions to provide insight, guidance and

⁵ An agonist is a drug that is capable of combining with a cell receptor and stimulating or initiating a biochemical response similar to the drug of dependence.

support for behavioural changes; and participation in peer help groups (e.g. Narcotics Anonymous) to provide continued support for abstinence.

- **Aftercare** - Some structured treatment programmes distinguish a period of less intensive treatment after a client has completed the main programme, called aftercare. It may be limited to a month or substantially longer after treatment has finished, but is based on the intention to provide ongoing support to clients at the level required to maintain the earlier benefits and goals.

2.5 Detoxification

The previous section has established that detoxification (managed opioid withdrawal) is an important component of an effective treatment system for opioid dependency. Detoxification may be defined as a process of medical care and pharmacotherapy that seeks to help the patient achieve abstinence and physiologically normal levels of functioning with the minimum of physical and emotional discomfort (Margolin et al, 1991). Pharmacotherapy involves the administration of a suitable agonist medication, in progressively diminishing amounts, to minimize withdrawal discomfort from opioid, barbiturate and benzodiazepine dependence, where a characteristic rebound physiological and emotional withdrawal syndrome is experienced usually around 8-12 hours following the last dose of the drug.

The detoxification phase of treatment is designed for people who experience withdrawal symptoms following prolonged abuse of drugs. There is a complex range of variables that can potentially influence the course and subjective severity of withdrawal, including the type of opioid used, dose taken, duration of use, general physical health, and psychological factors, such as the reasons for undertaking withdrawal and fear of withdrawal (Frank 1995; Farrell 1994; Preston 1985). According to Gossip et al (1991) 'the aversive nature of opiate withdrawal is a considerable barrier to achieving abstinence, and detoxifying without professional assistance is often not successful'. Thus assisting people who have become

dependent on opiates to safely overcome the period of withdrawal, and pass through it with minimal discomfort, would seem to be an important function of treatment services, even if they have an orientation towards methadone maintenance prescribing (Ward et al, 1998).

Success rates for opiate detoxification are highly variable (Milvey, 1988), and there is no consensus on the best approach to take. If used as a treatment entity in its own right, detoxification is associated with a high rate of relapse once the “withdrawal” period is completed (Mattick et al, 1996). Therefore, it is usually used as part of a treatment programme. In those EU countries which have favoured drug free treatment (as opposed to substitution treatment) programmes, detoxification is also associated with psychosocial/rehabilitation programmes (EMCDDA, 2001; Farrell et al, 2000). It may also be used as a first step for other forms of treatment or at the end of an extensive period of substitution therapy (Gowing et al, 2001). Managed withdrawal, or detoxification, is not in itself a treatment for dependence (Mattick et al, 1996). Rates of completion of withdrawal tend to be low, and rates of relapse to opioid use following detoxification are high (Broers et al, 2000; Gossop et al, 1989), but withdrawal remains a required first step for many forms of longer-term treatment (Kleber et al, 1982). It may also represent the end point of an extensive period of substitution treatment such as methadone maintenance. As such, the availability of managed withdrawal is essential to an effective and comprehensive treatment system.

2.5.1 Pharmacotherapies

As already mentioned, the evidence suggests that detoxification from illicit heroin and other opioids can be facilitated using dose tapered opioid agonists (mainly methadone), the partial antagonist buprenorphine and two non-opioid drugs, clonidine and lofexidine (both α_2 -adrenergic agonists). Evaluating the relative merits of those medications is hampered by differences in the operation of treatment programmes and various measurement issues to do with clinical assessments of withdrawal symptom severity. Allowing for this caveat, Gowing et al (2000) conducted a Cochrane review of 218 international detoxification studies and

calculated mean completion rates for inpatients and outpatients setting opioid detoxification of 75 per cent and 35 per cent, respectively, when using methadone and 72 per cent and 53 per cent, respectively, when using an α 2-adrenergic agonist.

For many years routine procedures for detoxification involved suppression of withdrawal with methadone and gradual reduction of the methadone dose (Kleber et al, 1982). This approach derived from observations that the withdrawal syndrome from methadone was milder, though longer, than that from morphine. Methadone's high oral bioavailability, efficacy and long duration of withdrawal relief (24 to 36 hours) were additional factors that have contributed to it being the main medication used in specialist withdrawal programs for most of the past three decades.

Ambivalence to the use of a drug of dependence to treat opioid dependence, government restrictions on prescription of methadone, and consumer dislike of the protracted nature of methadone withdrawal (Farrell, 1994) have culminated in the need for non opiate based detoxification. Discovery of the capacity of the α 2 adrenergic agonist, clonidine, to ameliorate some signs and symptoms of withdrawal led to widespread use of this drug as a non-opioid alternative for managing withdrawal (Gossop, 1988). One mechanism underlying opioid withdrawal is noradrenergic hyperactivity (Gold et al, 1989). The α 2 adrenergic agonists act centrally to moderate the symptoms of noradrenergic hyperactivity. Alpha2 adrenergic agonists bind presynaptically to α 2-adrenergic receptors located on the nerve endings of noradrenergic neurones and reduce the release of noradrenalin, which occurs when the inhibitory effects of opiates is removed (Gold et al, 1981). The noradrenalin induced withdrawal symptoms, such as chills, abdominal cramps, diarrhoea, rhinorrhoea, piloerection, pupil dilatation, lachrymation and yawning are suppressed (Akhurst, 1999)

Clonidine, used at the dosage needed to suppress opioid withdrawal syndrome is associated with a number of adverse effects (such as hypotension and sedation) and therefore patients require close medical supervision (Ward et al, 1998). This has led to the investigation of the effectiveness of other α 2 adrenergic agonists, such as lofexidine, in the management of opioid withdrawal, the aim being to find a drug

that has clonidine's capacity to ameliorate the signs and symptoms of opioid withdrawal, but with fewer side effects.

Gowing et al (2004) conducted a systematic review of α_2 adrenergic agonists in the management of opioid withdrawal. The focus of the review was to evaluate the effectiveness of these agents in this indication relative to other forms of treatment, placebo and each other. A total of 68 studies were identified in the data retrieval process of which 24 were judged to fulfil the criteria for inclusion in the systematic review. Six of the included studies evaluated the use of lofexidine (n = 200 subjects). See Appendix 1 for a summary of the included studies.

No significant difference in efficacy was detected for treatment regimes based on the α_2 adrenergic agonists clonidine and lofexidine, and those based on reducing doses of methadone over a period of around 10 days, for the management of withdrawal from heroin or methadone. Participants stay in treatment longer with methadone regimes, have similar or slightly higher rates of completion of withdrawal and experience less adverse effects. Lofexidine appeared to cause less hypotension than clonidine. Because of this finding and the fact that clonidine and lofexidine are equally effective, the reviewers recommend that lofexidine should be the preferred option, particularly for withdrawal in an outpatient setting, if an α_2 -adrenergic agonist is to be used.

The National Advisory Committee on Drugs (NACD) (2003) commissioned a review to evaluate the potential usefulness of lofexidine in the overall management of opiate dependence syndrome in an Irish setting. The review concluded that lofexidine may be regarded as a useful additional treatment option in the overall management of opiate dependence. The results of the review may be summarised as follows:

1. Lofexidine has been evaluated for use in managed opioid withdrawal (detoxification) and has been seen to be at least as effective as clonidine and reducing doses of methadone, the currently used treatment modalities.
2. Use of lofexidine was not associated with significant levels of hypotension, making it a suitable treatment for use in the outpatient setting.

3. It is not possible to make definitive statements about use of lofexidine in specific subgroups, but it has been suggested that response is better in younger opiate users or those with a shorter history of abuse. It is not recommended for use during pregnancy and there is no information on its use in this subgroup.
4. Reports from usage in clinical practice suggest that managed withdrawal using lofexidine requires the close involvement of all members of the drug treatment team with the patient during treatment and that lofexidine detoxification should be followed by further treatment (such as opioid antagonist therapy) and counselling to prevent relapse.

2.6 Use of Lofexidine in Clinical Practice

2.6.1 United Kingdom

Since being licensed for opiate detoxification in 1992, lofexidine has become widely used in the UK (Arkhurst, 1999). It is authorised to relieve symptoms in patients undergoing opiate detoxification. Since its launch, usage has increased steadily and one report noted that more than 18,000 courses of lofexidine treatment were used in the UK in 1998 and this usage was estimated to increase to more than 21,000 in 1999 (Strang et al, 1999).

The results of a national survey on the efficacy, and safety of lofexidine were recently published (Akhurst, 1999; Akhurst, 2000). The survey was conducted under the guidelines for company sponsored safety assessment of marketed medicines (SAAM). A total of 1,074 questionnaires from 40 randomly chosen drug dependency units were completed and available for evaluation. The data set comprised 793 males and 270 females. Approximately 43% were taking heroin, 28% methadone and 20% both. The majority had been dependent on opiates for ≤ 5 years and almost three quarters had either never attempted a supervised detoxification before or had a maximum of 2 previous attempts. Detoxification with lofexidine was undertaken in the community in 63% cases. The mean starting dose used was 0.8mg/day with the majority of patients achieving their maximum dose by

day 3. Most patients were titrated to a mean maximum dose of 2.2mg/day although doses up to 5.6mg/day were recorded. The mean duration of treatment was 8.9 days (range 1-33 days) with a mean of 10 days for those who successfully completed treatment. Information on efficacy was available on 686 detoxification episodes, of which 342 (49%) were rated as very successful, 261 (38%) as moderately successful and 83 (12%) as poor. Follow-up information was not available from all questionnaires but 333 patients were reported to be opiate-free for a period ranging from 3 days to 3 years and 327 patients were known to have relapsed. Of interest, 221 questionnaires recorded an improved lifestyle relating to relationships, employment and/or health status.

Adverse events were reported in 351/1074 (32.7%) detoxification episodes. Commonest events reported were dizziness (8.5%) sedation (6.6%) insomnia (4%) and dry mouth (5%). Hypotension was recorded in 7.5% cases and this resulted in discontinuation of treatment in 16 cases and reduction in dosage in a further 47 cases. It is important to note that not all of the treatment units routinely monitored blood pressure and pulse rate, but from the data available it was noted that if hypotension and/or bradycardia were to occur, this usually happened within the first few days.

The study involved a retrospective review of patient files and therefore data collection was incomplete for a number of the parameters. In addition the adverse events recorded in the files related primarily to symptoms as routine blood testing which might have picked up “concealed adverse events” (e.g. liver or renal dysfunction) was not undertaken. However, useful information on the general safety of lofexidine has been made available from this survey.

The use of lofexidine in 194 patients undergoing 214 opioid detoxifications over a 24 month period was reviewed by Sheridan et al (1999). Results showed that 81 patients (37.9%) remained in treatment by day 8 and 52 (24.3%) were considered to have completed detoxification. Reasons for non-completion included failure of lofexidine to adequately control the withdrawal symptoms, psychosocial problems, or expulsion from the programme due to breaches of the treatment protocol (use of prohibited drugs or alcohol). Blood pressure was recorded for the first 5 days of

treatment. In general, hypotension, when present, occurred early in treatment and generally began to return to normal by the fourth day. Of 144 instances of hypotension recorded, only 23 resulted in a withholding or reduction of the dose. The remainder resolved spontaneously on continuing medication. Other adverse events were not recorded routinely but where they were, they consisted most commonly of dizziness, drowsiness, lethargy, nausea and vomiting. Although the data represent a retrospective review they are still useful in highlighting the practical issues involved in the use of lofexidine. They confirm that lofexidine can be used safely, even at maximum doses.

Finally, the practical issues of use of lofexidine at primary care level was discussed by 3 GPs in a published article (Smith et al, 1998). This report highlighted the need to ensure that lofexidine is used as part of an overall treatment plan (including counselling, self-help groups as well as other pharmacotherapy modalities such as naltrexone⁶), in order to ensure long-term abstinence.

2.6.2 Ireland

Lofexidine is currently not authorised for use in the management of opiate withdrawal in Ireland, although it has been used by some inpatient units and outpatient clinics on a named-patient basis. The NACD (2003) reviewed the availability and, where data was available, treatment outcomes for the use of lofexidine in an Irish setting. In Dublin three outpatient treatment centres and one inpatient facility were offering lofexidine to clients. Staff at one of the outpatient centres recorded and analysed the treatment outcome data from December 2000 to December 2002. A total of 84 clients (98 cases) participate in the ten – day programme using a maximum dosage of 2.2mg/day. They were primarily heroin smokers or users with a relatively small heroin habit (1 to 2 bags per day) with a desire to become drug free. Also included were those on an existing methadone programme who had reduced down to low doses (less than 20 mls) and wished to become drug free. Successful detoxification was achieved if the patient's urine was free of opiates at the end of the programme. Lofexidine was administered in

⁶ Naltrexone is a drug that antagonises the effects of opioid drugs while producing no pharmacological effects of its own.

conjunction with full medical and counselling support and patients were seen on a daily basis (including weekends). Symptomatic medications were also prescribed on “as required” basis. After successful detoxification patients were offered Naltrexone therapy and counselling to prevent relapse.

The overall success rate for patient attempts was 38% (37/98 attempts). Success was highest among those stable on methadone 80% (8/10) and pure heroin smokers 39% (13/33). Those patients classified as unstable on methadone had a very low success rate 14% (2/14). Serious problems with hypotension were not reported.

The review also highlighted that:

- The Lofexidine programme offers patients an important choice in treatment options. The only other outpatient detoxification option hitherto available was a gradual methadone dose reduction. This type of detoxification option has a tendency to lead onto methadone maintenance.
- Lofexidine is not suitable for all opiate users wishing to undergo managed withdrawal. Exclusion criteria include pregnancy or underlying cardiac or renal dysfunction and users with serious co-existing psychiatric morbidity. In addition, a history of polydrug use or high levels of alcohol consumption make successful detoxification less likely.
- It was felt that the best indicator of success was the patient’s motivation to become drug-free.
- Lofexidine managed withdrawal requires intensive input from all clinic staff, (doctor, nurse, pharmacist and counsellor) because of its short duration.

2.7 Effective Treatment Components

The UNDCP (2003) carried out a review of the substance abuse treatment literature to identify patient and treatment process variables that have been shown to be important in determining outcome from addiction treatment efforts. What follows is a brief description of the factors identified as having an influence on the outcome of treatment efforts.

2.7.1 Patient-Related Factors

2.7.1.1 Severity of Substance Use

A variety of studies of treatments in different national contexts have shown that the chronicity and severity of patients' substance use patterns have been reliably associated with poorer retention in treatment and more rapid relapse to substance use following treatment (Rouns-Bryant et al, 1999; George et al, 1999).

2.7.1.2 Severity of Psychiatric Problems

International epidemiological population surveys and clinical studies have shown that people with substance abuse and dependence disorders are prone to have anxiety, affective and anti-social and other personality disorders (UNDCP, 2003). Outcome studies of dependent opioid patients suggest that, for most patients, psychiatric symptoms improve early on in treatment and that, on average, there are sustained reductions in symptom levels over medium- and long term follow-up (Bromme et al, 1999). However, a consistent finding across many studies and contexts is that severe psychiatric symptoms and disorders at intake to treatment are a reliable predictor of dropout and poorer follow-up outcomes (McLellan et al, 1996).

2.7.1.3 Treatment Readiness and Motivation

According to Simpson et al (1997) patients who report being ready and motivated to receive treatment tend to engage more successfully with the therapeutic programme and stay in treatment for longer periods of time.

2.7.1.4 Employment

Many people with drug abuse problems have enduring difficulties with obtaining and retaining paid employment. Employment has been found to predict retention in treatment and good outcome (Simpson et al, 1986). For example, in a sample of primarily employed, multiple substance abusers entering private inpatient or outpatient programmes, McLellan (1994) showed that employment problems were one of the most significant predictors of post-treatment substance abuse and other aspects of poor health and social functioning.

2.7.1.5 Family and Social Supports

Social supports have been widely studied in the drug abuse and dependence field. Social support has been conceptualised variously as the availability of relationships that are not conflict-producing and supportive of abstinence; and the active participation in peer supported treatments such as Narcotics Anonymous (UNDCP, 2003). Treatment goals may not be reached at all or may attenuate rapidly following treatment if the patient's environmental resources are limited. Thus it follows that effective treatments for substance abuse look beyond the programme to assist the patient in becoming included in society and improving family relationships and personal resources (McKay, 1994).

2.7.2 Treatment Related Factors

2.7.2.1 Setting of Treatment

Many studies have investigated differences in effectiveness between various forms of hospital inpatient and outpatient/day rehabilitation treatments. One such report concluded that for most treatment systems, it is likely that patients who have sufficient personal and social resources and who present with no serious medical complications should be assessed for outpatient/day treatment (Alterman, 1994). The UNDCP (2003) have suggested that given the typically high demand for residential care, it seems logical to prioritize that setting for those with acute and chronic problems who have social stressors and/or environments that are likely to interfere with treatment engagement and recovery.

2.7.2.2 Treatment Completion and Retention

There is a substantial amount of literature to support the assumption that patients who complete treatment will have better outcomes than those who leave prematurely. According to the UNDCP (2003) given that most people who are studied in drug abuse treatment programmes have chronic and diverse problems, it is to be expected that the longer they remain in treatment, the greater the likelihood that significant lifestyle improvements will be achieved and consolidated. A consistent finding from the United States' national outcome studies is that patients who stay for at least three months in residential programmes have superior post-departure outcomes than patients with shorter stays (Grella, 1999). Staying in treatment enables the patient to acquire new skills and to make progress in the programme. Toumbourou et al (1998) found that the time spent in treatment was related positively to improved outcomes, but the extent or level of therapeutic progress attained emerged as a stronger predictor of outcome than simply the time spent in treatment.

2.7.2.3 Counselling

The UNDCP (2003) identifies that access to regular substance abuse counselling can make an important contribution to the engagement and participation of the patient in a treatment programme and to its outcome. The positive impact of individual or group counselling and attendance at 12-step meetings was observed in one study where greater frequency of attendance at counselling and self-help groups were associated with higher completion rates and lower risk of relapse over the subsequent six months (Fiorentine et al, 1997)

2.8 Summary

Lofexidine, a α_2 adrenergic agonist acts centrally to suppress the opiate withdrawal syndrome. It offers a non-opiate, rapid withdrawal treatment from opiates, without the risk of dependency. Lofexidine is seen as the preferred option for the management of withdrawal in an out-patient basis, if a α_2 -adrenergic agonist is to be used. Clinical studies carried out in the United Kingdom on the efficacy and safety of lofexidine found that the drug can be used safely in a community setting. In general, it has been found to be suitable mainly for younger users with a short history of opiate dependence. It is less effective in those who have a long established use or a high dosage requirement of opiates. It may also play a role as adjunctive therapy at the end of reducing doses of methadone, used for detoxification.

Thus in considering an alternative model for community detoxification, lofexidine provides a viable, safe alternative to methadone. The following chapter outlines the research methods employed to identify the model for a community detoxification team.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

The aim of this study is to identify an appropriate alternative model for a Community Detoxification Team for implementation in Clondalkin, an urban area where there are high levels of opiate misuse. This chapter describes and discusses the research methods employed to collect and analyse the data in order to achieve the aforementioned aim. It also discusses the quality and validity of the research and identifies the ethical issues that arose in the data collection, as well as explaining the process involved in identifying the key informants and focus group participants.

3.2 Research Design & Rationale for its Choice

In contemplating researching the feasibility of developing a Community Detoxification Team using lofexidine the researcher identified that it was possible to use a qualitative approach. A review of research methodology highlighted the multifaceted nature of research, indicating that it is possible and valuable to look at something other than quantifiable outcomes whereby research may shed light on the processes and outcomes of practice, thus assisting in building knowledge and skills (Shaw et al, 2001).

There are many aspects to an individuals experience and point of view and these may not all be accounted for in a purely objective and statistical study. It therefore seemed appropriate to take a qualitative approach, facilitating a more descriptive and contextual account of the key informants' experiences. As the research is intended to be a vehicle for the expression of their experiences in order to identify a model for the development of a Community Detoxification Team, the use of qualitative methods was considered to be more appropriate, by focusing on their own perceptions, meanings and descriptions. (Dey, 1993; Mason, 1996).

Another reason for adopting a qualitative approach was the fact that there is no theory as such to prove or disprove. The study is more interested in developing a position from the data collected from the key informants. The study is an exploration of the topic, from which possibly theories or ideas may develop in an emergent rather than positivistic way (Dey, 1993; Robson, 1993). This does suggest a grounded theory approach, which can be described as "...an approach and set of methods for developing theories, concepts and hypotheses direct from the data rather than a priori assumptions, other research or existing theoretical frameworks". (Shaw et al, 2001) However, grounded theory in its pure form (Glaser et al, 1967) was not adopted, but rather elements were borrowed such as aspects of theoretical sampling and coding, in an effort to ground the theory in the data (Scourfield, 2001).

3.3 Data Collection

The data collection took the form of two focus groups and ten semi-structured interviews. Contact was made with specific experts in Ireland to identify the practical issues associated with use of Lofexidine in out patient detoxification. Focus group participants were selected from two existing groups from the Clondalkin area. One such group, the North Clondalkin Drug Users Forum, was used to identify service users' perceptions. The second group, the Clondalkin Community Representative Forum, was used to identify the perspectives of families who are living with drug dependency in the home. Thus it can be said that sampling was purposive. Mason (1996) defines purposive/theoretical sampling as "...selecting groups or categories to study on the basis of their relevance to your research questions, your theoretical position and analytical framework, your analytical practice, and most importantly the explanation or account which you are developing".

Focus Groups have become widely used to both examine people's experiences of disease and health services and assess health and social needs (Murray et al, 1994). Kitzinger (1995) defines focus groups as 'a form of group interview that capitalises on communication between research participants in order to generate data'.

Focus groups were used for the following reasons:

- They do not discriminate against people with literacy difficulties (Kitzinger, 1995), this was especially relevant to the service user group, a cohort which would normally exhibit literacy difficulties an outcome of very low educational attainment rates;
- Group dynamics can stimulate discussion and ideas (Krueger, 1994; Berg, 1998).
- Group dynamics can encourage disclosure (Krueger, 1994).
- Interaction between group participants can be observed (Berg, 1998).
- The ‘safety in numbers’ factor can encourage the participation of those who are wary of an interviewer or those who are anxious about talking (Kitzinger, 1995)
- The flexibility afforded by focus groups allows the researcher to select participants to reflect the needs of the study (Kitzinger, 1995)

The idea behind the focus group method is that group processes can help people to explore and clarify their views in ways that would be less easily accessible in a one – to – one interview (Kitzinger, 1995). In order to facilitate this, a number of open ended questions were developed by the researcher (see Appendix 2) to encourage the research participants to explore the issues of importance to them, in their own vocabulary, generating their own questions and pursuing their own priorities.

The focus groups were facilitated by the researcher who was supported by a scribe. A video ‘A Turkey’s Conclusion – A Guide to Lofexidine’ was shown at the beginning of each focus group to introduce the topic for discussion. The focus groups consisted of a set of individuals from the community identified as having an investment or expectation in the efficient and effective operation of a treatment service. As already mentioned the focus groups were made up of either service users or family members from the Clondalkin area. Table 1, shown below, gives a profile for the focus group participants.

Table 1: Profile of Participants on Focus Group Interviews

Focus Group	Total	Male	Female	Age Range
Service User	9	4	5	22 - 30

Families	11	4	7	25 - 54
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Semi-structured interviews were used so that the process could retain some of the flexibility of an unstructured interview allowing issues to arise, while ensuring that comparability and comprehensiveness would not be sacrificed. They foster the ‘appearance of a conversation or discussion’ (Mason, 1996) allowing for an informal style, utilising the interaction between interviewer and interviewee, while general themes or topics are covered (Mason, 1996). In contrast to questionnaires, interviews offer the possibility of modifying one’s line of enquiry, following up interesting responses and investigating underlying motives. (Robson, 1993). A further benefit to using interviews is that quotes can then be used to represent people’s views and experiences rather than relying on the interpretation of the researcher (Miller et al, 1997).

The semi-structured interviews were conducted on the basis of a loose structure consisting of open ended questions (see Appendix 3) that initially defined the area to be explored and from which the interviewer or interviewee diverged in order to pursue an idea or response in more detail. Key informants were identified from a target population made up of key personnel who had experience in the establishment and operation of lofexidine detoxification programmes as well as those who carried out research in the area of lofexidine. Two service users were also interviewed. A total of ten interviews were carried out. An introductory letter together with a sample copy of the semi structured interview questions were forwarded to each interview prior to the interviews taking place.

The key informants included:

- Clinical Director of Addiction Services
- Two Senior Counsellors
- Rehabilitation Consultant
- Director Centre of Advanced Clinical Therapeutics
- Senior Nurse
- General Practitioner involved with local clinic
- Community based Drugs Worker
- Two Service Users

Both focus groups and interviews were tape-recorded and later transcribed by the researcher. This meant that as much information as possible was gathered, and the researcher could concentrate on the interview and its process without being concerned about taking notes of what was being said. Having tapes and transcripts enhances the reliability of the analysis, as they can be accessed and examined for corroboration of findings and interpretation (Perakyla, 1997).

It also gave the researcher the opportunity to reflect on his own style of interviewing and it meant that in listening back on the tapes he could pick up on points that may have been lost in the process of the interview.

3.4 Analysis

Analysis of the data was a process, which moved through coding or categorization, refinement of codes, identification of linkages and patterns, and interpretation, by referring to previously developed theories and concepts (Mason, 1996).

The analysis began with a thematic ordering, that came out of the first reading of the transcripts, as well as general impressions that had been developed from conducting and transcribing the first few interviews. A 'two-pass' coding system was used, which involves a first reading and application of simple codes followed by the second reading where the codes are updated (Kreuger, 1998). As the codes had emerged as each transcript was being coded, it was necessary to return to the

transcripts a number of times and recode for themes that had not been identified on the initial reading. For example, general views in respect of detoxification and the need for alternative treatment options were lost in the original coding. This was time consuming, but did ensure that consistency was maintained throughout, as all transcripts were finally coded for all possible codes. This exercise also highlighted what could be missed, if the researcher is not looking for something in particular, or is in fact only looking for something in particular.

Through this process of going through the transcripts and coding for the general themes more refinement was developed, including what Dey (1993) describes as 'splitting and splicing'. This involved refining and combining categories, i.e. clarifying the broader categories and joining other categories where appropriate to the analysis, so that by the end of this initial categorization the conceptual tools required for the analysis had been significantly sharpened.

Returning to the research questions was crucial in keeping focused at this point, as the data was raising many possibilities, which were tempting to follow.

The process of coding was simplified and speeded up by the use of the Nud*ist 4 computer software package (Mason, 1996). It allowed each piece of text to be coded for many categories, initially 'free nodes' i.e. codes with no hierarchical relationship, without the need for endless copying and cutting. It also made it possible to quickly retrieve text that had been coded for a particular category, to remind the researcher what the code was referring to, so that similar coding for other documents could be completed in a consistent manner. Such consistency is essential if the findings and interpretations are to be considered methodologically valid and reliable (Silverman, 2000; Rudestam et al, 2001).

The possible disadvantages of the use of computer software packages were kept in mind. There is sometimes a temptation to consider the codes as variables and begin to compare their relationships to each other (Mason, 1996). This was indeed an avenue that was followed for a short time. Krueger also warns against using software packages to concentrate on counting rather than as an aid in analysis (Krueger, 1998). Counting does help to detect patterns and can be used as the

starting point for a more reflective interpretation of why these patterns occur. (Morgan, 1998)

The researcher must realise that the computer can show 'where' and 'when' but cannot answer the 'why' and 'how' questions (Morgan, 1998).

Codes were then systematized on a hierarchical basis in an attempt to begin to establish causal links (Lewins, 2001). This process of recognising linkages was also aided by the use of Nud*ist 4, by allowing the development of related codes i.e. Index Tree Nodes. This was the beginning of the process of identifying linkages, as the place of a code hierarchically implies a relationship (Gahan & Hannibal, 1998). The tree structure of the nodes made this hierarchy easier to work with and visually available.

Once the coding was completed, and the process of making linkages begun, patterns began to emerge. Possible linkages and patterns were tested by rigorously going back to the data to ascertain if they made sense. This initial analysis began the process of grounded theory by taking note of patterns which emerge, and reworking them to fit emergent patterns. (Fook, 2001). Nud*ist 4 was useful at this stage, as retrievals were instantaneous.

In an attempt to visualise the emerging patterns (Dey, 1993) a graph was developed that represented the relationships. This proved to be a useful tool for organising, thinking about, and presenting the qualitative connections between programme implementation and programme impacts.

Once the patterns were established it was possible to begin to interpret and establish them as findings. Some of this interpretation came from the data itself in a grounded theory way (Shaw et al, 2001) and more of it was related to previously accepted theories and concepts, which have been presented in the Literature Review chapter.

3.5 Validity & Quality of Research

There are no mechanical or 'easy' solutions to limit the likelihood that there will be errors in qualitative research, however there are various ways of improving validity

Respondent validation, or member checking, includes a range of techniques in which the investigator's account is compared with the accounts of those who have been investigated in order to establish the level of correspondence between the two sets (Pope et al, 1999). The technique employed in this study involved the validation of all interview/ focus group transcripts by the research participants prior to being analysed by the researcher. Lincoln et al (1985) regard respondent validation as the strongest available check on the credibility of the data collected.

Triangulation involves the comparison of results from two or more different methods of data collection (for example semi-structured interviews and focus groups) or, more simply, from two or more data sources (for example, interviews with members of different interest groups) (Pope et al, 1999). Thus to increase the reliability of the findings (Mason, 1996), a triangulated approach was used by combining results from both focus groups and semi-structured interviews together with data from the various interest groups. Therefore, acknowledging that by combining several lines of sight, researchers obtain a better, more substantive picture of reality; a richer, more complete array of symbols and theoretical concepts; and a means of verifying many of these elements. (Berg, 1998)

Many advise the researcher to take a reflective approach to their work (Mason, 1996; Shaw et al, 2001). Reflexivity takes into account the context and self of the researcher (Shaw et al, 2001) thereby making explicit the influences that could affect the approach, assumptions and interpretations being made as all research is situated in the personal context, and that my interpretations are necessarily made through the lens of my own embodied experience.

As a middle class, professional man in his thirties the researcher's own experiences and background are indeed very different to those of both the families and service users who participated in the focus groups, and should be acknowledged, so that any analysis can stand alone, or at least be considered in this context. This focus on what is known as reflexivity (Schon, 1983) and the interaction that occurs between researcher and researched is considered in the study and is made possible by the use of qualitative methods.

The final technique for reducing bias in qualitative research is to ensure that the research design explicitly incorporates a wide range of different perspectives so that the view point of one group is never presented as if it represents the sole truth about any situation (Pope et al, 1999). Thus the perspectives of both service users and families as well as the views of service providers and researchers were considered in this research.

3.6 Limitations

Qualitative research is sometimes considered not ‘scientific’ in the way that some quantitative research based on statistical sampling theory and formal methods of interviewing may claim to be. The previous section describes the various tools used by the researcher to improve the validity of the research.

The study is based on a reasonably small sample size which can make it difficult to generalise from the findings to other interest groups not considered in the research. Also the issue of proximity may have influenced the data obtained in the research, as the researcher was known to a number of the research participants. The use of an independent researcher may have gone some way in limiting the influence the researcher may have had.

3.7 Research Ethics

Great care must be taken in the protection of research participants when using qualitative methods. Most qualitative researchers are committed to abide by a set of guidelines of professional ethics (Agar 1980; American Anthropological Association 1990; Denzin et al, 1994). Three points are basic to these guidelines which were implemented when carrying out this study. First, the purpose of the research was made explicit to the subjects, in addition, people had the right to choose whether or not to participate. Second, the researcher was able to determine that no harm could come to the individual study subjects as a result of their participation in the research. Third, the researcher was able to ensure that the resulting research and publications could be used in such a way that they may bring harm to the participants as a group. Central to achieving these goals was the use of an informed consent form in which the guidelines of the research and the person's role in it were described (Appendix 4).

3.8 Summary

The grounds for taking a qualitative approach in this study are considered and the methods employed are explained and their limitations indicated. The validity and quality of the study was discussed together with the various tools used. The ethical considerations when using qualitative methods were highlighted which included informed consent, confidentiality and protection from harm. Each is reflected on in relation to the study, along with the safeguards that were put in place to ensure that the appropriate standards were met. Finally the methodological approach taken to the analysis of the data is explained. In particular the role that the use of the software package, Nud*ist 4, played in aiding this process.

CHAPTER FOUR

DISCUSSION

4.1 Introduction

This chapter outlines the outcomes and main findings from both semi-structured interviews and focus groups. The findings have been combined with relevant literature to provide a foundation for the development of a community based detoxification team. The findings of the study are presented in seven parts reflecting key theme areas identified in the analysis. The first deals with detoxification and the need for lofexidine, the second with the components of a lofexidine detoxification programme, the third with infrastructural requirements, the fourth with matching patients to treatment, the fifth with adverse events, the sixth with rehabilitation and the seventh with effective treatment components.

4.2 Detoxification

The literature review undertaken identified the high failure rate associated with detoxification. The interviews highlighted a number of conflicting views in relation to detoxification. Concern was raised by a number of interviewees in relation to the inappropriate use of detoxification as a treatment intervention with clients who are not ready for detoxification and the negative effect that this can have on the client. In essence, setting a client up to fail:

'...you can instil in somebody a mindset of failure around detoxification if it's used inappropriately ... I do have some difficulty with the idea of putting somebody on detox to be seen to be doing something for them when in your heart of hearts you know you're setting the person up to fail, and what that means to somebody's esteem, and what that means to somebody being able to eventually achieve abstinence, if they've done three or four detox's and they haven't been successful'. EK

Another issue which was highlighted regarding detoxification referred to the nature of addiction and the fact that people are looking for a quick fix solution to the issue that may not be the most appropriate response.

'...responses in addiction often mirror addictive behaviour in that people need a quick fix solution to their problem as they need a quick fix by buying heroin when they're strung out, the problem has to be dealt with, has to be sorted out now and while they're obviously very motivated now, now is the time to do it and the reality is that it may not be the time and you're setting someone up to fail...I think that can be quite devastating in some cases'. EK

Others identified that although the detoxification may not be successful, the client has had the opportunity to enter a treatment process which has facilitated the establishment of contacts with service providers which are necessary for long term success. This view was reflected by one interviewee when they commented that:

'...the contact that's been made between you and them is invaluable, in that we can address the individual, we've engaged the family, we've engaged parents, and for those who are not successful we can access further supports'. SMD

4.2.1 Need for Lofexidine Detoxification

A number of general views identified by the interviewees, which is reflected in the literature, demonstrate the need for lofexidine detoxification. These views provide an insight into interviewees' perceptions of lofexidine and the need for the provision of alternative treatment options to drug misusers. Both service users and families identified the need for more choice in respect of the treatment options available.

One service user stated:

'...I just think that's important that people have choices and families have choices and everybody has choices because while it may not resolve the issue of drug use at least it's giving people more choice'. Focus Group – Service Users

Those interviewed also referred to the perceived dangers associated with methadone, such as the risk of fatal respiratory depression in overdose, because of its full agonist properties and the risk of diversion of take-away doses (Mattick et al, 1998). These dangers were especially highlighted by families:

'... a lot of people have difficulties around methadone, you can understand why, because there's the resale value, methadone is another drug, you can die from overdose on methadone, if you take it with alcohol, all that kind of stuff so I think there's a community there that is quite open to looking at this as an alternative to methadone'. Focus Group - Families

These views were supported by a number of service providers:

'...why not offer alternatives that aren't opiate based, that aren't addictive, that can't be resold on the street'. DR

Service providers also identified the fact that lofexidine provides another type of intervention that can be provided to their clients.

'It helps me when I work; it enhances my work, gives me another tool in my toolbox, because I only had methadone or nothing. Now I have methadone or lofexidine'. SMD

4.2.2 Methadone versus Lofexidine

No significant difference in efficacy was detected for a treatment regime based on the α_2 adrenergic agonist lofexidine, and those based on reducing doses of methadone, for the management of withdrawal from heroin or methadone. (Gowing et al, 2004) Participants stay in treatment longer with methadone regimes, have similar or slightly higher rates of completion of withdrawal and experience less adverse effects. Service providers were asked to comment on the challenges that may arise in terms of managing the client for a lofexidine detoxification as opposed to a methadone detoxification. The main issue identified related to the length of treatment, interviewees had conflicting views in this issue. One interviewee stated:

'...methadone would be probably more structured, there's a specific time that you have set out for methadone, the reductions are set out, every body knows what they're doing and their role within it in terms of a professional, the individual patient knows from the outset what's going to happen over the next ten weeks or twelve weeks and they have a clear idea of what they're getting in terms of input. Sometimes with Lofexidine because you're dealing with a much shorter time you have to get things moving a little bit more quickly and sort of address things a little bit more quickly than you would perhaps given the time structure of methadone detox'. EK

Another stated that:

'...a methadone detox is more challenging because it's longer...it's a very long, drawn-out process, and in the meantime too many distractions, too many life situations can happen, there's many risks involved. Whereas with Lofexidine it's a ten day detox so if I have my ten days organised, after ten days I have my rehab organised. Now all I need for the rehab is clean urine, an opiate free urine. I can have that in ten days, and then I can have them go in to rehab'. SMD

4.3 Programme Components

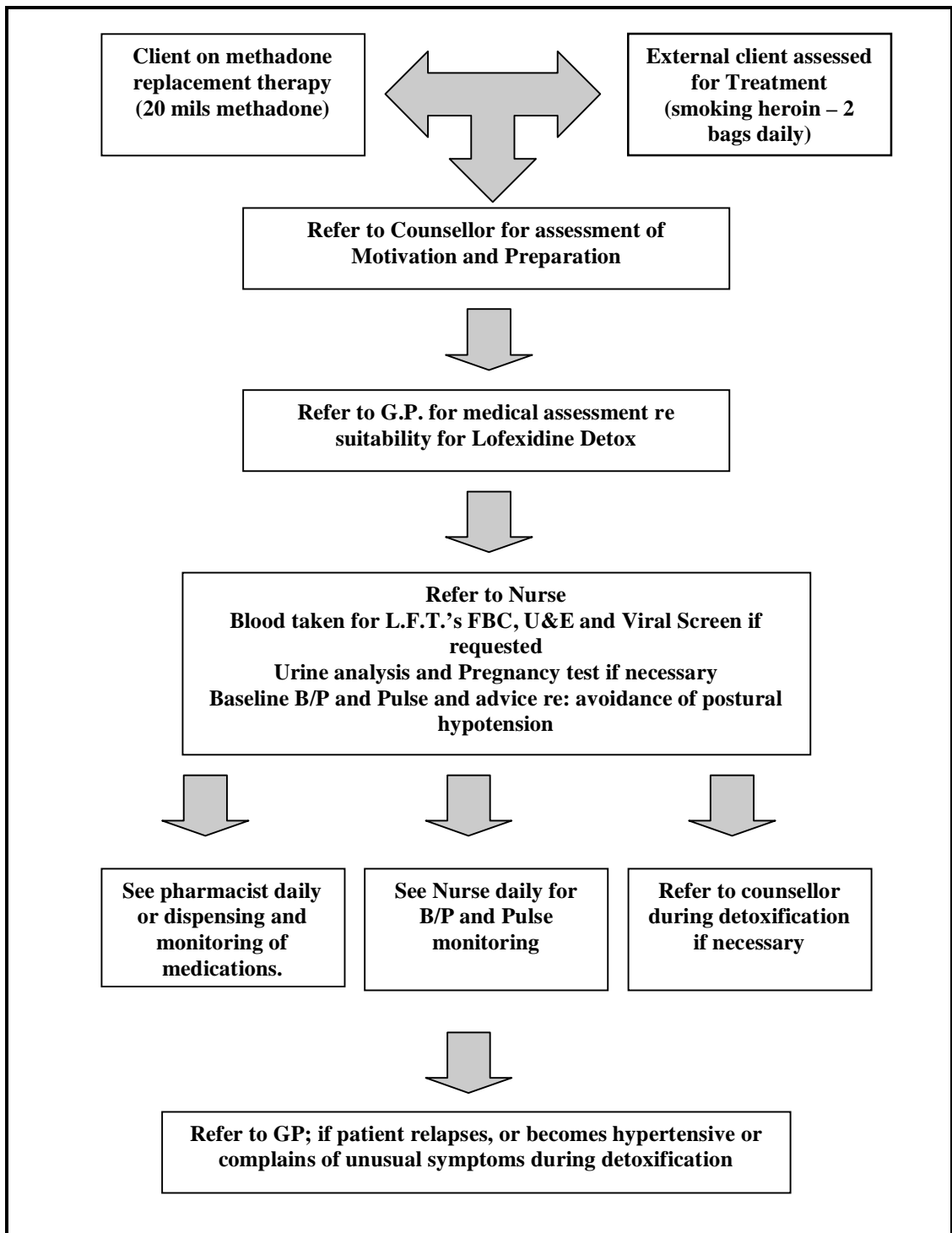
A number of protocols have been developed for lofexidine detoxification. All service providers that participated in this study were adhering to a 10-day regime using 0.2mg lofexidine tablets. Appendix 5 provides the recommended protocol for a 10-day lofexidine detoxification. Figure 2, shown on the next page, surmises the key programme components identified by the key informants for the 10-day regime.

Blood pressure and pulse are checked daily for at least the first 5 days, and clients attended daily at the dispensary during the process. Nursing and counselling staff were responsible for brief initial assessments, urinalysis and physiological monitoring.

Patients are discouraged from working and driving for the 10-day period:

'...it's very difficult on them from a physical point of view cause they're trying to work against the grain and then emotionally, everything else that goes with withdrawing, I would be suggesting that those two weeks are taken off'. AD

Figure 2: Components of a 10 – Day Lofexidine Detoxification Regime



All patients had open access to nursing, pharmacy, counselling or general practitioner if required. The general view of all service providers in relation to the components of the programme can be summarised as follows:

'...it's very simple really in that the most important part I think is the link in and being assessed. Usually either the nurses or the counsellors assess them and if they feel they might be suitable for a Lofexidine they bring it up at the waiting list meeting'. AD

If it is felt that the patient is suitable for the lofexidine programme a medical assessment is carried out by a General Practitioner, and if the client is deemed suitable for a lofexidine detoxification they are initiated on the programme.

'...they usually give three urines and start at the beginning of the week on a Monday because some people are much more sensitive to the hypotensive effect of lofexidine so if they're going to have some kind of a reaction, it would usually be by the third day. So they start off on a Monday on the lowest dose and build up to the highest dose of the tablets to day five and then from day five to day ten you gradually come down. And if they happen to be on methadone then you will gradually bring down the methadone so that by day five when you're on the maximum dose of tablets, you're off the methadone as well'. AD

4.3.1 Treatment Duration

The short duration of lofexidine detoxification was identified by a number of interviewees as being advantageous. One interviewee suggested:

'...the detox doesn't last as long as say three months when it's a methadone detox or a six week detoxification from methadone and in some ways we can fast track them into residential if they're willing'. SMD

While another stated:

'...you can see something happening fairly quickly whereas with the methadone it does take longer...you get a chance to plan to make some strategies for the future, goals for the future'. EP

4.3.2 Ancillary Treatments

Lofexidine does not appear to eliminate withdrawal symptoms completely (especially insomnia and lethargy) and ancillary treatments are unusually necessary. This was made clear when one service provider stated:

'...they're written up for other drugs that they might need, say for any tummy cramps, aches and pains and they do have difficulties with sleeping so I usually would prescribe something which is non-addictive, so you're looking after all the side effects as well that they may get'. AD

4.4 Infrastructural Requirements

Reports from usage in clinical practice suggest that managed withdrawal using lofexidine requires the close involvement of all members of the drug treatment team with the patient during treatment. The need for a skilled multi-disciplinary team was identified by all those interviewed:

*'...as with all of the treatments in terms of withdrawal, you need huge input from your team on a daily basis, so you need the drug support workers, you need the doctors to see them, nurses, the community, they need to be minded very carefully'.
MT*

All interviewees identified that the team should include, a general practitioner, nurse and counsellor. This is supported by the literature, Carroll et al (2001) identified that the minimum infrastructural requirements for lofexidine detoxification are a willing prescriber, an interested pharmacist, and a clinically satisfactory means of monitoring blood pressure.

'...your counselor, it's so important, you would need a GP obviously, that there would be experience and you would probably need a nurse as well. Then there probably will be project workers or outreach workers that are involved in the family set up that would have input on a daily basis, would know the social set up and what supports they have and that'. AD

Carroll et al (2001) went on to state that as in most other addiction treatments, the presence of an experienced counsellor improved both immediate and long term outcome. This view was reflected by all those interviewed:

'...part and parcel of them being in treatment for Lofexidine is that they link in with their counsellor and that's part and parcel of it'. AD

Another interviewee stated:

'...I think if you have counselling built in as part of a program, not issue based counselling, but just counselling that will support somebody through the process and reaffirm their commitment, and reaffirm their motivation, and allow them to talk about how they feel about the process they're going through'. DR

The nurse was identified by all interviewees as having the key role in providing a lofexidine detoxification as they see the patients on a daily basis. One stated:

'...a nurse would have a good inside understanding of the process of addiction, would have worked with an addiction therapist, know the issues which arise, is able to see the warning signals which people give off before they fail, before they relapse or drop out and to be able to engage with that person, work with that person and link that person into the appropriate individuals, be that the doctor, the counsellor or some form of rehabilitation support'. EK

While another commented:

'...I would see the nurse's role as being very much supportive and networking in with the other key parts of the team, the doctor, the pharmacist, or a counsellor'.

MH

4.5 Matching Patients to Treatment

There have been a substantial number of research studies that have attempted to “match” particular “kinds” of patient with specific types, modalities or settings of treatment. The approach to patient-treatment “matching” that has received the greatest attention from substance abuse treatment researchers involves attempting to identify the characteristics of individual patients that predict the best response to different forms of addiction treatments. In general, the majority of these “patient-to-treatment” matching studies have not shown robust or generalizable findings (Gastfriend et al, 1997). Those interviewed identified the need to pick participants very carefully for lofexidine detoxification.

‘...you pick your candidate very carefully for detox and it’s not going to be beneficial for everybody; but in the ones that it is beneficial, and you get them off and that’s fine. They get a chance to get back into society very quickly’. MT

Another approach to matching has been to assess the nature and severity of patients' problems at intake and then to “match” the specific and necessary services to the particular problems presented at the assessment. This has been called “problem-to-service” matching. One study (McLellan, 1997) suggest that matching treatment services to adjunctive problems can improve outcomes in key areas and may also be cost-effective as they reduce the need for subsequent treatment due to relapse. This view was reflected in by the majority of those interviewed. The following quote surmises the general view held by those interviewed in relation to those patients who would benefit most from a lofexidine detoxification:

‘...I think in my experience and looking at the literature who benefits most would be individuals who have a relatively short history of opiate misuse, individuals who would not have been on methadone previously for detoxification, individuals who would have good psycho-social support, ideally living at home with family back up and support in that regard. They wouldn't be injectors, which would be another thing. So it's the younger, more social smokers of heroin who would benefit most’.
EK

4.6 Adverse Effects

The literature identifies that the main adverse effects experienced by patients when using lofexidine include hypotension, dizziness, drowsiness, lethargy, nausea, dry mouth and vomiting (Gowing et al, 2004; Arkhurst, 1999; Arkhurst, 2000; Sheridan et al, 1999). Hypotensive effects associated with α_2 adrenergic treatment occurred much more frequently in the studies than did cessation of treatment because of adverse effects. This suggests that hypotension can be adequately managed by withholding doses and reducing the dose of medication according to blood pressure changes (Goweing et al, 2004). Hypotension was referred to by all service providers, one interviewee stated:

'...hypotension is an issue, although it does not appear to be a major problem in practise, you are looking out for it, you are aware of it, you either reduce the dose or you miss the next dose because you'll be dosing them a few times a day'. MT

All those interviewed identified that adverse effects can occur, but that the intensity or regularity in which it occurs depends on the individual patient.

'...there's no great adverse effect in relation to the drug itself, I've never heard of people coming in, a couple of times maybe, they might have head aches or that but there's no great adverse effects of the drug itself. No one has really come and given out that Lofexidine is this, that and the other, and whoever does it's normally not the Lofexidine at all, it's something, a whole different issue'. MH

The main adverse effect identified by both the service users and service providers was that of a reduction in energy levels.

'...Now the biggest problems - and I try and prepare them for it - is that they will be very draggy. They won't have huge energy levels, but they won't be sick - they just will not have huge energy'. SMD

Service users had conflicting views on the adverse effects experienced, one service user commented that:

'It takes your energy away, that's exactly what it does, it drains you'. Focus Group – Service Users

While, another stated:

'It didn't hit me at all what you are saying, not at all, I did see other people and they were like that on it, I was running around, it took the edge off and that's all I wanted, that's all I expected'. Focus Group –Service Users

It was identified that the multidisciplinary team, particularly the nurse and the counsellor, play an important role in reassuring patients, when they experience adverse effects.

'And it's to reassure for confidence, for a nurse or a counsellor to reassure the person that this is normal. But what I always say to them is - okay, so you're draggy, can you live with that? Yeah they can. It's not a big problem. It's only going to last for ten days. They're not going to be like this in ten days time actually. They're going through the worst of it now, can you manage it? Yeah I can. Are you in pain? No I'm not in pain, it's uncomfortable. Okay, is that bit of discomfort worth being clean for, going through a rehab for? Yeah, it is. That sort of motivation, just to win them through, that they can do it'. SMD

Another interviewee stated:

'...Yeah, the main difficulties were psychological and mood swings and disorientation, I think that's why the counseling was so important because it actually helped people to understand that they weren't going crazy, that what they were experiencing was actually a medical if you like reaction and it was something that would pass in time'. DR

4.7 Rehabilitation/ Relapse Prevention

Rehabilitation or relapse prevention is appropriate for patients who are no longer experiencing the acute physiological or emotional effects of recent substance abuse.

Goals of this phase of treatment are to prevent a return to active substance abuse, to assist the patient in developing control over urges to abuse drugs and to assist the patient in regaining or attaining improved personal health and social functioning.

Withdrawal symptoms, particularly drug craving, may continue to be experienced for weeks, and even months after detoxification, and the period of recovery from dependence is typically lengthy and influenced by a range of factors, both social and treatment related. If used as a treatment entity in its own right, detoxification is associated with a high rate of relapse once the 'withdrawal' period is completed (Mattick et al, 1996). The types of intervention ordered following the acute phase of withdrawal to promote recovery and prevent relapse are substantially different to those offered in the management of withdrawal and may include psychological and lifestyle counselling, support groups and pharmacological and medical treatment (Gowing et al, 2003). All of those interviewed including service users and family members agreed that it was important that lofexidine was part of an integrated care plan for the drug misuser. The views of all interviewees are adequately represented by the following statements:

'...I think if it's part of the bigger care plan, whether that care plan would be going back to training or whether it's going back to full time employment, once it's not just the case of doing detox for the sake of detox'. Focus Group - Families

'You definitely need something to link up to after a detox, a counselor or a key worker someone to just straighten out your head to get a course or something cause you're just going home and sitting around'. Focus Group – Service Users

Residential rehabilitation programmes were identified as an important option available to drug misusers who have completed a lofexidine detoxification, one counsellor described residential rehabilitation as:

'...if a boxer is going into a fight, he goes away and trains and shadow boxes to prepare himself for the big fight. So that's how I look at this. This is shadow boxing; this is imitation, what it's going to be like when you come back here. Give them three month's rehearsal time to build themselves up, they're getting used to the habit of not having a habit, if you like'. SMD

Naltrexone⁷, an opioid antagonist, was identified in both the literature and by those interviewed as an important Pharmacological intervention available to those who have completed a lofexidine detoxification. Those interviewed identified that Naltrexone is particularly useful for those who do not attend a residential rehabilitation programme and remain in the community after detoxification. One interviewee stated:

'...you'd really improve your success rate by using Naltrexone for six to twelve months, particularly if they're going to try and continue to live in their community'. AD

⁷ Naltrexone blocks the effects of opioid drugs; it produces no pharmacological effects of its own.

4.8 Effective Treatment Components

The patient and treatment process variables identified in the literature review as being important in determining outcome from addiction treatment efforts were used to inform the analysis of the finding. The following patient and treatment variables were identified by those interviewed as being important in determining a positive outcome for lofexidine detoxification.

4.8.1 Patient-Related Factors

4.8.1.1 Severity of Substance Use

The literature shows that the severity of patients' substance use patterns have been reliably associated with poorer retention in treatment and more rapid relapse to substance use following treatment (Rouns-Bryant et al, 1999; George et al, 1999). As already highlighted, the majority of those interviewed identified that those individuals who benefit most from a lofexidine detoxification would have a short drug history with low doses of methadone or heroin.

4.8.1.2 Severity of Psychiatric Problems

A consistent finding across many studies and contexts is that severe psychiatric symptoms and disorders at intake to treatment are a reliable predictor of dropout and poorer follow-up outcomes (McLellin et al, 1996). In fact serious personality disorder or psychiatric problems are included in the exclusion criteria for lofexidine detoxification.

4.8.1.3 Treatment Readiness and Motivation

The literature states that patients who report being ready and motivated to receive treatment tend to engage more successfully with the therapeutic programme and stay in treatment for longer periods of time (Simpson et al, 1997). This view was supported by all interviewees. All of those interviewed considered that patients need to possess sufficient motivation for detoxification to be successful. Many interviewees indicated that they would not consider initiating a patient on a lofexidine detoxification unless convinced that the patient's motivation was authentic. One UK based study which looked at the use of lofexidine by Drug Dependency Units emphasised the need to select patients who are committed to becoming opiate free (Arkhusrt, 1999). A common concern expressed by those interviewed was that unless patients were highly motivated to change, the detoxification process would be a pointless exercise.

'...the person who is motivated to detox. That's the whole basis behind it really, and that's what we would be looking at here with people coming in, the motivation behind it. You can have people who may be using what you may consider initially a little bit high and they can do very well because they're actually motivated to detox'.
MH

'...the patient has to be motivated, it's probably the most important ingredient, motivated to beat the band because it's difficult, it doesn't make coming off methadone or heroin easy, it's hard, it eases it a little'. AD

4.8.1.4 Family & Social Supports

Interviewees considered that a patient's environment and social supports can impact greatly on their chance of successful detoxification. As discussed in the literature review, social supports can be defined as the availability of relationships that are not conflict-producing and supportive of the drug misuser. All of those interviewed identified that those drug misusers with a stable supportive environment had the most positive outcomes. One service provider stated:

'...the whole psycho-social support being good is very important, there's no point in trying with somebody who's homeless because it's too chaotic but if somebody is at home and the family are supporting them through the process, in the evening time, the likelihood is that they're going to be able to achieve success more than somebody who doesn't have a good psycho-social background of support'. EK

This view was supported by another service provider, when they stated:

'...those who are in stable accommodation, families are reasonably stable, have supports around - maybe a girlfriend or a boyfriend who is not a drug user or who's stable on methadone'. SMD

The families, who participated in focus group discussions, identified a number of issues that they felt would be important in enabling them to provide adequate support to a drug misuser while participating in a lofexidine detoxification programme. These included:

- **Information** – information regarding lofexidine detoxification was identified as an important aspect by families. It was highlighted that families needed to know what to expect, when their son/ daughter started a lofexidine detoxification. This view was supported by a number of service providers, one stated:

'Sometimes families get nervous because they don't know what to expect, sometimes they feel that their son/ daughter are stoned when they're on it when really what's happening is the neuro-adrenalin is not being produced by the brain anymore, so they haven't got a huge energy, so they look as though they're stoned. So it's preparing families that's important'. SMD

- **Peer Support** – the availability of support from other families/ parents who have had experience of lofexidine detoxification within their home was also identified as being important. One focus group member stated:

'It's a good idea that as a mother you could ring up another mother or father, it would be nice to be able to ask a few questions'. Focus Group – Families

While another, stated:

'I suppose maybe to talk to people that have gone through it as well, a group of people who would have gone through it before with their own family'. Focus Group - Families

- **Family Counselling/ Therapy** - it was agreed that the availability of family counselling/ therapy would support the rebuilding of relationships within the home as well as providing a tool for all involved to explore their attitudes and heal 'old wounds'. One focus group member stated:

'... the old attitudes from the family are still there when people become drug free, the person has actually changed quite a lot within a small amount of time and the family need to move with that as well'. Focus Group - Families

While another focus group member felt that family therapy would support the re-establishment of trust within the home:

'...trying to build your trust up to the same as it was before'. Focus Group - Families

4.8.2 Treatment Related Factors

4.8.2.1 Setting of Treatment

The literature highlighted that for most treatment systems, it is likely that patients who have sufficient personal and social resources and who present with no serious medical complications should be assessed for outpatient/day treatment (Alterman, 1994). This view was supported by all service providers, in fact only clients who present with adequate personal and social resources in terms of motivation and support are considered for a lofexidine detoxification. One interviewee identified that people are selected:

'...in relation first of all to level of dependence, the amount of heroin they're using, the age of the individual, the family support, the living arrangements of the individual'. EK

4.8.2.2 Treatment Completion and Retention

There is a substantial amount of literature to support the assumption that patients who complete treatment will have better outcomes than those who leave prematurely. Both the literature and those who were interviewed identified that there was similar, or slightly less completion rates for lofexidine as opposed to methadone, the only available alternative.

4.8.2.3 Counselling

The UNDCP (2003) identifies that access to regular substance abuse counselling can make an important contribution to the engagement and participation of the patient in a treatment programme and to its outcome. Therapeutic involvement (measured by rapport between counsellor and patient and the patient's ratings of their commitment to treatment and its perceived effectiveness) together with counselling session attributes (the number of sessions attended and the number of health and other topics discussed) have a direct positive effect on retention in treatment (George et al, 1999). The availability of counselling during a lofexidine detoxification programme was identified as an important component, one senior counsellor stated:

'...somebody going to do a detox, they're very focussed. This is a big deal to them. They are putting their cards on the table with their family or with their girlfriend and they're saying to them -I'm going for a detox. It's very serious stuff. So they are coming into me, they want support, so it means they're really engaging with me in a very focussed way, so it's very important'. SMD

Hser (1995) suggests that programme counsellors who possess strong interpersonal skills, are organized in their work, see their clients more frequently, refer clients to ancillary services as needed and generally establish a practical and “therapeutic alliance” with the patient achieve better outcomes. This view was supported by a number of the interviewees, one stated:

'...human contact can make a huge difference, even if I'm not saying a whole lot, just the fact that another human being cares about you, believes in you, and has even got plans for you can make a huge difference'. SMD

4.9 Summary

This chapter provides an overview of the outcomes and main findings of both the semi-structured interviews and focus groups. The findings have been analysed and combined with the relevant literature to identify the key processes and infrastructural factors to be considered in developing a community based detoxification team.

The chapter sets the context by identifying the need for the provision of alternative treatment options to drug misusers. The key components of a lofexidine detoxification programme were identified together with the relevant infrastructural requirements. The chapter concludes with an analysis of the data in order to identify the patient and treatment related factors deemed necessary in determining a positive outcome from lofexidine detoxification. This analysis is summarised below in Table 2.

Table 2: Summary of Patient and Treatment Related Factors – Lofexidine Detoxification

Patient Related Factors	Lofexidine
Severity of Substance Use	It is recommended that entry criteria is limited to individuals with a relatively short opiate addiction who are on low doses of methadone or are smoking and using 2 bags of heroin per day
Severity of Psychiatric Problems	Individuals identified with serious personality disorder or psychiatric problems are excluded from the programme.
Treatment Readiness and Motivation	An assessment of motivation is carried out in the initial stages of the referral process
Employment	It is recommended that those employed take the detoxification period as leave
Family and Social Supports	Client should have a supportive non-drug using partner/ family member and stable accommodation

Treatment Related Factors	Lofexidine
Setting of Treatment	Lofexidine has been identified as being effective in an outpatient basis.
Treatment Completion and Retention	Completion rates for lofexidine are seen to be the same or slightly lower than methadone, the most widely used alternative for detoxification.
Counselling	The availability of counselling is seen as a key component to the programme

The following chapter incorporates the learning and main findings in order to identify an appropriate model, using lofexidine, for a Community Detoxification Team to be implemented in Clondalkin, an urban area where there are high levels of opiate misuse.

CHAPTER FIVE

RECOMMENDATIONS

5.1 Introduction

The aim of this study is to identify an appropriate alternative model for a Community Detoxification Team for implementation in Clondalkin, an urban area where there are high levels of opiate misuse. Its objectives were to:

1. To document the nature and extent of existing non-methadone based detoxification services using the α 2-adrenergic agonist lofexidine;
2. To identify a range of models of good practice at local, national and international level;
3. To identify appropriate protocols in which a Community Detoxification Team should operate; and
4. To identify an appropriate operational model for a Community Detoxification Team, taking account of the current structure of health care delivery in Ireland

These objectives have been met through the use of qualitative research methods, in which 20 people participated in two focus groups, while 11 participated in individual semi-structured interviews. This chapter outlines the recommendations and conclusion as drawn from the completed study.

5.2 Implications for Practice

Lofexidine is a central α_2 agonist, similar to Clonidine but without the risk of hypotension at significantly high doses. Simply said, it suppresses the chemicals which produce the acute withdrawal symptoms clients experience when they are detoxing from opiates. Both the literature and findings have identified that when used in the management of opioid withdrawal, lofexidine is typically administered orally, in three or four doses per day, to a maximum of around two milligrams per day. The primary clinical advantage for lofexidine is its efficacy and safety for rapid opiate detoxification, together with the fact that the drug has little or no abuse potential.

Lofexidine has not yet been used in a community setting in Ireland, thus it is recommended that a Community Detoxification Team be established on a pilot basis for a twelve month period.

5.3 Community Detoxification Team Model

In considering the main findings in the previous chapter, it is recommended that the community detoxification team be made up of a Co-ordinator, Drugs Worker, Nurse and GP. It is envisaged that the Drug Worker will have counselling skills. The team and the client will also require the assistance of a support person; typically this person will be a partner or family member. Their roles and responsibilities include:

- **Community Detoxification Co-ordinator** – co-ordinates and manages the day to day running of the programme. He/ she will facilitate and develop the linkages within the overall team to ensure consistency and continuity of detoxification regime;
- **Drug Worker** - provides information to both the client and the support person about the course of the withdrawal process; helps to identify and establish goals; provides education more broadly about drugs and drug use according to need, visits the client on a daily basis; re-assesses goals and

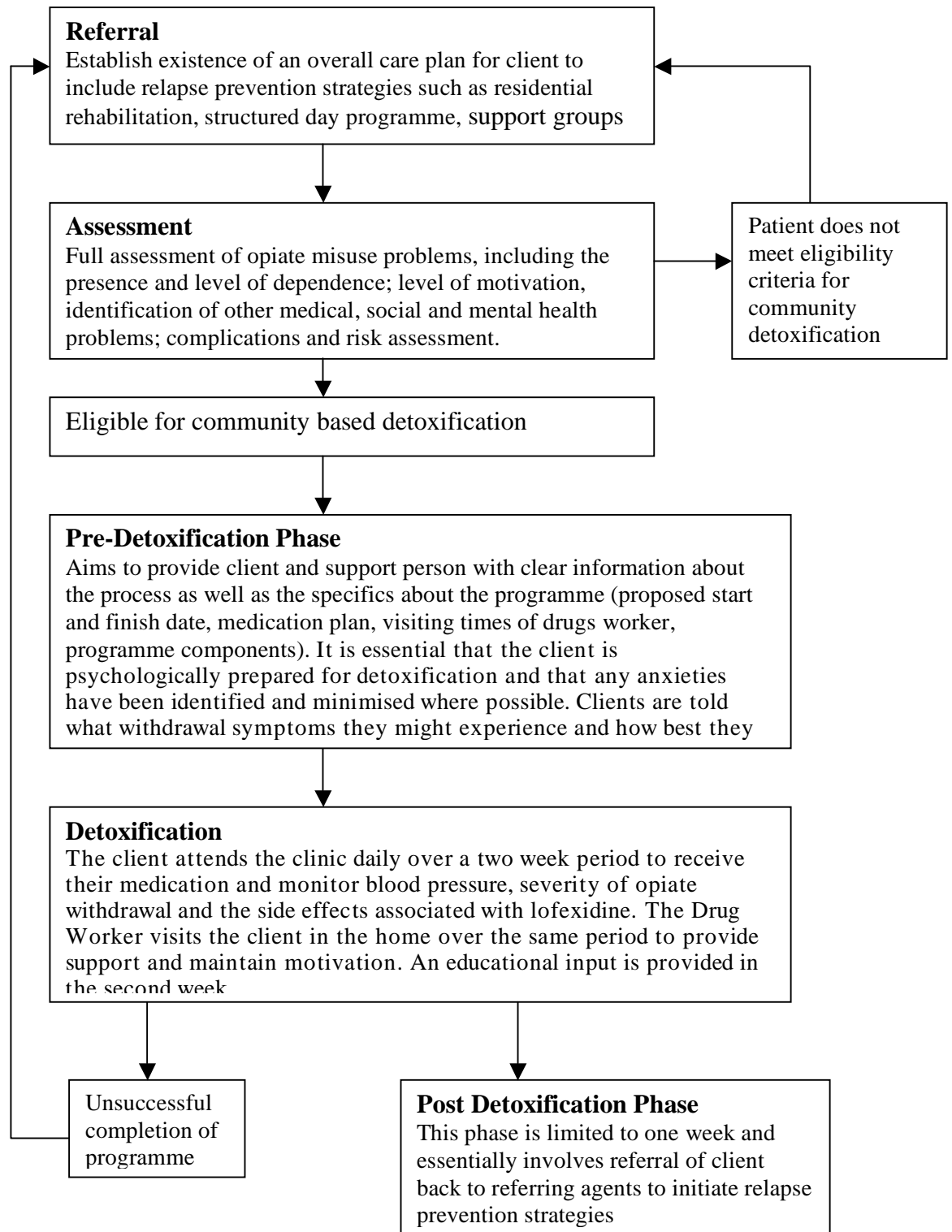
interventions if drug use resumes before the completion of withdrawal, provides linkage to post-withdrawal support

- **Nurse** – assess blood pressure; monitors the effect of medications; and contacts GP should any complications arise during withdrawal.
- **General Practitioner** – The GP carries out a medical assessment of clients' health to assess suitability for lofexidine detoxification, as per agreed protocols. He/ She initiates the clients' detoxification by prescribing both the lofexidine and appropriate symptomatic medication. They are also available should a client experience any adverse reactions. Conducts diagnostic testing, feedback results of testing to clients. Reviews symptomatic medication if required.
- **Support Person** – the support person agrees to provide emotional, and if necessary physical support to the client. This may include things such as sharing activities to distract from the withdrawal process, or giving massage, running baths and lifting and fetching. The support person will often also be asked to take responsibility for storing withdrawal medications and providing them to the client at the appropriate times.
- **Client** – the client commits to abstaining from the consumption of un-prescribed drugs and alcohol for the duration of the withdrawal period. They agree to discuss any drug use lapses with the drug worker, as well as any urges to use and difficulties encountered in the withdrawal process.

5.4 Community Detoxification Programme

It is proposed that the community detoxification programme will take place over a four-week period. The programme will begin with a pre-detoxification phase in week one, followed by the medical detoxification in week two and three, and finally the post detoxification phase occurs in week four. Figure 3, shown below, outlines the proposed integrated care pathway for the Community Detoxification Team.

Figure 3: Integrated Care Pathway – Community Detoxification Team



5.4.1 Referral

Clients are referred from locally based service providers. At the referral stage it is important to focus the client on what they will do after the detoxification, and not allow them to see the detoxification process as the "cure" to their dependence. Thus it is important to establish the existence of an overall care plan for the client to include relapse prevention strategies such as residential rehabilitation, structured day programmes or support groups. It is the responsibility of the referral agency to ensure that this plan is in place.

During the referral, other significant aspects of the client's life are reviewed and appropriate support is provided by the referral agency where applicable. It may be necessary to help the client with benefit or housing problems, in order to help stabilise their lives before the community detoxification. It is important at this stage to be realistic with the client in terms of attainment of goals. The goal of the community detoxification is a short term, specifically focused task of obtaining a drug free status. More medium and long term goals are viewed as being part of the remit of the referral agency.

5.4.2 Assessment

Referrals are assessed in a thorough manner to determine whether they meet the strict criteria for receiving the intervention. Table 3, shown on the next page, identifies the suggested indicators applied to clients requesting detoxification using lofexidine. Note that the negative column does not necessarily exclude a client, it means that extra caution should be exercised during the programme. However in the case where the client is pregnant lofexidine should not be used in the community.

Table 3: Lofexidine Detoxification Indicators

Positive Indicators	Negative Indicators
Motivation	Unstable/no accommodation (hostel etc.)
Stable accommodation 24 hour support	No support/ support from drug user
Systolic blood pressure 90 hg or above	Systolic below 90 hg
Good mental health	Clinical depression. Suicidal
Good physical health	Poor LFT (Hep. B/C+)/Pregnancy

The initial assessment is conducted by a drug worker. Information is collected on the drug and alcohol history of the client, dependency level, state of physical and psychological health, and motivation level. The major concern is safety, so the drug worker will conduct a risk assessment and look for any contra-indications. If deemed suitable the client is referred to the GP for a medical assessment. There are several key factors that should be considered in determining suitability. Table 4 identifies the inclusion and exclusion criteria that should be considered when assessing a client for community detoxification.

Table 4: Inclusion and Exclusion Criteria – Lofexidine Detoxification

Inclusion Criteria
<ul style="list-style-type: none"> • Clients must be well motivated; • They must express a clear desire to detoxify and agree to comply with the instructions of the community detoxification team; • Clients must have a supportive environment; and • The client must have no concurrent mental or physical health problems that may be exacerbated by the withdrawal process
Exclusion Criteria
<ul style="list-style-type: none"> • Pregnancy • High levels of heroin or methadone use including polydrug users • Major heart, liver or respiratory problems • Serious personality disorder or psychiatric problems

5.4.3 Pre-Detoxification Phase

The pre-detoxification phase aims to alleviate any concern the client or support person may have and to make practical suggestions as how to support can be given or received. Clear information is provided about the process of home detoxification, as well as the specifics about the particular detoxification to take place (e.g. proposed start and finish date, medication plan, visiting times of the drug worker, information about what to do in case of emergency). It is essential that the client is psychologically prepared for detoxification and that any anxieties have been identified and minimised where possible. Clients are told what withdrawal symptoms they might experience and how best they might deal with them. They are also talked through what to expect once the detoxification is complete.

5.4.4 Detoxification Programme

The medical aspect of the programme will begin in week two using a 10-day lofexidine detoxification regime (see Appendix 5 for protocol). The client attends the clinic for the first five days to receive their medication and monitor their blood pressure. Severity of both opiate withdrawal and the side effects associated with lofexidine are also monitored using a rating scale filled in by client and by the observation of physical signs (see Appendix 6 for scales). The nurse also determines the level of appropriateness of medication. Any medical problems during the detoxification are reported immediately to the GP.

The drug worker visits the client in their home during the same period, at a time when medication levels are at their highest and clients are experiencing most discomfort and psychological difficulties. During the drug worker's visits, motivation is also looked at and worked on, encouragement and support is given to the client and the support person.

It is envisaged that most service users will start to feel the benefits of the detoxification by the end of the first five days. The drug worker visits the home at the start of the second week and generally two or three times more that week. The client will continue to attend the clinic on a daily basis to receive educational inputs on areas such as the process of addiction, power and powerlessness, decision making and co-dependence.

5.4.5 Post-Detoxification Phase

Contact is made with the initial referral agency to initiate relapse prevention work. Although relapse prevention work is initiated during the pre-detoxification phase, much of this work is carried out post-detoxification. The relapse prevention program is dependent upon the individual's circumstances. It may include residential rehabilitation programmes, structured day programme or support groups

If a detoxification is not completed by a client it is considered as a learning experience. If another detoxification is to be considered then assessment will include evaluation of changes in behaviour taking into account the previous attempted detoxification.

5.5 Monitoring and Evaluation

Outcomes of the pilot phase should be assessed in terms of severity of withdrawal experienced by the clients, retention in treatment, completion of withdrawal and occurrence of adverse effects - in terms of amelioration of the signs and symptoms of withdrawal, retention in treatment, capacity to support completion of withdrawal, and the occurrence of adverse effects - including lethargy, fatigue, dry mouth and hypotensive effects. Also, qualitative data should be collected in respect of both the clients' and support persons' views and perceptions of the effectiveness of lofexidine.

5.6 Recommendations for Research

A paucity of information exists in respect of a number of key areas related to the use of lofexidine in the management of opiate withdrawal. A pharmacoeconomic analysis is required of the impact of introducing lofexidine as an alternative to methadone in the management of opiate withdrawal in Ireland. There are two features that characterise pharmacoeconomic analysis. Firstly, it determines both the input (costs) and output (consequences) resulting from drug intervention. Second, economic analysis concerns itself with choices as resource scarcity necessitates that choices must be made. As a result, pharmacoeconomic evaluation is frequently a comparative analysis of alternative courses of action (in this case methadone versus lofexidine in the management of opiate withdrawal) in terms of their costs and consequences.

Comparisons between reducing doses of methadone and lofexidine could be improved. The possible introduction of bias through prolonged periods of administration of placebo should be avoided, and outcomes should again be assessed in terms of severity of withdrawal, retention in treatment, completion of withdrawal and occurrence of adverse effects - in terms of amelioration of the signs and symptoms of withdrawal, retention in treatment, capacity to support completion of withdrawal, and the occurrence of adverse effects - including lethargy, fatigue, dry mouth and hypotensive effects.

With the increasing popularity of buprenorphine, and the potential effectiveness of this drug in the management of heroin withdrawal (Gowing et al, 2002), further comparisons of lofexidine with buprenorphine regimes would be of value. In particular it would be of interest to compare lofexidine and buprenorphine in an outpatient setting given that both drugs are considered suitable for this setting, lofexidine because it has less hypotensive effect than clonidine, buprenorphine because it has a lower risk of overdose than methadone.

There remains uncertainty as to the nature of withdrawal signs and symptoms that are not significantly ameliorated by treatment with alpha₂ adrenergic agonists. This is a further area of potential investigation, with value lying in exploration of adjunct medications to address those symptoms that are of significance to patients. These are likely to include sleep disturbances, anxiety and aches and pains, aspects suggested

by studies included in this review to be incompletely suppressed by both α_2 adrenergic agonists and reducing doses of methadone.

It would be of interest to directly compare the efficacy of lofexidine in managing withdrawal from heroin and withdrawal from methadone. In particular, it would be of interest to determine whether outcomes differ for patients withdrawing after a prolonged period of methadone maintenance treatment, as opposed to a short period of stabilisation on methadone prior to detoxification, or illicit use of methadone. Given that people who are dependent on heroin or methadone are likely to also use other drugs, particularly benzodiazepines, cocaine and alcohol, it would also be of interest to investigate the efficacy of lofexidine when polydrug use is involved.

5.7 Conclusion

Lofexidine is not an opiate and has no role to play outside the detoxification context, and very many injecting opiate misusers will continue to need methadone maintenance therapy. Potential clients and community organisations need to understand that the product is not something which cures opiate addiction. Lofexidine is no wonder drug, but is most useful when used in a planned and considered manner. We are now in a position to start providing other treatment modules for opiate addiction. The future will offer us the challenge to develop/improve the protocols for delivering the drug and to explore the settings in which the drug can usefully be prescribed.

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APPENDIX 1

Summary of Lofexidine Studies included in Cochrane Review “ α_2 -adrenergic agonists for the management of opioid withdrawal” (Gowing et al, 2004).

Study	Type	Numbers	Doses**	Comparator	Results
Bearn et al, 1996	RCT db	42 Lofex; 44 Meth; on heroin +/- meth	Lofex: 0.6mg/d increasing by 0.4mg/d until day 4; max dose of 2mg/day x3d + tapering x3d	Meth: variable start dose ↓ x10d	“Broadly equivalent” but more w/d symptoms with lofex early in treatment. No BP problems
Bearn et al, 1998	RCT	22 Lofex (1) 20 Lofex (2) 19 Meth; on heroin +/- meth *(All subjects stabilised on meth prior to w/d treatment)	(1) Lofex 0.6mg/d ↑ to 2mg/d tapered to zero by d10 (2) Lofex 1.6mg/1d; 1mg/x3d; 0.6mg x 1d	Meth variable start dose ↓ x10d	Overall similar rates of completion. (1) lofex achieved earlier detoxification. No BP problems
Carnwarth et al, 1998	RCT db	26 Lofex; 24 Clon; (+10 left trial before treatment on heroin +/- meth)	Lofex 0.6mg/d ↑ to 1.6mg/d Then ↓ over 3d to zero at d12	Clon 0.2mg/d ↑ to 0.8mg/d then ↓ x 3d to zero at d12	17/26 + 12/24 completed treatment (ns). More hypotension with Clon.
Howells et al, 2002 Unpublished at time of Cochrane review	RCT db	32 Lofex; 36 Meth; (8 who were randomised not included); “opiate- dependent” non-specific	Lofex 0.6mg/d ↑ X 0.4mg/d to 2mg/d x3 ↓ 0.4mg/d x3 (10 days)	Meth 30mg x 1d ↓ x 5mg every second day to zero by d10	No significant difference in symptoms.
Kahn et al, 1997	RCT db	14 Lofex; 14 Clon; all stabilised on meth	Lofex 0.4mg/d ↑ to 1.8mg/d if necessary. Tapered to zero by d18	Clon 0.2mg/d ↑ to 0.9mg/d if necessary. Tapered to zero by d18	No significant difference in completion rates but lofex caused less hypotension.
Lin Et al, 1997	RCT Db	40 Lofex; 40 Clon; on heroin	Lofex 0.8mg x 1d ↑ to max of 1.6mg/x2d then tapered to zero	Clon 0.3mg x 1d ↑ to max of 0.8mg x 2d then tapered to zero	No significant difference in completion rates but lofex caused less hypotension.

**Lofexidine usually administered in divided daily doses

Lofex = Lofexidine

db = double blind

Clon = Clonidine

w/d = withdrawal

Meth = Methadone

BP = blood pressure

RCT = Randomised Controlled Trial

APPENDIX 2

FOCUS GROUP QUESTIONS

- 1. What do you think about lofexidine detoxification**
- 2. What do you see are the advantages of lofexidine detoxification**
- 3. What do you see are the disadvantages of lofexidine detoxification**
- 4. What supports do you feel are required for:**
 - Families**
 - Drug Users**

APPENDIX 3

SERVICE PROVIDER & SERVICE USER SEMI-STRUCTURED INTERVIEW QUESTIONS

- 1. How many clients have undergone a Lofexidine Detoxification**
- 2. From your experience who do you feel benefits most from Lofexidine Detoxification**
- 3. How are clients selected for the programme, is there a clinical policy**
- 4. Can you describe the components of the detoxification programme (staffing etc)**
- 5. Were there any additional supports provided or available during the detoxification (i.e. external voluntary agencies, key working)**
- 6. Did the participants experience any difficulties during the programme**
- 7. What challenges does operating a Lofexidine Detoxification programme present you as a service provider**
- 8. Did any difficulties arise in terms of managing the client for a Lofexidine detoxification as opposed to a methadone detoxification**
- 9. What works well in Lofexidine Detoxification**
- 10. What does not work so well in Lofexidine Detoxification**
- 11. Is cost an issue in providing Lofexidine**

SERVICE USER SEMI-STRUCTURED INTERVIEW QUESTION

- 1. Were did you do your Lofexidine detoxification**
- 2. How long did you have to wait for a Lofexidine Detoxification (Was time factor important contributor for choosing Lofexidine)**
- 3. What happened while you were waiting (i.e. active use, attend counsellor)**
- 4. What sort of waiting time would you think was acceptable to you**
- 5. How long was your Lofexidine detoxification**
- 6. What was involved (i.e. day programme, structure)**
- 7. What additional supports were provided**
- 8. Were they enough, if not what would have helped you**
- 9. What role did your family play, if any? How important was their role?**
- 10. Do you feel it was successful, Why**
- 11. What was good about your Lofexidine Detoxification**
- 12. What was not so good about it**
- 13. Have you had experience of methadone detoxification?**
- 14. How did that experience compare to Lofexidine**
- 15. Which approach benefited you most, why?**

APPENDIX 4

CONSENT FORM

The Clondalkin Drug Task Force in its consultation process for its Area Action Plan 2001 identified the limited capacity of existing detoxification services in the Clondalkin area to respond to the need for non-methadone based treatment. In response the Task Force proposed the establishment of a Home Detoxification Team based on a model of good practice identified from other areas

I agree to participate in this study and am aware that all information given in this interview will be strictly confidential. My name will only be used on this consent form and the identity of each interviewee will only be available to the research staff.

Signed: _____ (Interviewee)

Signed: _____ (Interviewer)

Date: _____

APPENDIX 5

LOFEXIDINE COMMUNITY DETOXIFICATION PROTOCOL 10-DAY REGIME

Lofexidine Detoxification Protocol

- (i) A 10 day detoxification programme using Lofexidine 0.2mg tabs/Symptomatic medications (as below)
- (ii) Dispensed daily
- (iii) The patient attends the clinic daily to see the Nurse/Counsellor for Blood Pressure/Pulse, Respiration Monitoring, Support and Advice.
- (iv) A patient is advised to use no drugs (including cannabis/alcohol) and to take their last dose of methadone/heroin the day before they start.)

Patient Selection

Entry Criteria

- Patients showing a firm intent to become drug free
- Heroin smokers or users with a relatively short heroin habit and low level of use
- Those who have weaned down to a low level of methadone (20mls) and wish to detox
- Ideally a patient will have a supportive non-drug using partner/family member or friend
- Urines + ve for opiates (+ve for benzo's, cocaine etc)
- BP and pulse within normal limits
Sys. B.P. > 90mm hg
PR > .50

Exclusion Criteria

- Pregnant
- Poly drug users or heavy alcohol consumption
- Serious personality disorders or psychiatric problems
- Medical Hx
 - Heart Dx
 - CVA
 - Raised L.F.T.'s
 - Renal failure

Dosage & Administration

- This may be increased by increments of 0.2mgs – 0.4mgs per day up to: Max of 2.4mgs (12 tablets) per day
- Duration of 10 days is recommended
- At the end of treatment dosage should be reduced gradually over 2-4 day period

Tab Dispensing for 10 days

Day	Frequency	Tablets
1	1 1 1	3
2	2..2..2	6
3	2..2..3	7
4	3..3..3	9
5	3..3..4	10
6	3..3..4	10
7	3..2..3	8
8	2..2..3	7
9	2..1..2	5
10	1..1..1	3
	Total	68

Supportive Medications:

- Buscopan 10mgs tds/ Hyoscine (stomach cramps) up to 6 tabs daily
- Ponstan 500mg tds/ Mefenamic Acid (arthraigia)
- Zimovane 11 nocte (Hypnotic) 7.5g tabs
- Lomotil (diarrhoea) 2.5mg – up to 8 daily

During Detoxification

- If BP <90/60 then,
 - Stop
 - Withdraw gradually 2-4/7
 - Withhold
- If BP 30% from baseline or pt develops physical symptoms – omit next dose and seek medical advice
- If HR <55BPM/60BPM – do not proceed/withhold dose
- If pale/sweaty/faint and BP <90/60HR <55BPM. Call a doctor a.s.a.p
- If BP diastolic >30mmhg seek medical advice
- Day 1/2/3 until max. dose reached stay @ clinic min. 2-3 hours
- Start on a Tuesday
- Day 1/2/3/4/5
- Monitor – Bp 10/15/30/60.120 minutes. H.R as above and SSA card
- Offer quiet area to sit

APPENDIX 6

LOFEXIDINE SIDE EFFECTS SCALE

Name: _____

Date: _____

Rate each symptom using the following scale:

0 = nil

1 = mild

2 = moderate

3 = severe

Day	1	2	3	4	5	6	7	8	9	10
Dizziness										
Difficulty concentrating										
Feeling faint										
No energy										
Drowsiness										
Headache										
Dry mouth										
Total score										

SEVERITY OF OPIATE WITHDRAWAL SCALE

Name: _____

Date: _____

Rate each symptom using the following scale

0 = nil

1 = mild

2 = moderate

3 = severe

Day	1	2	3	4	5	6	7	8	9	10
Feeling sick										
Stomach cramps										
Muscle spasms										
Feeling cold/gooseflesh										
Sweating										
Heart pounding										
Muscular tension										
Aches & Pains										
Weakness										
Yawning										
Runny eyes										
Difficulty sleeping										
Total score										

B.P										
Pulse										