

Medical Treatments for Drug Misusers in Tayside:

Tayside Prescribing Protocol December 2005







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Foreword

Caring for people who are substance misusers can be a worrying and challenging role for professionals.

The Tayside Prescribing Protocol provides a clear philosophy and reinforces our commitment to work with outpatients and their carers and with our partner organisations to improve the outcomes for patients and their carers. Quality standards and safety are highlighted and our expectations of the responsibilities of prescribers made clear.

Particularly welcome are the best practice statements and the quick guide for GP colleagues. The protocol represents a step change in both the quality and the service we will provide for our patients and their carers.

Dr Bill Mutch

Chair, NHS Tayside Health Advisory Forum Acting Medical Director, NHS Tayside

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This protocol was presented to the NHS Tayside Area Drugs and Therapeutics Committee and endorsed on 21st November 2005.

The undersigned provide assurance to the Area Drugs and Therapeutics Committee that the protocol will be reviewed and developed regularly and in accordance to latest evidence.

Dr. Brian Kidd Lead Clinician Pam Gowans Service Manager

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Executive Summary

- □ This prescribing protocol was commissioned by the NHS Tayside Health Advisory Forum the body with lead strategic responsibility for the health element of drug and alcohol issues in Tayside. It has been created by leading health staff (clinicians and managers) from primary care and specialist services in association with the Drug & Alcohol Action Teams and Tayside Police.
- Prepared in response to many national and local drivers (including national guidance to avoid drug deaths), the protocol is a key document in the redesign of service delivery for the care of substance misusers in Tayside and is relevant to all clinical settings where people with substance misuse problems may be in receipt of medical treatments.
- ☐ It defines best practice and sets standards underpinning the future clinical governance of prescribing practice for substance misusers in Tayside.
- □ Prescribers in Tayside will be expected to reflect this protocol in all prescribed treatments for substance misuse.
- The protocol sets out a clear philosophy of care for substance misusers in Tayside. Changes include:
 - All medical treatments will follow a full and comprehensive assessment of need and risk
 - A full range of treatment options will be available, delivered to the highest standards, which are clearly defined & measurable.
 - The emphasis will be on delivering quality services with the aim of improving clinical outcomes and safety of individuals and their communities.
 - □ Appropriate licensed treatments which are currently available (e.g. methadone maintenance, diazepam detoxification, opiate detoxification, Naltrexone blockade) are included along with plans to develop protocols for delivering specific interventions (e.g. Buprenorphine) or treatments for high-risk groups (e.g. Pregnant drug users; dual diagnosis) in the future.
 - □ Clear guidance on inappropriate prescribing for substance misuse (e.g. Dihydrocodeine & other unlicensed opiates; diazepam maintenance) is included.
 - ☐ The guidance sets high standards of clinical quality and defines the clinical governance processes, which will support this.
 - Detailed appendices give practical advice on delivering quality care and also contain examples of paperwork, which may facilitate improved service delivery.
 - □ "Quick guide" shows good practice in a graphic flowchart form, for general practitioners (Page 51)
 - ☐ The Draft protocol has undergone wide consultation with comments and advice fully incorporated into the final document.
 - □ Supporting clinical governance processes have been developed in association with the HAF and NHS Clinical Governance structures.

Introduction

Background & key drivers for change

This Protocol was created by the Methods of Prescribing sub-group of the NHS Tayside Health Advisory Forum (HAF). The HAF is the strategic body with key responsibility to address substance misuse issues within the Health setting in collaboration with the Drug & Alcohol Action Teams (DAATs). The membership of the Methods of Prescribing Group is included in Appendix 10.

The aim of the protocol is to clearly describe the accepted use of prescribed medical treatments for drug misuse in Tayside. It will form the basis of all working arrangements for prescribing within all elements of NHS Tayside (including General Practice, Specialist Drug Treatment Services, Acute Services & Mental health Services) and their local authority and voluntary sector partners. Areas covered include:

Treatments for Opiate dependence

[NB. The drugs listed below are the only drugs approved for the treatment of substance misuse within NHS Tayside.]

- Methadone mixture (1mg/ml)
- Lofexidine
- Naltrexone
- Buprenorphine*

Treatments for Benzodiazepine dependence

Diazepam

Treatments associated with stimulant misuse

Ritalin*

(* Asterisk defines drugs that are not covered by protocol in this document. Protocols will be developed in future versions.)

The protocol takes into account existing live national guidance documents and good practice statements and is the basis for all clinical governance over the treatment of substance misuse in Tayside. Reference lists are included in Appendix 1.

This protocol is being introduced at a time of considerable change in Tayside services for drug misusers – including significant service redesign across all three DAAT areas. It will focus on the key areas of work identified by local clinicians – recognised prescribed treatments currently available for users of opiates and benzodiazepines. However, it is acknowledged that some treatments, which may add to the care of opiate users, must now be considered by NHS Tayside (e.g. Buprenorphine). Also concern about stimulant use and the development of standard approaches to the care of ADHD (i.e. use of Ritalin) has the potential to impact on the care of substance misusers. These new medical treatments will require guidance for doctors in Tayside. However, it has been agreed that the development of such guidance will require considerable consultation and should not hinder the production of this protocol.

Future versions of this protocol will incorporate any available local guidance for Buprenorphine and stimulants (including Ritalin).

Once launched, the protocol will be reviewed after 12 months to determine any alterations, which may be required in the light of these developments and at agreed intervals thereafter via the approved NHS Tayside clinical governance process.

Drivers for Change

- 1. Scottish Executive treatment service review: In light of an increase in drug deaths in Scotland despite significant new investment in treatment services for substance users over the last 3 years, the Scottish Executive undertook a national review of services in 2003/4. This review made clear recommendations regarding availability of high quality services which are in line with national guidance.
- 2. Need to review existing policies: Ten years ago Tayside Drug Problem Service (TDPS) created policies & procedures primarily to cover the prescribing of methadone within the specialist service and formal shared care arrangements with GPs. It is some time since the high standards contained in these documents have been audited. In recent years there have been demands from local communities and professionals to review the local approach to treating drug misuse. Internal & external reviews of the treatment services available in Tayside have encouraged a more systematic and comprehensive approach with key service elements cooperating to deliver "integrated care" dealing holistically with drug misusers' needs. This approach is in line with the Scottish Executive's "Integrated Care for Drug Users" document (EIU 2002).
- **3.** *Personal choice:* There is a need to ensure that all relevant treatment options are available to people in Tayside including methadone prescribing programmes, detoxification medications such as Lofexidine, a Naltrexone programme and Buprenorphine prescribing programme.
- **4. Service pressures**: In recent years TDPS and its general practice partners have found it difficult to respond to ever increasing demand for medical interventions. Waiting lists have reduced accessibility to services. Meanwhile the locally negotiated methadone dispensing budget repeatedly overspends year on year reflecting a need to consider redesign of these services to ensure those with most need are being dealt with as a priority.
- 5. Clinical Governance issues: NHS Tayside has seen increasing concerns being raised from professionals and the public about the prescribing of methadone. The perception is that some prescribing occurs outside accepted best practice. (Examples include provision of methadone without appropriate pre-treatment preparation or tolerance testing/ test-dosing; high dose prescribing; prescribing of drugs or formulations outside normal good practice; inadequate dispensing arrangements). These governance concerns are highlighted by the most recent results of the Confidential Enquiry into drug-related deaths in 2001 which show that Tayside has the highest prevalence of such deaths in Scotland with an unprecedented proportion (10/14) involving methadone alone. It is interpreted that this reflects prescribing practice in Tayside (CRAG 2003). There is a need to ensure that all such concerns are addressed in this protocol through the development of appropriate minimum standards for prescribing practice.

- **6.** Performance Assessment Framework benzodiazepines: NHS Tayside has traditionally shown high prescribing in the category of hypnotics and anxiolytics. The June 2003 report states that the prescribing rate is decreasing faster than the rest of Scotland and that the trend is moving in the right direction. It is therefore essential that prescribing of benzodiazepines within substance misuse is carried out within a robust protocol, to further facilitate this trend.
- 7. Service redesign: Tayside DAATs commenced a process of service redesign in June & July 2003 to improve the flow through services and to identify and address unmet need. In association, NHS Tayside prescribing services will be reconfigured in December 2005. This protocol will support this process.
- 8. Scottish Executive waiting times initiative: In response to the National Treatment Agency guidance on reducing waiting times for treatment the Scottish Executive, Substance Misuse Division is developing guidance for Scotland regarding access to all elements of treatment services. Prescribing issues will inevitably be part of this initiative.
- **9.** New GP/Pharmacist contracts: The new GMS contract and new arrangements for contracting pharmacy services will create an opportunity to review constructively how these services are delivered with regard to substance misuse.
- 10. A Joint Future: The guiding principle of the Joint Future agenda is the improvement of outcomes for those people who use services and their carers. This will be achieved through better use of resources, better management of services (possibly under single management) and better systems with less bureaucracy, less duplication and clearer responsibilities. The prescribing protocol fits directly within the Joint Future agenda and will contribute to the introduction of Joint Future systems.

Implications & Communication of changes

The introduction of this policy will impact on service users as well as professional partners. There will be a need to communicate these changes clearly in a way, which ensures the highest impact. The impact will depend on the timeframe and phasing of these changes.

As commissioning body, the HAF will be responsible for:

- Agreeing/delivering a communication strategy
- Developing & administering a clinical governance process in association with the NHS Clinical Governance structures.

Philosophy of Care for Drug Misusers in Tayside

Treatment of drug misusers incorporates many approaches, which may seem to be in conflict – ranging from "harm reduction" approaches, aiming to reduce the biological, psychological or social "harm" a drug misuser is causing themselves and their community, through to total abstinence. People attending drug treatment services will include those presenting with a broad range of problems and it must be recognised that all people do not require (or may not want) a replacement prescription to overcome their drug problem. Any philosophy of care must recognise this.

Underpinning principles

- Tayside services offer a comprehensive range of interventions for people living in Tayside who have problems with drug use
- Tayside services deal with substance misuse by working within a broad harm reduction framework, which includes the aim of helping people achieve abstinence.
- Tayside services offer a person-centred, needs-led service and will respond appropriately to requirements following a full and comprehensive assessment.
- Tayside services deliver evidence-based practice within nationally agreed standards
- Tayside services work in partnership to ensure that a full range of high quality interventions is available.

Aims of a prescription – detoxification & abstinence

Prescribing of specific drugs, which deliver a clear outcome, is relatively straightforward for most doctors. Detoxification (allowing a dependent individual to become drug free with the minimum of discomfort or risk) using Lofexidine or blockade of opiate receptors using Naltrexone are treatment options which have clear indications and for which protocols should improve safety and effectiveness. These options still require keyworking and close cooperation between professionals. They will be covered later in this document (Lofexidine – page 18; Naltrexone page 19)

Aims of a prescription – replacement prescribing programmes

Prescribing programmes may seem more controversial. Evidence clearly shows that replacement prescribing of methadone for those dependent on opiate drugs can be an important element of a treatment package. Its availability can encourage drug users to attend services and retain them in contact which gives the service the opportunity to deliver psycho/social interventions which have been shown to increase the likelihood of a positive outcome (the ART – Attract, Retain, Treat - principle). Prescribing of methadone, however, can also be dangerous to the user and their community and also inevitably commits most people to a long-term treatment programme which has the potential to have a negative impact on their lives. Some people may see methadone as a source of legally supplied drugs, which add to their repertoire of drug use or can support their illicit use. When delivering methadone programmes it is essential to balance the benefits with these potential risks or detrimental effects.

There is no significant evidence base to support replacement prescribing for any drug group other than opiates. In some services oral amphetamines are used to treat amphetamine misuse – this is not common practice and is not recommended in national guidance. Benzodiazepine misuse is commonly seen alongside opiate misuse and most Scottish services have some policy for dealing with this. Again, there is no significant evidence base to support long term replacement prescribing. A fixed detoxification regimen involving associated psychosocial support seems most likely to be beneficial. This will be covered later in this document (Ref to page 17)

Best Practice 1

In Tayside being in receipt of a replacement prescription is never an end in itself. People must demonstrate a readiness and commitment to change their behaviour prior to a prescription being issued. Prescribing methadone is not the provision of a legal addiction. People must continue to show commitment to an agreed treatment programme for prescribing to continue.

Aims of the prescribing programme are:

- To replace illicit use with a clean controllable regular supply of an appropriate drug
- To prevent symptoms of withdrawal.
- To help stabilise the person's drug/use and lifestyle reduce sharing; stop injecting; rationalise drugs used; reduce & ultimately stop illicit drugs
- To help the person to become drug-free when appropriate.
- To help enable drug users achieve more fulfilling and healthy lives and to assist their inclusion into society.

Prescribing programmes in Tayside

Opiate dependence

All replacement prescriptions from Tayside Services must adhere to the protocols below. In a special case, where a person's needs dictate that a variation is indicated, this must involve a discussion with the specialist team or Consultant in Addiction.

Formulations

Replacement prescribing as part of a treatment programme in Tayside will only include the use of medications licensed for that purpose. Licensed medications are:

- Methadone mixture (1mg/ml) standard treatment
- Methadone Oral Concentrate (10mg/ml) Specialist use only. Care is required in the prescribing and dispensing of the correct strength, since any confusion could lead to an overdose. [NB. All other forms of Methadone tablets & injectables are not licensed for the purpose and are not supported by this protocol in any circumstances]
- Buprenorphine hydrochloride (Subutex) 0.4mg, 2mg, 8mg sublingual tabs –
 Specialist use only. (Not currently used in Tayside)

Best Practice 2

Dihydrocodeine (DF118) and all other opiate-based analgesics are NOT LICENSED FOR THE TREATMENT OF SUBSTANCE MISUSE AND SHOULD NEVER BE PRESCRIBED FOR THIS PURPOSE

Methadone Mixture 1 mg / 1 ml

This formulation of methadone is exclusively used to treat substance misuse in Tayside. There are <u>NO</u> circumstances in which the use of alternative formulations is indicated outside the Specialist prescribing service.

Prescribing process

Before prescribing:

- Prescribed treatment will only be considered once a person has been adequately and comprehensively assessed. Assessment will involve a specified specialist counselling/treatment service working in conjunction with any involved medical staff. Presently the main support service is Tayside Drug Problem Service (TDPS) and the treatment element of the Drug Treatment & Testing Orders Service (DTTO). Service redesign will aim to increase the services supporting prescribed treatments and as other service providers are introduced to Tayside they will be included in future guidance.
- Prescribed treatment will only be considered once it has been fully established that the person is dependent on a specific drug/group. This will involve self-report by the user; supported by self-completed drug diaries covering 2 seven day periods; two urine tests at least 7 days apart; observation of clear signs of opiate withdrawal (tachycardia; dilated pupils; sweating, pilo-erection and goosing of the skin; yawning; rhinorrhoea & lachrymation; loose bowels or diarrhoea; tremor, agitation & restlessness). Failure to demonstrate a withdrawal syndrome should prevent any prescribing of drugs of misuse.
- Prescribed treatment will only be considered once a person is fully engaged with the GP or services and has agreed a treatment plan with their keyworker following discussion covering all of their options. The keyworker will discuss with the person their obligations regarding attendance, illicit use and behaviour and will ensure the person is in agreement with these. If not NO PRESCRIPTION WILL BE FORTHCOMING at that time. This process should take no more than 3 weeks. NB. The aim is to ensure that any prescribed treatment is fully integrated into a treatment programme with a care plan, which has clear aims. This may be achieved rapidly the aim should be to complete this assessment as soon as possible and should not have arbitrary timeframes set which may delay initiation of prescribed treatment.
- Doctors/keyworkers should clearly set out the expectations users may have of the service and the service has of those in treatment. This may be laid out in a written agreement that can be signed by the staff and service user. Alternatively the agreement can be used as a written source of information. (Example included in Appendix 3)
- The keyworker & doctor will agree any proposed prescribed treatment with the person. Again the doctor will ensure the person is in agreement with their obligations regarding attendance, illicit use and behaviour. The doctor & keyworker will initiate the generation of a prescription which will adhere to Tayside quality standards (see Best Practice 3)
- Doses to be used will reflect the person's regular use of opiates. (Key to methadone-equivalent doses is contained in Appendix 4). Clearly the dose of methadone, which reflects use of illicit heroin, is difficult to estimate. Users often over-estimate their use and the initial dosage must therefore be conservative to be safe.
- Special cases e.g. pregnancy; dangerous/chaotic drug use; concurrent chronic physical/psychiatric illness; recent release from prison; young people; service transfers should be assessed & discussed with the specialist service urgently.

• Police custody – this protocol covers ALL prescribing for drug misusers in Tayside. Advice to Police surgeons is included in Appendix 5.

Best Practice 3

Quality standards for prescribed methadone:

- Never prescribe in isolation involve a specialist service
- Never prescribe at the first assessment
- Never prescribe unless you are continuing that person's treatment or have agreed with another service provider to continue it.
- Always assess the person fully before considering a prescription
- Always ensure a drug screen is seen before proceeding
- Always demonstrate dependence before proceeding
- Always carry out a tolerance test on the first dose
- Always start with a supervised dispensed prescription for 3 months Never permit less than daily dispensing thereafter

Starting a methadone prescription

- Once agreed the prescription should be started as soon as safe arrangements can be made. (A good standard would be within a maximum of 7 days)
- All new prescriptions should commence with an observed test dose or tolerance test (see below test dosing/tolerance testing procedure).
- Prior to their first dose date the person will nominate a preferred pharmacist through which their prescription will be dispensed. If the pharmacist is unable/unwilling to supervise then alternative arrangements must be made which ensure supervision of consumption is carried out.
- The doctor will not commence any prescriptions without supervised consumption. New scripts will be supervised for a minimum of 3 months. Service transfers will begin as supervised scripts but this may be reviewed more rapidly (1 month minimum) once the doctor & keyworker have established stability.
- The person will attend the pharmacy with their keyworker to be introduced prior to prescription commencing.
- The first prescription (starting day after tolerance test/test dose) should be sent or handed to the pharmacist prior to the starting date.
- Test dosing and tolerance testing should be carried out in a safe setting with specialist supervision. In the community this will mean only Specialist doctors will tolerance test (i.e. specialist service or specialist GPs with a specialist interest in drug misuse).

Methadone tolerance testing/test dosing procedure

The first dose of methadone has the potential to be extremely dangerous, especially if a patient has not been adequately assessed (see above). If the Best Practice Points from box 3 are adhered to the dangers can be limited.

Test dose or tolerance test?

When test-dosing the aim is to administer the first dose in a safe setting to ensure the person can tolerate a significant dose. Risks are managed by delivering this dose in a safe setting with medical & nursing cover. Subsequent (often higher) doses are based on the assessed tolerance and can be delivered safely via supervised pharmacy places. Tolerance testing takes this principle further, giving a low (and if adequately assessed, very safe) first dose on day one and then bringing the person back to the clinic regularly to titrate their methadone dosage to their symptoms of withdrawal & craving. In some settings this is done using "blind prescribing" - where the dose received is not known by the person receiving the methadone.

Whatever technique is used, the aim is to have the person on adequate doses of methadone as quickly and safely as possible, with the aim that they are capable of remaining drug-free from as early a stage as possible.

Tayside practice

In Tayside, the specialist services has traditionally carried out tolerance testing – with first prescriptions started at low doses not exceeding 40mg and regular review by the clinic doctor being associated with increases as required until the patient is objectively stabilised on an appropriate dose.

In such a system it is essential that patients are reviewed weekly and doses are not increased more frequently as it takes some days for any methadone dose change to stabilise. Close keyworking (no less than weekly) must be initiated and any evidence that the patient is being overdosed should trigger urgent review by medical staff.

Dosages

There is a significant evidence base supporting the need to consider higher doses of methadone in some heroin users. Doctors may be criticised for giving inadequate doses of methadone and it is important to recognise that some peoples may require an increase. Current National Guidelines suggest that, unless doses of 60-120mg have been tried it cannot be assumed that methadone has been unsuccessful. Obviously these dosages must be seen in the context of each individual person and their needs. If higher doses than 100mg are felt to be required this should only follow discussion with the specialist service or Consultant in Addictions.

Best Practice 4

New prescriptions/initiation

- All new methadone prescriptions will be initiated by TDPS or specialist GPs
- If other doctors feel compelled to prescribe they are advised to contact TDPS doctors at the earliest convenient time and should always endeavour to get advice before commencing (eg acute hospital, mental health).
- Methadone will only be commenced following adequate assessment as above
- Methadone prescribing must only occur in dependent individuals
- •The first dose of methadone should reflect the person's daily use and should not exceed 40mg
- The first dose of methadone should be administered in a setting in which observation is available with the person observed for at least 3 hours with regular assessment for over-sedation.
- All subsequent doses will be supervised at the pharmacist for minimum 3 months
- The following doses will depend on each weekly assessment and increases should either i) reflect the daily dose identified during a comprehensive assessment process or ii) increase at 10mg increments no less than one week apart.
- If there are concerns that stabilisation is not being achieved rapidly TDPS should be contacted immediately.

Ongoing methadone prescribing, monitoring & review

There is a requirement that those in receipt of a replacement prescription regularly attend keyworking appointments, resist illicit drug use (or use of prescribed or over the counter opiates, benzodiazepines, alcohol) and behave appropriately in their interactions with the services they attend. Failure to do this should result in review of the case and appropriate action. This action may be an increase in the methadone dosage if insufficient or introduction of an appropriate treatment to resolve other problems (pain, insomnia, anxiety etc.). In some cases the person has clearly chosen to continue their illicit use, is avoiding alternative treatments to resolve the problem and is simply supplementing their illicit use with prescribed drugs. In such circumstances review of the case has the potential to withdraw any prescription until an agreed care plan can be created.

Concessions - Holidays or "emergencies"

Once stabilised on methadone many patients are able to enjoy significant normalisation of their lifestyle. Many will request reductions in frequency of dispensing. This is **not recommended** as it increases the likelihood of relapse and leakage of methadone into the community. Less than daily dispensing should only be considered as a "one-off" response in cases where a stable person has a legitimate request, which requires an urgent response (e.g. visiting a sick relative; unexpected work changes). Most significant changes in lifestyle do not occur rapidly. Holidays are booked with some notice and changes of legitimate employment do not occur overnight. Good practice would be to advise that there is a minimum response time for prescription changes/concessions – 7 days would be reasonable. If a person is

holidaying or visiting within the UK, a pharmacy locale to where they will be staying can be contacted, availability of methadone dispensing confirmed and a prescription sent by recorded mail.

If holidaying abroad, more notice may be required. The home office will require to issue a license to allow more than 500mg of methadone to be taken out of the country and this can take some time to arrange. People should be asked to give as much notice as possible and clinicians should confirm the plan by seeing tickets etc. The home office drugs branch should be contacted and advised of the request. The prescriber should also issue a covering "to whom it may concern" letter.

The amount of methadone to be made available will depend on clinical judgement of the person's stability. The methadone should be dispensed in individual daily bottles to avoid inconvenience should a bottle be broken. Before prescribing, clinicians should ensure that adequate safe storage is available.

If there is any reason to believe the person is not stable their request should be declined until objective stability is achieved.

Standards

- All people prescribed for will be the subject of regular review by the doctor. This should occur no less than 3 monthly. These meetings must be recorded in legible handwriting in the contemporaneous notes.
- All people prescribed for must be seen regularly by their keyworker depending on need and ongoing therapeutic work. This will occur no less than monthly (and at early stages will occur more frequently first 3 months weekly; at least fortnightly until stabilised). Monitoring activity will include: testing (supervised urine or oral fluid); physical examination; completion of any outcome measures. These will be recorded in legible handwriting in the contemporaneous notes.
- All new prescriptions will be supervised daily dispensed for 3 months minimum. The keyworker should liaise with the pharmacist prior to 3 monthly review.
- Thereafter supervision may be lifted if the person is 100% compliant with treatment (attendance, use, behaviour). In some cases ongoing supervision is required for longer even if compliance is achieved. These include: living with an active user; no safe storage of methadone available with children in the house; recent history of dealing; personal characteristics which imply the person is unable to take full responsibility for their prescription (eg <18s); any safety concerns. Some people will request to stay on supervision to avoid "taxing" (people demanding their takeaway script) or because they have good insight into their vulnerability.
- All people prescribed for must be subject to 3 monthly review by their therapeutic team (prescriber, keyworker), which will generate a care plan for the next 3 months. This should be recorded in the contemporaneous handwritten notes or a specific review sheet may be used. (An example form is included in Appendix 6).
- If a person is unable to comply 100% then supervision may be re-applied as a therapeutic tool to ensure a professional sees the person daily. This also allows the application of clear boundaries, which can positively influence behaviour and service use.

• Any "special cases" for whom an exception is being sought should be discussed with the specialist team and Consultant for advice.

Stopping methadone prescriptions

In the event of completion of a successful treatment programme a prescription would stop through negotiated agreement following a reduction schedule or prior to a detoxification. Prescriptions may require to be stopped if they are seen to be ineffective or dangerous to the person or others. Ineffective prescriptions will be reviewed with the person and alternative strategies discussed and initiated.

It is not helpful to stop prescriptions as some sort of "punishment" for misdemeanours. Prescriptions will only stop if clinically indicated and the reasons will be explained to the person whenever possible. In special cases (such as pregnancy) every effort must be made to retain the prescription. However, at times cessation will be necessary until a full review of the case can occur and this procedure should be undertaken as safely as possible. No treatment should be stopped arbitrarily – cessation of treatment can be associated with increased risk of chaotic drug use and death.

Indicators for immediate review of methadone prescription:

- Continuous ongoing illicit use (self-report, testing or injection sites): Two consecutive reports or tests should trigger **review by doctor and keyworker.**
- Repeated failure to attend appointments (DNA): Two consecutive DNAs should trigger **review by doctor and keyworker.**
- Threats or acts of violence or intimidation towards staff/GP/pharmacists: Any such episodes make a safe & meaningful therapeutic relationship impossible unless dealt with and make prescribing dangerous. Any episode should trigger a review by doctor and keyworker.
- Dangerous use of script to self e.g. alcohol, IV use: In such cases the user should be challenged with the issues and counselled regarding safety of their prescription. Any issues they may have should be addressed. Clear plans and expectations should be laid out and review dates set. Failure to demonstrate behaviour change should lead the clinical team to set clear boundaries for the user. Continued dangerous use in the face of this action should trigger a prescription stop and reassessment of the person's needs.
- Dangerous use of script to others e.g. Children or evidence of dealing/fraud relating to prescription: In a case of children being exposed to these drugs or a confirmed episode of prescription fraud/seeking of double-script the prescription should cease immediately pending an immediate review of the case. Staff should also consider seriously the need to instigate child protection procedures.
- Failure to collect prescription (2 days or repeated event): **prescription** should cease immediately pending an immediate review of the case.
- Failure to supply test sample on request: **prescription should cease** immediately pending an immediate review of the case.
- Information received from a third party should trigger review and discussion e.g. police information regarding law breaking activity

Cessation of prescription will lead to discussion with the person and an assessment of risk by doctor & keyworker with view to creating a care plan, which delivers the most

appropriate treatment option to meet need. Discussion should cover the following issues if relevant:

- *Ineffectiveness of prescription* the person will require a re-assessment of their needs which will address the place of any prescribing in their future treatment plan. Clearly a return to prescribing is an option if the person can demonstrate an understanding of the rationale behind prescribing, has been under-treated and commits to a programme. The prescription will normally be reinstated at an appropriate dose with a clear review plan in place.
- Failure to attend failure to attend does not allow for the adequate monitoring of the person's health, progress and safe use of their medication. DNA should result in a written notice stating they must attend the next appointment. If the next timetabled appointment is missed the prescribing should be withheld temporarily by the pharmacist until they are seen and their safety/compliance confirmed. This process may require to be repeated in some cases.
- Poor compliance/unsafe use of medication Any prescriber must reserve the right to stop a prescription immediately if there are concerns that it is unsafe. Excessive use of alcohol or illicit drugs increase the risks of overdose & death and can lead to script cessation pending review. Any reports that vulnerable groups (eg children) are at risk from prescribed medications should always lead to cessation pending review.
- Inappropriate behaviour, violence etc. aggressive, violent or intimidating behaviour impairs the staff member's ability to work with a drug user safely & effectively. Any such behaviour may lead to immediate cessation of the total treatment plan pending review

When a prescription is stopped the person will be notified verbally if attending and will always be notified in writing. If stopped by a specialist team the pharmacist & GP will be informed by phone with the GP being advised of the circumstances and advised regarding ongoing care. This will be followed up in writing. If stopped by a GP his/her partners should be informed and the situation clearly recorded in the contemporaneous notes to avoid accidental prescribing by others. This should include information being passed back to the specialist team, and a procedure for pharmacists to contact GP and specialist team.

Considerations & options

Although the experience may be unpleasant, opiates can be stopped without any immediate medical risk. If the person is on a benzodiazepine prescription, a rapid reduction should be initiated to prevent withdrawal seizures. (Appendix 7 gives a useful guide for dosage).

Reinstatement of a prescription should follow a full treatment review involving the keyworker, prescriber and service user. In complex cases a specialist opinion should be sought.

Best Practice 5

Stopping prescribed methadone/diazepam

- Stopping prescriptions should only be used <u>as a last resort</u> when safety is a concern, treatment is not progressing or therapeutic engagement is lost.
- Those in receipt of prescriptions should be given the option to avoid loss of the prescription if at all possible and the decision should never be taken without the person being aware that it is an option being considered.
- If a prescription is to be stopped the person should be seen as soon as possible and alternative treatment options discussed and agreed. Loss of a prescription does not mean loss of a service.
- Doctors should not simply supplement prescriptions with other opiates or benzodiazepines.
- Use of medications such as Loperamide for symptom relief is reasonable but must be time limited.
- Any case where methadone is stopped should be reviewed by the treatment team as a clinical governance exercise
- Diazepam may require a reducing regimen to avoid seizures
- Any such prescription change should be clearly recorded and followed by communication with all relevant professionals involved with the case.

Prescribing Practice - Other drugs

Benzodiazepines

Benzodiazepines were introduced in the 1960's and quickly replaced barbiturates for the treatment of anxiety and insomnia, as they were thought to be safer and less addictive. The reality now, however, is that these drugs are markedly addictive and widely misused. Indeed of the 19 drug related deaths reported in Tayside in 2001, 15 had diazepam cited as being involved and 2 involved temazepam. The "Orange Book" cites references stating that in 1987, 90% of attendees at drug misuse treatment centres reported benzodiazepine use in a one-year period and in 1994, 49% of benzodiazepine misusers had injected them. Substitute prescribing is not appropriate as there is no evidence to suggest that this regime reduces the harm associated with misuse.

The Committee on the Safety of Medicines (CSM) have issued guidance that benzodiazepines should only be prescribed for the short-term treatment of anxiety or insomnia that is **severe or disabling** and that treatment should last no longer than **two to four weeks**. The CSM further states that long-term chronic use is **not recommended**. There is an increasing body of evidence that long term prescribing of benzodiazepines may cause harm. **Prescribers should therefore, not initiate maintenance prescribing of benzodiazepines**.

There are a number of diverse presentations in which benzodiazepines may be considered as a prescribed treatment. People presenting to addiction services or requesting prescriptions from GPs/hospital departments are often using benzodiazepines as an intoxicant but will claim to be "dependent" or "addicted". Dependence to benzodiazepines is impossible to demonstrate consistently and it is likely that there is significant over-prescribing of benzodiazepines in these circumstances. There is **no evidence base** to support the prescribing of benzodiazepines as a treatment for opiate misuse or benzodiazepine dependence.

Why prescribe at all?

People may be using large amounts and, if stopped (because of their requirement not to use on methadone) may risk withdrawal seizures. This problem may reduce the likelihood of success on a methadone or detoxification programme.

Best practice

Clinicians should deal with benzodiazepines in the pre-prescribing phase. People should be encouraged to stop using benzodiazepines. This is readily achievable if the drug is being used purely as an additional intoxicant or as a replacement when opiates are unavailable. In the former, counselling around controlling use of illicit benzodiazepines will augment success while in the latter case, adequate dosing of methadone will circumvent the need to use benzodiazepines. Patients should be given access to supportive programmes to deal with issues of insomnia or anxiety. These may include counselling services, complementary therapies or specific self-help programmes (Examples of such programmes are included in Appendix 7).

If, at the time of consideration of methadone prescribing they have proven unable to stop using benzodiazepines then a detoxification prescription may be considered. The following programme is run by TDPS and is recommended. This programme would only be considered if the patient commits to stop their illicit use of benzodiazepines.

- Only Diazepam will be used
- No other benzodiazepines will be prescribed
- People will be given no more than 30mg Diazepam on daily pick up.
- Dose will reduce to zero over 12 weeks without exception
- Keyworkers will support and treat the person using alternative strategies
- The regimen will not be repeated.

*** Best Practice 6 ***

Benzodiazepine prescribing

- The treatment of anxiety is primarily psychological
- The treatment for misuse of benzodiazepines is primarily counselling
- If patients are misusing benzodiazepines alongside opiates the issue must be addressed pre-prescribing
- Relaxation & sleep hygiene programmes should be sought (Appendix 7)
- If prescribing is deemed necessary it should involve only diazepam, should be low dose, should involve rapid reduction (30mg to zero over 12 weeks) and should not be repeated
- The dangers of benzodiazepine prescribing alongside opiates should not be underestimated.

Lofexidine

Background

Lofexidine is an α adrenergic agonist, which is prescribed for the alleviation of symptoms of withdrawal in individuals undergoing detoxification from addiction to opiate drugs of all types. Tayside Drug Problems Service (TDPS) has been carrying out a limited Lofexidine detoxification service for some years. TDPS only uses Lofexidine as part of a formal agreed and time-limited detoxification procedure. TDPS does not use Lofexidine or other medication as a "stand-in" drug for those whose methadone dosage is insufficient or who attend in "emergency" situations claiming to have lost or mislaid their prescribed drugs.

The protocol for use of Lofexidine is contained in Appendix 8. It takes into consideration TDPS experience, research and practice evidence and the extensive experience of Forth Valley CADS in this intervention. This protocol has been adapted from the Forth Valley CADS protocol. It is recommended that this protocol is followed for all Lofexidine detoxifications carried out in Tayside. This protocol can be used by TDPS staff & is also available for use by GPs in Tayside area. It is however recommended that any staff undertaking a Lofexidine detoxification procedure are advised and supported by TDPS staff in order to increase the likelihood of a successful outcome. The document reflects the partnership nature of this work.

Buprenorphine

Buprenorphine is an opiate partial agonist/antagonist. As the analgesic Temgesic it was readily misused in Scotland and became the subject of local voluntary prescribing bans in many areas. In the late 1990s it was re-introduced as a sublingual tablet (Subutex) and has had extensive use in France and Australia. Attempts to introduce it to Scotland were strongly influenced by the history of Temgesic misuse as well as practical concerns - suitability for supervised consumption; lack of testing facilities; fear of leakage into the community. In 2000 the Scottish Drug Specialists Committee agreed not to use it until feasibility work was carried out on these areas of concern and advised the Scottish Executive accordingly. Recent surveys suggest it is being used by ~30% of specialist services in Scotland - mainly as a detoxification drug under close supervision via specialist clinics.

Buprenorphine is not currently to be used in Tayside. Any new policy will be introduced following full consultation with all partners (including pharmacists and GPs) and endorsement by NHS Tayside Clinical Governance systems.

It is anticipated that a Buprenorphine based detoxification programme will be introduced by TDPS in 2006. In the meantime, any queries or service transfers should be referred immediately to TDPS.

Naltrexone

Naltrexone is an opioid antagonist, which blocks the action of opioids and precipitates withdrawal symptoms in opioid dependent people. The euphoric action of opioid agonists is blocked, thus Naltrexone is given to opiate free people as an aid to prevent relapse. The evidence-base for this drugs effectiveness is weak but developing. It is implied that, in those highly motivated to detoxify but who are subject to impulsive relapse, the drug may reduce the rate or extent of relapse.

The drug should only be used in association with a relapse-prevention programme delivered by a specialist counselling agency. Occasionally patients may return from a "rapid detoxification" facility (e.g. "Detox 5"), which initiate a Naltrexone prescription, or from prison. These facilities should not have proceeded with Naltrexone (a drug with potential side effects) without liaising with the GP first and agreeing ongoing prescribing plans.

A full protocol for the use of Naltrexone in Tayside is included in Appendix 9.

Ritalin

Use of Ritalin for ADHD children is well recognised and practiced in Tayside. There is a potential for such cases to become a prescribing issue for addiction services and GPs as they grow older. To date no agreed protocols exist for its use in these circumstances.

Ritalin is not currently to be used in Tayside for any persons not being supported by Child & Adolescent services or in association with those services' processes. Any new policy relating to substance misuse services will be introduced based on need and will follow full consultation with all partners (including pharmacists and GPs) and endorsement by NHS Tayside Clinical Governance systems.

In the meantime, if there are any concerns with adults being prescribed these drugs or transferring into the area please contact TDPS.

Good Practice & Clinical Governance

All clinical activity should be underpinned by a strong clinical governance process. Clear quality standards relating to prescribing programmes in Tayside are in place. These will be audited against regularly (6 monthly) in a process administered by the Tayside Addiction Services Clinical Governance Group, a subgroup of the HAF.

Quality standards

Clearly quality standards will relate to the setting in which any prescribing is taking place – especially with regard to the degree of keyworking or counselling/support available. Expectations created by the new GP Locally Enhanced Service contract will clarify roles and will generate a process of quality assurance for GPs involved in the care of substance misusers. However, with regard to assessment before prescribing, initiation of replacement prescribing of methadone and ongoing prescribing of methadone, all Tayside medical staff will be expected to adhere to the standards below (marked *).

- Only methadone mixture will be prescribed in any prescribing programme for opiate dependence*
- In TDPS or Shared Care, all people will be keyworked no less than 4 weekly. Appointments will be clearly recorded in the contemporaneous notes. No GPs should be prescribing outside these arrangements. *
- All people will see their prescriber no less than 3 monthly in all services. This will be recorded clearly in the contemporaneous notes.*
- All people will have their progress recorded and a care plan agreed prior to prescribing, at 3 month review and at discharge. This should be recorded on a specific care planning sheet but may also be recorded in the contemporaneous notes.*
- No prescriptions will be initiated without a full assessment including two
 valid drug screening tests and demonstration of tolerance on objective testing.
 This will be recorded in the notes*
- Assessment (to the point of agreeing a care plan) should not exceed 3 weeks
- Once a care plan involving prescribing is agreed, test-dosing and tolerance testing should occur in no more than 7 days. (ie from first assessment to "treatment" should not exceed 4 weeks (National Standard).
- Initial doses should be given in a safe setting with medical and nursing cover.*
- Initial dose should reflect assessment of tolerance but should not exceed 40mg Methadone mixture.*
- In all cases where prescribing is initiated outside primary care the GP will be informed in writing of any treatment changes
- Good practice would be for no prescriptions to be handed to people. Instead, they should be delivered by hand or by post to the pharmacist whenever possible. This will be the standard for TDPS and formal shared-care settings.
- All new prescriptions will be supervised daily pick up. There will be no exceptions. All new scripts will remain supervised for at least 3 months. Others (service transfers) will be reviewed at 1 month and altered if appropriate*
- All subsequent prescriptions will be daily dispensing. Only those *already on a concession prescription* who are complying 100% will be permitted to have

less frequent dispensing continued. (ie Very stable people – no positive tests, near-perfect attendance and clear evidence of progress)*

- Only the named person will collect their prescription. Special arrangements
 may be considered on their merits but any arrangements will be time limited
 and subject to review. It is essential that, if any concession is applied it is
 reviewed after no more than 7 days by the prescriber/keyworker and
 pharmacist. If no review takes place the pharmacist will return to standard
 dispensing until another concession is discussed.
- No prescriptions will be replaced once the medication is dispensed

The number of people prescribed for by the services delivering the methadone programme will be set at a level, which promotes safety & effectiveness. Tayside prescribing practice will not reduce quality (clinical governance) in response to inadequate resourcing (corporate governance). Commissioners must ensure they are aware of local need and review service quality against capacity on a regular basis.

Performance indicators (HAF)

NHS Clinical Governance systems require to harmonise with DAAT governance systems. HAF & DAATs have identified a number of Key Performance Indicators regarding prescribing practice.

- Reduction in methadone-related deaths
- Change in pattern of methadone related deaths
- Consistency of prescribing practice across Tayside
- Improved access to prescribing services across Tayside (W/L initiative)
- Improved objective clinical outcomes

It is proposed that in association with its key partners (including the DAATs, CHPs) the HAF develops these further as part of the HAF clinical governance framework. This process will be activated in 2005.

Appendix 1 - References

Key reference documents used in the development of this protocol include:

- Tackling Drugs in Scotland Action in Partnership (Scottish Office 1999)
- "The Orange book": Drug misuse & dependence guidelines on clinical management (DOH 1999)
- "The Red book": Reducing drug related deaths. ACMD (HMSO 1999)
- Effectiveness of treatment for opiate dependent drug users an international review of the evidence. Effective Interventions Unit. (Scottish Executive 2002)
- Integrated care for drug users principles and practice. Effective Interventions Unit (Scottish Executive 2002)
- Substance of Children's Needs
- American Psychiatric Society Practice Guidelines (1996) APA. Washington.
- "Mind the Gaps meeting the needs of people with co-occurring substance misuse and mental health problems" (Scottish Executive 2003)

Appendix 2 – Example Contract

TREATMENT AGREEMENT

Name: CHI:

The General Practitioners, Tayside Substance Misuse Services, community pharmacists, the Social Work Drug and Alcohol teams and voluntary services are providing specialist services to patients with drug problems. In order for care & treatment to run smoothly, it is necessary to have some rules and regulations, which we ask you to follow.

Patients in receipt of prescribed treatments may experience different drug problems to varying degrees. To this end, when prescribed, you will be seen in accordance to your needs. You will be seen either by:

A) Your keyworker and the doctor employed by Tayside Substance Misuse Services,

- B) Your keyworker and your GP
- C) Your GP supported by a specialist drugs worker from social work or the voluntary sector
 - D) The community pharmacist, normally on a daily basis

Assessment

- 1. All patients presenting with drug problems will be assessed by a specialist drugs worker.
- 2. After assessment, a treatment plan will be devised in conjunction with you, your keyworker and your GP or TDPS doctor.

Treatment Plan

1. The treatment plan will include: Advice and Information

Education Detoxification Harm Reduction Drug Counselling

Referral to another agency / professional (It may include a prescription as well)

Prescription

- 1. **Any prescription received will form a SMALL PART** of the overall **treatment plan.** The purpose of this prescription will be to help patients keep withdrawals at bay whilst addressing their substance dependence.
- 2. The medications prescribed by Tayside Substance Misuse Services are:

Patients dependent on opiates

Methadone, this medication can be prescribed for maintenance, reduction or detoxification, for opiate dependent patients.

Lofexidine, this medication can be prescribed for detoxification for opiate dependent patients.

Naltrexone, this medication may be prescribed following detoxification to help sustain abstinence from opiates.

Patients dependent on benzodiazepines

Diazepam, this medication will only be prescribed in extreme circumstances and on a **strict reduction programme**, which will not exceed 12 weeks.

Information Sharing

The local information sharing protocol embodies a commitment from the partnership agencies to the sharing and the safeguarding of patient information, recognising this as an essential precursor to the development and delivery of integrated services.

Drug services in Tayside function within an integrated framework, and as such, sharing of information is key for patients to be referred to appropriate service and for moving patients on to the next stage.

In order to facilitate each patient's optimal care, it is important that each patient consents to Tayside Substance Misuse Services sharing information with relevant agencies.

Consent requirements are detailed as below:

Consent Required:	Consent Not Required:			
 Referral to the identified service 	- Child Protection			
 Sharing of Assessment information 	- Criminal Justice			
- Sharing of progress information	 Harm to self and to others 			
- Referral to another agency				

Service Responsibilities – What you can expect from the service

- 1. Each patient can expect to be treated fairly, non-judgementally and with respect by staff at all times.
- 2. Each patient will be informed about their treatment and care plan, and will be asked to contribute to the development of this plan.
- 3. Any complaints will be dealt with promptly and without discrimination as per NHS Tayside policy.
- 4. If staff are unable to attend an arranged appointment they will endeavour to contact patients as soon as possible.
- 5. Each patient can expect to receive support as required by their treatment plan.
- 6. Any supportive other will be kept informed and included in this process, as appropriate.
- 7. Each patient can expect that despite the information sharing agreement, confidentiality will be maintained as rigorously as possible.

Patient's responsibilities within the service

Attending to see any of the professionals providing this service:

- 1. I agree to participate fully in my treatment plan.
- 2. I understand that continuity of care is important to the success of my treatment plan, and that it is essential that information, regarding my care, be shared between relevant professionals.
- 3. I will attend at the specified appointment times.

- 4. I will attend appointments on my own unless otherwise agreed.
- 5. My behaviour will at all times be socially acceptable.
- 6. I will not behave in an aggressive or threatening manner towards staff or other patients. Actual or threatened physical violence will result in loss of any prescription, potential expulsion from the service and ultimately prosecution. NB. For DTTO patients, any such behaviour will be reported to the supervising officer, this may result in application to breach or revoke the Order.
- 7. I will leave the premises promptly after I have been seen.
- 8. I will not attend in an intoxicated state.
- 9. I will attend a one-day Tolerance Test to assess my opiate tolerance, before a prescription will be issued **OR** when my prescription is being reviewed.
- 10. I understand that any prescription that I receive will only form a small part of my overall treatment.
- 11. Once I receive a prescription, I will abstain from using other illicit drugs. If I am unable to comply with this, my prescription will be reviewed.
- 12. I will provide supervised samples (urine; oral fluid) for testing during my treatment, as requested. Refusal to do so could adversely affect the decision to continue my prescription. **NB. for DTTO patients, failure to comply will be reported to the supervising officer.**
- 13. My prescriptions will be dispensed on a daily basis
- 14. I will participate in the supervised self-administration of my medication when indicated.
- 15. I will request holiday prescriptions at least 14 days in advance.
- 16. For holidays abroad, I will give at least one month's notice of my intention to travel. *The response to any request will be dependent upon my compliance with treatment to date.*
- 17. I will not request that lost/stolen dispensed medication be replaced.

Patients Name
Patients Signature
Keyworkers Name
Keyworkers Signature:
Date:

Once completed this form should be filed at the front of the patient's notes.

Appendix 3 – Drug Licenses & Dose Equivalences

Drug Group	Drug	Licence status for		
		treatment of dependency		
Opiates	Methadone mixture or oral	LICENSED		
	solution			
	Methadone tablets	NOT LICENSED		
	Methadone injection	NOT LICENSED		
	Methadone linctus	NOT LICENSED		
	Lofexidene	LICENSED		
	Naltrexone	LICENSED		
	Buprenorphine	LICENSED		
	Dihydrocodeine	NOT LICENSED		
	Codeine	NOT LICENSED		
	Diamorphine Injection			
Benzodiazepines	Diazepam	LICENSED FOR		
		BENZODIAZEPINE		
		WITHDRAWAL		
	Chlordiazepoxide	LICENSED FOR		
		ALCOHOL		
		WITHDRAWAL		

Opiates

Drug	Dose	Methadone equivalent		
Street Heroin	Cannot accurately be estimated because street drugs			
	vary in purity, though 1g of street heroin is roughly			
	equivalent to 50-80mg meth	adone. Dose should be		
	titrated against withdrawal s	ymptoms.		
Pharmaceutical heroin	10mg tablet	20mg		
	30mg ampoule	60mg		
Morphine	10mg ampoule	10mg		
Dipianone (Diconal®)	10mg tablet	4mg		
Dihydrocodeine (DF118)	30mg tablet	3mg		
Dextromoramide (Palfium)	5mg tablet	5-10mg		
	10mg tablet	10-20mg		
Pethidine	50mg tablet	5mg		
	50mg ampoule	5mg		
Buprenorphine	200microgramme SL	5mg		
(Subutex®)	tablet			
	2mg SL tablet	??		
Pentazocine (Fortral®)	50mg capsule	4mg		
	25 mg tablet	2mg		
Codeine Linctus (100ml)	300mg codeine phosphate	20mg		

Benzodiazepines

Benzodiazepine	Dose	Diazepam Equivalent Dose (Approx)				
Chlordiazepoxide	15mg	5mg				
Loprazolam	0.5-1mg	5mg				
Lorazepam	500 microgrammes	5mg				
Lormetazepam	0.5-1mg	5mg				
Nitrazepam	5mg	5mg				
Oxazepam	15mg	5mg				
Temazepam	10mg	5mg				

Appendix 4 – Special groups

There are some characteristics of individuals/groups or situations where care should be taken to ensure the person is in contact with an appropriate specialist service to best meet their needs or where particular issues require specific guidance with regard to their drug treatments. Examples include:

- Under 18s/under 16s
- Pregnancy
- Dual diagnosis (substance misuse plus major mental health disorder)
- Admissions to hospital
- Police custody
- Prison throughcare (admission & release)
- Service transfers

Specific protocols will be developed in association with the appropriate clinical groups (children & young people's services; Obstetrics & gynaecology; mental health services; TUH; Police surgeons; Scottish Prison Service). Meanwhile some guidance will help that people interacting with these services are not being disadvantaged when they cross clinical interfaces.

Under 18s

There is an increasing problem of young IV drug users in the UK – probably reflecting a generational change, with this group affected less by the HIV issues of the 1980s and their recklessness impacted upon more by the recreational drug use of the 1990s. These will often be patients GPs have known from birth and they may present first to their GP. Their drug use (and lifestyle) will often be very high risk and chaotic.

Action

Do not prescribe methadone or any other drugs of misuse. Make as full an assessment as possible as directed in this protocol. Refer directly to the Harm reduction Centre and also refer to TDPS or any specialist team in your locality. If for some reason a specialist service will not respond – contact the Consultant Psychiatrist at TDPS directly. Specialist services for this group include:

TDPS: Tel. 01382 424544

Harm reduction Centre: Tel. 01382 424533

Consultant Psychiatrist addiction: Tel 01382 424512

Pregnancy

Female drug users become pregnant. They may present to services in many ways, including:

- Drug use admitted at booking or ante-natal appointments
- Patient of TDPS/GP with drug problem who becomes pregnant
- Hidden drug use becomes apparent during course of pregnancy or even delivery

Action

The aim here is to identify pregnancy in a drug user/drug use in a pregnant woman as early as possible to allow an appropriate work up for any treatment she may be willing to undertake. Actions required are:

• Do not prescribe methadone without specialist advice

Screening

- In O&G, always ask about drug use at booking/follow up
- In drug services be aware of potential of pregnancy

Referral

- O&G refer immediately to TDPS who will give high priority to the case (ie allocate a keyworker immediately) and commence assessment
- Drug services contact O&G services immediately and request assessment

Joint working

- Ensure close communication ideally between named members of all teams involved
- Ensure user informed of concerns and need to communicate with all agencies based on risk & need.
- Drug service rapidly progress assessment and move to any medical treatments seen as appropriate. (This is likely to be methadone but if so the aim is to stabilise on as low a dosage as possible <20mg is ideal.)
- Case conferences
- Child protection involvement at early stage
- Close liaison & good communication throughout pregnancy to delivery.

Plans to develop a clear protocol are underway. In the meantime any concerns or queries about the treatment of pregnant drug users should be directed to TDPS.

Dual diagnosis (mental health & substance use)

Substance users have a higher than normal prevalence of mental illness and those who suffer from mental illness are more likely to misuse substances. This means that people with these needs will present to services. This can occur in many ways:

- Person is engaged in mental health services and drug use becomes apparent as it is perceived to be influencing their mental health or reducing effectiveness of treatment
- Substance use is simply identified in MHS
- Person is engaged in addiction services and mental health issues present as serious management problem
- Mental health problem requires treatment unavailable within substance misuse services

In all of these presentations the outcome will be affected by how well services attempt to meet the needs of the person involved as they negotiate the interface.

Action

The aim of services should not be to exclude the person, simply because they have these complex needs. It should not be assumed that a substance misuse issue is the cause of any mental health presentation nor should it be assumed that substance misuse must be eradicated before any mental health issue can be dealt with.

• Each service should make early contact with the other to request appropriate assistance in meeting those needs which are outside their expertise or remit.

- In the case of admission, any prescribed treatment already in place should be continued (as in any other medical condition) once the facts have been gathered. In cases where the person's history is in doubt, medical staff can clarify facts from TDPS, the patient's GP or (if on a methadone prescription) from their community pharmacist. If no such sources are available (e.g. Sunday evening) the clinical staff must treat the person symptomatically based on clinical assessment as described below "admissions to hospital".
- Clinical staff should contact the caring agency as soon as is practicable for advice.
- Close liaison is necessary to maximise effectiveness.
- Whenever possible prescribing should follow advice from the specialist agency or Consultant in Addiction.

Work is moving forward within the mental health services to explore interface issues for those with dual diagnosis. In the meantime advice is available from the Consultant in Addiction – Tel 01382 424512.

Admissions to hospital/Police custody/Prison throughcare/Service transfers

All of these groups present a similar set of problems. These are:

- how to ensure those already in treatment are not disadvantaged by a change in their circumstances
- how to assess & treat those not already in treatment in a way which best meets their needs

In treatment

Those in treatment will usually be on methadone. If detoxified a person may be on Naltrexone prescription, or in contact with a counselling agency (though many disengage from services with the aim of moving on in their lives). A person in receipt of methadone has a prescriber (GP or TDPS), a counsellor/keyworker (usually) and a Community Pharmacist. If a person presents there are therefore a number of sources of information, which can verify any history given.

Action

- Do not prescribe until you are clear of the person's situation. (NB Methadone deaths are commonly associated with doctors prescribing for people of whom they have little up to date information and have not fully assessed before prescribing).
- Gather contact names from the individual and contact them. Request verification of the history in writing/fax including dose of medication; when last dispensed; evidence of compliance tests etc.; future plans.
- If verified to your satisfaction, commence prescribing.
- If on a concession prescription (i.e. less than daily dispensing) convert to daily dispensing. This is not negotiable.
- If it is not possible to get information (night admissions etc.) treat the person symptomatically based on clinical findings until contact with services can be made. [i.e. Take history. Do full physical and note IV sites. Urine drug screen challenge history if not concordant. Observe for any signs of opiate withdrawal. If they appear (See OWS in Appendix 8 Lofexidine chart) consider treatment with methadone to alleviate symptoms. Give 20mg methadone mixture in first instance and reassess as required, titrating up to no more than 40mg on the first

- day.] In these circumstances do not prescribe if no symptoms appear and always withhold prescribed drugs if sedated.
- If the person is also a benzodiazepine user, confirmed by testing, observe for any signs of withdrawal and prescribe diazepam in a rapid reduction if required (see Appendix 7).
- If in any doubt, withhold prescribing until symptoms verify dependence.
- Whenever possible contact TDPS or the Consultant Psychiatrist in Addiction before prescribing.

Special Cases – Prison throughcare

The key to ensuring that appropriate care is delivered at this interface is good communication.

Action

For treatment services, ensure that patients are aware of the need to adhere to their treatment programmes, as this will increase the likelihood that SPS medical staff will continue prescriptions from the community. On admission, telephone contact and written verification of any prescribed medications will ensure ongoing care. Be aware that all prisons are unique and that the prison is a complex environment in which the relevant professional may not be clear. Patience is required.

For SPS doctors/clinical teams, contact the receiving community service in advance so that they can ensure keyworking support & any prescription are in place for the discharge date. They may even be able to assess the person in prison. Setting up prescriptions can take time and advance notice is essential.

Special Cases - Police custody

If a person on a methadone prescription is arrested and taken into police custody they must receive their prescribed medication. This may require the police service/surgeon to contact the prescriber for verification. There is no argument for withholding their medication or replacing it with other drugs such as Dihydrocodeine – this can destabilise users, and at the very least creates a problem for services whose drug screens will show dihydrocodeine, which may jeopardise the ongoing prescription. Those going on to prison may be refused prescribed methadone, as their urine tests will be inconsistent with their community prescription.

Action

If it is brought to the custody staff's attention that the person is in need of their methadone prescription, the following actions are required:

- Staff should verify history with prescriber/dispenser
- If confirmed they should make arrangements for that prescription to be made available to the person either by arranging collection or arranging for the medical staff to prescribe.
- Any prescribing in this setting should be notified to the usual prescriber by phone and in writing.

In conclusion

Doctors will always make clinical judgements. These must be based on best practice and should be person-centred and needs-led. Drug users are a demanding group and they present all clinicians with dilemmas. When in doubt prescribers should default to

good medical practice, ensuring they fully assess the situation before prescribing, communicate their decisions clearly and ensure specialist support is requested if they feel unable to fully meet the needs of their patients.

In Tayside the TDPS is happy to discuss any case with medical or support staff. When in doubt, phone 01382 424512.

Appendix 5 – Case review sheet example											
NAME:					DOB CHI:						
ADDRESS:											
Date Patient Taken On:					Date of Review						
Review	v 1/2/3/4/5	5/6				Date of a	dmission for th	is episode	÷		
Number Keywor Doctor		intmen	ts:		<u>'</u>		Number of Non Keyworker Doctor	attendanc	ee		
	P	L	TO	1	\mathbf{C}_{HAO}	s F	REGULARISA	TION	STABIL	LISATION	Socialisa tion
ע	UG EHAVIOU	R	Daily D	epertoire Pose Variation Route	>2 Drugs Max/Min > High Risk I	>2	<3 Drugs Max/Min <2 Low Risk IV		No Va	cribed Drugs O Variation on Injecting	Drug Free Drug Free Drug Free
R O	UTINE			rence Times	No Daily Rou Early/Middle		1 Reference Tin 2 of Early,Middle,		2 Reference Times 1 of Early,Middle,Late		3 Reference Times Good Sleep
U	NHEALTHY Weight FEATURES Physical Co-morbidity Mental Co-morbidity		l Co-morbidity	Untreated Treate		Low (steady) Treated (symptom Treated (symptom		Low (rising) Treated (asymptomatic) Treated (asymptomatic)		Normal/High Well Well	
u	OGRAPHIO EATURES	c	_	g in Same Bed Housing	2 nights/we Homeless		3 nights/week Own Bed		_	ts/week Room	5 nights/week Own House
2	CIAL EATURES			ationships Legal Finance	Alone & Lor Non-complia Debt Increas	ince	Unsupportive Ad Order Outstandi Debt Steady		1 supportive Adult Compliance with Order Debt Reducing		>1 supportive Adult No Trouble No Debt
Drug Use (in detail) Daily prescribed methadone dose Illicit use – Drug Dose Illicit use – Drug Dose Illicit use - Drug Dose Illicit use - Drug Dose Number of Urine Sepcimens			btained	Daily prescrib Frequency of Frequency of Frequency of	use use use	consistent urin	ne specimen	Mode of use Mode of use Mode of use			
Clinical Work Carried out:- Education about drugs Session(s Change management Session(s Sleep management Session(s		(s)	Harm Reduction work Anxiety Management Other Please state		Session(s)Session(s)						
Comments Evidence Programmes 1=Started 2=Full Participation		3-Semi port	cipation	4=Little Particip	ation C		ssion(s) ssion(s)				

Comments/Evidence	Rating	Low	Mediu	n High	
Liaison with Other Agencies:					
Issues for Review:					
N 1. 11					
Needs Identified: 1.					
1.					
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3.					
4.					
I agree with the above identifica	ation of need(s	s). YES/NO.	Name (Staff)_		
Signed (client)		(s	taff)		
Plan Following review:-					
1.					
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3.			Neyt Re	oview Date	
3.		COMMENTS	Next Re	eview Date	
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3.		COMMENTS	Next Ro	eview Date	
3.		COMMENTS	Next Ro	eview Date	

Appendix 6 – Benzodiazepine withdrawal schedules

If a person gives a history of regular Benzodiazepine use (daily) and tests repeatedly support this history OR has been admitted to an in-patient facility, gives a history of benzodiazepine use and tests positive, the following procedure should be followed:

- Do not prescribe benzodiazepines
- Observe for physical evidence of withdrawal or agitation/restlessness

If signs become evident it is reasonable as a one-off event to prescribe a reducing regimen of benzodiazepines to prevent any problems associated with precipitant benazodiazepine withdrawal (eg seizures). An example of such a programme is given below.

Time	8am	3pm	10pm
Diazepam dose	es		
Day 1	10mg	10mg	10mg
Week 2	10mg	5mg	10mg
Week 4	5mg	5mg	10mg
Week 6	5mg	5mg	5mg
Week 8	5mg	-	5mg
Week 10	-	-	5mg
Week 12	Stop		

This medication is not designed to replace any dependence but simply to give an acceptable detoxification should the person be dependent.

If the person becomes over-sedated the prescription should be stopped immediately.

Advice should be sought from TDPS as soon as possible – preferably prior to commencing any prescribed medication.

For "Good sleep guide" & "Good relaxation guide" as well as sleep & anxiety diaries - see below.

The Good Sleep Guide

During the Evening

- Put the day to rest. Think it through. Tie up "loose ends" in your mind and plan ahead. A notebook may help.
- Take some light exercise early in the evening. Generally try to keep yourself fit
- Wind down during the course of the evening. Do not do anything that is mentally demanding within 90 minutes of bedtime.
- Do not sleep or doze in the armchair. Keep your sleep for bedtime.
- Do not drink too much coffee or tea and only have a light snack for supper.
 Do not drink alcohol to aid your sleep it usually upsets sleep.
- Make sure your bed and bedroom are comfortable not too cold and not too war.

At Bedtime

- Go to bed when you are "sleepy tired" and not before.
- Do not read or watch TV in bed. Keep these activities for another room.
- Set the alarm at the same time every day, seven days a week, at least until your sleep pattern settles down.
- Put the light out when you get into bed.
- Let yourself relax and tell yourself that "sleep will come when it's ready". Enjoy relaxing even if you don't at first fall asleep.
- Do not try to fall asleep. Sleep is not something you can switch on deliberately but if you try to switch it on you can switch it off!

If You Have Problems Getting to Sleep

- Remember that sleep problems are quite common and they are not as damaging as you might think. Try not to get upset or frustrated.
- If you are awake in bed for more than 20 minutes then get up and go into another room.
- Do something relaxing for a while and don't worry about tomorrow. People usually cope quite well even after sleepless night.
- Go back to bed when you feel "sleepy tired".
- Remember the tips from the section above and use them again.
- A good sleep pattern may take a number of weeks to establish. Be confident that you will achieve this in the end by working through the "Good Sleep Guide"!

The Good Relaxation Guide

Dealing with Physical Tension

- Value times of relaxation. Think of them as essential not extras. Give relaxation some of your best time not just what's left over.
- Build relaxing things into your lifestyle every day and take your time. Don't rush. Don't try too hard.
- Learn a relaxation routine, but don't expect to learn without practice.
- There are many relaxation routines available, especially on audio tape. These help you to reduce muscle tension and to learn how to use your breathing to help you relax.
- Tension can show in many different ways aches, stiffness, heart racing, perspiration, stomach churning etc. Don't be worried about this.
- Keep fit. Physical exercise, such as a regular brisk walk or swim, can help to relieve tension.

Dealing with Worry

- Accept that worry can be normal and that it can be useful. Some people worry more than others but everyone worries sometimes.
- Write down your concerns. Decide which ones are most important by rating each of them out of ten.
- Work out a plan of action for each problem.
- Share your worries. Your friends or your general practitioner can give you helpful advice.
- Doing crosswords, reading, taking up a hobby or an interest can all keep your mind active and positive. You can block out worrying thoughts by mentally repeating a comforting phrase.
- Practice enjoying quiet moments, e.g. sitting listening to relaxing music.
 Allow your mind to wander and try to picture yourself in pleasant, enjoyable situations.

Dealing with Difficult Situations

- Try to build up your confidence. Try not to avoid circumstances where you feel more anxious. A step by step approach is best to help you face things and places which make you feel tense. Regular practice will help you to overcome your anxiety.
- Make a written plan and decide how you are going to deal with difficult situations.
- Reward yourself for your success. Tell others. We all need encouragement.
- Your symptoms may return as you face up to difficult situations. Keep trying and they should become less troublesome as your confidence grows.
- Everyone has good days and bad days. Expect to have more good days as time goes on.
- Try to put together a programme based on all of the elements in the "The Good Relaxation Guide" that will meet the needs of your particular situation. Remember that expert guidance and advice is available if you need further help.

[Adapted from original material in the report of the Scottish National Medical Advisory Committee on the management of anxiety and insomnia.]

SLEEP DIARY

It will help us to find the best way to deal with the problem you are having with sleep at the moment if you can keep a sleep diary for a short time. All you have to do to use the chart below to note down your sleep pattern (how much you sleep and when) and the quality of your sleep. It is best to try and fill in the diary as soon as possible after getting up; it only takes a few minutes. If this is not possible, make sure you fill it in before the end of the day – it is very difficult to remember details of sleep after more than one night. When you come back to see me, we can discuss what you have written in your sleep diary. This should help us to decide together the best way to deal with the problem.

Name.....

Measuring the Pattern of Your Sleep

- 1. At what time did you get up this morning?
- 2. At what time did you go to bed last night?
- 3. How long did it take to fall asleep (mins)?
- 4. How many times did you wake up during the night?
- 5. How long were you awake during the night (in total)?
- 6. About how long did you sleep altogether?
- 7. How much alcohol did you take last night?
- 8. How many sleeping pills did you take to help you sleep?

1	2	3	4	5	6	7
	1	1 2	1 2 3	1 2 3 4	1 2 3 4 5	1 2 3 4 5 6

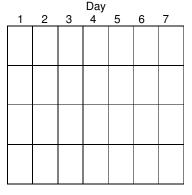
Day

Measuring the Quality of Your Sleep

Please answer these questions about the quality of you sleep using the following scale:

0 1 2 3 4 Not at all Moderately Very

- 1. Do you feel well this morning?
- 2. How enjoyable was your sleep last night?
- 3. How mentally alert were you in bed last night?
- 4. How physically tense were you in bed last night?



ANXIETY DIARY

It will help us to find the best way to deal with the anxiety you are feeling at the moment, if you can keep an anxiety diary for a short time. Use it to keep a note of when and where you feel anxious, and how anxious you feel. The chart below is designed to make this as easy as possible. The best way to record how anxious you feel is by using an anxiety scale. On this chart the scale is 0 - 10, where 0 = not anxious at all, 5 = moderately anxious and 10 = extremely anxious.

By filling in the chart it will be easier to identify the times and situations where you feel most anxious. When you come back to see me, we can discuss what you have recorded in your anxiety diary. This should help us to decide together the best way to deal with the problem.

Name.....

Day, date & Time	Where are you?	What are you doing?	Anxiety scale 0 – 10
			Not at all Extremely
			1 2 3 4 5 6 7 8 9 10
Example <i>Monday 10th November 03</i>	At home	Watching news of a disaster on TV	

Appendix 7 – TDPS - Lofexidine Detoxification Procedures & Paperwork

Aim

To achieve a opiate free state in patients, in as short a period as is feasible, with the minimum of discomfort to the patient.

Assessment & Prioritisation

Detoxification should never be undertaken without a full and comprehensive bio/psycho/social assessment of the patient, which supports the use of a detoxification approach.

Areas to note:

• Patients with drug problems often present to services stating that they "want to come off drugs", as a result of some crisis – such as lack of availability of illicit drugs, arrest and legal proceedings or family/social problems. This group often are looking for a "quick fix" in the form of a methadone script, referral to a "rehab" or a "detox" – usually as an inpatient. They are often chaotic in every domain and indicators show that they are not ready for a detoxification programme. Before entering into a treatment programme every patient must be fully assessed.

Suitability for Detoxification

Some patient characteristics and lifestyle factors support a decision to progress detoxification in the community. The following are essential:-

- The patient must have social stability (e.g. stable accommodation, evidence of a daily routine etc.)
- Support from a responsible adult in their home
- The patient must have stabilised their drug use
- The patient must show high motivation for change (positive for action within the cycle of change)
- The patient must have shown good use of services to date (regular attendance, positive attitude etc.)
- The patient should have no history of cardio-vascular disease or problems (see later under Lofexidine Detox)
- The patient should have no ongoing or unstabilised mental health problems (see later under Lofexidine Detox)

Patient Preparation

As opiate detoxification is mentally, physically and emotionally demanding it is essential that patients are properly prepared for the process.

Patients must receive sessions to increase their knowledge and enhance their skills in the following areas:

- Information about the medication lofexidine, naltrexone, zopiclone, and symptomatic relief
- What to expect from lofexidine, rationale for use, and its limitations
- What to expect from zopiclone, rationale for use, and its limitations
- Knowledge about tolerance and overdose
- Anxiety Management symptoms may break through during detoxification
- Sleep Management most will have serious sleep problems even if medicated

- Managing Change
- Developing strategies for relapse prevention
- Developing coping skills

Process

The two main reasons for patients failing to complete a lofexidine detoxification in the community are:

- Light-headedness secondary to postural hypotension
- Poor symptom control.

As lofexidine works by influencing the adrenergic surge, which occurs as withdrawal from opiates develops, the hypotension problem can be avoided if lofexidine is only used when individuals are clearly in withdrawal. To this end, lofexidine will only be given to individuals showing objective signs of withdrawal (>5 on Opiate Withdrawal Scale, see below). Titration of lofexidine dosage to Opiate Withdrawal Scale scores allows dosage regimes to follow individual's patterns of withdrawal whilst maximising symptom control.

Prior to the Lofexidine Test Dose:

- Staff will also ensure that appropriate supplies of medication are available
- Ordering:
 - The ordering should be done at least monthly by dedicated staff.
- <u>Storage and handling of medication</u> shall be in accordance to NHS Tayside policy for the Safe & Secure handling of Medicines (Appendix 1)
- Staff will ensure that medical cover has been arranged
- Staff will ensure that clinical rooms are available for lofexidine initiation
- The patients will be given an appointment to attend for a test dose to be administered.
- It is essential that the patient's General Practitioner is informed of this appointment and any opiate prescriptions cancelled, with the last opiate prescribed dose dispensed 48 hours prior to the Lofexidine test dose.
- Patient should be advised that it is essential that they demonstrate evidence of an opiate withdrawal syndrome for the detoxification procedure to start.
- Patient should be advised that they should not attend under the influence of any drugs or alcohol, otherwise the detoxification procedure will not start.

First Day - includes Lofexidine Test Dose

- Patient attends demonstrating evidence of an opiate withdrawal syndrome. If the patient attends and appears under the influence of drugs or alcohol or with no evidence of opiate withdrawal, using the modified OWS the test dose will not proceed on that day. In this instance, at the very least, the test dose will be postponed and retesting will be considered at the next available appointment. The patient's general practitioner must be informed. It may be that the entire plan should be reconsidered.
- The patient must be examined by a member of the medical staff prior to receipt of the test dose. The interview should focus on any concurrent physical illnesses in particular cardio- vascular or respiratory illness. Any evidence of cardiovascular illness must be excluded by physical examination. Specific examination for postural hypotension is mandatory and should be noted clearly in the notes. The doctor will complete the drug Kardex for the administration of the test dose.

Blood Pressure (BP) and Pulse (P). As stated previously lofexidine can cause a reduction in blood pressure and pulse. It is essential that these be monitored before commencing lofexidine, to give a base line measurement, and regularly throughout the dose titration period. Tolerance to the hypotension usually occurs quite rapidly within a few hours. Patients should be counselled regarding sufficient fluid intake in order to help maintain BP (three litres of fluid over 24 hours is recommended).

Lofexidine Test Dose

- If there are no physical problems, the patient should receive a test dose of 0.2 mg of Lofexidine and then be accompanied to a designated room for observation. He/she will be observed for a minimum of 2 hours and must be accompanied by staff at all times. He/she should be checked for any signs of distress or light-headedness and should have blood pressure checks at half-hourly intervals. These should be recorded by staff on the appropriate BP chart and the Lofexidine Detox Chart in the medical records.
- Prior to leaving the unit the patient should be seen by the medical staff and further detoxification plans agreed. If all is well, the patient should be counselled regarding the treatment plan for next 24 hours. The prescriber writes in the Drug Kardex "detoxification as per protocol", as well as in the contemporaneous notes. The patient will be given one pack of 4 lofexidine 0.2 mg tablets, for self-administration. This pack will be clearly labelled with the patient's name and date of supply, plus dosage instruction stating "up to 4 tablets to be taken depending on symptoms of withdrawal". The patient will also receive a pack of 2 Zopiclone 7.5 mg tablets to help with night sedation this pack will also be labelled with the patient's name and date of supply and clear dosage instructions. Insomnia is a common side effect of opiate withdrawal, and can cause such distress to patients that the detoxification could fail. It is for this reason that the decision has been taken to provide 15mg of Zopiclone for sleeplessness despite the licensed dose being 7.5mg daily.

Prior to the patient leaving the clinic, staff will ensure that the patient is aware of the times that staff will visit.

Subsequent Days

- The patient will be seen by qualified nursing staff and support staff. The qualified nurse will visit the patient at least once daily until the detoxification using lofexidine is complete. Support staff will complement the work of the qualified nurse and also participate in the measuring of Blood Pressure, Pulse and temperature.
- The patient will be assessed each morning using the OWS as well as the patient's self-reporting, and lofexidine will be administered in appropriate doses. Maximum dose is 3 packs of 4 tablets 12 tabs/day with clear instructions written on the packs. Where it is indicated that a patient will require more than 12 tablets a day, medical advice is sought. The dose will be prescribed on a, day by day, basis until the patient is back to 12 tablets daily. This occurrence should be recorded in the contemporaneous notes by nursing and medical staff.

NB. It may be necessary to increase the dosage rapidly on day 2 if symptoms are not well treated. Remember that heroin withdrawal symptom will "peak" on day 20r3, dihydrocodeine on day 30r4 and methadone on day 40r5. Failure to increase the dosage sufficiently on day 2 will result in poor symptom control which may result in relapse (See table 1)

- Zopiclone should be continued and counselling and support of individual and his/her carer will depend on individual circumstances.
- The patient will continue on individually assessed maximum dose until OWS=0, where upon the lofexidine is reduced until the patient is completely off the medication.
- Patient will continue on the same zopiclone dose until OWS=0, and then reduced (see Table 1)
- Urine tests will be taken at specific intervals during the detoxification period, and also at clinical staff's discretion.
- The naloxone challenge and introduction of naltrexone will take place prior to the patient's coming off lofexidine completely
- The GP should be notified of the outcome by phone and letter, and follow up arrangements completed.

Examples of lofexidine detoxification are in Table 1 for Moderate Opiate Withdrawals, Severe Opiate Withdrawals and Very Severe Opiate Withdrawals.

Management of low Blood Pressure or pulse

The following criteria will be used:

- Low Blood Pressure (BP) will be considered to be a reading of 90/50 or blow, however, if the patient's baseline was 90/50 then the criteria will be moved to 80/40.
- A low pulse rate suggestive of bradycardia, will be considered to be 55 beats per minute (bpm) or less at rest. However if the patient's baseline was 55 bpm then the criteria will be moved to 50 bpm.

Pulse

- In all instances where the pulse is <55 bpm (<50 if low baseline) the doctor should be contacted immediately, and ECG arranged through primary care.

BP

- The patient should be advised of the importance of standing slowly.
- If hypotension is mild, delay increasing the daily dose of lofexidine until hypotension resolves.
- If hypotension is moderate, the next lofexidine dose should be withheld until the BP improves markedly; the overall daily dose should not be increased until the BP is within normal limits.
- If hypotension is severe, the patient should be advised to remain lying down with legs raised; upon rising the patient should be advised to stand slowly and to walk with support from another individual.
- Should hypotension be problematic for two or more doses of lofexidine and is deemed to be coincidental with administration of the lofexidine dose, the doctor should be consulted and the rate of increase and continuation of treatment discussed. The outcome of this should be documented in the contemporaneous notes.

Clinical Opiate Withdrawal Scale

For each item, record the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Resting Pulse Rate:beats/minute	GI Upset: over last ½ hour
Measured after patient is sitting or lying for one	0 = no GI symptoms
minute	1 = stomach cramps
0 = pulse rate 80 or below	2 = nausea or loose stools
1 = pulse rate 81-100	3 = vomiting or diarrhoea
2 = pulse rate 101-120	5 = multiple episodes of diarrhoea or vomiting
4 = pulse rate greater then 120	
Sweating: over past ½ hour not accounted for by room	Tremor: observation of outstretched hands
temperature or patient activity.	0 = no tremor
0 = no report of chills or flushing	1 = tremor can be felt, but not observed
1 = subjective report of chills or flushing	2 = slight tremor observable
3 = beads of sweat on brow or face	4 = gross tremor or muscle twitching
4 = sweat streaming off face	
Restlessness: observation during assessment	Yawning: observation during assessment
0 = able to sit still	0 = no yawning
1 = reports difficulty sitting still, but is able to do so	1 = yawning once or twice during assessment
3 = frequent shifting or extraneous movements of	2 = yawning three or four times during assessment
legs/arms	4 = yawning several times/minute.
5 = unable to sit still for more than a few seconds	
Pupil size	Anxiety or Irritability
0 = pupils pinned or normal size for room light	0 = none
1 = pupils possibly larger than normal for room light	1 = patient reports increasing irritability or
2 = pupils moderately dilated	anxiousness
5 = pupils so dilated that only the rim of the iris is	2 = patient obviously irritable or anxious
visible	4 = patient so irritable or anxious that participation
	in the assessment is difficult
Bone or Joint aches. If patient was having pain	Gooseflesh skin
previously, only the additional component attributed to	0 =skin is smooth
opiates withdrawal is scored	3 = piloerecetion of skin can be felt or hairs
0 = not present	standing up on arms
1 = mild diffuse discomfort	5 = prominent piloerection
2 = patient reports severe diffuse aching of	
joints/muscles	
4 = patient is rubbing joints or muscles and is unable to	
sit still because of discomfort	
Runny nose or tearing. Not accounted for by cold	Score:
symptoms or allergies	8-12 = mild
0 = not present	
1 = nasal stuffiness or unusually moist eyes	13-24 = moderate
2 = nose running or tearing	25-36 = moderately severe
4 = nose constantly running or tears streaming down cheeks	> 36 = severe withdrawal
CHECKS	- 30 - Severe withurawar

Detoxification Programme

Medication Regime								
		Regular Lofexidine Dosage			PRN Lofexidine	Zopiclone	Specimen	
Phase	Day	OWS 8-12	OWS 13-24	OWS>25				
	1	Test dose	Test dose	Test dose	4 x 0.2 mg	15mg	✓	
	2	4 x 0.2mg	4 x 0.2 mg	8 x 0.2mg	2 x 0.2 mg	15mg		
[ndu	3	4 x 0.2mg	6 x 0.2 mg	10 x 0.2mg	2 x 0.2 mg	15mg		
Induction	4	6 x 0.2mg	8 x 0.2 mg	12 x 0.2mg	2 x 0.2 mg	15mg		
	5	8 x 0.2mg	10 x 0.2 mg	12 x 0.2 mg	2 x 0.2 mg	15mg	✓	
	6	10 x 0.2mg	12 x 0.2 mg	12 x 0.2 mg		15mg		
P	7	10 x 0.2mg	12 x 0.2 mg	12 x 0.2 mg		15mg		
eak	8	10 x 0.2mg	12 x 0.2 mg	12 x 0.2 mg		15mg	✓	
Peak dosing	9	10 x 0.2mg	12 x 0.2 mg	12 x 0.2 mg		15mg		
ng	10	10 x 0.2mg	12 x 0.2 mg	12 x 0.2 mg		11.25 mg	✓ Naloxone challenge- introduction of Naltrexone	
	11	8 x 0.2mg	10 x 0.2mg	10 x 0.2mg		11.25 mg	The state of the s	
Re	12	6 x 0.2mg	8 x 0.2mg	8 x 0.2mg		7.5 mg		
Reduction	13	4 x 0.2 mg	6 x 0.2 mg	6 x 0.2 mg		7.5mg		
on	14	0	4 x 0.2mg	4 x 0.2mg		3.75 mg		
	15		0	0		0mg		

Understanding the Medication Regime (Table 1)

- Patients may move from one scale to another depending on severity of opiate withdrawal.
- The number of days treatment outlined in Table 1 is meant as a guide.
- Some patients may require greater or fewer days at the peak dosing phase, depending on OWS.

Similarly the dosage regimes stipulated show the maximum dose recommended for the severity of withdrawal.

- Some patients may require less medication to achieve symptom control.
- Staff will document the reasons for altering the number of days the patient is prescribed within the peak dosing phase, and this will be evidenced by entries on the OWS.
- Qualified staff may also decide not to administer the maximum recommended dose of lofexidine, again this will be documented in the contemporaneous notes and be evidenced by the OWS.

The prescriber must be contacted immediately when any patient requires in excess of the recommended dosage regime for the severity of withdrawals, and a decision will be taken regarding ongoing treatment and prescribing.

Other drugs, which can be prescribed, as required, for the symptomatic treatment of withdrawal include:

- **Ibuprofen**. Can ease the pain and pyrexia associated with withdrawal. Recommended dose is 400mg, to be taken when required up to three times a day.
- **Loperamide**. Can ease the diarrhoea and associated stomach spasms caused by opiate withdrawal. Recommended dose is 4mg to start, then 2mg as required after each loose stool, up to a maximum of 8mg daily. *This may be increased to 16mg daily if symptoms are severe*. Maximum recommended length of treatment is 5 days.

Prescribing and Dispensing Responsibilities

For each patient detoxified the following is required:

- Maximum of 18 packs of 4 x lofexidine 0.2mg tabs (to address moderate to very severe opiate withdrawals)
- A original pack of lofexidine should always be in stock to allow for test dose to take place
- Maximum of 12 packs of 2 x zopiclone 7.5 mg tabs

Roles and Responsibilities:

The doctor or designated prescriber will prescribe in the Drug Kardex: "lofexidine as per protocol". The Doctor / Designated Nurse Prescriber will write in the contemporaneous notes regarding this prescription.

On each day of the detoxification the qualified nurse will make decisions each day of the detoxification in relation to the patient's daily dose. This will be driven by the assessment of the opiate withdrawal using the Opiate Withdrawal Scale as well as the patient's self-reporting. The qualified nurse will record daily observations and doses in the contemporaneous. All medical advice sought will also be documented.

All medication taken from the drugs cupboard, for home visits, will be entered in a bound record book.

Communication

All contacts should be noted in the medical records as well as recorded in the detoxification charts. Drugs must be entered in a Drug Kardex as per NHS Tayside regulations. GPs should be kept informed of progress by phone and letter.

Aftercare

The degree of aftercare required will depend on each individual case.

In the event of a failed detoxification alternative treatment options should be explored as required.

Appendix 8 - Naltrexone

Background

The opiate antagonist Naltrexone (Nalorex) blocks the subjective and physiological effects of opiates. It is hypothesised that repetitive testing of this pharmaceutical blockade can lead to extinction of conditioned craving for opioids (Ref. APA Practice Guidelines 1996). The 1999 UK guidelines on clinical management of drug misusers acknowledge the place for Naltrexone as an "adjunct to prevent relapse in detoxified, formerly opioid-dependent, patients who have remained opioid free for at least 7-10 days" (HMSO 1999). However, the place of this treatment has proved difficult to determine in UK drug treatment services - mainly because of lack of compliance and the lack of negative effects if the treatment is discontinued. Another negative factor is the fact that few services use treatment programmes based on detoxification, resulting in few patients completing the move to a drug-free state. Even those completing detox. programmes will be unlikely to remain opioid free for the required 7-10 days. Evidence supporting the effectiveness of Naltrexone is sparse - other than for specific highly motivated groups. The result is an under-utilisation of this drug despite its apparent pharmacological advantages.

Naltrexone prescribing is available in Tayside – but as in the case of all prescribed medications for drug misuse they should only be used in well-prepared patients in association with a counselling/supportive approach delivered by a specialist agency.

Process

The treatment should be offered following full needs assessment which indicates that Naltrexone is the agreed optimum treatment for that individual's case. In case of any dispute around this decision the case should be discussed with the specialist team or Consultant in charge. Once agreed, the patient will receive a date for a Naloxone challenge (see below). This requires a doctor & nurse to be available in a clinic setting.

1. Assessment

Medical clinic:

A full history of problem opioid use is confirmed - especially completion of detoxification or cessation of prescribed opioids; patient examined for sedation or IV sites; LFTs checked; urine drug screened and urgent response requested/dipsticks used. When result is available and clear the date of the test is recorded as **DAY 1.** If urine **NOT CLEAR OF OPIOIDS** patient is requested to attend daily until clear urine is obtained. The day of the first clear urine is recorded as **DAY 1.**

On the 7th day patients will be tested again by dipstick or urgent response (next day) requested. They will be physically examined by the Doctor to confirm lack of active IV sites, lack of signs of withdrawal or sedation. LFT results will be seen by doctor before commencing. Once 2nd clear test is available the process can continue.

2. Test dose - Naloxone Challenge

The patient receives Naloxone 0.2mg IV through a butterfly which remains in situ. (If poor IV access the drug may be given intramuscularly). If adverse effects (i.e. signs of

acute opiate withdrawal) the procedure is stopped immediately - see below. If no adverse effects after 30 seconds the patient receives a further bolus of 0.6mg of Naloxone. If the doctor is in any doubt regarding objective signs of opiate withdrawal this procedure can be repeated up to a dosage maximum of 2.4mg. The patient will be observed for 30 minutes by nursing staff - Pulse, BP and pupils (P, BP & P) will be examined and all findings recorded in the notes.

3. Naltrexone dosing

If 2. is uneventful the patient receives 25mg Naltrexone orally in the clinic and is observed for a further 30 minutes. If well they may leave the clinic. A prescription for 50mg Naltrexone/day is delivered to the chemist for supervised daily dispensing.

4. Follow up

The patient is reviewed weekly by the Keyworker and examined/urine screened. Results will be clearly noted on each occasion.

In general, normal service rules apply. If the patient is defaulting the Keyworker discusses with doctor/team for consensus decision re: ongoing prescribing. The use of Naltrexone is specifically for the treatment of opioid use. Some other drug use may be more acceptable than in the case of methadone prescribing as the risk of overdose through use of mixed drugs is lower. However, any continued chaotic use should be noted and concerns discussed with the team or doctor on a case by case basis.

At one month the patient is reviewed by the Doctor. LFTs are taken. If successful treatment the patient embarks on script - 100mg dispensed Monday & Wednesday/ 150mg dispensed Friday.

Patient is then reviewed PRN by Keyworker (+ routine examination/urines as per service policy), 2 monthly by Doctor (+LFT check). Patient is reviewed 3 monthly as per service policy.

5. Case review –the case should be reviewed at 6 months and a decision taken regarding the need for further prescribing.

Appendix 9 - Members of Health Advisory Forum Prescribing Group

Member

Dina Ajeda Dr Andrew Cowie Steven Dalton Dr Mike Duffy Karen Fettes Pam Gowans Dr Brian A. Kidd (Chair) Dr Harry Leadbetter

Karen Melville Ian Smillie Iain Turnbull Chris White

Organisation

Tayside Drug Problems Service GP Sub-committee

Dundee DAAT GP, Wishart Centre

Pharmacy Contractors Committee Substance Misuse Services Health Advisory Forum

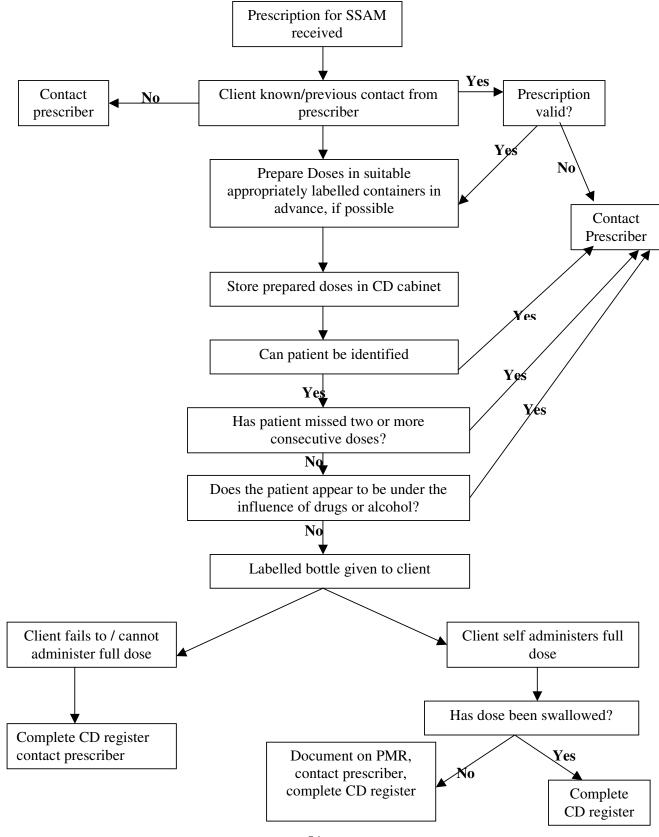
Primary Care - Tayside Primary

Care Trust

Specialist Pharmacist Perth & Kinross DAAT

Angus DAAT Tayside Police

Appendix 10 - Pharmacy SSAM Algorithm



Appendix 11 – Quick Guide for GPs

All cases seen in General Practice

Clearly there will be cases where drugs which have abuse potential may have a clinical role. However, there is no doubt that some drugs (eg dihydrocodeine; diazepam) may be prescribed in a way which increases the likelihood of their misuse by those to whom the drugs are prescribed or leakage into the community. These risks will be reduced if the GP:

- Always prescribes such drugs with a time limit or regular review to ensure they are stopped as soon as possible.
- If prescribing to a person with a history of substance misuse ensures that drugs are always prescribed as daily dispensed
 with regular review to ensure drugs are being used appropriately.
- Ensures they do not commence such medications as a proxy for legitimate drug treatment programmes.
- Is clear (s)he can justify the prescription as appropriate & reasonable

When in doubt GPs should avoid these prescriptions until they have fully assessed the person's needs.

Substance misuse identified

Patient requests help to deal with substance misuse OR suspected substance misuse

Assessment: All GPs should make a basic assessment of the person's needs. This should include a history of their current drug & alcohol use – drugs used & extent of use; route of administration; associated problems (physical, psychological or social). A physical examination and urine drug screen are desireable.

Action: For all cases the GP should supply information/material; advise on availability of harm reduction services (HRC – 01382 424533); treat medical conditions as required; offer support; agree to refer if appropriate

It is not appropriate to prescribe drugs of misuse without support of a specialist counselling agency

Referral On

Referral to specialist treatment agency

Referral to a specialist treatment agency is indicated if:

- Assessment clearly indicates the person has a drug problem
- They are clearly expressing a desire to change their circumstances
- They are requesting a prescribed treatment

<u>Urgent</u> referral is indicated if *pregnant*, high risk IV use, significant mental health problems, under 18, transfer from another area, prison release.

Standard referral by letter/referral form. If urgent, contact keyworker (if clinic in surgery) or phone 01382 424544

Referral to other agencies may be indicated –eg Social Work team if needs are clearly social; Harm Reducation Centre if injection site problem; Choice Project if under 18 in Dundee; TCA if uncomplicated use if low risk drugs requiring counselling only

Initiating treatment

Initiation of any Prescribed Treatments & Shared Care

Prescribed treatments for drug misuse should only be initiated by specialist treatment services. On rare occasions where it may be appropriate for the GP to initiate the prescription this <u>MUST</u> be with the support of the specialist service. These prescriptions will only commence following an appropriate assessment of need.

Shared Care. Once persons are objectively stable (if on methadone) or drug-free (if detoxified) they are eligible to be considered for "shared care" which involves a formal relationship between the GP and specialist service. Stability means the person is showing little substance use and is demonstrating social change. The person will be introduced to shared care by agreement and will continue to have GP & keyworking involvement throughout. The GP will always prescribe within agreed standards. If the person destabilises (returns to drug use; behaviour deteriorates suggesting drug use) they will return to the core service until stable again.

Appendix 12 – Good Practice Guides

Best Practice 1 (Page 8)

In Tayside being in receipt of a replacement prescription is never an end in itself. People must demonstrate a readiness and commitment to change their behaviour prior to a prescription being issued. Prescribing methadone is not the provision of a legal addiction. People must continue to show commitment to an agreed treatment programme for prescribing to continue.

Best Practice 2

Dihydrocodeine (DF118) and all other opiate-based analgesics are NOT LICENSED FOR THE TREATMENT OF SUBSTANCE MISUSE AND SHOULD NEVER BE PRESCRIBED FOR THIS PURPOSE

Methadone Mixture 1 mg / 1 ml

This formulation of methadone is exclusively used to treat substance misuse in Tayside. There are <u>NO</u> circumstances in which the use of alternative formulations is indicated outside the Specialist prescribing service.

Best Practice 3 (Page 9)

Quality standards for prescribed methadone:

- Never prescribe in isolation involve a specialist service
- Never prescribe at the first assessment
- Never prescribe unless you are continuing that person's treatr or have agreed with another service provider to continue it.
- Always assess the person fully before considering a prescription
- Always ensure a drug screen is seen before proceeding
- Always demonstrate dependence before proceeding
- Always carry out a tolerance test on the first dose
- Always start with a supervised dispensed prescription for 3 months Never permit less than daily dispensing thereafter

When in any doubt consult a specialist

Appendix 12 – Good Practice Guides (Cont)

Best Practice 4 (Page 10)

New prescriptions/initiation

- All new methadone prescriptions will be initiated by TDPS or specialist GPs
- If other doctors feel compelled to prescribe they are advised to contact TDPS doctors at the earliest convenient time and should always endeavour to get advice before commencing (eg acute hospital, mental health).
- Methadone will only be commenced following adequate assessment as above
- Methadone prescribing must only occur in dependent individuals
- •The first dose of methadone should reflect the person's daily use and should not exceed 40mg
- The first dose of methadone should be administered in a setting in which observation is available with the person observed for at least 3 hours with regular assessment for over-sedation.
- All subsequent doses will be supervised at the pharmacist for minimum 3 months
- The following doses will depend on each weekly assessment and increases should either i) reflect the daily dose identified during a comprehensive assessment process or ii) increase at 10mg increments no less than one week apart.
- If there are concerns that stabilisation is not being achieved rapidly TDPS should be contacted immediately.

Best Practice 5 (Page 16)

Stopping prescribed methadone/diazepam

- Stopping prescriptions should only be used <u>as a last resort</u> when safety is a concern, treatment is not progressing or therapeutic engagement is lost.
- Those in receipt of prescriptions should be given the option to avoid loss of the prescription if at all possible and the decision should never be taken without the person being aware that it is an option being considered.
- If a prescription is to be stopped the person should be seen as soon as possible and alternative treatment options discussed and agreed. Loss of a prescription does not mean loss of a service.
- Doctors should not simply supplement prescriptions with other opiates or benzodiazepines.
- Use of medications such as Loperamide for symptom relief is reasonable but must be time limited.
- Any case where methadone is stopped should be reviewed by the treatment team as a clinical governance exercise
- Diazepam may require a reducing regimen to avoid seizures
- Any such prescription change should be clearly recorded and followed by communication with all relevant professionals involved with the case.

Appendix 12 – Good Practice Guides (Cont)

*** Best Practice 6 *** (Page 18)

Benzodiazepine prescribing

- The treatment of anxiety is primarily psychological
- The treatment for misuse of benzodiazepines is primarily counselling
- If patients are misusing benzodiazepines alongside opiates the issue must be addressed pre-prescribing
- Relaxation & sleep hygiene programmes should be sought (Appendix 7)
- If prescribing is deemed necessary it should involve only diazepam, should be low dose, should involve rapid reduction (30mg to zero over 12 weeks) and should not be repeated
- ullet The dangers of benzodiazepines prescribing alongside opiates should not be underestimated.