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<td>Best practice guidance</td>
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<tr>
<td>Unique identifier:</td>
<td>CP0056</td>
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<tr>
<td>Title:</td>
<td>Worcestershire Substance Misuse Services in Primary Care: Prescribing Standards and SMS Operational Guidelines</td>
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<td>Target Audience:</td>
<td>GPs, drug workers and managers of SMS services</td>
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<tr>
<td>Description:</td>
<td>Local guidance on prescribing and the management of service users in receipt of substitute Opioid prescribing via their own GP, in a shared care arrangement with SMS.</td>
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<td>Ratified by:</td>
<td>Clinical Effectiveness, clinical governance</td>
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<tr>
<td>Ratification date:</td>
<td>8th February 2010</td>
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<td>Implementation date:</td>
<td>8th February 2010</td>
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<td>Review period:</td>
<td>3 years</td>
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<td>Version update date:</td>
<td>8th February 2010</td>
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<tr>
<td>Review date:</td>
<td>8th February 2013</td>
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KEY RECOMMENDATION FROM THE DEPARTMENT OF HEALTH

Drug misusers have the same entitlement as other patients to services provided by the National Health Service. It is the responsibility of all doctors to provide care for both general health needs and drug related problems, whether or not the patient is ready to withdraw from drugs. This should include the provision of evidence-based interventions, such as hepatitis B vaccinations, and providing harm minimisation advice. Every doctor must provide medical care to a standard, which could reasonably be expected of that practitioner in his or her position. No practitioner should be put under duress by colleagues or patients to provide treatment beyond that standard unless he or she wishes to.

Where the DoH definition of Shared Care is:

The joint participation of specialists and GPs (and other agencies as appropriate) in the planned delivery of care for patients with a drug misuse problem, informed by an enhanced information exchange beyond routine discharge and referral letters. It may involve the day-to-day management by the GP of the patients’ medical needs in relation to his or her drug misuse. Such arrangements would make explicit which clinician was responsible for different aspects of the patients' treatment. These may include substitute drugs in appropriate circumstances.

CLINICAL GOVERNANCE

In the broadest terms clinical governance is concerned with developing a framework in which high quality health care can be demonstrated and safeguarded, with monitoring systems designed to improve quality.

In the context of this set of principles, quality improvement measures embraced by a clinical governance framework will include:

- Accountability
- Clinical Audit
- Evidence based clinical practice
- Education and training programmes for professional development.
- Service user / patient feedback.
- Management of clinical activity
- Evaluation of treatment
- Clinical Supervision

These measures are and will be met through the Shared Care Monitoring Group and links to WMHPT, PCT & SMAT governance arrangements.
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EXECUTIVE SUMMARY

This document contains standards and guidelines that are intended to govern the treatment of substance dependence in Primary Care in Worcestershire. The standards are derived from the Department of Health Guidance on Drug Dependence (2007), NTA revised Models of Care 2006 (see Appendix 1) and from national and local experience and expertise. The standards are aligned with the Worcestershire Prescribing Standards for Specialist Care i.e. CDT to allow smooth transition between the two elements of the service.

The standards intend to develop consistency in the treatment of primarily drug but also alcohol use in primary care, to improve the quality of service provided to patients, to support GPs, and to use the resources available in Worcestershire most effectively. They aim to provide a framework for services to develop, and to allow for the auditing and monitoring of services to take place. The Shared Care Monitoring Group, a multi-agency forum co-ordinated by GPs, commissioners and statutory and voluntary services, will take the development of shared care in Worcestershire forward. This document will be reviewed at three yearly intervals.

The success of the shared care scheme has meant that Worcestershire has continued to grow but at slower rate than has previously been achieved, which is to be expected. The Substance Misuse Action Team (SMAT), has set targets in future:

- To increase the number of GP surgeries in Worcestershire involved in substitute prescribing within a shared care framework to 70% by April 2010 – presently 64% as of April 2009
- For prescribing GPs to provide a prescribing service to those presenting for treatment, and deemed suitable, within 3 weeks – presently 80% achieving these levels
- For regular training to be offered to GPs on an annual basis and two-yearly for review training linked to these guidelines

It should be noted that those people that are deemed suitable for their substitute prescribing service from their GP but they do not participate in Shared Care are seen by a suitably qualified GP. Although these patients are seen at the CDT bases attempts are made to keep these patients distinct from the secondary care patients to provide some parity of service.

The default setting for all service users to receive their prescribed drug treatment is Primary Care unless assessment indicates that their needs are better met through the consultant service namely secondary care.

AIMS OF MULTI-AGENCY SHARED CARE SERVICES IN WORCESTERSHIRE

For the purposes of this document, shared care will refer to the multi-agency joint work of GPs, the Worcestershire Community Drug Team (WCDT), Primary Care Drug Workers (PCDW), Turning Point (TP), and Community Pharmacists in delivering a service to people with a primary opiate dependency.

Drug dependency is regarded as a potentially long term, enduring and chronically relapsing condition. As such, Shared care services in Worcestershire will aim to:

- Deliver a multi-agency approach that is integrated and community focused which adds value to the care of patients
- Offer treatment that emanates from a harm minimisation principle because there is an evidence base for this.
- Improve the health and social functioning of patients
- Promote safety for the patient, service providers, and the community
- Provide an accessible and flexible service that offers choice to service users
- Encourage service user involvement in the development of services
- Promote evidence-based effective ways of working
- Encourage every GP prescribing for drug dependency in Worcestershire to be involved in shared care arrangements and to have received locally provided training
- Engage patients in the process of care coordination as per the Worcestershire Care Coordination Policy for Drug Services (Appendix 12)

**THE ROLE OF THE SHARED CARE MONITORING GROUP (SCMG)**

The Worcestershire SCMG was established in 2001 as a result of a strategic drive prompted by the NTA to develop Shared Care nationally as a means to reduce waiting times at specialist services and provide integrated care. However, the benefits of Shared Care go way beyond simply reducing waiting times particularly towards ‘normalisation’.

The group meets bi-annually and the chair is a practising GP in Shared Care, which is widely regarded as the ideal. The SCMG is an open forum and welcomes participation from anyone interested in Shared Care though particularly GPs, pharmacists, service users, non-statutory agencies, public health representation and commissioners.

The role of the group includes:

- Establish and review aims and objectives of the scheme
- Strategic development; to influence and inform local decisions
- Overseeing, monitoring and coordinating shared care
- Advisory group to other groups and agencies e.g. Service Improvement Group (SIG) and Joint Commissioning Group (JCG)
- Focus on the ongoing maintenance of local systems once initial development is achieved
- To ensure that clinical effectiveness is attained through clinical governance including clinical audits are undertaken and service user feedback is employed

**THE ROLE OF THE SHARED CARE COORDINATOR or PRIMARY CARE MANAGER**

The role of the Shared Care Coordinator has been highlighted nationally as a central element of Shared Care development, as noted at the 2006 Management of Substance Use in Primary Care conference.

This is ideally a non-clinical role that focuses on the following areas:

- To act as the focal point for developments agreed through the SCMG
- To take responsibility for the implementation of these developments
- To report back to the SCMG the developments effectiveness
- To ensure that high standards of patient care are maintained in Shared Care as outlined in this document
• To ensure a high standard of professional development in substance use occurs throughout the Shared Care workforce

WORCESTERSHIRE SHARED CARE ARRANGEMENTS

Worcestershire will offer General Practitioners a payment in line with the recommendations within the nGMS Contract for Enhanced Services or locally agreed conditions for patients who are being prescribed methadone or buprenorphine, conditional that the GP undertakes to meet the following criteria:

• Attend an initial local training course on opioid substitute prescribing and substance misuse management annually.
• They agree to undertake ongoing training as arranged by the SCMG. This is presently set as three-yearly- to detail the content of this revised and updated document. For the other two years there will be an evening session that all GPs will be required to attend for professional development.
• Offer appointments with the patients at regular intervals (when clinically appropriate) with a focus on medical and care-plan review [See Operational Guidelines]
• Liaise with Primary Care drug worker at regular intervals for clinical review of patients and provide effective in-house means of communication between GPs and PC drug workers.
• Undertake regular audit of outcomes e.g. prescribing audit / care-plan audit etc – locally and nationally.
• Provide space within the practice, where possible and practical, for the PC drug worker to meet the patients regularly.
  • Undertake to facilitate staff training (Receptionists and where appropriate Practice Nurses.)To produce prescriptions for their own patients
  • It is proposed that a maximum limit of activity be set which may be subject to review. This could act as a quality control measure and would also aid surgeries initially registering.

1 GENERAL

All GPs treating patients, whether formally involved in shared care arrangements or not, should:

• Prescribe within the guidance set out in the Department of Health Guidelines (Drug Misuse and Dependence - Guidelines on Clinical Management 2007)¹ which are translated in to a local arrangement within these prescribing standards and practice guidelines
• Be aware of the local shared care agreements (see 2)
• Complete thorough assessment and risk assessment when treating a patient in whom a drug problem is identified (see 5)
• Work to their own level of competency (not the PC drug workers), which will for some appropriately experienced GPs enable them to work beyond these guidelines but are advised to clearly document their rationale for so doing and / or at the direction of the specialist consultant.

2 AGREEMENT BETWEEN WORCESTERSHIRE COMMUNITY DRUG TEAM AND GPs INVOLVED IN SHARED CARE
2.1 GPs can provide an effective intervention for substance misusers in the community. Some of the advantages of GPs treating patients in the community include:

- Non-stigmatising environment which ‘normalises’ the service user experience
- The service is available in the local community and usually within close proximity
- GPs have a holistic view of patient needs
- Provide continuity of care
- GPs can provide a full range of health interventions as well as prescribing
- GPs can refer to other local community based services

2.2 The vast majority of patients requiring opiate substitute prescriptions can be safely looked after in general practice transfer from Shared Care should be done so on the basis of risk. Hence, for a patient to be initiated or transferred to Shared Care a triage risk assessment (see Appendix C) must be undertaken. Followed by a Treatment Assessment both of which should be used to inform the ongoing process of comprehensive assessment (see Appendix C). Similarly, patients being transferred from Shared Care in to secondary care or indeed when treatment is discontinued should be decided on the basis of risk (see also 17).

Obviously, levels of risk are a spectrum ranging from low to high. And so, broadly speaking, patients who are assessed as low to medium risk are suitable for shared care, and those from medium-high to high risk will generally require more specialist input from the consultant services.

Decisions to which modality a service users needs may be best met is generally decided at the weekly referral meeting which is attended by drug workers with medic representation. The decision then places the service user on a waiting list whereby once a drug worker has a space on their caseload they will pick a service user in chronological order from the list. A discussion will then take place with the GP whether they are happy to start prescribing to the patient and an appointment arranged to undertake a treatment assessment to commence substitute prescribing.

As previously stated some GPs with the appropriate levels of knowledge and skills may opt to initiate, receive or maintain patients of higher risk for legitimate reasons. Again, it is advised that the justification for working with higher risk patients is clearly documented and / or undertaken at the specialist consultants direction.

The application of these processes will also ensure that risk assessment is embedded at the core of Shared Care work which clearly must be balanced with the service users needs.

The following patients should not be initiated by a GP but some may be transferred in to Primary Care at the direction of the consultant services:

- Pregnant patients – but could be transferred from secondary care or maintained (see 19 and Appendix 13)
- Young People (Under 18 years) – refer to young people’s drug service, SPACE Team (see 22 & Appendix 8)

2.3 Where a joint assessment between a GP and the Primary Care Drug Worker (see 5) indicates a risk level beyond that deemed suitable for Shared Care i.e. high risk, then the patient will be referred to the specialist prescriber.
2.4 The specialist consultant(s) will offer a weekly one hour slots in both the North and South of the county to all GPs which can be utilised for telephone discussion and / or the review of primary care service users. This system will provide rapid access to the consultant if required.

2.5 If a patient prescribed to in general practice is assessed to be of a level of risk above the experience of the GP, where appropriate the specialist prescriber will take on the care of the patient, with the aims of providing specialist support. It may be however that the patient is not suitable for either service: the decision to discontinue treatment / discharge should be agreed via a locality MDT meeting with the GPs view clearly presented also (see also 17.1).

2.6 If a patient of the specialist prescribing services, CDT reduces their risk rating to a suitable level then with the GPs consent they should be passed back to the care of the GP involved in Shared Care arrangements

2.7 Movement of patients from one service to another should involve effective communication and agreement with the patient (where possible), the specialist prescriber, the GP and the PC Drug Worker. The forum for discussion for transfer of patients would usually be the relevant CDT locality team meeting, with the views of the GP expressed by the GPLP attached to that surgery and the view of the patient by the relevant key worker.

3 TASKS, ROLES & RESPONSIBILITIES

THE GP

GP provides General Medical Services (GMS) to patients registered with the practice

- To undertake a minimum level of training, as provided locally by the Specialist Substance Misuse Service before undertaking any substitute prescribing.

- The degree of the GP’s involvement in drug related interventions might vary according their level of interest, experience and/or confidence.

To undertake two-yearly training in-line with the revision of these guidelines and one evening session per year organised by the SMS

- Prescribe substitute medication for opiate dependency for the purposes of maintenance and detoxification.

- To undertake responsibility for the handwriting or computer generation of their own patient’s prescriptions in-house

- Screening for HIV, Hepatitis A, B and C (see Appendix 7)

- Provide Hepatitis B vaccinations and Hepatitis A, as required (see Appendix 7)

- Other biomedical tests as indicated especially FBC, LFT for patients particularly those with concurrent alcohol problems and / or a positive Hepatitis C status; ECG for those on higher doses of methadone [>100 mgs daily – See 8.3]
• Health checks and health promotion advice including referrals to secondary medical care if required, including CMHTs.

THE PRIMARY CARE DRUG WORKER

• Receive referrals and undertake, triage assessment and comprehensive assessments (Appendix C) with full risk assessment when required (Appendix C)

• Advise GP on assessment and risk assessment outcome, suitability of shared care option and treatment plans following the weekly referral meeting

• Provide access / follow up care for the patient

• Monitor and review patient's progress (including toxicology)

• Ensure the prescribing GP is consulted on all aspects of the patient’s care and receives regular progress reports.

• Patient reviews with GP, updating treatment and care plans, liaison with other service and acting as care coordinator where appropriate.

• Maintain professional relationships with other agencies involved e.g. DIP, Turning Point, social services, probation service, housing, benefits agency etc.

• Liaison with dispensing pharmacy

• Keep up-to-date NDTMS (National Drug Treatment Monitoring Service) and TOPs (Treatment Outcome Profile) records and returns.

• Undertake directed audit as part of the SMS annual audit plan

SPECIALIST DRUG SERVICES (Substance Misuse Service / CDT)

• Ensure that shared care work is incorporated into the review and monitoring process

• Evaluate data in relation to this aspect of the service and provide reports to the Shared Care Monitoring Group

• Provide supervision to all PC drug workers

• Maintenance of central patient files to include; triage assessment, comprehensive assessment, up-to-date risk assessment, care plan and prescribing details.

• Clinical consultancy to GP’s

• To develop and implement effective care pathways particularly incorporating Tier Two interventions from partner agencies such as Turning Point

• These tasks, roles and responsibilities form the basis of the agreement between GPs and the Worcestershire Community Drug Team (see 2).

• Ensure smooth transition for patients from one part of service to the other
THE COMMUNITY PHARMACIST

Community pharmacists are integral to the Shared Care team and their contribution to making patient care effective is widely recognised, not least as they often have the most frequent contact with patients.

The tasks, roles and responsibilities for pharmacists dispensing to Shared Care patients are to:

- Adhere to national and local guidelines
- Attend and receive training through both the CPPE and locally arranged training (both of which are, for pharmacists dispensing under a supervised arrangement, mandatory as part of the Worcestershire SLA)
- Provide Needle Exchange facilities
- Where possible arrangements should be made for prescriptions to be delivered direct to the pharmacy
- Ensure that patients are aware of local factors such as opening times of individual pharmacies especially on Bank Holidays.
- Not to dispense when a patient presents intoxicated or there are 3 days of medication known to have been missed.

Be consulted and encouraged to join the shared care scheme, and will be included in consultations on local policy, and invited to the Shared Care Monitoring Group and / or Pharmacy Liaison Group*. The PLG will:

- Liaise with commissioners in order to ensure the option of supervised dispensing is available to all GPs.
- Maintain close links with substance misuse service and should ensure that patients are aware of this.

The specific working practices between drug services [including GPs] and pharmacists are detailed in the Substitute Opioid Medication for Substance Users – Local Guidance for Community Pharmacists [Feb 2008] – See Appendix 10

* The Pharmacy Liaison Group (PLG) provides a governance forum for pharmacy professionals, CDT, Turning Point, Young People’s services as well as Service Users that enables the standardisation and development of pharmacy-based provisions to patients to occur more rapidly. Furthermore, the group acts as a strategic and advisory body for other groups such as the JCG, LPC, DAAT and the SCMG.

4 ACCESSING SHARED CARE

Presentation to the GP
No GP should prescribe methadone, dihydrocodeine, buprenorphine, benzodiazepines or other substitute medication at a first visit, or on a one off basis. This applies particularly to patients who are temporary residents, new registrations, or those recently released from prison.

- Presentation to the GP may be the starting point and GPs will always be involved in the care pathway.
- GP to briefly ascertain the nature of the patient's drug problem and any previous involvement with treatment agencies - GP Assessment Form (see 5 & Appendix C)
- Check patient details
- If considered appropriate outline to patient what shared care is and how it is operated within the practice. It must be stressed that suitability for shared care is determined following a triage assessment with the PC drug worker.
- Outline confidentiality issues
- Ensure that the patient is aware that they will be entering into an agreement should treatment be offered.
- Provide the patient with a copy of the practice information leaflet.
- Advise patient how an assessment appointment with the PC drug worker can be arranged. Where necessary appointments can be offered at alternative sites and at flexible times to help accommodate the speed with which patient assessments can take place.
- Make a further appointment following the arranged PC drug worker triage assessment.

Other referral points may include Turning Point [particularly if needle exchange is required], DIP, Social Services, Probation, self etc. For a comprehensive view of referrals and assessment refer to the Worcestershire Drug Services Partnership Care Coordination Policy (see 7.2 & Appendix 12)

5 ASSESSMENT

5.1 GP ASSESSMENT (see appendix C)

Assessment and care-planning should form the core of all interventions in the interests of good patient care, appropriate use of resources, and safety. All GPs, whether involved in Shared Care or not, should offer basic harm minimisation interventions which should include the following:

- Advice regarding safer injecting and avoidance of blood borne viruses
- Advice on local needle exchange facilities
- Advice on safer sex and sexual health
- Testing for hepatitis A, B and C (see 20 & Appendix 7)
- Promote HIV testing (Appendix 7)
• Vaccination for Hep B (and Hep A if patient is Hep C positive or there are other risk factors such as poor living conditions) for patient and where appropriate family members/partners (Appendix 7)
• Inquiry about patterns of substance misuse, including alcohol and previous treatment outcomes
• Inquiry about other drug related problems
• Referral to specialist services, where appropriate – see 2b
• Initial risk assessment
• General health needs, other health problems including mental health needs

Following the initial assessment by the GP, the details are provided to the PC drug worker then an assessment appointment will be offered to the patient at the earliest opportunity (usually within one week).

**Note:** NTA targets require that from the time of referral (in this case presentation to the GP) to the patient receiving substitute medication, where appropriate, should be a maximum timescale of 3-weeks.

### 5.2 PRIMARY CARE DRUG WORKER ASSESSMENTS (Appendix C)

*The PC drug worker with designate responsibility for the surgery will normally undertake this. Its function is multi-faceted and should include;*

• Recent drug use and drug history.
• Level of risk taking behaviours and risk assessment
• Physical and psychological health
• Social situation – relationships, accommodation, employment, legal and financial matters.
• Previous drug treatment episodes.
• Motivation for change
• Advice on harm minimisation and healthier life styles.
• The patient receives Trust approved user-friendly literature relevant to their substitute medication and receipt is documented in their patient history notes

1. The assessment will be undertaken using the triage assessment form
2. Discuss, identify and agree possible goals with the patient that will formulate an initial care plan. This will assist the evaluation process.
3. A copy of the *Patient Guidelines* (Appendix C) given to the patient, and documented in patient notes.
4. Make known to the patient who is their care coordinator. This may also be a Turning Point or DIP worker if they initially undertook the comprehensive assessment (see Appendix C)
4.5. Undertake saliva or urine drug test – treatment will not proceed until results are satisfactorily confirmed.

5.6. A GP or PC drug worker follow up appointment will be offered (usually 7 days later). This appointment will be to discuss suitability for shared care and will be subject to drug screen results, triage assessment outcome and the discussion between drug worker and GP who will be responsible for medical care.

6.7. Drug workers will ensure information is entered into the practice patient records. It is important that information is shared with the GP and information should be faxed to the surgery if the drug worker is off-site within 24 hours (for standard fax form please see Appendix C).

7.8. Report changes to NDTMS data records (see also 6).

8.9. Notification of a new patient start by the PC drug worker at the locality team meeting and a provisional countywide check of CDT & NDTMS records will be made to ensure the patient is not receiving substitute prescribing from any other source locally.

9.10. A general health check should be undertaken at a GP appointment arranged prior to the onset of the treatment plan.

6 Confidentiality

Patient information will not be shared with any other agency or individual outside the PC drug worker, CDT and the GP practice without the patient’s permission, except in the following circumstances:

- There is a risk of suicide
- There are serious concerns about the safety of others
- There is risk of harm to a child
- If a police or court order is produced
- Terrorist activity is disclosed

Other areas of shared information, which will be explained to the patient at the comprehensive assessment by the PC drug worker, and include:

- Under normal circumstances, providing information to a third party will only occur with the consent of the patient.
- In the case of a person under the age of 18, information must be shared to protect the best outcome for the child / young person, as outlined in the Worcestershire Safeguarding Children guidelines.
- Anonymous data submitted to the NDTMS
- Information held by the Police Pharmacy Inspector for those prescribed controlled drugs

As employees of the Worcestershire Mental Health Partnership NHS Trust PC drug worker working in the Community Drug Team have specific duties and responsibilities around confidentiality.

7 Interventions following assessment
7.1 Formulating a treatment plan

Treatment plans will be formulated by discussion between patient, GP and PC drug worker and determined from:

- A full saliva screen result that includes benzodiazepines, amphetamine, cocaine as well as methadone and buprenorphine. A confirmatory 6-MAM test can be considered for new patients that are previously unknown to services to indicate whether they are using street heroin and not just legally purchased opiates.
- Information from the triage assessment (Appendix C)

If it is considered by the GP and the PC drug worker that the patients' needs are complex (see 2.1 & 2.2) i.e. the level of risk exceeds that stated in 2.2, then the care of the patient should be passed to the specialist consultant.

If the patient is assessed as appropriate for General Practice, then the GP with advice from the PC drug worker will make a decision on the medical care of the patient based upon the information available.

Soon after treatment has commenced the PC drug worker will be expected to undertake the comprehensive assessment which is a living documented that should be updated throughout treatment and also devise a care plan for the patient providing a written basis for their work. Care plans along with risk assessments, and TOPs forms should be reviewed at a maximum interval of 3 months.

7.2 Inter-agency working

The development of the Worcestershire Drug Services Partnership Care Coordination Policy (Appendix 12) in 2005 provides a framework for enhanced levels of care to patients, and aims to prevent patients “slipping through the net”.

Furthermore, at assessment it should not be assumed that substitute prescribing, or detoxification are the only options for the patient. The comprehensive assessment will indicate perceived need and risk, and indicate whether a patient has been referred to or from other agencies. The PC drug worker, as care coordinator, could consider the following services for all patients whether or not they go on to receive a medical intervention:

- Housing advice – Turning Point’s Social Reintegration service, and / or Stonham Housing or local housing organisations and hostels
- Harm reduction advice (including safer injecting)
- Social Reintegration – through Turning Point’s Social Reintegration service
- Employment and training advice
- Benefits from the DSS
- Group work – Turning Point
- Counselling – Turning Point
- Alternative therapies – Turning Point

This is not, of course, a comprehensive list and care coordinators are expected to meet the patients need, where possible, either themselves when they have the appropriate skills or by ‘subcontracting’ work through Care Coordination, to other agencies.

7.3 Ongoing Patient Care
7.3.1 In the interests of good patient care, and safety to the patient, practitioner and the community, the patient should regularly see both the GP and a PC drug worker. All three parties along with community pharmacists should work together to ensure that the treatment is working effectively.

- Patients should be seen by their GP more frequently at the outset of treatment, and eventually a recommended maximum length of time between appointments being once every 3 months.
- Patients should be seen frequently (usually weekly) by the PC drug worker at the onset of treatment. The maximum length of time between key worker appointments should be 3 months, in the case of very stable patients, though in practice most patients would be seen more frequently.
- A joint care plan with treatment goals should be drawn between patient, PC drug worker and GP, to be completed within a month of treatment being initiated.
- The care plan and risk assessment will be reviewed at a maximum interval of three months. Ideally this review would take place during a three-way appointment. However, doctor appointments will finalise and sign-off any agreed care-plan arrangements with the service user’s input if in attendance. Care-plans will be reviewed with or without the service user [see 25 & Appendix B].
- Clinical Review Meetings – between GP, PC drug worker and the senior PC drug worker (when available). All Shared Care patients for a particular GP and / or surgery should be formally discussed on an agreed basis. The meeting can be as a weekly ‘catch up’ or more formally set up on a regular basis and any discussion should be appropriately recorded in the patient notes.

To enable effective joint working between the GP, the patient and the PC drug worker, all information that may affect prescribing issues and medical issues will be shared.

8 Substitute Prescribing for opiate dependence

Substitute prescribing should be considered where a patient’s welfare is affected by their opiate dependence. Substitute prescribing should be considered for the following aims:

- Long term maintenance
- Short term stability prior to detoxification

In short the ‘three rules’ of substitute prescribing are influenced by duration and retention of the patient, dosage levels and safety, particularly dispensing arrangements. Three rules are abbreviated as, substitute prescribing should be:

- Long Enough
- High Enough
- Safe Enough

All drugs should normally be used within their licence: dihydrocodeine is not licensed for the treatment of drug misuse: methadone injectables are not licensed: benzodiazepines are licensed only for the treatment of benzodiazepine withdrawal, not for maintenance. Methadone mixture and buprenorphine (sublingual) are licensed for maintenance and detoxification.
Also where a decision is to be made to either prescribe methadone or buprenorphine [Subutex] the DoH clinical guidelines recommend:

“Any assessment should be combined with the prescriber’s experience of working with the different medications to provide a decision . . . . . . NICE’s recommendation is: “If both drugs [methadone and Subutex] are equally suitable, methadone should be prescribed as the first choice” [NICE, 2007a]”

8.1 Oral methadone prescribing

Guidelines

Methadone is the most widely used and researched opioid replacement therapy (Hall et al 1998 1-2) “Involves the administration of a long-acting opioid drug to an opioid dependent person, usually by a non-parenteral route of administration, for the therapeutic purposes of preventing or substantially reducing the injection of illicit opioids, such as heroin. Its goal is to improve the health status and psychological and social well-being of the opioid dependent person.”

Oral methadone is an option for patients who require a period of stabilisation on an opioid and who are not ready to detoxify. It is not the complete answer to the problems of opioid dependence but enables people to stabilise their lifestyle and reduce the physical and social harms associated with illicit opiate use. Whilst a number of patients may reach a point where they are ready to reduce and detoxify fairly quickly, a significant number will require long-term maintenance.

The target outcomes of such an approach are as follows:

• To help patients stop/ reduce injecting
• To reduce criminality
• To stop/reduce use of street drugs
• To reduce the risk of overdose / drug related death (Zador, D et al 1998)
• To improve psychosocial functioning

It should only be prescribed following full assessment the purpose of which is to determine:

• That the person is physically dependent on opioids. (i.e.: a history of daily use, withdrawal symptoms, tolerance and persistent use to control symptoms.)
• Saliva screen test +ve to opiates or methadone.
• That there is a consistent history of use and route taken with appropriate physical signs e.g. injecting sites.

Cautions

• Concurrent heavy alcohol / benzodiazepine use or other sedating medications
• Severe hepatic impairment (close monitoring needed during initiation due to reduced clearance leading to nausea and sedation)

(see latest BNF for full list)
Interactions

- Enzyme inducers e.g. carbamazepine, phenytoin, rifampicin and phenobarbital will cause onset of withdrawals (severe with rifampicin)
- Cyclizine: if injected with methadone can cause marked hallucinations
- Naloxone/ Naltrexone: will lead to severe precipitated withdrawals
- Tricyclic antidepressants: increased sedation
- Zopiclone: Increased sedation

(see Methadone Briefing / BNF for full list)

Initiation

- A prescription should only be initiated after a full joint assessment and a urinalysis or saliva screen positive for opiates has been conducted (except where the patient is transferring from another service and prescribing has already been safely initiated by another clinician)
- Physeptone SF is the preferred and most cost effective product, 1 mg/ 1 ml sugar-free should always be used
- The starting dose should not exceed 40 mls daily
- Patients should be notified that is illegal and dangerous to share their medication
- The patient should be told that methadone and other prescribed drugs should be kept out of reach of children (and those that are opiate naïve) and ideally stored in a locked cabinet or box.
- GPs should make appropriate efforts to ensure that any drugs prescribed are used appropriately and not diverted onto the illegal market, e.g. by using instalment dispensing and supervised consumption where available and appropriate
- All patients should be warned about the risks of overdose and told what to do if this occurs, and warned about the risk of mixing methadone with other respiratory depressants, especially alcohol and benzodiazepines
- All new patients presenting for treatment should be notified that confidential information will be recorded on a local database (PiMS) with restricted access.
- Sick Notes (Med5) should not be issued as standard for patients in receipt of substitute medication. Short-term sick notes may be appropriate whilst a patient stabilises at the initiation of treatment.
- At assessment, many service users report depressed mood and disturbed sleep. However, mood usually improves after stabilisation on methadone or buprenorphine, and it is not normally appropriate to initiate anti-depressant treatment during induction. Review of mental state should be apart of an ongoing assessment. Patients already on anti-depressants, particularly tricyclic antidepressants or fluvoxamine, may need careful monitoring during induction as these medicines may interact with methadone. Antipsychotic medications may potentiate the hypotensive effects of methadone and separately increase the risk of cardiac toxicity.

8.2 Getting the right dose

The guidance given here applies to patients within the normal ranges of body weight, body mass index and liver and kidney function. Patients outside of the normal ranges may need to have their dose adjusted up or down accordingly, although variations are usually small and taken care of by normal induction.
• After initiation at no more than 40 mgs methadone daily, GPs are advised to increase doses of methadone by no more than 5-10 ml on one and by no more than 30 mgs in the first seven days. It is therefore recommended that increases take place every couple of days by a maximum of 10 mgs on each occasion and by no more than 30 mgs in any one week.
• The PC drug worker will be available to provide a follow-up appointment shortly after treatment has been initiated.
• Following the first week, doses can continue to be increased incrementally up to a total of between 60 and 120 mg a day, and occasionally more – a level at which the patient reports feeling comfortable and is no longer using illicit heroin. Caution needs to be exercised and it may take several weeks to reach the desired dose.
• There should be a few days between each dose increase.
• For further guidance see RCGP guidance on the use of methadone for the Treatment of Opioid Dependence in Primary Care (Appendix 3) and the DoH clinical guidelines.

8.3 Methadone Maintenance

Harm reduction rather than abstinence should be the aim of maintenance prescribing. This aim is achieved by prescribing a dose that is adequate for patients not to use opiates ‘on top’ of their prescription (though it is recognised that many will on occasion). Regular appointments and joint care planning with the PC drug worker can enhance the patient’s care and safety.

• Physeptone SF 1 mg / 1 ml of methadone mixture should be the usual drug prescribed for once daily administration. More concentrated versions should not be used, as they can be dangerous if used on the illicit market. A mixture of methadone with sugars is available if a patient finds this easier to take, but health and dental implications should be highlighted if this is the case.
• All methadone prescriptions will normally be started for daily supervised consumption where available (and daily collection when not available), with take home doses for Sundays and bank holidays
• GPs should ensure prescriptions are completed prior to collection day or an appointment is made with the patient prior to their prescription lapsing
• GPs should ensure that the dispensing pharmacy is written on the prescription
• If a patient’s saliva screen is regularly morphine-specific positive (i.e. heroin), increasing the dose of methadone should be considered. Usually by no more than 30 mg per week.
• Daily dose of methadone should not exceed 120mg. Unless a GP feels confident then advice should be sought from the consultant service if a patient is not stable at this level.
• High doses should be taken under supervision for as long as is needed for the practitioner to be sure that the patient is consuming the total dose. Take-away doses should be phased in and consideration given to dosage levels, other drug use (including alcohol), maturity and stability. Frequency of collection is a safety parameter, not a rewards and sanctions system.
• Monitoring for dosages > 100 mgs and with other QT prolongation risk factors where appropriate requires regular ECG monitoring and re-assessment where any arrhythmia is highlighted [see Appendix 2; DoH clinical guidelines Appendix 1 p. 98/99]
• Daily-supervised consumption should normally be continued for up to three months, where possible, or until the patient is stable and drug screening shows no illicit drug
use. In situations where the patient is in stable full-time employment, it is important that supervised dispensing does not affect their ability to work.

- Prescriptions should normally be suspended if three consecutive days doses are not collected and treatment not re-instated until a drug screen has been provided and reviewed and dosage amended and re-titrated, as necessary. Tolerance can drop quickly, therefore for doses above 40 mgs it may be necessary to re-titrate from this dose if assessment shows that they have been using an equivalent amount of street opiates or opioids. Where assessment indicates that re-titration to their previous dose is required then this should take place as quickly as is possible [see above].
- Effective lines of communication should be established with dispensing pharmacies. A system should be in place for the pharmacist to report uncollected doses where appropriate.
- Where practical, late opening pharmacies should be used for working patients on daily supervision.
- Drug screening should be undertaken regularly, but should not form the sole basis of clinical decision-making.
- No patient should take home more than 500ml home at any one time and prescriptions should be dispensed at least twice a weekly except in exceptional circumstances (e.g. holidays).
- With the exception of annual holidays patients should pick up no more than a weeks worth of methadone.
- Only the patient him or herself may collect their medication from the pharmacy unless the prescriber authorises otherwise for exceptional circumstances
- Concomitant hypnotic medication will generally not be prescribed (see 16)
- The prescribing PC drug worker should maintain close links with the dispensing pharmacy and should advise patients of this.

8.4 Methadone Tablets

Methadone tablets should not be routinely prescribed because of their increased transferability and potential risk of injecting (Dept. of Health Clinical Guidelines). They may be prescribed in the short term for holiday periods as this eliminates the risk of spillage.

Where a patient is transferred from the CDT to primary care (Shared Care) as they have satisfied the Primary Care criteria and have been receiving methadone tablets it would be appropriate to continue this arrangement at the direction of the consultant services.

Furthermore, where methadone mixture causes a pregnant service user difficulties to ‘keep down’ then methadone tablets can be considered following a risk assessment.

8.5 Buprenorphine

Buprenorphine (Subutex) has proven effectiveness in the treatment of opiate dependence similar to methadone.

Subutex is a partial opiate agonist at the principal opioid receptors. Because of this it produces a milder, less sedating and less euphoric effect than other opiate agonists such as methadone or heroin. It is effective in relieving the physical withdrawal symptoms / cravings from opiates. Although lacking in the breadth of evidence that underpins methadone, a systematic review has been undertaken regarding its efficacy (Mattick et al 2003)
Note: There is no supervised buprenorphine protocol for Worcestershire at present and therefore cannot be provided within a model of supervised consumption.

Indications

- It is a well-researched drug for the treatment of opioid dependence.
- It can be used to detoxify patients as well as being used for stabilisation/maintenance.
- It may be particularly useful for patients who are on a low dose of methadone who have occasional relapses and need to break the pattern or make lifestyle changes before they are ready to undergo detoxification. It may also be useful for patients wanting a short detoxification or for patients with a short history of opiate use.

Contraindications

- Pregnancy and breastfeeding. Women of childbearing age on Subutex should be advised of the contra-indication and to seek early advice if pregnancy is suspected.
- Severe respiratory or hepatic impairment.

Drug interactions

- Alcohol – increased sedation/ CNS depression
- MAOI antidepressants
- benzodiazepines - increased sedation (deaths have been attributed to this)
- Tricyclic antidepressants-increased sedation
- Some antibiotics e.g. Erythromycin may increase the plasma concentration of Subutex
- Concurrent use of Subutex in addition to heroin, methadone or other full agonists will provoke withdrawal symptoms.
- Opioid antagonist Naloxone will precipitate withdrawal symptoms in patients on Subutex. Because Subutex is not easily displaced by Naloxone, high dosages (10-30 times the normal amount) are required to reverse the effects.

Side effects

The side effects to Subutex are similar to other opioids for example constipation, disturbed sleep, drowsiness, sweating, headaches and nausea. It is probably less sedative than other opioids, however patients should be warned about the possible effect on the capacity to operate machinery or drive in the early stages of treatment and following an increase in the dose.

Onset of action

Subutex starts working 30-60 mins after the first dose and has its peak clinical effect at 1 to 4 hours. In low dosages i.e. under 4mg it lasts 8-12 hours. However in higher dosages can last between 24 and 72 hours.
**Initiation onto Subutex**

The guidance given here applies to patients within the normal ranges of body weight, body mass index and liver and kidney function. Patients outside of the normal ranges may need to have their adjusted up or down accordingly, although variations are usually small and taken care of by normal induction.

- The patient should have been given written and verbal information via patient information guide (Subutex: Your Guide, Schering-Plough) and precipitated withdrawal clearly explained and how to proceed if they occur.
- The patient should be advised that it is crucial to arrive at the pharmacy in withdrawal from methadone/or heroin to reduce the risk of precipitated withdrawal. This typically is 8hrs for heroin and up to 36 hours with methadone. If symptoms are experienced within the first 2 hours of initial dose it is likely to be precipitated withdrawals.
- When converting the patient from methadone to Subutex the dose of methadone should be no more than 30 mgs to avoid interaction leading to withdrawal symptoms. Ideally the methadone should be as low as possible. Transfer can take place whilst the patient is on up to 60mg of methadone but the reaction may lead to intolerable discomfort and ideally should take place as an in-patient or within a specialist setting. Some of this discomfort can be overcome by using lofexidine as a 'bridge' providing symptomatic relief in the interim.
- There is limited evidence for the effectiveness of adjunctive medications for the management of symptoms associated with withdrawal. The prescribing of other opioids, any other respiratory depressants drugs, during induction onto buprenorphine treatment is therefore not recommended.
- Patient should be reminded that Subutex should be taken sublingually and that if swallowed will be inactive.
- They should also be advised not to use heroin on top as it may cause nausea, headaches and will make stabilisation more difficult.

**Day 1.** Most dosing regimens involve starting with a low dose [4-8 mgs] and rapidly increasing. If precipitated withdrawals are experienced then the patient should be advised that any further dosages that day will not help and that symptomatic relief should be sought. The patient should be reassured that the withdrawals are only temporary (1-4 hours).

**Day 2.** Dose can be increased to 8-16mg daily

**Day 3.** Review dose and continue to increase in 2mg increments until the patient is stable up to a maximum dose of 32mg daily (for patients not stabilising at this dose will be transferred to the specialist service)

Regular review will need to take place to monitor for signs of withdrawal/ cravings during induction period. (Ford et al 2003)

It should be noted that this starting regimen is within Schering-Ploughs license for Subutex however, the regimen above is taken from the DoH clinical guidelines [2007]

**Stabilisation**
Stabilisation can be achieved within 3 days with Subutex. The dose should be increased to achieve minimal intoxication/cravings.

Missed doses

Due to the risks of reduced tolerance following missed dosages the patient should be invited in for a urine test to check for the presence of opioids prior to further dosages being administered if 3 or more days have been missed.

Withdrawal

Subutex dissociates form the receptors slowly and this probably accounts for its milder withdrawal symptoms. The symptoms usually appear between 24 and 72 hours after last dosage. They peak between days 3 and 5 (if during a short-term episode but peak between day 5 and 14 in longer treatment episodes. Mild withdrawals can be expected for some weeks following completion of treatment e.g. cravings, sleep and mood disturbances.

Process of Stabilisation/Detoxification

Negotiate and agree a care plan including monitoring arrangements throughout.

Detoxification

- If detoxification is appropriate (see 10), agree 12 to 36 day plan
- Detoxification should start on a Monday where possible to ensure adequate monitoring
- If the patient is planning to have naltrexone then the PC drug worker should aim for the patient to have last dose on a Sunday/ Monday so that support can be given during the 3 drug free days before relapse prevention treatment is commenced

Stabilisation

Once stability has been achieved further goals in terms of reduction/ maintenance, care co-ordination into primary care should be negotiated.

Transfer back to Methadone mixture

Some patients may need transfer back to methadone for example due to intolerable side effects, pregnancy, inadequate response or complications such as patients needing frequent opioid analgesia for pain relief.

In such cases methadone can be commenced 24 hours after the last dose of Subutex at an initial maximum dose of 40mg. Care should be exercised in increasing the dose too quickly thereafter as Subutex may prevent maximum methadone response for several
days due to its higher receptor affinity action which may persist for several days after stopping the dose.

9. **Buprenorphine-naloxone (Suboxone)**

PLEASE NOTE: At the time of writing these guidelines Suboxone has not been given local APC clearance and therefore cannot be used in the treatment of drug dependence. It is hoped that clearance will be agreed before the next review of this document hence its inclusion.

A new form of buprenorphine has been developed that includes the opioid antagonist naloxone (buprenorphine: naloxone 4:1) in a combined sublingual tablet. This new form is for use at the same buprenorphine dose (the current 8 mg sublingual buprenorphine being considered as the same therapeutic dose as the new combination of 8 mg buprenorphine plus 2 mg naloxone). It has been presented as a new product, under the trade name Suboxone®, and received product approval for addiction treatment throughout the European Union in December 2006. The rationale is that, when taken sublingually as intended, the naloxone has very low bioavailability and does not diminish the therapeutic effect of the buprenorphine. However, if injected, the naloxone has high bioavailability and is liable to precipitate withdrawal in an opiate-dependent patient, therefore discouraging further misuse. If taken intranasally, the effect of the naloxone appears to be variable. The combination tablet is therefore expected to provide the same therapeutic benefit while preventing or reducing the liability for misuse. Clinical experience with this new combination product is, at the time of publication, extremely limited in the UK, and it is too early to indicate the relative positions of these two versions of buprenorphine. Suboxone should be initiated in the same way that Subutex is – see 8 above.

10 **Detoxification and Relapse Prevention**

There are some patients for whom maintenance prescribing may not be appropriate initially, but who may be considered for detoxification. The following patients should be encouraged to undertake detoxification in the first instance:

- Those with short-term, non-entrenched, drug use
- Those who are presently stable on a substitute prescription
- Those who have achieved abstinence previously
- Those who have good psycho-social support
- Those with little active physical and / or mental health problems

There are three forms of opiate detoxification available for patients

1. Inpatient detoxification – limited availability locally
2. Community Home Detoxification
3. Reduction regimens for methadone and buprenorphine

The decision to undertake detoxification must always be with the patient\(^2\). Slowly reducing methadone doses without consent is proven to be not at all useful\(^2,3\). People should either be on maintenance or detoxification not slipping between the two\(^2\). In each case the patient, GP and PC drug worker, should agree the decision for detoxification jointly. The PC drug worker will offer pre and post detoxification work including referral and support from Turning Point to provide aftercare arrangements.

Patients who wish to undertake a detox should be allowed to unless deemed medically unsafe. Patients should not be prevented by clinicians from detoxing simply because they
feel they will not be successful. Furthermore, patients should be reassured that their present prescription will not be in jeopardy by undertaking the detox and appropriate provisions will be made if detoxification is not completed as better outcomes are achieved when this anxiety is removed.

Follow up

- Detoxification is the first step and should never be undertaken without the after care plan put in place.
- Dosage regimens should be allowed to move up and down according to the service users needs throughout the detox and all detox regimens detailed here should be used as a guide only.
- Naltrexone will only be initiated by the consultant service and continued in Shared Care with consultation with the PC drug worker, who will advise GPs of appropriate follow up arrangements.
- The patient will be offered post detoxification support from Turning Point.

11 Guidance For Use Of Lofexidine In Detoxification From Opiate Dependence

As a new addition to these standards it is strongly advised that no GP undertakes lofexidine prescribing until they have undertaken locally arranged training.

Background

Lofexidine is a presynaptic alpha_2 adrenergic agonist that is licensed for use in the management of the symptoms of opiate withdrawal. It is a similar drug to clonidine, the use of which is limited due to the likelihood of postural hypotension; this side effect is less marked with lofexidine. Because lofexidine does not act directly on the opiate receptors it doesn’t give any heroin like effects. It is therefore non-addictive, relatively safe to use and has no value on the “black market”.

Lofexidine blocks the adrenaline / noradrenaline related withdrawal symptoms of opiate withdrawal. These are abdominal cramps, lacrimation, dilated pupils, piloerection, diarrhoea, restlessness, vomiting, rhinorrhea, and profuse sweating. It does not affect other opiate withdrawal symptoms such as muscle aches, insomnia and craving.

It is licensed in the UK for the management of the symptoms of opiate withdrawal (1). There is evidence to suggest that it is equally as efficacious as methadone in withdrawal (2). Lofexidine has a role in the treatment of opiate-dependant individuals seeking abstinence and whose drug use is already well controlled. It is used extensively as a safe and effective method to help people detox in the community. The available data indicate that it is a useful addition to the armamentarium of the clinician (3).

Patients should be carefully selected as being motivated to become opiate free. Persuading patients to come off opiates if they are reluctant or unwilling is unlikely to be successful. Unsuccessful detoxification and relapse are common, even in carefully selected patients. Before undertaking a lofexidine detox, consideration should be given to relapse prevention and the possible use of naltrexone. After an uncompleted or unsuccessful detox the patient should be reassessed and consideration given to other treatment modalities, for example substitute opiates for withdrawal or maintenance (for example methadone or buprenorphine).
Prior to prescribing lofexidine, a physical examination and a full assessment of the drug taking history must be carried out. The assessment must establish their suitability for detoxification and their ability to comply with self-administration of the medication schedule. It is advisable that they have an established support network i.e. partner, carer(s), or friend(s) who can assist them. A lofexidine detox is usually only advocated for patients using less than 1gm of street heroin or less than 50mls of methadone daily (4,5). Though in practice it is usual that someone would be using significantly less than these amounts before being considered for lofexidine detoxification. The likely range being <0.5g heroin and <20mls of methadone (6). Detox in combination with buprenorphine is also possible: the dose of buprenorphine at which an individual should be detoxed in combination with lofexidine would be 2mg or less of buprenorphine daily (7).

The following points should be noted;

- Before starting on lofexidine, a baseline blood pressure and pulse rate reading must be taken; it is also important to check that the patient is not on any other medication that lowers blood pressure.

- The dose should be increased gradually; the usual period of detox is 14 days but will need to be longer for patients previously on methadone. To avoid rebound hypertension, lofexidine should be reduced gradually and not stopped suddenly. This should be explained to the patient.

- Lofexidine is contra-indicated with cardiac disease, following CVA (stroke), in chronic renal failure as well as pregnancy and breast-feeding. It should not be considered for poly-patients (including excessive alcohol use), significant mental health issues, chaotic/unstable patients and maintenance patients on high doses of methadone or Subutex.

- Side effects are limited but may include mild sedation or feeling light-headed. Sedation is increased with concurrent use of alcohol and CNS depressants e.g. benzodiazepines, tricyclic anti-depressants. Overdose can result in hypotension, bradycardia, sedation and coma. Patients sometimes complain of a metallic taste in their mouth and that their urine smells of yeast.

- Patients should be seen on a daily basis for the first five days of treatment to check for withdrawal symptoms, to monitor pulse every day, general support and encouragement. Frequency of attendance will be reviewed after stabilization is complete. Additional short-term medication for the symptoms detailed below.

**Contraindications / Warnings**

The only absolute contraindication is sensitivity to lofexidine or other imidazole derivatives (for example clonidine). Caution is advised in severe coronary insufficiency, recent MI, cerebrovascular disease, marked bradycardia and renal failure. Safety is not established in pregnancy and breastfeeding. Patients who are pregnant should be referred to the specialist service

The following side effects have been reported drowsiness, dry mucous membranes, hypotension (usually postural) and bradycardia. Although serious hypotension is rare, pulse and blood pressure need to be measured before and during treatment.

Lofexidine may enhance the CNS depressive effects of alcohol, barbiturates and other sedatives.
Concomitant use of tricyclic antidepressants may reduce the efficacy of lofexidine. To prevent rebound hypertension, lofexidine medication should be reduced gradually over 2-4 days. There is no indication for long-term treatment with lofexidine.

If opiates are stopped abruptly, treatment with lofexidine is usually required for a further 7-10 days.

**Dosage**

1 tablet (200mcg) twice a day, increasing if necessary in steps of 1-2 tablets daily up to a maximum of 12 tablets (2.4mg) daily. See attached possible regimes

**Other Medication**

In addition to lofexidine other medications are sometimes prescribed in the short term (usually maximum 10 days) to alleviate symptoms of detoxification not relieved by lofexidine.

**Abdominal cramps and diarrhoea**

Prescribe loperamide 4mg stat and 2mg after every loose motion, maximum 16mg daily.

Mebeverine 135mg tds (taken 20 minutes before food) may help stomach cramps and colicky pains.

**Muscle aches**

Prescribe Ibuprofen 200-400mg up to three times a day.

**Insomnia**

Sleep is often disturbed during opiate withdrawal. Patients should be reassured that their natural sleep pattern should be restored after a number of weeks. The first week may be the worst and it may be appropriate to prescribe zopiclone 7.5mg at bedtime. These should be short-term prescriptions only, and consideration should be given to non-drug treatments e.g. establishing a regular sleep pattern, avoiding sleeping during the day, increasing daytime activity and exercise, reducing caffeine intake, relaxation and anxiety management techniques, herbal sleep teas and alternative therapies i.e. Indian head massage or auricular acupuncture.

**Guidance for The Use Of Lofexidine in Opiate Dependence**

1. Lofexidine can be used to ameliorate symptoms of opiate withdrawal as part of a detoxification programme.

2. A urine test should be obtained to confirm current use of opiates.

3. If withdrawing from street heroin, the patient should reduce heroin use as far as possible. Patients using smaller quantities of heroin daily appear to benefit more from lofexidine than those using larger amounts.

4. The patient should not be dependent on, or in a pattern of chaotic misuse with, other drugs (prescribed or non-prescribed e.g. benzodiazepines, stimulants, alcohol) before starting a lofexidine detoxification.
5. Lofexidine can be used at the end of a methadone reduction programme. The methadone dose must be low enough to make the switch to lofexidine approximately 10-15mls daily.

6. The patient must have an awareness and understanding of the proposed treatment package prior to starting. It is the responsibility of the doctor or GPLP to provide this information verbally supported by written materials – Britlofex patient information leaflet (Appendix 20)

7. Lofexidine should not be used if patient has heart failure, recent MI, cerebrovascular disease, or renal failure. It should not be used in pregnancy or breastfeeding.

8. Due to the sedative effects of lofexidine (and benzodiazepines) the patient should be advised not to drive or operate machinery.

9. Blood pressure and pulse should be measured before the start of treatment. If the pulse is less than 55 lofexidine should not be used.

10. It is useful to issue separate successive prescriptions for the lofexidine and other medication to encourage patients to re-attend and to avoid overuse of benzodiazepines.

11. GP and/or GPLP should see the patient three times weekly for support, pulse and BP, and dose adjustment. If the patient has symptomatic hypotension the dose of lofexidine should be reduced or stopped.

12. It is important to remind patients of the risks of reduced tolerance to opiates during and after detoxification.

**LOFEXIDINE ASSISTED DETOXIFICATION FROM HEROIN OR LOW DOSE METHADONE**
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<th>Breakfast</th>
<th>Lunch</th>
<th>Tea-time</th>
<th>Night</th>
<th>Total</th>
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<td>Day 1</td>
<td>Usual Dose of opiate</td>
<td>1 tablet 0.2 mg</td>
<td>1 tablet 0.2 mg</td>
<td>1 tablet 0.2 mg</td>
<td>4 tablets 0.8 mg</td>
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<td></td>
<td>Plus 0.2 mg</td>
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<tr>
<td>Day 2</td>
<td>Usual Dose of opiate</td>
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<td>1 tablet 0.2 mg</td>
<td>1 tablet 0.2 mg</td>
<td>5 tablets 1.0 mg</td>
</tr>
<tr>
<td></td>
<td>Plus 0.4 mg</td>
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<tr>
<td>Day 3</td>
<td>Stop Opiate</td>
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<td>2 tablets 0.4 mg</td>
<td>1 tablet 0.2 mg</td>
<td>7 tablets 1.4 mg</td>
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<td>Day 4</td>
<td></td>
<td>2 tablets 0.4 mg</td>
<td>2 tablets 0.4 mg</td>
<td>2 tablets 0.4 mg</td>
<td>8 tablets 1.6 mg</td>
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**Note:** Some patients may omit days 6-8 if withdrawals are not severe

**Note:** Days 6, 7 and 8 may need to be repeated for patients withdrawing from methadone

Total 52
For clinical sheets relating to pre-treatment assessment and post commencement - see Appendix 5

12 Naltrexone

Note: That the DoH guidelines for the clinical management of substance misuse clearly state that only specialists should initiate naltrexone. However, it is appropriate that GPs take over prescribing once compliance and stability has been determined for the patient, and then at the consultant psychiatrist’s direction.

Information

Naltrexone is an opiate antagonist. It works by blocking the opioid receptors in the brain and therefore blocking the effects of heroin and other opioids. It has also been shown to reduce craving and consumption for some patients who are alcohol dependent. Those who take it know that they cannot achieve a ‘high’ from using heroin and that any money therefore spent on heroin will be wasted. It does not directly stop a person wanting to use heroin, although it may reduce or prevent cravings in some people.

The drug’s success in helping someone abstain is dependent on many of factors, including their willingness to follow a course of medication and the level of available support. Naltrexone is only one part of a comprehensive treatment program, which should include regular counselling. Recent studies have suggested that many patients do not remain on naltrexone treatment and will often return to heroin use.

You cannot become physically dependent on naltrexone and it does not produce any euphoric effects.

It should only prescribed following a full assessment the purpose of which is to determine:

- Previous treatment interventions and response i.e. what, when and success or otherwise. Clearly where a patient’s circumstances do not indicate previous consistent engagement with treatment agencies towards establishing a stable and managed position regarding their drug use, and preferably some indication of previous attempts to withdraw from opiates, then it may be reasonable to take the view that naltrexone might not be the best option. Exceptions to this may include a long prison sentence where the patient has clearly engaged consistently with treatment and support agencies in the prison and in the community, and has developed a clear perspective on naltrexone prescribing as part of a detailed treatment package upon release.

Furthermore:

- Liver Function Test (LFTs) clearly indicate the suitability of the patient, these must be repeated throughout treatment

Warning: Patients need to be warned that any attempt to overcome the block could result in acute opiate intoxication

Cautions:

- Hepatic and renal impairment
- Avoid concomitant use of opioids but increased dose opioid analgesic may be required for pain (monitor for opiate intoxication)
- Pregnancy and breast feeding
(See BNF for full list)

Contra-indications

- Patients currently dependent on opiates
- Acute hepatitis or liver failure

Initiation (via specialist clinics only)

- 25 mgs – stat dose
- Then 50 mgs daily
- Supervision initially by a relative or partner has shown some evidence of increased compliance.

13 Crack Cocaine and Cocaine

The use of crack/cocaine has been steadily rising over the past decade, and increasing numbers of crack/cocaine users are presenting in Shared Care either as sole crack/cocaine users or as poly drug users. Locally there has been a rise in Crack use over the last 5+ years, also many heroin users access crack from the same place as they do Heroin and it is therefore often unrealistic for crack use to cease until their heroin use ceases.

Historically, Shared Care schemes and Tier 3 services nationally, have been developed to manage opioid users and have rarely been able to meet the needs of cocaine/crack users. Shared care schemes should be able to meet the needs of the individual not the specific drug as combination (poly) drug use of crack cocaine/opiates/alcohol and often benzodiazepines are becoming increasingly common in terms of presentation at drug services.

Methadone/buprenorphine and crack/cocaine users have the added complication that one is a short and one a long acting drug that increases the risk of overdose. Crack/cocaine use may escalate if heroin is not available, alcohol and/or benzodiazepines may be used to boost the effects of crack/cocaine, and secondary or even tertiary dependencies may develop.

 Injecting heroin and crack together (speedballing) is an increasing practice which carries the risk of overdose along with tissue damage due to frequency of injecting and the anaesthetic properties of crack/cocaine.

13.1 Main physical / psychological effects

Crack/cocaine is a stimulant drug – users will feel more alert and energetic, confident, physically strong and believe they have enhanced mental capacities.

Large doses, or quickly repeated doses over a period of hours can lead to extreme anxiety, paranoia, visual and auditory hallucinations. The after effects of crack/cocaine use may include fatigue, depression, paranoid ideation and depersonalisation.

Once drug use is stopped the user may experience extreme emotional and physical distress. This can manifest itself in symptoms including diarrhoea, vomiting, body tremor, insomnia, anorexia and sweating. Chronic every day use may result in restlessness, nausea, hyperactivity, insomnia, depression and weight loss.
Patients may present at the surgery with crack/cocaine as a new (additional) drug problem or changes in their physical and/or mental health and continued cocaine positive swab results may draw attention to the change in drug using behaviour.

The extent and effects of the problem should be assessed – including

- Current amounts used and routes of administration.
- Alcohol use – when a patient uses alcohol with crack/cocaine, co-caethylene is produced. This is dangerous as it is toxic and can increase the risk of liver and heart disease, seizures and epilepsy. (liver function tests, BBV screening).
- Physical health – Injecting/smoking? Tissue damage burns.
- Weight – Dietary advice. Monitor weight loss/gain.
- Lung capacity – Record and monitor peak flow rates.
- Heart screening - chest pains/palpitations? Monitor blood pressure increase/decrease.
- Sexual health – Crack/cocaine has aphrodisiac qualities and promotes disinhibited sexual behaviour in men and women. These increase the risk of contracting STIs as a result of unsafe or unprotected sex. Screening for STIs, BBVs. Provision of condoms.
- Mental Health – mental health review.

Other risks that are indicated when using Crack Cocaine include:

- Breathing difficulties, chest pains and burns
- BBVs and STIs
- Teeth and gum disease
- Damage to heart, lungs and liver
- Hallucinations, delusions, paranoia, depression and anxiety
- Complications with pre-existing conditions such as epilepsy, asthma and sickle cell disease

And for more chronic use:

- Overdose (in extreme cases but are rare)
- Poor nutrition (especially during ‘binges’)
- Acute asthma attack, myocardial infarction
- Suicide threat or attempt
- Injecting Damage (increased due to local anaesthetic effect of cocaine)
- Severe agitation and possibly aggression

13.2 Treatment Options in Surgery

Harm Reduction

Some crack / cocaine users may have got to the point where they want to stop altogether, however, others will want help to be able to better manage their drug use. There is a body of experience to support harm reduction, particularly with crack/cocaine use, including a number of principles and safer practices that can be discussed with the patient in order to reduce crack/cocaine related harm. These interventions may take place as part of the wider harm minimization principle of substance misuse treatment within Shared Care.

13.3 Psychological Interventions
These are, arguably, the most useful of treatments, and may for the most part, be conducted as part of the remit of Shared Care. Locally agreed integrated Care Pathways and clear care co-ordination is essential to prevent repetitive re-assessment of the patient’s needs and a timely referral into the most appropriate services. These could include Motivational Interviewing, Relapse Prevention, Group Work and Complementary Therapies.

Currently, within Worcestershire we are lacking a consistent approach to Crack and Cocaine use across the partnership as to date a Stimulant Strategy is not in existence. Hence, there is a recognised need to ‘skill up’ primary care worker to effectively address primary and secondary crack and cocaine use.

13.4 Prescribing

Prescribed medication should not be used in isolation from a wider package of care. There is no substitute medication, and no established evidence base for pharmacological interventions other than in treating individual symptoms such as depression or insomnia (short term only) after stimulant use has ceased.

Benzodiazepines may be used with great caution [given their inherent dependency and overdose potential] to help the ‘come down’ from acute agitated states. Use should be restricted to less than 30mg diazepam for less than two weeks.

Antidepressants - particularly SSRIs are relevant only if underlying depression is confirmed and crack or other stimulant use ceases. SSRIs should be used with caution if crack/cocaine use continues because of the risk of ‘serotonergic syndrome’

13.5 Pregnancy (see also 17)

There is some evidence that suggests that there is a link between stillbirths, miscarriages, placenta abruptio (placental detachment), premature labour and delivery, low birth weight and small for date babies. However, many of these complications may be more due to lifestyle than the drug used. Patients who are using crack/cocaine regularly whilst pregnant should be transferred into Secondary Care for specialist input.

For further in formation see RCGP Guidance: working with Cocaine & Crack Users in Primary Care (Appendix 14)

14 Amphetamines

For whatever reason it is not common for amphetamine users to present to the Shared Care team. Reasons for this could include; there genuinely is not an acute problem locally with those using amphetamines and that those that do experience problems may be more likely to be seen by mental health teams when symptoms of psychosis occur or, drug services are largely perceived as for Heroin users. To really understand the answer to this question there is a need for local research of both amphetamine users and local services (drug and mental health).

However, as with anyone presenting with a drug-related problem the Shared Care team will undertake an assessment and offer Harm Reduction advice. Following the assessment the PC drug worker will liaise with the referring GP and is likely to recommend one of the following:
• Treatment of any problems highlighted by the assessment, such as injecting related problems and / or mental health issues such as depression or anxiety by the GP.
• Referral to Turning Point where no medical intervention is either requested or required. Turning Point will offer non-medical care-planned interventions working towards the patient’s goals.
• Referral to specialist service for consideration for a dexamphetamine prescription where a medical intervention is assessed as required. The DoH Orange Book guidelines clearly state that dexamphetamine is a specialist treatment and should therefore not be undertaken by a GP.

15 Cannabis, Ecstasy & other ‘recreational’ type drugs

The term recreational is possibly unhelpful as all drugs obviously have the potential to be harmful and used dependently and hence not recreationally.

As stated above, anyone presenting with a drug-related problem then the Shared Care team will undertake an assessment and offer Harm Reduction advice to them.

However, where there are no physical or mental health problems identified at assessment then most patients with problems with ‘recreational’ drugs are referred to Tier 2 services locally. Therefore, where a patient is receptive, a referral will be made to Turning Point for further work to be undertaken.

16 Benzodiazepines

Many doctors are more comfortable with prescribing benzodiazepines than methadone to problem patients, whereas the reverse should be true. The evidence for the value of methadone maintenance is overwhelming. There is no such evidence for the value of substitute prescribing of benzodiazepines and hence benzodiazepines will not routinely be prescribed under this protocol.

This may be of particular significance to GPs who are not working within a Shared Care arrangement as they may be approached as patients know those GPs that are working within Shared Care will as a rule refuse requests for benzodiazepines. As stated there is no efficacy for benzodiazepine prescribing for the management of opiate dependence and certainly not for detoxification purposes.

As a result, for known drug using patients, Shared Care and non-Shared Care GPs are strongly advised not to prescribe benzodiazepines and instead offer a referral to Turning Point or a PC drug worker, if the surgery has one. This is particularly where this is a first presentation. Refusal for this referral may provide GPs with an insight to what the intention is for the medication e.g. their financial and / or abuse value. Neither should they be used as an interim measure while the referral is processed. Ultimately, It is worth noting that there is no such thing as an emergency in terms of a patient presenting with an opiate dependency, as abrupt cessation of their heroin use without medication is highly unlikely to bring them to harm (unless there is a contraindicating co-existing medical condition such as cardiac problems).

Benzodiazepines should not generally be prescribed but exceptions may include aiding detoxification alongside a detox agent (such as Lofexidine - see 10) and therapeutic purposes, these are outlined below:
16.1 (a) Benzodiazepines and other hypnotics should not be used at the start of substitute prescribing as sleep problems incurred at this time are due to the patient changing from a short-acting drug (heroin) to a long-acting one (methadone). It is necessary for the patient to be properly prepared for a reduction in sleep and understand that it should improve fairly quickly.

(b) Where problems of insomnia are identified after 4-8 weeks then short-term prescribing of a hypnotic may be considered (usually zopiclone 7.5 mg nocte but others may be considered - see N.I.C.E. guidelines; Appendix 9) for a period of 2-weeks (4-weeks maximum) followed by no more prescribing should take place for a 4-week period to assess the effects on sleep.

(c) If following assessment no or little improvement to sleep is identified after the use of a hypnotic re-considers the diagnosis e.g. mental health assessment, and if necessary seek advice from the consultant services.

16.2 (a) Where an illicit dependency to benzodiazepines is identified (and confirmed through a drug screen) then a reduction regimen should be devised. For guidance on benzodiazepine reduction / detoxification (Appendix 6)

(b) Where an individual is unable to reduce their benzodiazepine use completely, through an agreed reduction regimen, then advice should be sought from the consultant service.

Note: It is now possible to prescribe Diazepam (and only Diazepam not any other benzodiazepine) on a blue FP10MDA-S, allowing for instalment issues. Where a risk assessment highlights concerns for patient safety in prescribing larger amounts of benzodiazepines this option should be considered in the same way it is for methadone or buprenorphine (Often this will be in-line with their methadone or buprenorphine collections). However, it is not possible to request a supervised consumption arrangement.

17 Alcohol

Alcohol is widely used by service users in varying patterns as it is across society and is like benzodiazepines as both act upon the same neural receptors and hence have similar effects, as well as presenting challenges in their management particularly when there is a concurrent opiate problem.

Alcohol is known to increase the risk of dropout from treatment and exacerbates mental health problems. Alcohol increases the risk of hepatic cancer in people who are hepatitis C positive. Most of these risks are increased when alcohol and other drugs are taken in combination (ACMD, 2000).

There are many skills that are transferrable for drug workers when working with alcohol users but specific harm reduction or safe drinking guidance that should be conveyed by all clinicians as most opiate / opioid overdose include alcohol and / or benzodiazepines.

The DoH ‘safe’ drinking levels can provide a helpful guide for clinicians. However, it becomes more difficult to determine the difference between harmful or hazardous drinking and dangerous levels or patterns of consumption. Therefore, it is more helpful, as with other areas of these guidelines that assessed risk should determine whether a service users alcohol use can be catered for in Primary Care and this is then matched to the GPs experience and confidence to manage the assessed risks. Factors to consider when assessing the alcohol use risk in conjunction with substitute prescribed medication / continued street heroin use are:
• Levels and pattern of alcohol use – steady high levels of use are generally less hazardous / dangerous than infrequent high levels of ‘binge’ type use
• Stability on opioid medication
• Any known levels of tolerance
• A history of overdose / near misses
• Unstable accommodation and / or solitary use
• An indifference to alcohol and other risks
• Hepatitis and / or known liver damage
• An assessed physical dependence to alcohol
• Other poly-drug use particularly sedative drug use such as heroin and / or benzodiazepines

Where over time or at initial assessment, risk indicates that it is not appropriate to treat a service user in primary care due to their concurrent use of alcohol then a referral should be made to the secondary care service and smooth transfer of care to quickly take place. This should always be the case when a service user is shown to be physically alcohol dependent. The reasons for this action should be properly explained to the service user and detailed to them that this is to ensure that their needs can be better met within a specialist arena.

Referral and self-referral can be made for and by service users to the Worcestershire Community Alcohol Team [WCAT] who offers alcohol interventions and community detoxification. There have been some good examples of joint working between our two services to date, however at the time of writing no care pathways are in existence.

18 Relapse

It should be noted that detoxification is not an end point but one element of the process of the cycle (or spiral) of change. Often patients will need to attempt detoxification on many occasions before long-term abstinence is achieved, and the average length of time for treatment is seven years normally over several treatment episodes. This is important when we attempt to define successful treatment outcomes. Relapse should not be used as a negative term but regarded as an accepted inevitability from which many important lessons may be learnt. Hence, detoxification and relapse can be framed positively in aiding future detoxification attempts.

Furthermore, patients who undertake detoxification are at increased risk of overdose and should be properly informed of the risks involved with reduced tolerance to opiates when detoxified.

Following disclosure from the patient or through drug screening it is shown that the detox has not been completed, or is proving too difficult and / or a return to daily drug using behaviours has occurred i.e. relapse, then a reassessment will occur followed by the appropriate provision of substitute medication either from the GP or CDT.

19 Pregnancy and Care Pathways

Pregnancy can be a cause for concern and present complications particularly when the expectant mother is using illicit drugs and / or prescribed medication. However, GPs are
well versed in the management of pregnancy and Shared Care inherently provides an ideal opportunity for enhanced integrated care.

Therefore the following care pathways are proposed for deciding where pregnant patients are best managed:

19.1. Initial presentation when pregnant – for patients who present using illicit drugs and are confirmed as pregnant then an urgent referral, possibly via the PC drug worker, to the specialist service CDT is required for the consultant psychiatrist to commence treatment as soon as possible, for stabilisation. Pregnant patients are obviously regarded by the specialist services as high priority and will be responded to as a priority.

19.2. Patients who become pregnant that are already in Shared Care – the course of action will be determined by the level of risk assessed as a result of the pregnancy determined by:

- The level and type of illicit drug use, if any, by the patient e.g. the use of benzodiazepines, alcohol and crack generally carry higher risks that heroin use in pregnancy. Any I.V. drug use obviously further increases risk to mother and unborn child.
- Previous known complications in pregnancy particularly as a result of drug use.
- The effects on the patient were a transfer to specialist care to occur.
- The experience and confidence of the GP to continue treatment

*Note: Both methadone and buprenorphine carry a special warning in pregnancy and should therefore be given equal consideration in pregnancy with, as usual, patient choice having an strong influence on the final decision making.*

Where a GP is undecided whether to transfer the patient to CDT or to maintain the patient in Shared Care they can then call upon an assessment from the consultant psychiatrist. The consultant and the GP can then decide the most appropriate treatment plan and treatment provider but should always ensure that the patients view is taken in to consideration.

19.3. Stable pregnant patients at the specialist service, CDT – if a pregnant patient stabilises on methadone while pregnant, to the point where illicit drug use is ceased then transfer to shared care is advised where it may be appropriate. Management of pregnancy in Shared Care can be desirable as it can localise patient care through their surgery and therefore improve the effectiveness of care. Transfer of pregnant patients will be at the direction of the consultant psychiatrist in discussion with the relevant GP. Once transfer has been agreed and occurred the GP will have access to call upon the consultant input either verbally or by requesting that the patient is assessed face-to-face. However, before any transfer is considered patient choice will initially determine where the provision of their care will take place, as it may also involve a change of worker at what can be a difficult time for them.

For Transitional Care Unit (TCU) Guidance and Worcestershire Pregnancy Care Pathways for Substance Use - see Appendix 13?

For further information see *RCGP Methadone Guidance and Buprenorphine* (Appendix 3 & 4)

20  Blood Borne Viruses (BBVs)
Tasks, roles and responsibilities

- Harm reduction advice to minimise risk of infection and/or transmission
- Screening for Hepatitis A, B and C; and HIV.
- Provide Hepatitis A and B vaccinations.
- Refer to Hepatitis and HIV specialist services.

Injecting patients are at high risk of acquiring and transmitting Hepatitis A, B and C and HIV due to sharing of injecting equipment and/or sexual contact. Blood borne virus testing should, therefore, form an integral part of the holistic harm minimisation service provided to patients in shared care.

Patients should be able to make an informed choice about whether or not to be tested / vaccinated, and should be made aware of the implications of the results. Testing and vaccinations should only be undertaken with the patient’s verbal and/or written consent.

HEPATITIS B

Hep B testing and vaccinations should be offered routinely to patients in Shared Care. Practices should keep a stock of Hep B vaccines.

Pre-testing should never act as a barrier to, or delay, vaccination.

Patients should have access to vaccination without testing if desired.

When testing for Hep B, the first dose of vaccine should be offered at the same time.

Testing for Hepatitis B surface antigen (HBsAG) is necessary if those found Hep B positive are to be followed up in primary care with advice about prevention of transmission and contact tracking.

All HBsAG positive patients should be offered referral to the specialist hepatitis services for further assessment. (see care pathway – Appendix 13)

If the patient is positive for antibody to HepB core antigen (anti-HBc) further Hep B vaccinations are not necessary, as this result indicates present or past Hep B infection.

PRIMARY VACCINATION SCHEDULE

Emphasis should be placed upon giving as many doses as possible in the shortest time frame. Lack of information regarding infection status should not act as a barrier to vaccination, and patient’s recall of vaccination history should not be relied upon.

Standard schedules (0, 1 and 2 months) are most appropriate for patients at high risk, however the accelerated schedule 0, 7 and 21 days schedule is currently being promoted by the Department of Health.

Even incomplete vaccination schedules offer some protection, but there should be a robust system for recall.

BOOSTER DOSES
Current best practice is to give a booster after 12 months if the accelerated schedule is used.

**VACCINATION OF PARTNERS AND CHILDREN OF PATIENTS IN SHARED CARE**

The need for testing and vaccination of the partners and children of patients should not be overlooked as they are also at risk of Hep B infection,

Children infected with Hep B have a much higher risk of chronic infection than adults.

Whole family vaccination should be considered.

**HEPATITIS A**

Injecting patients are at a higher risk of Hepatitis A infection mainly due to poor living conditions with spread probably occurring through faecal contamination or injecting paraphernalia. Blood to blood spread may also occur.

Hepatitis C positive patients and/or patients with chronic liver disease are at a higher risk of serious illness if they also become infected with Hepatitis A.

The Public Health Laboratory Service Advisory committee on Vaccination and Immunisation recommended in 2001 that all injecting patients should be vaccinated against Hepatitis A.

As for Hep B, patients should be offered Hep A vaccine regardless of knowledge of current status because of the risk that the opportunity to vaccinate might otherwise be lost.

Hepatitis A vaccines are available as a single component vaccine or combined with Hepatitis B vaccine.

One dose of the single Hep A vaccine offers more protection than the combined A/B vaccine, therefore two single vaccines administered at the same time offer more protection than the combined vaccine.

A robust recording system for monitoring uptake and completion of vaccine schedules should be developed if not already in place.

- Vaccinate all shared care patients against Hep A and B.
- No need to carry out pre-vaccination testing.
- Use accelerated 0, 7 and 21-day schedule.
- Offer Hep B vaccination to partners and children.
- Single component Hep A vaccine offers greater protection.
- Devise and utilise a recording and recall system.

**HEPATITIS C**
Injecting patients are at greater risk of Hep C infection due to sharing of injecting paraphernalia and, more uncommonly, sexual contact.

Over 30% of injecting patients attending specialist services had evidence of Hep C infection.

About 60-80% of patients who acquire the virus become chronically infected. The rest clear the virus spontaneously.

5-20% of chronically infected patients may develop serious liver disease after 20 years, and a small proportion of these will go on to develop primary liver cancer.

Depending upon genotype, treatment for Hep C with 6/12 months combination treatment of pegylated interferon and ribavirin is becoming increasingly successful in clearing the virus.

Patients in shared care that have a history of injecting or who show evidence of liver disease that may indicate infection should be tested.

Testing provides an opportunity to refer those infected to specialist services for further investigation and, if appropriate, treatment.

Testing provides an opportunity to discuss harm reduction around possible infection routes, and lifestyle changes to minimise damage to the liver.

A negative test result should be followed up by a repeat test after 6 months if the person has been exposed to risk activity in the previous 6 months.

**HEP C TESTING**

A positive Hep C blood test for antibodies to the virus indicates whether a person has been exposed to the Hep C virus but it does not distinguish between previous cleared infection and current infection.

In order to determine whether the virus is still present an HCV RNA detection test (PCR test) should be undertaken.

All patients testing positive to Hep C should be referred to the specialist services for further investigations (see Care Pathway).

**HIV**

As HIV has become a more treatable condition there has been a major attitude change towards testing. HIV testing should take place alongside other blood borne virus testing and vaccinating in shared care.

HIV testing can ensure that patients are able to take advantage of appropriate life-prolonging treatment and minimise the risk of onward transmission.

All patients testing positive to HIV should have a repeat test from a separate sample of blood to confirm status.

HIV positive patients should be referred to specialist services for further investigations and treatment.
A negative test result should be followed up by a repeat test after 3 months if the person has been exposed to risk activity in the past 3 months.

For Worcestershire BBV Care Pathways and related policies – see Appendix 13

21 Community Patients involved with the Criminal Justice System: The interface between primary care and the Drug Interventions Programme (DIP).

The purpose of the guidelines are to formulate a working agreement for those patients who are active within the criminal justice system but also fall into a low risk category thus suitable for drug treatment through the shared care model. This document is designed to facilitate and clarify a seamless pathway, and to provide equity in service for all patients.

The guidelines will incorporate patients who a) are existing shared care patients and then become involved in the criminal justice system, or b) have been highlighted through DIP and post 12 week engagement (national target), are deemed appropriate for shared care services.

The working arrangements will encompass two groups of patients:
1. PPO’s (Prolific and Priority Offenders)
2. Patients subject to Probation Orders

| Overarching principles |

For all new patients who have a current involvement in the criminal justice system, should enter the service via DIP and be retained for 12 weeks before moving into other modalities.
These patients include the following but are not exclusive:
- Those who have active criminal proceedings ongoing
- Those who are on a current probation order
- Those who declare they are actively committing crime to fund their drug habit

For patients who are actively receiving treatment from the SMS team, regardless of modality, but fall into one of the above categories, a discussion should take place between the current keyworker and a DIP team leader to decide where the patient should be placed. The patient should be placed in the modality that can provide the most suitable treatment depending on patient need and continuity of care.

Those subject to a DRR or are classed as MAPPA, regardless of current status in the service will default back to DIP for the length of the order.

Those patients who have entered treatment through the DIP route but have no current orders will continue to managed under the current service guidelines.

PPO’s
PPO’s fall into a high risk category relating to community safety and criminality. For this reason it is agreed that the following information will be shared with partner agencies. Where possible an information sharing agreement should be made with the patient, and patients should be encouraged by means of the positives for sharing information about their treatment. Where a patient refuses to share consent the following can be shared under the Data protection Act and Caldicott Guidelines 1997:
• Engagement and motivation with drug services
• Test results that relate to their engagement and motivation to change (it is important to note that these will not be used in isolation and should formulate an overall picture of the patient)
• Care co-ordination plans.
• Any information that maybe able to prevent and/or detect crime. It is recommended that prior to this sharing this information, it should be discussed with a team leader, and where possible the PPO representative for your area. (This is usually the DIP team leader)

The process for reporting back to partners on PPO’s is led through the DIP Team leaders North and South respectively. A request for updates will be made to keyworkers on a monthly basis by the DIP team Leader, who will attend the PPO meeting on behalf of the service. The DIP Team Leader will then feedback any relevant information to the keyworker.

There maybe times when information needs to be shared outside of the agreed meetings. Where this occurs it is recommended that the keyworker contacts the relevant DIP team leader for advice and the relevant police representative should be contacted as the partnership link.

All PPOs will be encouraged to sign the confidentiality waiver giving permission to share information with the PPO scheme i.e. Police, Probation Service etc. This will form the basis for information that is able to be disclosed. Where offenders opt out of signing the confidentiality waiver it will be made clear to them that they may be targeted by the police in order to reduce criminal activity.

Partner agencies and Police can request information on a PPO where they believe the information is necessary. DIP Workers will update the members of the meeting group on attendance and engagement levels. Each case will be treated by its own merits and the benefits to disclosing this information. DIP Workers will disclose information around risk and previous levels of service engagement as a method of highlighting those service users who would benefit from the PPO scheme.

Further guidance around PPOs can be found on the Shared drive under DIPs.

| Probation Order patients |

Probation Order patients are those who have been subject criminal proceedings and directed by the courts to engage with probation services as an attempt to reduce offending behaviour.

There is no expectation of information sharing with probation order patients; however it is to be encouraged to share relevant information around engagement and motivation with probation partners. This can be seen as a positive step in the rehabilitation pathway for offenders.

However, some patients are subject to probation orders with a caveat to attend and engage with substance misuse services. Where this arises, ideally a 3 way agreement to sharing information between probation, SMS and the patient should be made to establish what information will be shared with partners and the court.

It is accepted that the probation service and their patients may require written reports for presentation at court. With the patient’s consent Shared care practitioners will provide
such reports but should use the guidance of disclosing relevant information as outlined in the section above.

Naltrexone on Prison Release

All those who meet the set criteria for naltrexone prescribing (Appendix 22) will be initiated via the specialist services. Compliance with treatment will result in a referral to the patients GP by the GPLP agreed by a locality team meeting (see also 11)

22 Transition of patients from young person to the adult drug services

There are policies for the transfer of patients from the young person’s drug service, SPACE to the adult drug services. Patients who are over 18 and considered mature enough will be considered for transfer. Due to the nature of the young person’s service, which is far more assertive in its interventions i.e. the service is taken to them, the adult service can prove significantly different where increased self-responsibility is expected. To guide clinicians through this process there exists the Young Person’s Transition Policy (Appendix 8)

Patients who are considered for transfer to the adult service should of course be able to access shared care according the usual criteria based on risk. Initial decisions to decide which part of the service of the patient is best treated will again be decided at locality referral meetings.

23 Guidance on driving and substitute medication – See appendix 11

24 Proposed Future Developments

- Improved Sexual Health links
- Developing care pathways with the Gateway Mental Health service

25 SMS Operational Guidelines

Engaging Service Users in Treatment: Boundaries and Treatment Agreements in Substance Misuse Services

This Service policy represents a set of minimum standards, for service users and staff, in terms of a service user demonstrating engagement with clinical treatment interventions. The Policy is developed with a view to harm reduction principles, and should be implemented with a clear focus on supporting service users’ ability to address their problematic use of substances, through a process of positive engagement in an effective key-working relationship. The key-working relationship is seen as critical in terms of motivating and enabling the service user to progress in treatment, and the Treatment Care Plan, which will be jointly agreed between the service user, key-worker and doctor, is seen as the most important tool in agreeing the progress potential. This should help the service user access the full range of treatment options which might help them achieve the best possible outcomes from the treatment experience.
Following assessment, and ascertaining that opiate substitute prescribing (methadone or buprenorphine) is appropriate, service users will sign a Treatment Agreement with the Treatment Provider and then, with the key-worker and doctor, a more detailed individualised treatment care plan that will cover expectations including:

- levels of contact/communication
- demonstrating positive progress towards treatment objectives
- review of treatment objectives

These Treatment Care Plans will reflect the different needs of service users at different stages of treatment, so as to ensure a safe prescribing environment and maximise the outcomes of treatment intervention for each individual service user.

(N.B. These operational requirements do not apply to the monitoring of naltrexone or dexamphetamine prescriptions, both of which will have their own distinct policies/procedures.)

**Week 1 to week 12**

- Key working appointments are generally weekly, although the time between appointments may be less than a week if appointments are missed. In certain circumstances, where a service user has demonstrated early improvement (possibly a combination of regular attendances and early opiate-free test results) key-working sessions may be less frequent with the agreement of the service user, doctor and key-worker.
- For the purposes of this treatment agreement both key-working and doctor’s appointment will count toward compliance with the treatment agreement.
- Methadone dispensing will usually be on a daily supervised basis, although some flexibility may be possible where a service user has demonstrated early improvement.
- Service users are expected to attend all appointments with key-working and medical staff as arranged.
- Late attendance at appointments, where it is not possible for the clinician/doctor to see the service user, will be considered a DNA unless the service user can demonstrate legitimate reasons for lateness.
- Cancelled appointments, with 48 hours notice, will not count as a DNA.
- Where a patient misses one appointment this may result in appropriate action being taken to facilitate the earliest possible next appointment, e.g. contact with pharmacy/script placed on hold pending contact with key-worker. This decision will be based on current high risk concerns.
- The patient cannot miss two consecutive appointments without immediate action being taken, particularly at this early stage of prescribing e.g. contact with pharmacy/script placed on hold pending contact with key-worker.
- The service user cannot miss three consecutive appointments without immediate appropriate action being taken. This will include an urgent clinical and treatment care plan review to consider the treatment options that are in place, and the appropriate next steps. This may include discharge from the service where continued engagement in the treatment process is considered unsafe.
- Correspondence to the service user, to arrange new appointments, will indicate when the next appointment is a deadline appointment around attendance.
- The service user cannot miss, or fail to pick up, three consecutive days methadone without immediate action being taken, e.g. contact with pharmacy/script placed on hold.
The consequence of not engaging with any of these treatment agreements will result in a clinical review where a range of treatment options will be considered, by the doctor, key-worker and the service user. Failure to attend the clinical review, or if the outcome of that review is that it is not appropriate to continue the individual in treatment, may result in the prescription being brought to an end, through a planned medication reduction regimen, and the service user may be discharged from the service and where possible formally referred on to Turning Point for ongoing support.

Week 13 onwards

- Key working appointments arrangements can be flexible depending on the agreement between the doctor, key-worker and service user, although the time between appointments may be less than a week if appointments are missed.
- For the purposes of this treatment agreement both key working and doctor’s appointment will count toward compliance with the treatment agreement.
- Methadone dispensing arrangements can be flexible depending on the agreement between the doctor, key-worker and service user and based on an assessment of risk.
- An important treatment objective from this point will be supporting the service user to stabilise on prescribed substitute medication/s and work towards providing an opiate free sample. The appropriate time frames for this outcome will depend on ongoing assessment of the service user’s previous and current usage, risk features and a range of other indicators of service user engagement with, and progress in, treatment.
- Service users are expected to attend all appointments with key-working and medical staff as arranged.
- Late attendance at appointments, where it is not possible for the clinician/doctor to see the service user, will be considered a DNA unless the service user can demonstrate legitimate reasons for lateness.
- Cancelled appointments, with 48 hours notice, will not count as a DNA.
- In high risk circumstances a patient missing one or two consecutive appointments may result in appropriate action being taken, to facilitate the earliest possible next appointment e.g. contact with pharmacy/ script placed on hold pending contact with key-worker.
- The service user cannot miss three consecutive appointments without immediate appropriate action being taken. This will include an urgent clinical and treatment care plan review to consider the treatment options that are in place, and the appropriate next steps. This may include discharge from the service where engagement in the treatment process is considered unsafe.
- Correspondence to the service user, to arrange new appointments, will indicate when the next appointment is a deadline appointment around attendance.
- The service user cannot miss, or fail to pick up, three consecutive days methadone without immediate action being taken, e.g. contact with pharmacy/ script placed on hold pending contact with key-worker.

Taken in conjunction with Treatment Care Planning processes it is anticipated that this policy will offer a comprehensive and consistent approach to the management of service users along available treatment pathways. Whilst the Policy provides the framework for managing engagement, it is clearly the outputs from the key-working relationship and the ongoing engagement of the service user in harm reduction initiatives, and the broad range of treatment options appropriate to their needs, that will enhance the number of successful outcomes achieved by service users and the Substance Misuse Service more generally.
The Treatment Care Plan review will always be the critical point at which the service user’s
- level of contact/communication
- engagement in treatment agreements
- demonstration of positive progress towards treatment objectives
will be discussed and reviewed and further assessment and agreements made about appropriate next steps in treatment. Where a service user is assessed as not engaging fully in the treatment process, and is not demonstrating positive progress, then a detailed review of what additional interventions might assist progress and promote change should be considered. Where the presenting situation is felt to have become unsafe, then discharge should be considered by the doctor and key-worker.

Decisions to discharge will require the service to:
- agree the discharge via the weekly multi-disciplinary team meetings
- discuss and explain to service user why discharge is felt to be necessary
- agree a planned and phased reduction of medication where appropriate
- discuss and seek to agree a referral on to Turning Point if the service user is not already engaged with them
- provide information on harm reduction, and overdose risks
- explain how the service user may present themselves for treatment again at a future date
- confirm all of the above in a letter

The treatment process should be delivered consistently to every service user. The process requires trained and competent drug workers to motivate, support and certainly, at appropriate points, challenge service users to engage in a positive change process, which is clearly reducing risk of harm from drug use, and promoting a long-term objective of becoming free from street/illicit opiate drug use.

Allied documents to the SMS operational Guidelines all in Appendix B:
- Care Plan [Substance use]
- Care Plan [Health]
- Care Plan [Social Functioning]
- Care Plan [Crime]
- Care Plan review sheet
- Car Planning guidance
- New Treatment Agreement

All documentation prepared by the Primary Care team.
REFERENCES


2 Gossop M, Marsden J and Stewart D (2001) NTORS After Five Years (The National Treatment Outcome Research Study), Changes in substance use, health and criminal behaviour during the five years after intake. London: National Addiction Centre

3 NTA Briefing May 2004: Methadone Dose and Methadone Maintenance Treatment.

4 NTA Briefing May 2004: Engaging and Retaining Drug Users in Drug Treatment.

5 NTA Models of Care: For treatment of Adult Drug Misusers

6 ADVISORY COUNCIL ON THE MISUSE OF DRUGS Reducing Drug Related Deaths London HMSO

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18. Seivewright N, Withdrawal from Methadone... Methadone Matters (Msrtn and Dunitz) 2003: 83
21. Zador, D et al 1998 Deaths in Methadone Maintenance Treatment... Australia
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34. Department of Health – ‘Hepatitis C – Guidance for those working with drug users.’ (not dated)
35. Department of Health – ‘Hepatitis C – essential information for professionals and guidance on testing’ 2004
36. Dr. Chris Ford – ‘Screening and management of Hep c in primary care’ 2003
37. British Association of Sexual Health and HIV (Clinical Effectiveness Group) – ‘United Kingdom National Guidelines on HIV testing’ March 2005


### SECTION ONE: SCREENING / PRIORITISING FOR FULL IMPACT ASSESSMENT

Name of the Function/Policy/Procedure…\\

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<th>How much evidence do you have?</th>
<th>Is there any public concern that the function or policy is being carried out in a discriminatory way?</th>
<th>Priority (add columns 3 &amp; 4)</th>
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