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PRESCRIBING METHADONE

**By Duncan Raistrick, Christine Godfrey, Alastair Hay,
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YARTIC OCCASIONAL PAPER 7

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EXECUTIVE SUMMARY

- ☐ Consideration is given to adopting local prescribing policies, at least until such time as a wider consensus on the objectives of methadone prescribing is agreed.
- ☐ In determining local policy objectives a balance is struck between prescribing in support of social and public health gain against the possible conflict with individual gain: the correct balance will depend upon the value given to different elements of policy at different times.
- ☐ A hierarchy of methadone programmes aimed at the needs of different individuals is proposed. Methadone programmes and detoxification protocols are defined.
- ☐ Prescribers have a responsibility to balance cost and patient convenience against safety and risk of leakage onto the illicit market when setting the frequency of methadone dispensing.
- ☐ Prescribing style is an important factor in determining compliance which is, additionally, checked by urinalysis and plasma methadone measurements.
- ☐ Training reflects local policy and service provision.
- ☐ Training for general practitioners comes primarily from medical practitioners, focuses on interventions which are realistic at the primary health care level, and is conducted at times convenient to general practitioners. Training has PGME validation.
- ☐ Costs of methadone programmes vary markedly depending particularly upon frequency of dispensing, therapeutic input, and monitoring of compliance.
- ☐ There is an enormous potential for shifting costs and benefits of methadone programmes between health care, social care, the criminal justice system, families and individual drug users. Programme evaluation is complex.
- ☐ Evaluation of methadone programmes combines clinical and econometric outcomes.

THE ISSUES

Introduction

Behind every prescribing decision there should be a clear understanding of how the chosen medication works and its expected efficacy. Writing a prescription for methadone demands the same clinical rigour as writing a prescription for any other drug. There is, however, a problem in that the purpose of substitute prescribing is controversial and vigorously debated even within the addiction field: essentially the question is whether prescribing methadone is an act in support of a social and public health policy, or, alternatively, a medical treatment for individual opiate users. Confusion, sometimes obfuscation, exists at both policy maker and practitioner levels.

The key issues considered here are:

- The changing character of the 'British System'
- Prescribing as social policy or individual treatment
- Reducing harms
- The addictive potential of methadone
- Types of methadone programmes

The 'British System'

The so called 'British System' refers to the framing of legislation in the UK which allows doctors tremendous freedom in the way they prescribe for patients with substance misuse problems. This is in contrast to most other countries where strict protocols prevail, particularly within methadone programmes, defining such details as maximum permitted doses, preparation of the drug, method and frequency of collection, and so forth. Further, most countries outside the UK proscribe the use of diamorphine and injectable preparations as treatments for opiate dependence. Doctors in the UK have always enjoyed a large measure of clinical freedom and those specialising in the treatment of dependence have argued in favour of retaining this freedom and having available as wide a therapeutic repertoire as possible, including diamorphine and injectable preparations, at

least until such time as research demonstrates unequivocally that these treatments have no place. (Strang et al, 1994).

Few doctors would argue against clinical freedom, but most are cautious in identifying clinical responsibility. Clearly, prescribing opiate drugs, which are of themselves dangerous not least because of their dependence potential and risk in overdose, but also because of illicit use and major involvement in criminal activity, cannot be compared to prescribing aspirin or penicillin: most people favour strict controls and expect doctors to play a part in restricting availability. Arguments in favour of 'the unthinkable', the legalisation or, in some way, the decriminalisation of heroin use have gathered momentum in recent times, but are far away from political agendas, and indeed are the antithesis of government policy, which has been robustly restated in the green paper Tackling Drugs Together (1994). What seems to have been missed is that heroin, cocaine and other powerful drugs are already available legally on a doctor's prescription. So, the policy question is:

Are doctors capable of self regulation within the 'British System' which allows the legal supply of heroin, methadone and other opiates?

If the answer is *yes* then the roles of specialists and general practitioners treating addicts need clarification. If the answer is *no* then the role of policy makers in further controlling the prescribing of opiates needs clarification. In practice the addiction field has been small enough for specialists and a number of interested general practitioners to achieve some conformity and regulation of prescribing policy. The Substance Misuse Section of the Royal College of Psychiatrists and the Society for the Study of Addiction have been particularly important in providing arenas for productive debate. However, as the number of specialists, many of whom are part time, increases and general practitioners are expected to contribute ever more to the treatment of addicts, then so regulation by networking and consensus becomes more problematic, and the damaging influence of the maverick and the ill prepared doctor gains exposure to a wider audience. One quick solution, and perhaps a last opportunity to hold onto the benefits of the 'British System', is to establish local prescribing policies supported by local health care purchasers. Local policies can reflect the very different patterns of drug use that exist in the UK.

The Rolleston Committee (Departmental Committee 1926) established the principles that underpin what is still known as the 'British System'. The Committee's report concluded that addiction to opiates is a medical problem with the implication that it is proper to prescribe:

- i) to effect a gradual and complete withdrawal from opiates
- ii) where complete withdrawal has failed and severe withdrawal symptoms are experienced in the absence of opiates
- iii) where an individual is capable of leading a useful and normal life when prescribed a minimum dose of opiate, but not when opiates are discontinued.

The emphasis given to different elements of the Rolleston principles has fluctuated over the years under pressure of fashion and of crisis rather than research. Interestingly maverick doctors are frequently implicated in policy shifts and have undue influence on change whether for better or worse. In a fascinating historical account Spear (1994) describes the prescribing habits of a small number of general practitioners in the 50's which acted to catalyse calls for a review of the 'British System', and in particular the role of the general practitioner. The following extract gives a good feel of the problems facing Home Office Inspectors at the time and is reminiscent of rogue prescribers today:

“Thereafter until his (the patient's) death he continued to be a patient of both doctors and in the period 27 August 1954 until 19 January 1955 he received 38 NHS prescriptions from Dr Maguire for a total of 3750 tablets of heroin and 47 NHS prescriptions for a further 3005 tablets from Dr Rourke. On five occasions prescriptions were issued by both doctors on the same day.”

Policy was reviewed and in 1961 the Brain Committee reported. The first Brain Committee found no cause for concern, but was hastily reconvened and the second Committee reported in 1965. On this occasion wide ranging recommendations became law and were ultimately consolidated in the Misuse of Drugs Act 1971 which remains the principle legislation governing drug policy. The act defines regulations for the production, possession and use of specified drugs. Important implications for prescribers are that:

- i) only doctors licensed by the Home Office can prescribe diamorphine, dipipanone or cocaine to addicts for the treatment of dependence (any doctor can prescribe methadone).
- ii) the Home Office can take away doctors' prescribing rights.
- iii) doctors are obliged to notify the Home Office of patients they believe to be dependent on a specified list of drugs which in effect is cocaine and the potent opiates.
- iv) the establishment of the Advisory Council on the Misuse of Drugs (ACMD), which gives expert advice to ministers, who, in turn, have power to vary regulations pertaining to drug misuse without recourse to legislation.

In the 1960s and 1970s, and following on from the second Brain Committee's recommendations NHS Drug Dependency Units were established with a virtual monopoly on the treatment of illicit drug use. However, in 1982 the ACMD published its Treatment and Rehabilitation Report; this was the first in a series of influential reports (ACMD 1982, 1988, 1993), which largely reversed the policy of the previous two decades by re-establishing general practitioners as major agents of treatment and promoting both voluntary and statutory sector Community Drug Teams. In the 1980s the UK experienced a marked increase in the number of opiate users and also an awareness of HIV risk among drug users. The government response was to link central funding initiatives to the earlier ACMD reports, which created exponential growth of drug and HIV services. The result has been an impressive public health success story as far as containing the spread of HIV is concerned. Success has, quite rightly, been attributed to the dominance of a harm reduction philosophy throughout the 1980s and early 1990s, but the policy question for the late 1990s has shifted:

How much harm reduction is too much? What in the late 1990s, is the right balance between public health and individual treatment?

Social Policy and Individual Treatment

Prescribing methadone as a social policy measure is not necessarily incompatible with prescribing for individual treatment; social policy prescribing can be characterised as having the reduction of crime and prevention of the spread of infectious diseases by IV use as its main objectives, while

individual treatment aims to reduce opiate dependence and its harmful consequences to the individual by gradually moving towards a drug free state.

Supporters of prescribing as an individual treatment are likely to conceptualise opiate dependence as a psychological state rather than an illness, but, crucially, a state which is inconsistent with mental health. From this perspective it is unethical to prolong dependence by prescribing methadone in higher doses than necessary for longer than necessary. It is implicit that, to succeed in treatment, individuals will need to make significant lifestyle changes and, additionally, difficult psychological problems may need to be dealt with. It would normally be expected that if 'treatment' failed it would be discontinued.

Supporters of prescribing as a social policy measure are likely to conceptualise opiate dependence as an illness, or as a deficiency state, or to use a public health model of addiction; from these viewpoints the nature of dependence is irrelevant and what matters is that there is little expectation of an individual being able to change their drug use. It follows that long term, high

dose prescribing of oral methadone or possibly higher tariff drugs is indicated in order to achieve the desired social and public health gains.

Characteristics of Prescribing for Social or Individual Gains		
	Social Policy	Individual Treatment
Opiate Dependence	maintained	reducing
Psychological Well being	improved	variable
Criminal activity	reduced	variable
Safe Drug Use	increased	increased
Expected overall change	moderate	high
Culture Shift	drug using orientation	non-using orientation
Duration	> 5 years	< 2 years
Programme failures	low	moderate
Cost	high	moderate

In the real world doctors working outside structured methadone programmes are pragmatists and try to get maximum benefit from prescribing by a series of *stabilise-and-deal-with-problems-then-reduce-methadone* steps. Initially this works well: methadone often

brings about a dramatic improvement in physical and mental health, as well as reducing criminal behaviour. The problem arises when progressive reductions in methadone are accompanied by a relapse into illicit opiate use. This is the time when the purpose of prescribing can seem confused because the social and individual goals become two conflicting objectives: the question is whether or not the prescribing is now a failed 'individual treatment', or whether prescribing should continue, possibly at increased dosage, to reduce the probability of high risk drug using behaviour or criminal activity.

Methadone programmes that have a single objective, rather than allowing clinicians to achieve the optimal result across all outcome objectives, might pose difficult questions for the NHS internal market. Suppose a criminal justice system purchaser wanted to buy a prescribing programme solely to reduce criminal activity: in order to maximise this single outcome, prescribing would probably be high dose, long duration and include high tariff drugs such as diamorphine and injectable preparations. Such a strategy would be at the cost of health gain in terms of reducing dependence, but without necessarily reducing high risk drug use behaviour. Purchasers need to see substitute prescribing as a package and resist contracting for gain in one area at the cost of another. Equally purchasers need to be informed of the limitations of methadone prescribing, recognising that there are individuals for whom prescribing may achieve nothing.

Reducing Harm

Prescribing for 'social policy' and 'individual treatment' both aim to reduce harm: the difference is that the former requires and expects little change in substance use behaviour by the individual. The 1980s saw a shift to 'social policy' prescribing as one measure to prevent the spread of HIV infection and in the process the philosophy of *harm minimisation* was reinvented, but without agreement on its real meaning.

Purists would argue that harm minimisation should not require *any* change in the use of the substance itself, otherwise how does harm minimisation differ from treatment? Examples of pure harm minimisation strategies are needle and syringe exchange schemes, and hepatitis B vaccination. Stimson (1994) adopts harm minimisation as a political construct embracing an

hostility to doctors and an acceptance of prescribing to meet users' perceived need for drugs. Raistrick (1994) has argued that the polarisation of the drugs field caused by the politicisation of harm minimisation philosophy is unhelpful, fails to recognise the purpose of NHS prescribing clinics, and, taken to extreme, pressurises doctors to over prescribe by preventing constructive dialogue as to the purpose of prescribing from the viewpoint of the health care system. In short, harm minimisation has come to have political, prevention and treatment meanings and is a term that should be used with some caution.

In a major review of methadone treatment for opiate dependence Farrell et al (1994) were able to conclude that methadone was effective in:

- reducing illicit opioid use
- reducing criminal activity
- reducing drug related mortality
- reducing injecting and sharing behaviour
- reducing rates of HIV infection

These overall findings hide much variation and need further analysis. As would be expected, outcomes indirectly related to prescribing showed the greatest variance. In the most effective programmes reviewed 25% of patients continued to inject, indicating the need for clean injecting equipment to be available as part of oral methadone treatment. Criminal activity was found to be more complex and the authors suggest a need to build links between the criminal justice and health care systems better to understand the connections between addiction and crime.

It would be expected, and generally holds true, that the more closely substitute prescribing approximates to the users' wishes, the more likely they are to stay in a 'treatment' programme and, overall, have fewer problems. Two studies illustrate this principle particularly well: Hartnoll et al (1980) compared prescribing injectable diamorphine against oral methadone: at 1 year follow up 74% of the diamorphine group and 29% of the methadone group remained in the programme, and 10% and 30% respectively achieved abstinence: 43% and 61% respectively reported an income from criminal activity: McGlothlin and Anglin (1981) compared high dose

(typically > 60 mg) against low dose (typically < 40 mg) methadone programmes and found benefits in terms of reducing illicit opioid use, reducing drug dealing, reducing days involved in crime, and increasing days employed for both methadone regimens but significantly more so for the high dose regimen.

All prescribers will be familiar with the dilemma of 'getting stuck': after a period of stabilisation, reductions in methadone dose are made, but, at some point, further reduction is resisted.

*When does substitute prescribing stop being a treatment and become no more than a legalised opiate supply? Can an arbitrary timescale define the difference?
Who should pay for the supply of opiates?*

The Addictive Potential of Methadone

Raistrick et al (1994) report on the development of a questionnaire to measure opiate dependence, where dependence is viewed as a purely psychological state, explained by learning theory and departing from psychobiological views of dependence in that tolerance and the resulting withdrawal symptoms are relegated to the realm of consequences of regular drug use, albeit that they have powerful negative reinforcing properties which feed the growth of dependence. The authors argue for equal weight to be given to positive reinforcing properties, such as 'topping up' the loss of drug effect for hedonistic purposes. The pharmacological properties of a drug that determine its addictive potential are:

- potency
- speed of CNS availability
- half-life
- plasticity

Using these criteria, methadone is very much a 'gold standard' for substitute prescribing: it is of relatively low potency compared to other opiates, particularly heroin: it is normally taken orally,

and is not rapidly available at opiate receptors: it has a long half life so that loss of drug effect and any withdrawal symptoms are slow and usually delayed by 1-2 days following a significant reduction in methadone dose: it has low plasticity, which is to say its effects are predictable and independent of the environment. All opiates are of low plasticity and on this criterion methadone is equivalent to other drugs in its group; by the other three criteria methadone is less addictive than the commonly misused opiates. Bickel et al (1986) point out that, although methadone is seen as a low tariff drug, treatment retention is, in part, associated with its reinforcing properties. In a study using a free choice paradigm subjects maintained on methadone had the option of taking capsule A, which contained methadone 50 mg, or of taking capsule B which, in different trials, contained either methadone 50 mg, 60 mg, 75 mg or 100 mg, in place of capsule A: capsule B was chosen 50%, 73%, 87% and 97% respectively of occasions: in other words subjects in the different trials showed a preference for higher doses of methadone. At the highest dose subjects identified an *opiate effect* and a *liking* for the drug but no *high* or *withdrawal* was reported.

So, methadone is well suited to the needs of substitute prescribing, but is itself addictive. Though less addictive than heroin and some other opiates, patients often find it difficult to withdraw from methadone because of its high receptor affinity and long half life. In short, patients may be keen to start methadone, but will have legitimate cause for complaint when it comes to withdrawing if the prescribing doctor has not fully alerted them to its dependence forming potential and long duration withdrawal syndrome.

Types of Methadone Programme

There is a need to move forward from the '*What kind of programme is best?*' question, to the question '*What kind of programme can deliver for different needs?*'. Matching has become increasingly sophisticated in the alcohol field (Donovan & Mattson 1994) but has received less attention in the drugs field when at times social policy objectives dominate drug policy to the exclusion of treating dependence. Ward et al (1992a) in a review of patient characteristics and outcome in methadone programmes concluded that, in general, social stability was associated with good outcome, while high levels of dependence, polydrug use and psychological morbidity were

associated with poor outcome. Wolff et al (1995) have argued in favour of tailoring treatment to the individual taking account of these variables. However, formal matching is imprecise and the suggestion here is to use a hierarchy of methadone programmes, based on the following programme characteristics:

Major Variables of Methadone Programmes

- maintenance -v- reducing regimens
- high -v- low dose regimens
- therapeutic input

Minor Variables of Methadone Programmes

- prescription of injectables
- therapeutic use of compliance measures
- flexible prescribing in special circumstances eg. pregnancy, crisis

For the purpose of this paper *maintenance* means that prescribing is for an unlimited period and minimal effort is directed at moving towards an abstinence goal: *high dose* means a dose adequate to achieve receptor blockade (80 mg or greater): *therapeutic input* means therapy which actively promotes change, though often at the intra-personal as well as substance level. In an interesting collection of commentaries on one patient's experiences in a Dutch clinic, Wells (1994) confronts the issue of the purpose of methadone treatment and argues that counselling without pressure to change is a disservice to patients; this is a view commonly heard in private from members of Narcotics Anonymous and other ex-users. Prescribing is a very tangible therapy about which most people have strong, and often inconsistent, opinions; for example doctors are seen on the one hand as the instrument of benzodiazepine dependence but, on the other hand, too resistant to opiate prescribing. The need for a cohesive strategy is apparent. The 'British System' has meant that prescribers are not usually wedded to rigid programmes, but equally may be divorced from treatment informed by the available research data. It is timely, therefore, not least for the reason of preserving the 'British System', to bring clinical experience together with research findings. The proposal here is that local prescribing policies should test out a hierarchy of methadone programmes in order to bring clarity, conformity and structure to local practice.

Implicit in this approach is the idea that all patients should attempt complete withdrawal from opiates. This model attempts to combine the principles of matching with what practitioners do intuitively.

HIERARCHY OF METHADONE PROGRAMMES

Maintenance - High Dose - Low Therapy

- programme accepts limited prospects of reducing dependence
- aims for health and social gain in limited ways
- suited to high dependence and socially unstable users

Maintenance - Minimum Required Dose - High Therapy

- dose level is patient driven and change depends on individual fluctuations in social and psychological adjustment
- suited to moderate dependence, psychologically disturbed users

Reducing - Minimum Required Dose - High Therapy

- dose level is more doctor than patient driven and expectations of major change are implicit
- counselling is often at a practical level but will depend on individual needs

A POLICY AND PROTOCOLS FOR PRESCRIBING METHADONE

Prescribing in Context

Addiction problems are everyone's business: the sociologist, the politician, the biochemist, the doctor, the police officer, the parent, the pharmacist, the tax payer, the drug dealer, - the list is long, such is the diversity of interests vested in substance use and misuse. Everyone will have strong opinions about addiction including opinions about what doctors should prescribe. The 'British System' allows doctors clinical freedom which is highly valued by practitioners in the field. To protect this freedom it follows that

..... prescribers must be sensitive to the prevailing medico-political views on what constitutes good practice.

People who misuse substances, particularly illicit substances, will also have strong opinions about what doctors should prescribe. These views are likely to change depending where a person is within their addiction career. It follows that

..... prescribers must have an understanding of addictive behaviours. The Model of Change (Prochaska and DiClemente 1984) is a simple, commonly used tool that offers a framework for prescribing and other interventions.

For most people who have developed a moderate or severe dependence prescribing will be at some time an important part of treatment. Prescribing alone will never be sufficient. It follows that

..... prescribers must have a repertoire of skills, including behaviour therapy and psychotherapy, or, alternatively, must work with a co-therapist who has these skills. When working with a co-therapist the doctor must be satisfied with the reasons for prescribing and take responsibility for the prescription given.

General Precautions

The treatment of patients with addiction problems should be the same as any other patient. The precautions listed below are applicable to any prescribing, however patients who misuse both prescribed and illicit drugs are especially at risk, not least because prescriptions are often for controlled drugs in doses higher than normally recommended. There are unexpected dangers: for example children in the house who may overdose on prescribed medication (Binchy et al 1994). Doctors may be required to justify their prescribing to the Coroner's Court, the Criminal Justice System, the Home Office Drugs Branch, or the General Medical Council. A checklist may be helpful:

- prescribe drugs with low addictive potential
- prescribe drugs with low injection potential
- prescribe drugs with low 'street value'
- prescribe inherently stabilising drugs
- allow take home quantities commensurate with the patient's stability - assess:
 - i) risk of overdose by patient
 - ii) risk of overdose by others living with patient
 - iii) risk of diversion for profit or misuse
 - iv) risk of failing to control use as prescribed
- assess tolerance before prescribing potentially lethal doses
- check on other prescribed medications
- check on coexisting medical conditions
- monitor compliance

Before finally giving a prescription ensure that both the doctor and the patient understand the purpose of the prescription. There should be agreement on how to monitor whether or not the intended purpose is being achieved; if the purpose is not achieved then the prescription should be reviewed and possibly discontinued. This does not imply an end to therapy but rather consideration of a shift to an alternative, possibly non-pharmacological treatment.

Who is methadone for?

The temptation to prescribe methadone as a quick solution to addiction, and the pressure to prescribe as a harm minimisation strategy conspire together so that, for some practitioners, methadone has become the *only* treatment for opiate dependence or opiate use. Helping people to deal with their drug use problems is invariably time consuming, usually beyond the time available to prescribers; for this reason the doctor will often work with a co-therapist, indeed the availability of such an arrangement is almost a pre-requisite to prescribing. Even when a doctor/co-therapist relationship has matured the prospect of improving a person's social circumstances or, in the short term, resolving intra-personal conflicts, may seem so remote that opting for a pharmacological intervention, methadone, becomes the treatment of choice by default.

Ward et al (1992a) have reviewed the entry criteria for different methadone programmes. While there is considerable variation, reflecting different treatment philosophies and different theories of addiction, common themes are apparent. A first filter should include:

- patients with a diagnosis of opiate *dependence*
- a minimum 6 month history of regular use
- regular injecting, especially if high risk, of whatever duration
- failed attempts to achieve abstinence
- patients who, at initial assessment, are at the pre-contemplation stage or contemplation stage of change.

How to set up clinics

Substitute prescribing takes up a considerable amount of resource: doctors' time, co-

therapists' time, dispensing, drug costs. Demand is high and can only be met if general practitioners and other non-specialists contribute. In Leeds three levels of substitute prescribing have been adopted.

Level 1 - Specialist Service

Prescribing by Leeds Addiction Unit medical staff and the option of on-site dispensing for patients receiving treatment at the Unit. For:

- stabilising patients who would then be suitable to move to level 2 or 3 services
- patients requiring intensive supervision and support: typically people with multiple social and psychological difficulties
- patients with mental illness problems
- patients requiring injectable drugs, diamorphine, dipipanone or other 'high tariff' prescribing

Level 2 - Locality Services

Prescribing by Clinical Assistants under the supervision of the Addiction Unit Consultant and supported by a therapist. For:

- patients who are sufficiently stable to manage a programme of increasing take home privileges as part of a move to a satisfying non-using lifestyle
- patients who do not meet Level 1 needs but require a structured programme and regular therapist input
- patients whose needs would be met by Level 3 but whose general practitioner is a non-prescriber - this is an important safety net since general practitioners vary in their willingness, knowledge and skills to take on drug users.

Level 3 - Primary Health Care

Prescribing by general practitioners for their own patients, supported by the sector Community

Psychiatric Nurse from the Leeds Addiction Unit if requested. For:

- patients graduating from Level 1 and 2 needs
- patients electing general practitioner care in agreement with their general practitioner
- patients meeting Level 1 and 2 needs but having a general practitioner experienced in substance misuse and willing to provide care
- patients requiring maintenance prescribing

How to start a patient on a Methadone Programme

Once a patient has been assessed as a suitable candidate for a methadone programme then there should be a full discussion of how the programme will work day to day. The prescriber should ensure that the following steps are taken:

i) *Check out contra-indications*

Opiates should not be prescribed for patients with respiratory depression, obstructive airways disease, acute asthma or concurrently with MAOIs. Exercise caution if there is a history of current alcohol misuse. (see data sheet for more details).

ii) *Patient to complete substitute prescribing clinical tool*

It is useful to have either a printed clinical tool or to use some informal method of committing to paper exactly what the health and social gains expected from prescribing methadone might be and how achievement or otherwise can be measured. In setting the ground rules it is important to build in a mechanism for discontinuing treatment; make explicit what can be offered if a patient wants to change a prescription between appointments or if medication is lost or stolen.

iii) *Pre-entry confirmation of drug use*

This may have been adequately covered at the time of assessment. If not then, in addition to a patient's history, confirmation of prescribing by another doctor, or objective signs of opiate withdrawal can be taken as sufficient evidence of regular use. A positive urine

screen may be helpful in reflecting the range of substances used but says little about the patterns of opiate use (Wolff and Hay 1994).

If there is doubt about the amount of opiate used and the development of tolerance then a naloxone challenge and assessment of withdrawal provides an objective measure (Peachy and Lei 1988). The naloxone challenge may cause distress to some patients and an alternative, but less reliable test is the methadone challenge (Higgins et al 1985). Patients whose tolerance has not been established should not be prescribed more than methadone 30 mg orally, without a naloxone (0.4 mg) or methadone (20 mg) challenge.

iv) *Setting a starting drug and dose*

Guidelines to Good Clinical Practice (Department of Health 1991) contains a useful table to convert doses of pharmaceutical opiates to a methadone equivalent; there is such variation in purity of street drugs that no fixed conversion is available and practitioners must rely on local intelligence and experience to judge the methadone equivalent. It is often wise to start at a low dose and increase if required over a stabilisation period: it will take 6 days for plasma levels of methadone to reach steady state.

The use of preparations classed as higher tariff than oral methadone should normally reside with specialists. Battersby et al (1992) characterise the use of injectables as a treatment of last resort, perhaps suited to some patients in maintenance, high dose, low therapy programmes.

Diamorphine is an inherently destabilising drug, but has the advantage of being available in smokable form as an alternative to injecting (Marks and Palombella 1990). It is sometimes useful to prescribe diamorphine 'to get it off the agenda'; the expectation would be that the patient would not control diamorphine and would quickly ask to be reinstated on methadone. Before prescribing, doctors should be clear, and make clear to patients, what the upper dose limit will be; tolerance to diamorphine develops very quickly and many users will not plateau until receiving doses in excess of 300 mg daily. A few stable individuals are able to control diamorphine and find it preferable to methadone.

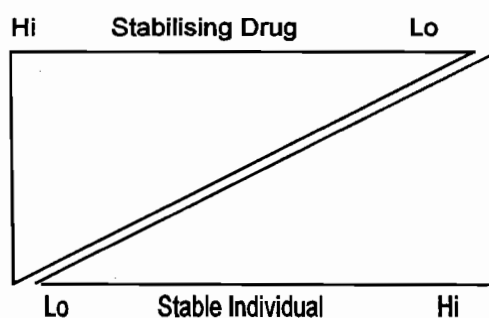
v) *Clinic Attendance*

Arrangements for attendance will depend on the type of methadone programme and the particular problems of the individual. Typically a patient on a reducing, minimum required dose, high therapy programme would attend to see a prescribing doctor every 4 weeks and a co-therapist every 2 weeks.

vi) *Compliance and take home medication*

There are medico-legal requirements to check on compliance, but also practitioners will want to assess the effectiveness of treatment. A urinalysis screen is a good way of getting an overview of recent drug use which can then be discussed with the patient and compared against the prescribing objectives initially agreed. The use of plasma methadone levels is discussed fully in the next section of the paper. The frequency of taking compliance measures will depend on an individual's stability, current circumstances, and progress to date, but a routine of monthly testing will normally be adequate. Testing might be carried out several times in one week if it is clear that all is not well.

The concept of a person's stability is important (i) in determining what drug to prescribe (the less stable the person the more stabilising a drug is indicated) and (ii) in determining amount of take home medication. The concept is illustrated below:



Elements of stability include:

- degree of dependence
- impulsive or immediate gratification personality characteristics

- social organisation
- personal time management

vii) *Confidentiality*

The need for free communication with the dispensing pharmacist, other involved doctors and therapists, and general practitioner should be agreed prior to programme entry.

Pregnancy and Methadone Prescribing

For many women pregnancy is an opportunity to change their behaviour away from a substance misuse career. Ward et al (1992b) have reviewed the use of methadone by pregnant heroin addicts and conclude unequivocally that methadone is better than no treatment. Opioids are not harmful to the foetus but are a factor in the neonate being small for dates; the growth deficiency, unlike alcohol foetal growth deficiency, is made up post nately. The main problems of opiate use in pregnancy are:

- repeated withdrawal, especially from short-acting opiates, which carries a risk of spontaneous abortion, particularly in the first trimester, and premature labour, particularly in the third trimester
- neonatal opiate withdrawal syndrome

It is not unusual for addict mothers to present late in pregnancy; sometimes this is related to lifestyle, sometimes it is the surprise of being pregnant when menstruation has been suppressed by opiate use. Ideally mothers would be stabilised on an adequate dose of methadone through the first trimester and then withdrawn in the second trimester: in practice compromises need to be made in order to satisfy the mother's wishes and to ensure as safe a pregnancy as possible. There is an increased methadone metabolism rate in pregnancy and especially so in the third trimester: this may be due to the gathering pace of the foetal metabolism. Reductions should be handled with caution and monitored with plasma methadone measurement during the third trimester. If abstinence from opiates is not possible then a neonatal withdrawal syndrome, which may persist several weeks, is likely; Kempley (1995) views the severity of withdrawal as only weakly related to maternal dose of methadone, though conventional wisdom suggests a dose of

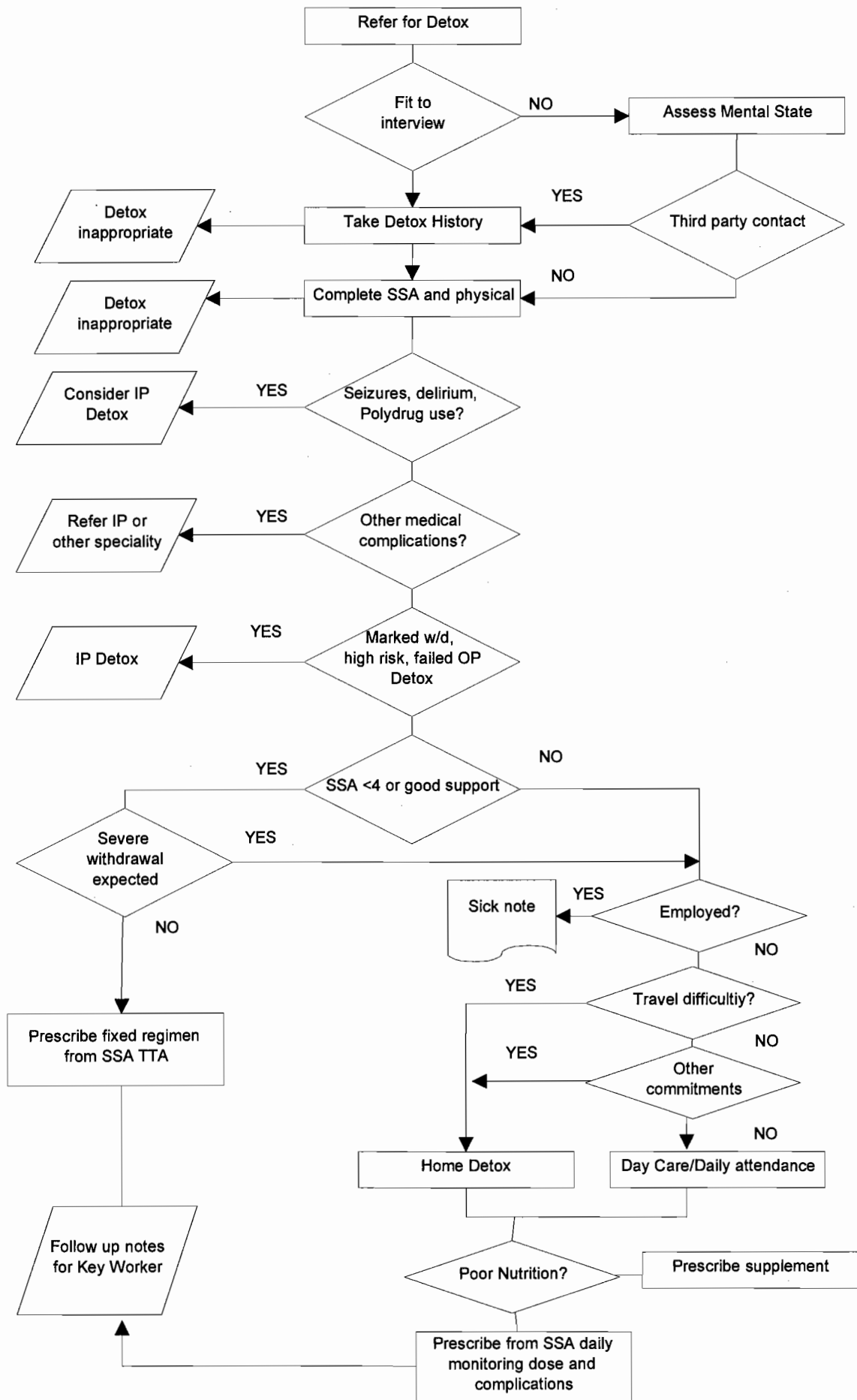
methadone 15 mg or less is not associated with a neonatal withdrawal syndrome.

Detoxification

Detoxification is the intended end point of most methadone programmes. Detoxification is the process of *rapidly* achieving a *drug free* state usually involving the prescription of a drug to *attenuate withdrawal* symptoms. The aim is to achieve this agreed objective with the minimum of discomfort to the patient and at the same time monitoring for co-existing or complicating conditions. Detoxification is for patients at the 'action stage' of change (Prochaska and DiClemente 1984), although some patients may require detoxification as an expedience, for example following unplanned hospitalisation, in anticipation of a custodial sentence, or because of deteriorated physical health. A detoxification flow chart is presented on the next page. There are some general principles to adhere to:

- even for patients in the action stage adequate preparation is essential: information about withdrawal symptoms, medication to be given, and expected duration are important.
- have a clear idea of what support will be available during and after detoxification and consider which of home/hostel, clinic or hospital is the best setting for detoxification
- monitor withdrawal and modify medication accordingly
- wherever possible use complementary 'feel good' therapies to minimise the need for medication and promote non-pharmacological solutions to psychological discomfort
- ensure an early post detoxification follow up appointment for relapse prevention counselling.

General Scheme for detoxification



Step 1 - create platform for detoxification

Ideally the dose of methadone, or other opiate, should be reduced to create a platform from which detoxification has the best chance of success. To do this establish a baseline of a maximum dose of methadone mixture 30 mg daily or diamorphine tabs 100 mg daily (or equivalent of short acting opioid). Action stage patients can easily achieve these dose levels without supplementing. Detoxification from higher dose levels are associated with more difficult withdrawal and therefore higher drop out rates.

Step 2 - choose a specific detoxification regimen

Most patients find withdrawal from methadone difficult because of the long half-life and receptor affinity of the drug; from stopping methadone 30 mg daily it will still be possible to detect positive plasma levels after 2 weeks. For these reasons consideration should be given to a 1-2 week crossover from methadone to dihydrocodeine and then the detoxification choices are the same as for patients on short acting opiates. Some patients require a longer crossover period: close monitoring of compliance is advised.

Symptomatic detoxification is the preferred option for low dose users and from any short acting opiate: from methadone, (without a crossover to dihydrocodeine) a symptomatic detoxification regimen is likely to stretch over 3-4 weeks. A cocktail of drugs is prescribed to deal with each withdrawal symptom: lofexidine is an alpha-2 agonist which is effective in reducing the adrenergic elements of opiate withdrawal (Gold et al 1981): blood pressure should be monitored: thioridazine is recommended as first choice of hypnotic because it has no cross tolerance with any opiates or benzodiazepines which may have been used prior to detoxification, and has a low dependence potential.

Naltrexone assisted detoxification is the preferred option for withdrawal from methadone (without a crossover to dihydrocodeine) or for any detoxification where speed is valued. Naltrexone has a greater affinity for opiate receptors than even methadone and displaces all opiates present causing a severe withdrawal syndrome which is attenuated by a symptomatic detoxification regimen instituted before giving naltrexone. Detoxification is complete within 3-4 days, but normally requires hospitalisation because of the need closely to monitor medication

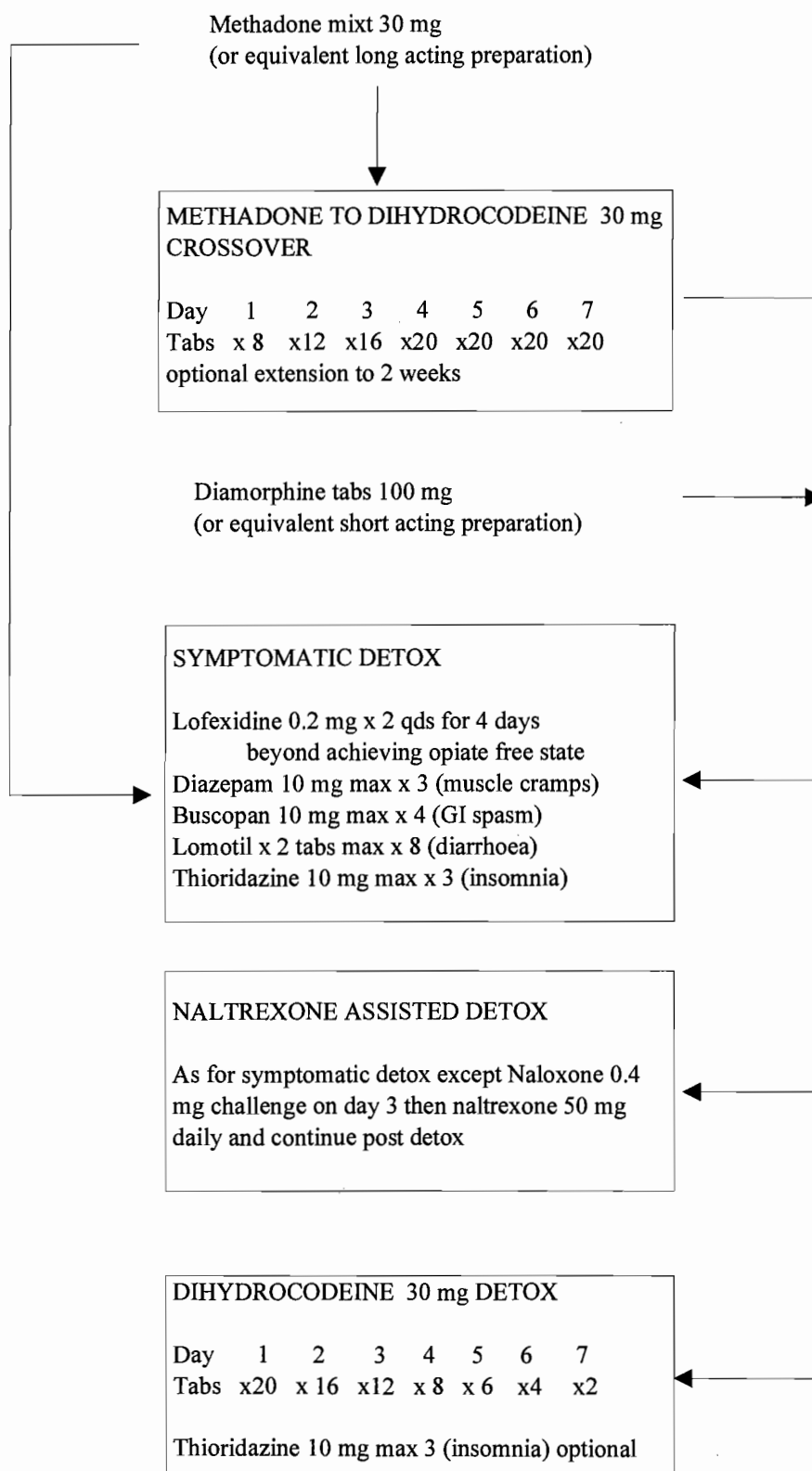
dosage.

Dihydrocodeine detoxification is the preferred option for those patients seeking minimum discomfort, but runs the risk of becoming an extended prescription with added symptomatic treatments. A hypnotic is often required.

Step 3 - follow up

Encourage all patients to take supervised naltrexone post detoxification as part of relapse prevention counselling.

General Schema for opiate detoxification



PLASMA METHADONE: A MEASURE OF COMPLIANCE

Patient Compliance and Self Report

Are addicts who are prescribed methadone likely to be more compliant than patients who are prescribed other drugs? Probably not. Only an estimated 50% of patients in general follow their prescription, and former heroin addicts prescribed methadone are no different, though the reasons for non-compliance may differ from patients taking, say, antibiotics.

Until recently, most toxicology assessments relied on urine screening. Urinalysis is an important tool, providing information about *most* of the drugs consumed by patients. Urine from patients prescribed methadone will signal the presence of this drug, and of most other illicit drugs. However, the urine test is only qualitative in nature. For example, a patient can be shown to have consumed methadone, but no indication can be given of the amount of drug which has been taken or when it was taken: urinalysis is of limited value where the issue of patient compliance is concerned. For treatment to proceed as successfully as possible, it is important to know whether each patient is complying with treatment, and in particular taking the correct methadone dose as prescribed. It may be, for example, that an individual has obtained and is using additional methadone or is using less than prescribed and selling some of their supply to other drug users. Where the clinician wants answers at this level, urine testing has proved insufficient: one solution to the problem is the analysis of plasma samples.

Self-reports and observer-reports are used alongside toxicology to assess and re-assess dosage. Both types of reporting have drawbacks: self-reporting, has proved to be relatively insensitive where adequacy of dosage is at issue. Where observer-reported systems have been assessed, the data collected have proved difficult to interpret. Such systems attempt to measure subjective and objective indications of opiate withdrawal. Confusion can arise because symptoms associated with severity of drug withdrawal are often not specific to withdrawal and similar to those observed in the assessment of other conditions, for example, anxiety. So, the accuracy of self and observer ratings has limitations and is likely to be confounded by co-existing psychological states. (Kleber, 1986; Peachey, 1986).

Despite the recognised value of accurate information on patient compliance, the majority of UK drug agencies, general practitioners, and hospitals involved in the prescription of methadone do not monitor its usage. This remains the case, despite information to suggest that there is substantial diversion of methadone in the UK (Farrell et al 1994) and that there has been an increase in deaths from the recreational use of methadone, probably by drug-naïve users (Harding-Pink 1993). The unsupervised and unauthorised use of the drug appears to be very much on the increase. In short, both urinalysis and plasma levels of methadone are required to give a comprehensive picture of compliance and current substance use. Hair analysis is not helpful for monitoring compliance. Plasma methadone estimations can be used:

- to check on compliance - either taking additional methadone or diverting the prescribed supply
- to quantify methadone tolerance
- to assess dosage requirements, when methadone metabolism is altered eg. by pregnancy, or by anti-TB drugs
- to predict time to achieve a drug free state after discontinuing methadone

Current Research

Work carried out in the Chemical Pathology Department of the University of Leeds during the last eight years has established that, as with other drugs, a relationship does exist between the dose consumed and the blood level of methadone. With patients known to be compliant Wolff et al (1991a), using a liquid chromatography (LC) technique to estimate methadone levels, established a linear relationship between dose and plasma concentration after taking into account body weight. The dosage range studied was 3 mg - 100 mg methadone per day for patients receiving a fixed daily dose of the drug during a maintenance treatment programme.

Wolff et al (1991b) assessed the compliance of methadone maintenance patients by the use of a pharmacological indicator: very low-dose phenobarbitone was successfully incorporated into the methadone medication. The total amount of phenobarbitone taken by any one patient was

insufficient to induce liver enzymes or cause drowsiness. Plasma phenobarbitone levels can easily and accurately be measured; normative data are available linking dose of phenobarbitone to plasma level. Using this methodology it was possible to detect both supplementary use of methadone and failure to take the prescribed dose of methadone. Thirty cases were studied in the following groups:

- i) 12 attended the Leeds Addiction Unit on a daily basis for maintenance treatment, and consumed their medication observed by staff.
- ii) 8 attended the Leeds Addiction Unit daily for a reducing methadone dose, again observed by staff.
- iii) 10 maintenance patients collected their medication from dispensing chemists in the community and consumed their methadone unobserved.

For most of the study period most patients had stable plasma methadone and phenobarbitone concentrations confirming that they had taken their medication as prescribed. Ten of the patients were found on occasion to have supplemented their prescriptions with illicit methadone. Although patients did not admit to supplementing their methadone in the course of routine monitoring by clinical staff, interviews conducted with the researcher at a later date confirmed that this had happened. Three patients consumed multiple doses of their methadone on a single occasion: one individual was shown to have taken an enzyme-inducing drug, resulting in an abnormally low methadone level: another patient failed to take any of the methadone prescribed. Most of these patterns of use could not have been detected by urinalysis.

In addition to the problems of treating dependence, difficulties of methadone treatment can also occur where there are alterations in the rate of clearance of methadone from the body (Wolff et al 1993). Concomitant administration of enzyme-inducing or enzyme-inhibiting drugs can influence clearance, and also alter plasma methadone concentrations. Reports suggest that rifampicin, phenytoin and disulfiram are associated with unexpectedly low plasma methadone concentrations. Other factors reported to influence the clearance of methadone include excessive alcohol consumption and pregnancy.

In summary plasma methadone estimation is a useful clinical tool which significantly advances the clinician's scope for monitoring compliance and accurately adjusting dosage. With the benefit of sophisticated monitoring clinicians can extend their prescribing regimens, in particular to higher dose or injectables, with greater confidence.

PLASMA METHADONE

Requirements for analysis:

- **10 ml blood (heparin tube)**
- **Daily dose consumed (Amps/mixture)**
- **Patient weight (kg)**
- **Pre-dose blood sample**
- **Time of last methadone consumption**
- **Time of blood collection**

TRAINING

Background

The lack of preparation for working with problems of addiction which is found in many occupational groups has been variously attributed to attitudes, mainly negative, to problems of substance misuse and to the lack of curriculum items on addiction in the relevant professional training courses (Glass and Strang 1989).

During the eighties a number of studies demonstrated the connection between these factors by showing that if professionals had received education in alcohol problems in their basic training they were more likely to have a positive attitude to working with these problems when qualified. (Cartwright 1980, Anderson 1985, Clement 1986). Cartwright showed that post basic training and education were important in the development of *role adequacy*, the belief in one's ability to work with these problems, and *role legitimacy*, the belief that it is a proper part of one's role. However, he showed that training and education, while being necessary factors in the development of what he called *therapeutic commitment* were not sufficient to ensure that professionals would become involved in working with people with alcohol problems. The influence of these factors was contingent upon having *experience* and *role support*.

Clement (1986) and Anderson (1985) both applied this work specifically to general practitioners. In the words of Clement:

“Education may act as a predisposing factor in the identification of alcohol problems in that it may facilitate feelings of role adequacy and legitimacy; however, unless general practitioners also experience involvement with drinkers as being rewarding and unless they are provided with adequate services to support them in their work they may remain reluctant to identify and work with drinkers”

In spite of these findings, many training initiatives in the addiction field have been aimed at a multi-disciplinary audience at the in-service training level and with the objective of “getting staff

in the primary health care sector to counsel problem drinkers". General practitioners have received a bad press for not attending such training events (Clement 1987) though some would take the view that the surprise was not so much that they did not attend but that anyone expected them to.

If post basic training is to build upon the role legitimacy which is created during undergraduate medical training then it is proper to offer medical training to medical practitioners. While a very few general practitioners may have an interest and indeed special training in counselling, and while in recent years counselling has come to be seen as a legitimate pursuit for general practitioners the majority are likely to feel that in the main their skills and the work for which their training is designed is the domain of medical practice. This will apply to their involvement in the treatment of addiction problems.

Using the principles of Cartwright's findings, Tober and Raistrick (1990) designed a strategy for training professionals who were likely to encounter problems of substance misuse which was designed to avoid a repetition of the difficulties encountered in multi-disciplinary training. With reference to general practitioners the strategy embodies the following principles:

- Training is delivered by medical practitioners and addiction specialists who teach medical skills in the treatment of substance misuse and dependence. Interventions taught are those capable of being delivered in the time allocated to patients in general practice and within general practice resources.
- Training is provided at a time convenient to general practitioners remembering that they have to pay for someone to cover for them during surgery hours.
- Training is validated by PGME so that general practitioners can use it to fulfill their postgraduate training requirements.
- Training is based upon a model which enables general practitioners to make treatment planning decisions and accompanied by protocols and clinical tools described elsewhere in this paper.

The Content of Training

The content of the training approach described by Tober and Raistrick (1990) is loosely based on Prochaska and DiClemente's Model of Change (1984) supplemented by brief interviewing techniques designed to assist general practitioners to distinguish those patients requiring harm reduction treatment strategies from those who are motivated to control and deal with their addiction. General practitioners are guided through specific steps in the assessment of patients and in the criteria for deciding the most appropriate management. They are given criteria to decide on the goals of treatment so that they are able to evaluate the achievement of those goals in patient review. The key elements of training are:

- The Model of Change as a framework for understanding addiction
- Interventions suited to general practice and matched to stage of change
- Use of clinical tools
- Prescribing protocols and policy
- Referral to and support from specialist services locally
- Outcome measures

The result of implementing this training strategy locally has been to attract local general practitioners to training events which are organised at three monthly intervals in the early evening (after evening surgery, in line with express wishes of general practitioners) and are attended by up to fifteen general practitioners. In order to update the content of training and respond to their training needs general practitioners are informally surveyed from time to time. One such survey with specific reference to opiate addiction was conducted in March 1995.

Survey Method

Sixty questionnaires were circulated by hand to GP practices by two community nurses, and 60 were distributed at a Postgraduate Medical Education meeting on the management of drug and alcohol problems.

The first section of the questionnaire enquired about confidence to work with opiate addicts with or without training and with or without specialist support and whether general practitioners thought that it was a part of their role to work with these patients (role legitimacy). The next two sections asked general practitioners to tick boxes on their perceived knowledge and skills training needs.

No information was requested on age, sex or any other details.

Results

Of the 60 questionnaires distributed to general practitioner practices, 32 (53%) questionnaires were returned. Of the 60 questionnaires distributed at the PGME meeting 27, (54%) were returned.

Of the 59 responses, 17 (28%), of whom 11 (19%) were from the practice based sample and 6 (10%) from the meeting distribution sample said they felt it was not the role of the general practitioners to treat patients with opiate addiction, though two of these also agreed that they would feel confident to treat these patients if they had more training and specialist support.

Of the 17 respondents who agreed that it was not the role of the general practitioner to treat patients with opiate addiction, 9 respondents also ticked items on the checklists for knowledge and skills they would require in order to treat these patients, with one of these wanting only knowledge of specialist services and skills to mobilize community resources. One of this group said general practitioners do not have time to treat these patients.

Of the 42 respondents who agreed that it is the role of the general practitioner to treat patients with opiate addiction: 6 (14%) said they felt confident to treat patients with opiate addiction, 8 (19%) said they would feel confident if they had more training and 28 (67%) said they would feel more confident if they had more training and specialist support. Remembering that a number of the general practitioners who said this was not their role also ticked checklist items for training, the total identifying training needs was 51 or 86% of the sample.

Of the knowledge items, the largest number, 86%, of respondents identified withdrawal regimes, a close second, 82%, identified prescribing regimes, then monitoring procedures, 63%, with 51% expressing an interest in training in “non drug treatments”. Of the skills items, the item ticked most frequently was decision making regarding appropriate treatment, 63%, and 55% identified “talking to patients with an addiction problem” as a training need. “Deciding which patients are suitable for treatment” and “Using community support services” were equally frequently ticked by 51% of those respondents who identified training needs. The additional comments elicited in the questionnaire were requests for guidance in dealing with “angry patients”, “violence” and “manipulative behaviour”.

Discussion

The survey reported here does not purport to reach a representative sample of general practitioners. On the contrary, the sample was highly selective of general practitioners who attended a meeting on alcohol and drug problems or worked in a practice where patients with these problems are seen. The Community Psychiatric Nurses who distributed questionnaires are addiction specialists who provide a support service to practices seeing these patients. However, even in the group attending the PGME meeting, 6 general practitioners felt it was not the role of the general practitioner to treat patients with opiate addiction.

The additional comments demonstrate that general practitioners find patients with addiction problems difficult to deal with and training experience has shown that this problem needs to be addressed. The patients are indeed a difficult group, and attributing such statements to the “attitude” of general practitioners will not alter this fact nor will it encourage communication and resolution of the difficulties of treatment.

It is as well to recognise the differences in motivation to work with addiction problems. Clement (1986) noted that the more senior the general practitioner the less likely they were to treat problems of alcohol misuse; equally the less likely they were to have received basic or post basic training in this field. These general practitioners would therefore be lacking in the necessary

therapeutic commitment identified by Cartwright (1980) namely role adequacy and role legitimacy. Attitude change is notoriously difficult to bring about and even where training is successful in achieving it, the relationship with behaviour change is uncertain. It is, therefore, deemed to be an inefficient use of resources to target those who do not believe it is the role of the general practitioner to treat patients with substance misuse problems. Rather training should target those self selected general practitioners who demonstrate role legitimacy, role adequacy and have experience working with substance misuse patients. The number of general practitioners falling into this category seems to be an ever growing one.

If general practitioners have received a bad press in the past regarding their willingness to address problems of substance misuse and dependence it is as well to look to the authors of these opinions and to ask what might have been done differently to encourage this most important professional group to participate in treatment. The knowledge to inform this question has been available since the early and mid-eighties and should be more vigourously acted upon. One of the clearest messages to emerge from our survey is the perceived need of general practitioners for training to develop *medical skills* for the treatment of addiction.

The training approach outlined in this paper has been generally well received and training events well attended. The approach is perceived as solving problems, not discovering new ones: it is perceived as being relevant to the role of the medical practitioner and equally importantly it is accompanied by the offer of different levels of support according to the general practitioners' needs.

ECONOMICS OF METHADONE PROGRAMMES

Economic Issues

Treating drug misusers involves the use of scarce public resources, and purchasers and providers may well question the cost-effectiveness of different methadone maintenance programmes. Cost effectiveness analysis is a method for comparing all the costs and outcomes of a number of alternative strategies. Several economic evaluation questions can arise when considering expanding (or contracting) methadone programmes:

- whether extra health authority resources should be devoted to drug misusers or other areas of health care, for example, cardiac care?
- whether resources should be redistributed between other approaches to reducing drug problems, for example, prevention rather than a treatment programme?
- whether resources should go to methadone programmes or some other type of drug treatment?
- which of the range of different methadone programmes is cost-effective? Should, for example, the programme be high dose and low therapy or low dose and high therapy or, as in the case described in this paper, what is the cost-effective way of mixing different approaches to ensure the use of resources maximises the outcomes for the local population

The answers to these questions will involve evaluation of the alternative actions. If drug misuse treatments and heart transplant programmes are the alternatives available to a purchaser, the decision should be made based on evaluations of the costs and benefits of these two alternative uses made in a comparable way. In contrast, questions about alternative methadone programmes may be considered by comparison of specific drug-related outcomes.

Answers to these evaluative questions will depend on the perspective taken. Drug misuse not only affects the *health* of the individual, but may also have other adverse outcomes which affect

quality of life, such as social functioning. In addition, drug misuse may result in costs for third parties, including both immediate family and others in society through, for example, drug-related acquisitive crime. If an economic evaluation was undertaken from society's perspective, all the costs and benefits would be included in the study. However, health purchasers may adopt a narrower perspective, and comparisons may be restricted to those costs and benefits which directly relate to the health of the individual and the consequences for the health service. Therefore, through exclusion of some costs and benefits, different perspectives may result in different overall results and rankings of alternative interventions.

While there is extensive literature on the effectiveness of different approaches to treating people with a substance misuse problem, there have been few studies that have included any information about the costs of treatment or attempted to undertake a full cost-effectiveness analysis. A few US studies have attempted to examine the question of whether investment of resources in drug treatment programmes results in more benefits than costs (the outcomes of programmes being measured in monetary terms). This type of study has generally compared the resources needed for treatment with the reduction in social costs which can be attributed to the treatment programme, particularly focusing on crime levels and the productivity of treated drug users. While these results have generally indicated that drug treatments are likely to produce net benefits for society within the US context, it is difficult to know if these results would be translated to current UK treatment programmes, where both treatment and some social costs, particularly crime, may be lower.

These cost-benefit studies would not be strictly comparable with more traditional cost-effectiveness studies of health care interventions. In cost-effectiveness studies, the main focus has been on the costs and benefits for the individual and the health care costs. Results are generally summarised in terms of the net costs per unit of health gain, such as life years, disease events avoided and so forth. The more general the study and outcome measure used, the more general the questions that can be addressed.

In most evaluations of drug treatments a variety of individual outcomes have been used. Most of the earlier studies used some measure of drug use, often an estimate of the numbers of

individuals that are drug-free. More recent studies have used a variety of measures including psychological and physical health, social functioning, employment, legal problems and extended drug use variables, including measures of harm minimisation behaviour. It is currently difficult to see how such measures could be combined into a single outcome measure which could be used to compare different programmes in an economic evaluation. This would be crucial if different programmes performed differently in achieving benefits for individual drug users across the different dimensions.

For a full economic evaluation it is important to evaluate the impact of programmes on the costs borne by non drug users. This suggests there should be studies which combine the measurement undertaken in the US studies with the individual approach usually adopted in health care interventions. A full checklist of potential costs and outcomes that may affect the comparison of different drug interventions with each other or with other uses of resources is set out in Table 1.

To answer evaluative questions it is necessary to compare all these factors to give a net cost (costs less benefits) per unit of improvement in quantity and quality of life for the drug user. Ideally, elements would be valued in a comparable way, usually in monetary terms. Cost-effective programmes may have large costs but also considerable benefits. Alternatively programmes may not be very effective but, because of low cost, may be economically efficient. One programme may have large individual benefits but smaller gains to the rest of society, while another may do little to improve the lives of drug users but have a major beneficial impact for the rest of society. If two such programmes had the same costs then the choice between the programmes would depend on the value given to outcomes from these different perspectives. These evaluation questions involve ethical issues that require wider debate.

While there are large gaps in knowledge about how costs and benefits vary between different treatment approaches, including the 'no intervention' alternative, the framework set out in Table 1 allows some discussion of the likely magnitude of the costs and benefits which would be associated with the different methadone interventions being considered in this paper. Clearly, those programmes that involve a maintenance commitment, and hence long contact between the user and the service, will have considerable direct costs. However, if other methadone

programmes are directed at the same user group, there may be higher indirect consequences, such as larger risks of hazardous drug use or more criminal activity. An initial examination of these potential direct and indirect effects across different options may help purchasers to avoid decision making based simply on financial costs. In the rest of this section, some of the factors which may influence the costs and benefits attached to different methadone programmes are reviewed.

Direct costs of interventions

The direct costs of any intervention breakdown into a number of separate elements. The first part is the cost of assessment. Of course, assessments may need to be undertaken on a larger number of individuals than will eventually be found suitable for the programme. Assessments will also be required to match treatment-seekers to appropriate parts of the programme.

Aside from assessment costs, there are other elements of methadone programmes whose importance will vary across different programmes. The obvious element is the cost of the drugs prescribed. The second is the cost of dispensing the drugs. Thirdly, there are costs associated with the accompanying therapeutic care. Finally, there are the on-going costs of any urine or other testing procedures associated with the programme. Whilst these may be the main elements of any programme, clients are also likely to use other services on offer at an agency.

Costs of methadone

The costs of the methadone and any other drugs prescribed will vary with the amount prescribed. These costs may also be linked to how they are dispensed. If the drugs are dispensed at the drug agency or nearby hospital pharmacy then it may be possible to obtain supplies of methadone at a cheaper rate than would normally be charged if the drugs were dispensed at a commercial pharmacy. However, because methadone is a controlled drug, arrangements for secure storage and some protection for the dispensing staff are needed if the drugs are dispensed from the agency. Methadone mixture is considerably cheaper than methadone tablets or methadone ampoules, and the mixture in itself is not particularly expensive. However, this is a drug that is

taken daily and hence annual costs can be substantial. For example, if community pharmacies are used, the costs of the drugs alone in a high dose (80mg) programme could be over £500 per year per client, in contrast to about £250 per year for a low dose (30mg) programme.

Costs of dispensing

While the costs of the drugs themselves are not insignificant, it is the dispensing costs that can add substantial amounts to the total direct costs. These costs will be particularly high if community pharmacies are used and dispensing days are frequent. Dispensing costs may vary but are likely to be in the range of £3 to £5 for each occasion, depending on whether other items are prescribed in addition to the methadone (Drug Tariff, 1994). Daily dispensing, through community pharmacies, therefore, will add considerably to the costs of a programme. Dispensing within an agency, particularly if the methadone mixture is consumed on the premises may be cheaper. This means of dispensing would not only allow the agency to negotiate for cheaper bulk quantities of methadone mixture from the manufacturers, but would also reduce the need for containers for dispensed drugs. However, it does mean that staff time will be involved in preparing doses and dispensing the drugs. These costs are difficult to estimate and could vary depending on how efficiently dispensing is organised within a clinic. Hospital dispensing costs, for example, are cheaper and available estimates suggest that the costs are more likely to be in the range of £1.60 to £2 per occasion. Several methods of dispensing methadone to large numbers of clients are being explored, including dispensing machines. These may reduce staff input and hence running costs of the scheme, although they may involve a substantial initial capital outlay.

Different dispensing arrangements also involve clients in different levels of personal tangible and intangible costs. Research in the United States suggests charging for a methadone programme has an effect on the success of a treatment programme. In a controlled study, Maddux et al (1994) found differences in retention between those charged \$2.50 per day and those who received the treatment free. At one year, 34 per cent of those required to pay a fee were retained, compared to 54 per cent of the no-fee subjects. Intangible costs to clients are also likely to affect the success of different programmes.

Community pharmacies are convenient for the client and may allow the drug user to minimise the interruption of continued therapy to their normal patterns of life. These dispensing arrangements may save clients both time and travel costs although, for some clients, travel costs may be paid for by the health service or treatment agency. Dispensing at the clinic could involve the client in more time and inconvenience, although it may, for some at least, initially substitute for the time involved in making drug purchases. The intangible costs to patients of collecting from an agency or a community pharmacy are largely unknown. There are probably differences between clients and between areas.

Dispensing costs will vary directly with the frequency of pick-up for individual patients. However, the frequency of pick-up strongly interacts with therapeutic regimes. Daily pick-up particularly at the start of a programme is one means of monitoring compliance and limiting leakage of methadone into the local illicit drug market. Less frequent pick-ups can then be used as a reward for those who limit their use of illicit substances or reach other therapeutic goals. Costs of any programme could well vary across client contacts, with much higher costs in the initial stages. Furthermore, costs are likely to vary across individual clients, as it may be expected that those with lower social support or more complex problems may be more likely to remain for longer on a daily pick-up regime. Cost differences between individuals could be even greater if the costs to clients are also considered.

Costs of therapeutic component

Drug agencies may be involved in delivering a range of interventions for people misusing drugs, and this may involve not only face-to-face work with clients, but liaison work with other welfare agencies. The major cost component of this work will, however, be staff time. The cost of the time will depend on: the expense of the therapist, duration of contact, whether this contact is individually-based or part of a group, the number of contacts made with each client, and the non-contact time involved. If services are based in the community and counsellors have to travel to the client, this may involve a considerable amount of non-contact time, as may a client with complicated legal, social or housing problems.

It is generally difficult to forecast the cost of any therapeutic component, especially since many programmes are client-led. An analysis of opiate users attending the Leeds Addiction Unit suggests that the average cost of care was £944 in 1992/3. Taking away the costs of drugs dispensed outside the Unit reduced the annual costs from an average of £841 to £449 for the 300 who only had outpatient care, and from £2,574 to £2,024 for those who had some inpatient care during the year. The average number of events (times patients attended for care) was 24 for those with outpatient care only and 35 for those with inpatient care, where each inpatient episode was only counted as one event. At this time the Unit did not operate structured methadone programmes, rather treatment was determined at an individual level. Across all the patients of the unit, the average cost per event varied from £87 for a new episode, £48 for a core therapy session, and £9 for a dispensing event. These costs include an allowance for non-contact time, management and other overhead costs of the unit, and the costs of drugs dispensed within the unit. There was considerable variation in the costs associated with different individuals, however, and hence these average costs may have little meaning. If the clients who would not be eligible for any of the methadone programmes had less need for therapist involvement, then the average costs of a structured programme may be higher. It is clear that for some patients the therapy element can involve considerable staff input and hence costs. (Coyle et al 1994).

Authors of another study, which gave estimates of some of the costs of delivering a methadone maintenance programme in General Practice, assumed each client had 3 minutes of GP time and 20 minutes with a counsellor each week (Wilson et al, 1994). The annual cost of the therapeutic component of this programme was estimated to be £381 but this makes no allowance for any non-contact time borne by the practice.

Toxicology costs

The Wilson et al (1994) study gives some indication of the potential costs for agencies of demanding frequent toxicology tests as part of a programme. Analysis of urine once-a-fortnight was estimated to add £520 per client every year, equivalent to £20 per test. The costs of such tests may be reduced in clinics with a large number of patients or access to a large centre, since this may facilitate negotiation of prices which reflect the lower costs associated with larger

numbers. Even at a lower cost, frequent testing, which may be seen as an important part of the monitoring process, can involve considerable resources.

Variations in direct costs

The available estimates of the different components of methadone programmes suggest that there are potential trade-offs between more frequent dispensing of methadone and more intensive therapy. While the high methadone, low therapy programme will have a more uniform cost, those programmes with therapeutic inputs being determined in terms of client need could have much greater variation between individuals. In this case it becomes more difficult to forecast the resource needs if client numbers expand. Also, the programmes described in this paper may have tapering costs over their length. Furthermore, there is the problem that those entering a maintenance programme may have a longer time in contact with the agency. This is problematic as additional resources would be needed to increase the numbers in the programme. However, to judge the 'worth' of any programme, it would be necessary to compare costs of total therapy over the drug-using career of the individuals.

The cost of the drugs and the therapy are important components of any structured programme, but other costs can be an important part of the total. Indeed, in the estimates of a general practice programme, dispensing fees of £806 and toxicology tests of £520 represent a major part of the £2,030 annual cost per client (Wilson et al, 1994).

Indirect costs

Types of costs which may be considered *indirect* include the time lost from work and the psychological costs of treatment felt by clients and their families (Drummond, Stoddart and Torrance, 1987). Since the vast majority of drug agency clients are unemployed, there are unlikely to be consequences of treatment events for employers in most cases. Moreover, motivated by a desire not to disrupt the working lives of clients, many treatment agencies will make more convenient time-slots available for the minority of working clients.

Differences in the psychological costs which different treatment approaches may impose on clients and their families may have an important influence on the choice of appropriate care. Parents of young drug users, for example, may find it difficult to accept treatment approaches which do not appear aimed towards helping their daughter or son to quit drug use.

Costs borne externally to the health sector, clients and their families

While it is possible to make some estimates of the direct costs of different programmes in different settings, it is much more difficult to estimate the indirect costs associated with different programmes. These indirect costs involve all additional costs falling on other agencies or the clients themselves. So, for example, some programmes may lead to more referrals on to other welfare agencies than others where the work is done within the programme. There is the possibility that some programmes will have low direct costs only because costs have been shifted to other agencies.

Another potential indirect cost is that associated with leakage of prescribed methadone to the illicit market. Programmes where methadone must be consumed on the premises, or supervised by a pharmacist, are likely to involve higher direct costs, but will minimise leakage. This type of regime may also minimise the risk of accidental poisoning. However, leakage of methadone may imply that more opiate users can benefit from substitute drugs than would be willing to present to services. For some, on the other hand, availability of cheap supplies on the illicit market may discourage help-seeking or attempts to detoxify.

There are other possible negative aspects arising from treatment programmes. The prescription of methadone may reduce the negative consequences of drug use just at a time when problems with drug use may be causing some conflict and resulting in thoughts of coming off drugs; potential abstainers may remain drug users as a result of receiving a prescription.

Methadone will often result in more severe withdrawal symptoms than heroin (Burr, 1987). The alternative to a protracted period of reducing-dose methadone is a switch to a short acting opiate

as described in the section on prescribing protocols. Some have argued that maintenance programmes may encourage experimentation and continued use by reducing the long-term costs of drug use to the individual.

Direct benefits

The Opiate Treatment Index (Darke et al 1992) and other drug treatment outcome measures indicate the range of direct benefits which substance misuse services may offer. Although provided by the health sector predominantly, services often realise non-health treatment benefits. The health benefits which may be generated include relief from addiction, reductions in the risks of injection-transmitted diseases and overdose, and improvements in overall health. Non-health benefits will include changes in social functioning, reduced criminal activity and improved work-capabilities. Without evaluation, however, it is impossible to predict the likely direct benefits from the alternative programmes outlined in this paper.

A further type of direct benefit of drug misuse treatment for the health sector will be the averted costs of other consultations with agencies in the health sector. In this case, perhaps the most pertinent of these effects will be saved Accident and Emergency Department episodes through avoidance of accidental poisonings. However, as in the case of alcohol, the various guises under which un-identified problems with substance misuse are likely to result in health care sector contacts may outweigh the cost of specific treatment alone (Godfrey, 1993).

Indirect benefits

Just as substance misuse services may have indirect costs on the productivity of employed clients in the short-term, improved life-stability and work-capability may imply indirect benefits of treatment in the long-term. Improved employment-profiles of treatment clients will add to the benefits of treatment.

Benefits accruing externally to the health sector, clients and their families

The focus of recent police efforts to promote the use of treatment services for drug-misusing offenders has arisen from the expected prevention of drug-related crimes and the saving of police resources. Reductions such as these in the costs of drug misuse to other parts of the public sector are the kind of benefits calculated by authors of US cost-benefit studies.

TABLE 1: POTENTIAL COSTS AND BENEFITS OF DRUG MISUSE TREATMENTS

A. Direct Costs

Capital - land and buildings

Running Costs

- Costs of drugs
- Dispensing costs
- Costs of therapeutic activity
- Toxicology costs

Clients and their families

- out-of-pocket expenses, eg. travel
- time and other costs associated with treatment input of clients and families
- possible extension of drug-using careers

B. Indirect Costs

Time lost from work

Psychological costs of treatment for clients and their families

C. Costs Borne Externally to the Health Sector, Clients and Their Families

Referrals to other welfare agencies

Leakage of prescribed drugs to the illicit market

Induced increases in experimentation and continued use

D. Direct Benefits

To clients, improved quantity and quality of life, through:

- reduced risk of injection-transmitted disease
- more healthy lifestyle in general
- improvements in social functioning
- reduction in drug-related crime
- benefits to families of reduced illicit drug use

To the health sector: reduced costs of other interventions

E. Indirect Benefits

Improved employment prospects and productivity

F. Benefits Accruing Externally to the Health Sector, Clients and Their Families

Reduced use of other welfare agencies in the long-term

Reduced criminal justice system costs

CONCLUDING COMMENTS

This paper has described the issues behind methadone programmes and the Leeds solution to the practical business of service structure and prescribing protocols. The importance and flexibility of 'The British System' is restated, but, against this background, the need for a locally sensitive prescribing policy and protocols is stressed.

Doctors are key individuals in the successful formulation and operation of a local policy. Doctors must take full responsibility for safe prescribing and giving patients information about their prescription. Equally, doctors will often need a co-therapist and should make sure of a suitable arrangement, either in-house or with a local agency before prescribing.

Prescribing methadone is not just a medical treatment. A lot of people, including government ministers, have strong opinions on substitute prescribing, so prescribers need to be aware of the political climate both locally and nationally. Maximising the benefits and minimising the costs of methadone programmes requires a measure of science, some art, and always optimism.

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