



GUIDANCE ON MEDICAL TREATMENT
OF DRUG ABUSERS IN SUBSTITUTION
TREATMENT FOR OPIOID DEPENDENCE

2008



GUIDANCE NO. 42 ON MEDICAL TREATMENT
OF DRUG ABUSERS IN SUBSTITUTION TREAT-
MENT FOR OPIOID DEPENDENCE, JULY 1ST 2008

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Guidance No. 42 on Medical Treatment of Drug Abusers
in Substitution Treatment for Opioid Dependence,
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Foreword

There are an estimated number of 27,000 drug abusers in Denmark of which about half are registered for drug abuse treatment. By far the greater part of drug abusers that seek treatment, use several substances. Heroin is one of the most commonly used substances among clients in treatment, and about 40 per cent have used heroin intravenously. In 2004 6,300 individuals were in long term medical substitution treatment.

Somatic and psychiatric morbidity among drug abusers is high. The health problems and consequences that follow from drug abuse, lead to a large number of hospital admissions and emergency ward visits and contribute to the high prevalence of drug related deaths. It is estimated that mortality among drug abusers is 10 times higher than in the general population.

As from 2007 responsibility for health and social care treatment of drug abuse rests with the municipalities. Medical treatment of opioid dependent individuals is primarily taken care of by the municipal treatment systems but may also be taken care of by general practitioners and within the Prison and Probation Service.

The government action plan from 2003, "Kampen mod narko" (The fight against drugs), underlined the significance of strengthening medical treatment initiatives within drug abuse treatment. In order to maintain and extend existing treatment services, an agreement was made to allocate funds from the social spending reserve in 2004 among other things in order to provide for quality assurance and quality development of substitution treatment.

The present guidance is meant to contribute to reducing morbidity and mortality among drug abusers by securing uniform and acceptable quality of the most important medical core services relating to substitution treatment of opioid dependent individuals.

The guidance has been produced on the background of existing national and international documentation in this area and in cooperation with expert

working groups from clinical practice and a reference group established for this purpose which includes representatives from the Ministry of the Interior and Health, the Ministry of Social Affairs, Local Government Denmark, the Danish Society for Addictive Medicine, Centre for Alcohol and Drug Research, the Association of Municipal Doctors and the Prison and Probation Service.

National Board of Health, July 1st 2008

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Introduction

Pursuant to Section 17 of Act no. 451 of 22 May 2006 on authorization of health care professionals and on professional health care practice (the Authorization Act), a doctor is under obligation to exercise care and conscientiousness when practising his or her profession.

The purpose of this guidance is to further specify the care and conscientiousness a doctor must exercise when handling problems related to drug abuse.

The guidance is a specification of existing rules for medical treatment of drug abuse.

The guidance has been made with special regard to the medical treatment of drug abusers in substitution treatment in the municipalities, but the guidance will be valid wherever medical treatment of drug abusers takes place, whether in general practice, in the hospital sector or in the Prison and Probation Service.

A number of annexes are appended to various chapters that elaborate the medical issues.

1.1 Concepts used

The following concepts are used in the Guidance:

Intoxicants: All substances that on repeated use may lead to mental dependence. Includes opioids, benzodiazepines, central stimulants, hallucinogenic drugs, cannabis and alcohol. (Nicotine, coffee and tea also belong in this group but have not been considered in this connection).

Drugs: Includes intoxicants other than alcohol.

Use/consumption of intoxicants: Occasional use of intoxicants that cannot be characterised as abuse or dependence.

Dependence: A syndrome consisting of a number of behavioural, cognitive and physiological phenomena that (in the case of some individuals) is developed on repeated use of one or several dependence-producing pharmaceuticals or intoxicants. Further particulars below in Chapter 4.

Abuse: Harmful consumption of an intoxicant or a dependence-producing pharmaceutical leading to social, somatic and/or mental harm. Further particulars below in Chapter 4.

Substitution treatment: Substitution of an inappropriate substance or pharmaceutical with a more appropriate pharmaceutical with a view to treating addiction.

Narcotics: The intoxicants that are prohibited pursuant to the act on euphoriants. This is a legal concept that cuts across ordinary pharmacological groupings.

1.2 Patients' legal status

The Health Care Services Act (Consolidated Act no. 95 of 7. February 2008) aims to safeguard respect for the individual human being and his or her integrity and right of self-determination. The Act includes among other things rules on patients' legal status, i.e. the obligation of health care professionals to provide information and obtain a patient's consent to treatment etc., on patients' right of access and on rules incumbent on health care professionals with regard to confidentiality and disclosure and obtaining of health information etc. These are fundamental rules that regulate relations between patient and health care professional.

Below a brief overview is provided of the rules of the Health Care Services Act on patients' legal status with a general reference to existing legislation in this area, i.e. Part III of the Health Care Services Act on patients' legal status.

1.2.1 Consent to treatment

No treatment may be initiated or continued without the patient's informed consent unless otherwise provided for in legislation or in rules laid down pursuant to existing legislation.

The requirement of consent underscores the patient's right of self-determination. Consent to treatment (examination, diagnosing, treatment of disease, obstetric aid, rehabilitation, nursing care and prevention and health promotion in relation to the individual patient) constitutes the patient's voluntary acceptance of a given treatment.

Consent must be based on adequate information. In order for consent to be considered valid, the patient must be able to assess consequences against the background of the information provided.

1.2.2 Information

In order for consent to have any significance, the patient must have received necessary and sufficient information on treatment options, risks etc. prior to

his or her decision. The relation between a patient and a health care professional is characterised by the special fact that often the health care professional has knowledge that the patient does not have. This concerns knowledge both about what the patient suffers from and treatment options etc.

The patient has a right to get information on his or her health condition and on treatment options including any risks of complications and side effects.

The requirements of the Act as to the content of information are minimum requirements. The individual patient's special situation may give rise to a need for further information.

1.2.3 Immediate treatment needs

In situations where immediate treatment is required to secure the patient's survival or to improve the patient's chances of survival in the long term or to achieve a significantly better result of treatment, a health care professional may initiate or continue treatment without consent from the patient or the holder of custody, closest relation or guardian.

This is the case both when temporarily the patient is not in a condition to take a decision concerning treatment e.g. because of unconsciousness and in connection with treatment of patients that are permanently unable to give consent or who are under the age of 15.

1.2.4 Voluntariness

Consent must be voluntary. Consent given in situations involving duress, coercion or fraud is not valid.

Naturally the health care professional should indicate to the patient what from a professional point of view would be best for the patient, but the health care professional should be careful not to seek to persuade the patient to such a degree that this may unduly influence the patient.

The patient cannot take decision on treatment. It is the health care professional who is responsible for the choice and the carrying out of treatment. Even if the patient wishes a treatment different from the treatment that from a professional point of view the health care professional finds most correct, the health care professional should treat the patient in the best possible way under the circumstances.

A patient may at any time withdraw his or her consent to treatment.

1.2.5 Content of consent

Consent must be given to a concrete treatment. This requirement means

that consent should be put in concrete terms so that it is clear and indisputable what the consent covers. It must be clear what treatment, including treatment method, that may be undertaken and what the aim of this treatment is.

Consent must be informed, and thus the health care professional must make sure that the patient has been sufficiently informed about the treatment to know what he or she gives consent to. The information that the health care professional gives to the patient contributes to clarifying and specifying the extent of the consent.

Consent must also be of current value i.e. given to treatment that is to be undertaken in the near future and not at some undefined future time. If new information becomes available or if the treatment plan is changed, renewed consent is required.

1.2.6 The form of consent

Consent to treatment may be given explicitly, orally or in writing, or it may be implicit, depending on conditions.

Explicit consent is when the patient consciously and concretely expresses that he or she agrees to the treatment under consideration. Such consent may be oral or in writing.

Oral consent is sufficient for a health care professional to initiate or continue treatment, but it must appear from the patient's record what information the patient has been given and what the patient has indicated against the background of this information.

Only seldom will written consent be necessary, and there is no obligation for the patient to sign a consent form.

Implicit consent is when the patient's signals and behaviour lead to the understanding that there is consent against the background of the information given. Implicit consent is only valid when it is indisputable that through his or her behaviour the patient has indicated agreement as to the treatment proposed or part of this treatment.

Implicit consent will, in general, only be relevant in connection with single elements in a course of examination and treatment. If for instance a patient goes to see his or her general practitioner, the doctor may assume that the patient has given implicit consent to the ordinary examinations that are undertaken in connection with such a visit.

If the health care professional has the least reason for doubt as to whether there is consent, explicit oral consent should be obtained.

1.2.7 Disclosure of health information in connection with treatment

Patients have a right to confidentiality on the part of health care professionals with regard to information that a professional learns or is lead to assume during the exercise of his or her profession as to health condition, other purely private matters as well as other confidential information. Thus it is a fundamental rule that the information that a patient confides to a health care professional goes no further than the patient and the health care professional in question and is not passed on to any unauthorized person. The patient has a right to protection of his or her privacy. Confidentiality is also a decisive precondition for the establishing of trust vis-à-vis the health care professional.

In the Health Care Services Act confidentiality is established as an actual patient right including both the right to confidentiality on the part of the health care professional and the right of decision in relation to information.

1.2.8 Disclosure with the patient's consent

Normally a patient will consent to the health care professional passing on information to other health care professionals on the patient's health condition in order to secure the best possible treatment. This also includes information about other purely private matters and other confidential information that may be a precondition for providing the best possible assistance to the patient.

It should be emphasized that with the patient's consent, a health care professional may always pass on information to other health care professionals on the patient's health condition, other purely private matters and other confidential information in connection with treatment of the patient.

Information on health condition is to be understood as information on a patient's former, present and future somatic and mental condition including information about an individual's contact with the health care services, e.g. that an individual has been or is admitted for treatment, as well as information on abuse of pharmaceuticals and abuse of narcotics, alcohol and the like.

Information other than health information may be e.g. information on the patient's family situation, social problems, criminal record, debt as well as income and tax information.

1.2.9 Disclosure without the patient's consent

If a patient does not want information to be passed on, it is up to the health care staff to estimate whether treatment can be carried out without the information required, and the patient must be informed about the consequences for continued treatment if information is not disclosed.

In certain situations health information may, however, be disclosed by health care professionals to other health care professionals in connection with treatment without consent having been obtained.

Thus health information etc. may be disclosed to other health care staff without consent when

1. this is necessary out of consideration for an ongoing course of treatment of the patient and if the patient's interests and needs are given due consideration,
2. disclosure consists of a discharge summary from a doctor in the hospital service to the patient's general practitioner or the practising specialist who has referred the patient for hospital treatment,
3. disclosure consists of a discharge summary from a doctor employed at a private hospital, clinic etc. to the doctors mentioned above under 2) when treatment has been provided following agreement with a regional council or a municipal council pursuant to the Health Care Services Act,
4. disclosure is necessary out of regard for justified attention to matters of evident public interest or out of regard for significant consideration for the patient, including a patient who is unable to take care of his or her own interests, the health care professional or others, or
5. disclosure is addressed to the patient's general practitioner by a doctor who acts as the general practitioner's substitute.

The patient may request that information under 1) to 3) above is not passed on.

Patients must be informed of their right to refuse disclosure of information. This information may be given directly by the relevant health care professional or in a more general form e.g. through patient information material such as a printed leaflet.

Information on the patient's health condition that is not necessary for treatment and that is included in the patient record, may not be passed on without the patient's concrete consent and thus a separation must be made.

Information on confidential matters other than health information may normally not be passed on as this information will not be relevant for the current course of treatment.

The responsible health care person must secure that no information is passed on that is not necessary for the current course of treatment.

Especially concerning discharge summaries reference is made to National Board of Health Guidance on discharge summaries etc. (1).

Disclosure out of regard to matters of evident public interest, by which is meant matters of general interest to society, will seldom be justified.

Disclosure because of significant regard to the patient's interests may be relevant when a patient because of his or her condition, e.g. unconsciousness, is unable to give consent and when out of regard for the patient, it is decisive to disclose health information to other health care professionals in order for the patient to get the best possible treatment. In this situation attention should also be given to the patient's presumed wishes.

These are situations when the patient is not in a current course of treatment. This is a case of opposing interests. The considerations that favour disclosure to other health care professionals for use in connection with treatment of the patient must clearly outweigh considerations for the patient's wish for confidentiality.

Disclosure to a substitute for the patient's own doctor may occur in the following situations:

- Doctors in out-of-hours service,
- Another general practitioner that substitutes for the patient's general practitioner, and
- Another general practitioner that treats the patient.

1.2.10 Specifically concerning the obtaining of electronic health information etc. in connection with treatment of patients

The Health Care Services Act contains specific rules according to which, when further defined general conditions of access are met, specified professional groups may retrieve information on a patient's health condition, other purely private matters and other confidential information through search in electronic systems.

Information may only be retrieved to the extent necessary, and the information retrieved must be required in connection with ongoing treatment of the patient. Furthermore the patient must not have made use of his or her right to refuse that information is obtained.

1.2.11 Keeping of records

It is the doctor in charge of treatment who is responsible for recording of necessary information concerning the drug abuser's condition, examinations, observations, treatment, indication for medication, patient information etc. The doctor in charge is also under obligation to record relevant information concerning consent to treatment and concerning disclosure and obtaining of health information etc.

The obligation to keep records also includes situations in which the patient declines an offer of treatment or leaves the place of treatment (2).

1.2.12 Right of access

The Health Care Services Act also contains rules on patients' right of access to patient records etc.

A request for access should be met within 10 days after it has been received by the relevant authority.

2 Organisation of and legal basis for drug abuse treatment including substitution treatment of individuals with opioid dependence

2.1 Responsibility of the municipalities for overall substitution treatment

The legal framework for the organisation of treatment is found in the Health Care Services Act (3), the Authorization Act (4), the Social Services Act (5) and the Legal Safeguards Act (6).

As from 1 January 2007 the Municipal Council must offer medical treatment with dependence-producing pharmaceuticals for drug abusers (substitution treatment). This obligation is found in the Health Care Services Act, Section 142, Subsection 1. The Municipal Council continues to be responsible for social treatment of drug abuse, cf. the Social Services Act, Section 101.

It is assumed that medical treatment is an integrated part of the overall treatment and care services for drug abusers in the individual municipality. It is the responsibility of the individual municipality to organise overall treatment services. The individual municipality may secure treatment services by establishing treatment places, by entering into agreements with other municipalities or a regional council on providing treatment places or through entering into agreement with private treatment services.

It is the responsibility of the municipal council to secure the required coherence between medical treatment and the related psychosocial services and initiatives with regard to the social problems that the drug abuser may otherwise have.

It is a medical task to assess the need for medical treatment of opioid dependence. Without a medical assessment, a municipality is not able, therefore, to judge the individual patient who is assumed to have a need for abstinence or substitution treatment.

The municipality may delegate overall drug abuse treatment including medical treatment to another municipality, a region or a private institution. Such delegation does not require medical assessment.

The possibility to delegate medical treatment to another municipality, a regional council or a private treatment service includes all drug abusers with a permanent address in a given municipality.

If the municipality wishes to delegate an individual course of treatment, this decision must be based on a medical assessment, cf. Section 3.6 below.

In the case of such delegation, the municipality continues to be responsible for securing that patients get the treatment that they are entitled to. Thus administrative responsibility clearly rests with the Municipal Council in the municipality where the drug abuser resides. It is this municipality that coordinates overall treatment of the drug abuser both with regard to medical and social aspects.

2.2 The right to prescribe dependence-producing pharmaceuticals as part of drug abuse treatment

Medical treatment of drug abuse includes primarily diagnosis and treatment of abuse/dependence. In addition medical treatment of drug abuse includes diagnosis of the somatic and mental problems related to drug abuse as well as initiatives to secure their treatment.

Assessment of the need for substitution treatment is a medical assessment.

Pursuant to Section 41 of the Authorization Act, prescription of dependence-producing pharmaceuticals as part of the treatment of individuals for drug abuse may be undertaken by doctors employed by the municipality or the region and by doctors employed by private institutions and by the Prison and Probation Service. Single prescriptions as part of short term abstinence treatment may be undertaken by other doctors.

If during long term hospital stay dependence-producing pharmaceuticals are prescribed as part of drug abuse treatment, the hospital should inform the doctor who is responsible for medical treatment in the municipal treatment system for drug abuse if the drug abuser wishes to continue drug abuse treatment after discharge from the hospital.

Pursuant to the Authorization Act Section 19, doctors in a municipality who are responsible for opioid substitution treatment of individuals with drug abuse must submit monthly reports about this treatment to the National Board of Health. These reports must also include the individuals whose treatment has been delegated to other doctors. Reports must be submitted before the 20th of a given month and include information about the individuals to whom opioids have been prescribed during the preceding month

as part of drug abuse treatment . The medical reporting obligation is taken care of through the municipal report to the National Board of Health "Register of drug abusers in treatment". If treatment is delegated to other doctors, responsibility for reporting rests with the doctor responsible for delegation.

Concerning delegation of prescription rights, cf. Section 3.5 below.

2.3 Action plans

The municipal council is responsible for referring individuals to medical and social treatment of drug abuse and for the establishing of an action plan for a more detailed course of treatment. This treatment plan must be combined with the action plan established according to the Social Services Act, Section 141.

The establishing of an action plan for each single drug abuser is meant to secure coherence between both health and social aspects of drug abuse treatment and social problems otherwise.

The medical action plan that is further described in Section 3.2 below, forms part of the overall action plan and is to be evaluated and adjusted according to need. This also concerns cases in which part of the treatment is not carried out within the municipal framework, e.g. by private treatment institutions or by general practitioners or medical specialists.

Furthermore the action plan forms the basis for regular follow-up of social services pursuant to Section 148 of the Social Services Act. The municipal council must regularly update the action plan on the basis of current needs.

2.4 Cooperation on and continuity in drug abuse treatment

In relation to the individual drug abuser, the action plan constitutes a framework for cooperation on drug abuse treatment.

Drug abuse treatment must be organized so that, to the extent possible, the drug abuser is not prevented from e.g. taking a job, moving to a different municipality, having a holiday etc. Treatment should also function in situations when for instance the drug abuser is placed in an institution under the Prison and Probation Service, and likewise it should be possible for a municipality to continue drug abuse treatment initiated in an institution under the Prison and Probation Service. Efforts should be made, therefore, to establish communication in due time before any known placement or release with a view to securing continuity of treatment.

Treatment for drug abuse and any other medical treatment in this connection must be coordinated with the patient's general practitioner.

If treatment for drug abuse is initiated in the hospital service, contacts should also be made, with the consent of the drug abuser, to the municipal drug abuse treatment system with a view to securing continuation of treatment following discharge from the hospital if the drug abuser so wishes. In the case of other long term or continuing treatment with dependence-producing pharmaceuticals, e.g. in connection with psychiatric treatment, contact should also be made with the municipal drug abuse treatment system always provided that the drug abuser consents to this (1).

3 The doctor's responsibility in the overall treatment of drug abusers

The medical treatment of drug abuse comprises primarily diagnosis and treatment of abuse/dependence. In addition medical treatment of drug abusers involves diagnosis and initiatives to secure treatment of somatic and mental problems related to drug abuse.

Assessment of the need for substitution treatment is a medical assessment. The right to prescribe dependence-producing pharmaceuticals as part of drug abuse treatment is explained in Chapter 2, Section 2.2. Professional guidelines on medical substitution treatment of opioid dependence are explained in Chapter 8 below.

3.1 Examination and referral

The municipal treatment services address several different conditions that include abuse of one or several illegal and legal substances. The clinical picture is often complex, and the choice of relevant treatment options presupposes a multidisciplinary assessment.

Initiation of substitution treatment of drug abuse is carried out following medical prescription based on an updated medical assessment.

The doctor's assessment/examination must include examination of the individual drug abuser, the establishing of a thorough abuse history and uncovering of any concomitant somatic and mental diseases. When the conditions of the Health Care Services Act are met, information may be obtained/disclosed concerning relevant prior hospital admissions and visits to medical clinics which should form part of the overall assessment.

Furthermore, information on the patient's use of medication may be retrieved from the national electronic system that records the individual's medication use.

3.2 Medical treatment plans

The medical treatment plan is part of the overall action plan, cf. Section 2.3

above. The medical treatment plan must specify the current aim of medical treatment and the agreements that have been made concerning the course of treatment. If delegation of treatment has been undertaken or is being considered, this must be further described in the treatment plan. Any cooperation and coordination concerning the drug abuser's concurrent treatment by a specialist doctor must also be described. The medical treatment plan is part of the patient record.

3.3 Contact between drug abuser and place of treatment

In order to take care of the required diagnosing and treatment the doctor must have sufficiently frequent contact with the drug abuser. The frequency of contact required will always depend on concrete assessment. In the initial phase of treatment where decision may need to be taken concerning dose adjustment of substitution treatment, a doctor must carefully evaluate the effect of treatment, and following this a medical assessment of treatment must be undertaken at regular intervals adapted to the individual drug abuser's condition and course of treatment.

In the case of disease, including abuse related conditions, the doctor who is responsible for drug abuse treatment should assist in referring the drug abuser to relevant diagnosing and treatment within the ordinary health care services. To the widest extent possible the health care services should seek to coordinate any treatment with dependence-producing pharmaceuticals with the doctor who on behalf of the municipality is in charge of drug abuse treatment of the patient.

3.4 Cooperation with the general practitioner

The aim of the contact between the treatment institution and the drug abuser's general practitioner is to coordinate the drug abuser's overall medical treatment so that the treatment staff involved have an overview of overall treatment provided. The drug abuser's general practitioner should be informed when the drug abuser is received in treatment and when he or she discontinues drug abuse treatment .

3.5 Delegation of medical responsibility for drug abuse treatment

Pursuant to the Authorization Act Section 41, Subsection 2, a doctor employed by a municipality or a region who is responsible for medical drug abuse treatment, may delegate prescription rights/treatment to another doctor including a general practitioner, a practising specialist or else to medical treatment services at a private treatment institution. In this connec-

tion it should be stressed that a drug abuser has no right to require delegation of medical treatment.

Delegation of substitution treatment to a general practitioner or to a specialist presupposes the patient's consent. Furthermore such delegation presupposes that the drug abuser is stabilized from a treatment point of view and can meet the conditions required for receiving treatment from a general practitioner or a practising specialist.

The doctor employed by the municipality or the doctor to whom medical drug abuse treatment has been delegated is responsible for securing that when delegation is undertaken there are guidelines/instructions for treatment, and this doctor must keep himself or herself oriented about developments and the results of a delegated course of treatment, including any concomitant diseases and medication status.

The doctor to whom medical drug abuse treatment has been delegated continues to have an independent responsibility for treatment.

Delegation should be revoked if the doctor responsible for treatment finds that treatment is not appropriate. This means that it should be possible for the municipality without delay to take over drug abuse treatment if because of changes in the drug abuser's condition there is a need for this and/or if the doctor providing treatment or the drug abuser so wishes.

The doctor employed by the municipality or the doctor to whom the municipality has delegated medical drug abuse treatment is, however, not responsible for drug abusers who are in police custody or who are serving a sentence in institutions under the Prison and Probation Service regardless of the duration of detention. In these cases the doctor of the Prison and Probation Service has full responsibility for medical treatment including any substitution treatment. In order to secure continued and appropriate treatment after release and provided that there is consent to this, there should, however, be the greatest possible exchange of information between the municipal or the regional doctor and the doctor of the Prison and Probation Service concerning the drug abuser's health condition.

3.6 A doctor's use of assistance for administration of medication

Only doctors have the right to order prescription medicine. A doctor may delegate administration of medication to assistants. As assistants the doctor may use authorized health care professionals as well as other individuals regardless of their training and background. In this respect the individuals in a

treatment institution that administer medication function as the doctor's assistants.

Pursuant to the Authorization Act a doctor must exercise care and conscientiousness when carrying out his or her profession. This applies both to prescription of medication and to the use of assistants. The doctor must make sure that the assistant has received sufficient instruction and has been informed to the extent required about the effects and side effects of relevant medication. Instructions should be adapted to a given assistant's level of competence.

The leaders of the institution are responsible for securing that instructions are available for professionally appropriate organisation of the handling of medication and that the staff that administer medication have been instructed and trained in this task. If the institution's staff are not able to take care of the administration of medication, the leaders should inform the doctor of this fact so that the doctor can secure that staff with the required level of professional competence administer medicine and observe the patient.

Both authorized and non-authorized health care workers have independent responsibility when acting as assistants to a doctor.

The doctor is responsible for securing that prescription of medicine is entered into the patient record, and on receiving the doctor's prescription the nursing staff should enter this into the record.

When initiating treatment with dependence-producing medicine, the doctor must always have taken a decision with regard to the concrete patient.

A doctor may prescribe medication to a specific patient according to need (p.n.). In these situations the doctor delegates to the assistant the task of assessing the patient's treatment needs and initiate treatment with medication within a fixed framework (dose, frequency, interval and maximum dose). This must be recorded.

For further details cf. Guidance on Prescription and Handling of Pharmaceuticals (7) and Guidance on nursing records (8).

4 Diagnosing of drug dependence and abuse

4.1 Delimitation, definitions and terminology

Mental dependence is defined as a craving for an intoxicant with a view to obtaining satisfaction/pleasurable sensation and/or avoiding discomfort.

Physical dependence is a predictable pharmacological effect that is a sign of adaptation to the substance. Physical dependence is characterised by withdrawal symptoms in connection with discontinuation of treatment or dose reduction. As a concomitant symptom to physical dependence there may be various degrees of tolerance.

Tolerance development differs very much from one intoxicant to another. It is modest in the case of alcohol and very considerable in the case of e.g. heroin. There is no connection between tolerance development and the severity of withdrawal symptoms. Cross tolerance means that there is tolerance also for related intoxicants.

According to the WHO ICD-10 disease classification and diagnostic criteria, the concepts dependence and abuse are defined as follows:

Dependence is a syndrome consisting of a number of behavioural, cognitive and physiological phenomena that (in some individuals) develop through repeated use of one or several dependence-producing pharmaceuticals or intoxicants. Dependence is characterised by a continuing or intermittent need for a substance which manifests itself through obsessive behaviour where the obtaining and use of the substance dominates the individual's life.

This diagnosis presupposes the presence of at least three of the following symptoms for at least one month or on repeated occasions during one year:

- Craving
- Reduced ability to manage consumption, discontinue or reduce consumption
- Withdrawal symptoms or substance consumption to counteract or avoid such symptoms
- Tolerance development
- A dominant role with regard to priorities

- Continuing use in spite of acknowledged harmful effects.

Abuse is defined as *harmful use*. In order for the diagnosis to be made, the following criteria must be met:

- Physical and/or mental harm (including impaired judgment and behaviour)
- Harm is clearly demonstrable
- Duration of at least one month or on repeated occasions within one year.

The concept of abuse involves harmful use of the intoxicant in question which leads to social, somatic and/or mental harm. Thus abuse may be seen as a kind of social and mental deviation characterised by destructive behaviour which is primarily self-destructive though also the individual's environment (family and friends) as well as community may be harmed.

Abuse may occur without physical and mental dependence (e.g. in the case of sniffing of solvents), but most often the abuser will be both mentally and physically dependent.

Dependence-producing pharmaceuticals are pharmaceuticals that may lead to the development of dependence syndrome.

- Morphine and morphine-like substances that have an effect on the opiate receptors
- Benzodiazepines and substances that act on the benzodiazepine receptors
- Pharmaceuticals that act on the central nervous system and with a narrow range of use
- Certain other pharmaceuticals with dependence/abuse potential.

4.2 Assessment of the abuse condition

4.2.1 Aim

When receiving a patient in treatment for drug abuse problems, the doctor should undertake a comprehensive assessment of the problem areas related to drug abuse with a view to being able to judge and organise adequate and individually adjusted treatment.

The doctor should be aware that drug abusers who start in treatment are often chaotic, they are often weak both acutely and chronically, and they are uncertain about what is going to happen.

The aim of the initial assessment is to

- Identify and treat any acute problem that requires treatment
- Confirm the patient's information about abuse problems through the taking of abuse history and physical examination, possibly urinalysis

- Assess the degree of dependence/abuse
- Identify abuse related complications and assess any risk behaviour
- Identify other somatic, mental and social problems
- Establish a treatment plan including indication for substitution treatment and the framework for such treatment, need for assessment and possibly treatment by somatic or psychiatric specialist as well as need for social treatment services
- Secure that serological screening for hepatitis and HIV including counselling before and after such screening is offered.

Regardless of the type of abuse, the overall aim of the initial assessment will be the same.

Diagnosing of dependence and abuse always includes taking of abuse history and objective medical assessment of somatic and mental health.

4.2.2 Abuse history

Below are listed the most significant areas that should be considered when taking abuse history:

Abuse history

1. Reason for contact

2. Earlier and current (= the past 4 weeks) use of intoxicants (including alcohol)

For each intoxicant information on:

- Age when first used
- Frequency of use (no. of days within the past 30 days)
- Form of administration
- Cases of poisoning/overdose
- Periods without use of the substance in question
- Withdrawal symptoms
- Expense for substance/alcohol (e.g. amount spent within past 30 days)

3. Earlier treatment for drug abuse

- What type of treatment and the results thereof
- Place of treatment (other doctors, hospital services, municipal abuse treatment system)

4. Injection behaviour, risk behaviour

- Earlier / within the past 4 weeks

Risk behaviour (shares syringes or other tools / paraphernalia)
Sexual risk behaviour

5. Somatic health history (see Chapters 5 and 6 below)

Complications related to drug abuse (abscesses, thromboses, poor nutritional condition etc.)
Hepatitis / HIV status
Most recent cervical smear
Contraception status
Most recent period
Injuries, operations, head traumas

6. Psychiatric health history (see Chapter 7 below)

Current / earlier treatment within psychiatry
Earlier overdose (accident / suicidal intentions)
Earlier episodes with depression or psychoses
Current/earlier treatment with psychoactive drugs

7. Social history

Civil status, network
Children
Housing
Livelihood (job/benefits/pension)
Crime

A contribution to a structured mapping of problem areas and standardised interview methods may be secured through the use of e.g. Addiction Severity Index (ASI), which may also further the multidisciplinary drug abuse treatment.

Urinalysis: May be used as a supplement to the abuse history. Concerning the use of urinalyses see Chapter 10 below.

4.2.3 Diagnoses

Any medical assessment should contain a diagnosis of the abuse condition. For further details on this see Annexes 1 and 4.

5 Somatic comorbidity in drug abusers

5.1 Introduction

A doctor who has a drug abuser as a patient should be aware of the most common somatic conditions that are seen in connection with drug abuse, partly in order to provide relevant guidance on prevention, but also in order to secure relevant assessment and treatment of both acute and chronic health problems. The doctor should also be aware of the fact that clinical manifestations may be atypical because of concurrent intoxication.

Generally drug abusers do not seek medical treatment unless this is quite unavoidable, i.e. most often only in connection with severe acute disease and traumas. Often they will suffer from untreated disease for a relatively long time, and insufficiently treated chronic diseases are often seen.

Drug abusers often have difficulty in complying with agreements in connection with receiving health care services. Therefore the risk of compliance problems should be considered when assessment and treatment is planned.

5.2 Diseases that are especially frequent in intravenous substance abusers

5.2.1 Consequences of intravenous abuse

Conditions may result from contamination/injuries and may result from transmission of infection in connection with intravenous abuse.

The consequences of transmission of viral infection related to intravenous abuse are described in Chapter 6.

Intravenous abuse involves a great risk of tissue damage in and around the veins used and thrombophlebitis in the deep veins is a complication that is often seen. The consequences of deep thrombophlebitis in the form of post-thrombotic syndrome are often seen in intravenous abusers.

Many diseases that drug abusers contract, result from non-sterile and technically faulty intravenous administration of substances. Local infections in and

around the place of injection (cellulitis, abscess, erysipelas) are frequently seen. Systemic bacterial infections with bacteraemia/sepsis, endocarditis and/or other organ abscesses (frequently in lungs and bones but also in the central nervous system and in the kidneys) are not uncommon.

In intravenous abusers attention should, furthermore, be paid to the seldom but rapidly developing and possibly fatal skin infection, the so-called "necrotising fasciitis", which is often caused by *Streptococcus pyogenes* and which may lead to severe tissue lesions resulting in necrosis of connective tissue and muscles. Early intravenous antibiotics treatment during hospital admission is required, and often surgical intervention will be necessary. Early symptoms are hectic flush and heat and tenderness around the area of injection. Untreated infection may develop into toxic shock syndrome that may be fatal.

5.2.2 Life style diseases

Other diseases that are frequent among drug abusers are related to the special life style that is often seen in connection with active drug abuse. The dental state of drug abusers is often quite poor with a high incidence of dental diseases. Therefore priority should be given to cooperation with a dentist as part of health care services for drug abusers. Chronic obstructive lung disease with frequent exacerbation and pneumonia is often frequently seen and often in relatively young drug abusers. Coughing, fever and night sweats should raise suspicion of tuberculosis. Patients that do not respond to ordinary antibiotics treatment against pneumonia should be conferred with lung/infection department. X-ray of thorax should be carried out on the basis of wide indications.

Female drug abusers often practice unsafe sex and some finance abuse through prostitution. Some gynaecological infections are often seen asymptotically, but symptom-producing and untreated pelvic infections also occur often. Human Papilloma Virus (HPV) infection in portio is frequent. Even though few HPV infections lead to cellular change or cancer, by far the greater part of all dysplasias is due to HPV infection. However, very few female drug abusers undergo the recommended cervical cytological screening every third year.

The doctor in the municipal drug abuse treatment system should secure that drug abusers in substitution treatment are offered information about safe sex as well as easy access to condoms and other contraception. Furthermore, the doctor should provide for gynaecological examination and counselling e.g. in connection with counselling on contraception and possibly through cooperation with the patient's own doctor/specialist or local contraception and counselling clinics. For further details see Chapter 11 below.

As a consequence of intoxication drug abusers often contract traumas, and the consequences of earlier traumas especially in the extremities are frequently seen in drug abusers. Often an emergency room is the first and sometimes the only form of contact that a drug abuser has with the health care services. Because of intoxication, symptoms are often hidden, and cooperation with the intoxicated drug abuser may be difficult. One cannot be certain that the patient is able to give an account of the symptoms or the event underlying the trauma. Therefore heightened attention is called for in order not to miss serious and possibly fatal injury.

Like non-abusing patients drug abusers should be secured sufficient pain treatment. Concerning pain treatment of drug abusers in substitution treatment see sections 8.2.7 and 8.4. Concerning general issues in relation to pain treatment otherwise cf. National Board of Health Guidance on prescription of dependence –producing pharmaceuticals (9).

Concerning diagnosis and treatment of sexually transmissible diseases (10), reference is made to National Board of Health Guidance on sexually transmissible diseases and Chapter 6 below.

5.3 General medical treatment of drug abuse

Any doctor who has a drug abuser as a patient should invite the drug abuser to undergo medical examination including serological assessment for hepatitis and HIV as well as examination for sexually transmissible diseases.

The doctor in the municipal treatment system for drug abuse should make sure that

- When received in treatment drug abusers are offered medical examination in the form of full physical examination including serological assessment for hepatitis and HIV and examination for sexually transmissible diseases.
- Drug abusers in the municipal treatment system are offered regular medical examination, e.g. once every year and otherwise when needed.
- There is a follow-up of the results of the medical examination, possibly in cooperation with the drug abuser's general practitioner/relevant specialists/hospitals.

In the case of hospital admission:

- When a drug abuser who is not in treatment, is admitted, the hospital should make sure that the patient is informed about treatment services in the municipal system for drug abuse.
- When a hospital has an inpatient who is receiving treatment in the municipal treatment system for drug abuse, the hospital should contact the municipal treatment system as a minimum in connection with admission and in connection with discharge (10).

- When a patient is admitted to hospital, the doctor in the municipal treatment system should make sure that the hospital is informed about the patient's current medication and should follow up on the hospital stay after discharge.

6 Viral infections in drug abusers

6.1 Hepatitis A, hepatitis B, hepatitis C and human immuno deficiency virus (HIV)

In drug abusers there is a widespread incidence of hepatitis A, hepatitis B, hepatitis C and human immuno deficiency virus HIV. This is partly a direct result of intravenous abuse, but is also caused by the drug abusers' lifestyle.

A doctor who diagnoses or treats a drug abuser should make certain that the patient in question is informed of the risk of these serious and infectious diseases. The doctor must offer examination with regard to these diseases as well as counselling on modes of transmission and prevention, including instructions on how to avoid infecting others.

When receiving a drug abuser in treatment, the doctor must offer examination for hepatitis A, hepatitis B, hepatitis C and HIV. Depending on infection and vaccination status these examinations must be offered once a year to all drug abusers in treatment. Furthermore, the doctor must offer vaccination against hepatitis A and hepatitis B to the individuals who have not already been infected. Given the much improved treatment opportunities, it is important to identify an infected individual with a view to assessing treatment options.

As part of the municipal treatment services for drug abusers there should be procedures for offering examination and treatment of viral infections and for counselling on risks and prevention in this regard.

The target group consists of all intravenous drug abusers that have been registered for treatment, also individuals who have only injected on a single occasion and thus may not really consider themselves as intravenous drug abusers. This service is not relevant for purely cannabis abusers, but may be relevant for individuals who have had blood contact with others, e.g. through sharing of sniffing tools.

Information on infection should be offered as concretely as possible. Information should be given for instance on the fact that there is an infection risk not only when sharing syringes and needles but also when using

common boiling utensils, rinsing water, scoops, cotton wool/filters and sniffing tools.

Drug abusers must be informed that infection with hepatitis B and HIV may occur both through blood and through sexual transmission. Furthermore information must be given that hepatitis C infection is seldom spread via blood and that hepatitis A infection is very rarely spread via blood but is spread via faecal-oral transmission.

For further details concerning these issues see Annex 3 and

- National Board of Health guidance on hepatitis (11)
- National Board of Health guidance on human immuno deficiency virus HIV and prevention of blood-borne infection (12)
- National Board of Health national action plan for prevention of hepatitis C among drug abusers (13).

6.2 Tracking of infection

Guidance on the tracking of infection is found in the National Board of Health guidance on sexually transmissible diseases (14).

For further details especially with regard to drug abusers, see Annex 3.

6.3 Vaccination and prophylaxis following exposure to infection risk (Post Exposure Prophylaxis, "PEP")

Pursuant to Ministry of the Interior and Health Order on free vaccination against hepatitis for especially exposed groups (15), vaccination free of charge may be offered to drug abusers.

For further details on vaccination and other Post Exposure Prophylaxis especially in relation to drug abusers, see Annex 3 and

- National Board of Health guidance on hepatitis (11)
- National Board of Health guidance on human immuno deficiency virus HIV and prevention of blood-born infection (12)

6.4 Legal issues. Notification obligations

Pursuant to National Board of Health Order on doctors' notification of infectious diseases etc (16), a doctor who receives a patient for treatment of certain diseases must notify the National Board of Health.

6.4.1 Notification of AIDS, hepatitis A, hepatitis B and hepatitis C

A doctor who diagnoses the following diseases must in writing notify the Medical Officer in the region where the patient stays and the epidemiology department of Statens Serum Institut using National Board of Health form no. 1515.

- AIDS
- Hepatitis A, acute
- Hepatitis B, acute and chronic
- Hepatitis C, acute and chronic.

6.4.2 Notification of HIV-antibody positive individuals

The doctor who examines a person for HIV-antibodies (anti-HIV), must, if the test is positive and confirmed, notify the epidemiology department of Statens Serum Institut. For this purpose National Board of Health form no. 4001-3 must be used, which is forwarded by the laboratory in the case of a positive response.

7 Psychiatric comorbidity in drug abusers

7.1 Introduction

Psychiatric comorbidity in connection with abuse of or dependence on intoxicants is understood as a mental condition that is found concurrently with abuse of or dependence on intoxicants.

This may be:

- Primary psychiatric comorbidity: A mental condition that occurs regardless of abuse of or dependence on intoxicants
- Secondary psychiatric comorbidity: Mental condition provoked by intoxicants

Generally it is difficult to distinguish between primary and secondary psychiatric comorbidity in cases of abuse of or dependence on intoxicants. Most often the conditions and the problems found are complex and with multifactorial causes.

Drug abusers have high mental morbidity, and patients with mental disease abuse various intoxicants to a considerable extent.

Therefore it is important that all doctors are aware of the prevalence of mental disease in connection with drug abuse and the prevalence of drug abuse in connection with mental disease, and that

- Doctors who refer patients either to psychiatric treatment or treatment for drug abuse consider the possible simultaneous occurrence of both drug abuse and/or mental disease,
- Doctors who treat abusers in the municipal system make certain that an assessment is made of the possible occurrence of mental disease in all drug abusers in treatment and that the results hereof are taken into consideration as part of overall drug abuse treatment ,
- Doctors within psychiatry are aware of possible concurrent drug abuse.

7.2 Psychiatric symptoms/conditions induced by intoxicants

The connection between dependence on/abuse of intoxicants and the occurrence of psychiatric symptoms is complicated. In order to diagnose and

provide relevant treatment it is important, in general, to be aware that

- abuse of/dependence on intoxicants may cause and may aggravate psychiatric symptoms,
- abuse of/dependence on intoxicants may mask psychiatric symptoms and psychiatric conditions,
- withdrawal state may cause psychiatric symptoms.

There are great individual variations in reactions to a given intoxicant both with regard to effect, intoxication and withdrawal symptoms. This is further complicated by multiple abuse. Therefore a *continuing* assessment of psychiatric symptoms and their relation to withdrawal or continuing abuse is called for.

When assessing a patient who is under the influence of intoxicants, it is important to establish what substances the patient has taken. What the patient believes he or she has taken is not always what has actually been consumed. The use of urinalyses may contribute diagnostically to establishing what reactions may occur and what may thus be expected during a period of observation.

Antagonists are only available against opioids and benzodiazepines. These should be used on the basis of broad indication, e.g. when opioid poisoning is suspected with concurrent alcohol intoxication.

7.3 Acute psychiatric assessment

The aim of acute psychiatric assessment, treatment and referral is to secure that the acute condition, e.g. suicidal impulses or delirious conditions do not lead to fatal consequences or that the patient's condition deteriorates because acute treatment is not provided.

The first task is to assess immediate treatment needs, and the acute assessment should clarify whether there may be:

- risk of suicide
- acute somatic disease
- psychosis
- severe depression
- risk of violence

In order to secure that diagnostic considerations are as precise as possible both in relation to substance consumption and to the psychiatric symptoms, psychiatric history taking should include systematic and thorough questioning that may help the patient to give a detailed and differentiated account of

his or her problems and which also allows for an opportunity to repeat these questions at regular intervals during observation/treatment with a view to being able to assess the patient's condition. Open and unbiased questions should be used concerning reason for contact etc. Information about début, development, duration and any earlier treatment should be acquired, possibly supplemented with information from relatives or others. Specific questions should be used involving systematic interview on family disposition, social conditions, somatic diseases, prior admissions (both somatic and psychiatric) and abuse history, possibly supported by urinalyses for medicine and substances, as well as current medical treatment. Information from relatives may be significant not least if the patient is acutely intoxicated and for this reason is a poor informant.

7.4 Treatment strategy

Overall responsibility for diagnosis and treatment of psychiatric diseases in drug abusers in the municipal treatment system lies with the medical staff.

Psychiatric problems and difficulties in a broad sense are frequent among drug abusers, but in a great many cases such difficulties will be superficial or temporary provided that required support in connection with treatment of drug abuse is given in time. Superficial mental conditions and problems among drug abusers may be taken care of at the level of primary contact, i.e. in the primary health care sector and by staff in the municipal drug abuse treatment systems.

Whether a drug abuser should be referred to psychiatric services will depend on an individual assessment.

Patients should always be referred to a psychiatric specialist if there is or is suspicion of:

- Psychoses, severe affective conditions
- Serious suicide attempts
- Serious, unclarified mental conditions, including hyperkinetic disorder/ADHD.

Indication for treatment with antipsychotics for more than 2 to 3 weeks is a task for a psychiatric specialist, and a psychiatric specialist should take care of continued treatment or advise on this treatment. As early treatment is thought to be of great importance for the course of disease, newly occurring symptoms in a patient that lead to suspicion of schizophrenia should immediately result in referral to a psychiatric department or community psychiatric centre. In case of psychotic relapse, it should also be carefully considered whether the patient should be referred to a psychiatric depart-

ment with a view to renewed assessment and decision on treatment.

Long term treatment of e.g. stable chronic psychoses in drug abusers, may be taken care of in the municipal system in cooperation with a psychiatric specialist (shared care).

In recent years hyperkinetic disorder/ADHD has often been found in association with drug abuse in adults. There are, however, considerable difficulties involved in diagnosing hyperkinetic disorder/ADHD in adults among other things because the diagnostic criteria have been established with a view to diagnosing children, and there are no specific diagnosis criteria for adults according to the WHO ICD 10 disease classification. Furthermore hyperkinetic disorder in adults may be difficult to diagnose because adults compensate for problems they may have to a higher degree than do children. Psychiatric comorbidity is often seen (personality disorder, depression, anxiety, abuse) for which reason differential diagnostics may be difficult.

Among other things because of the high psychiatric comorbidity, the final diagnosis of young people/adults must always be given by a specialist in child and adolescent psychiatry or a psychiatric specialist prior to the initiation of treatment with central stimulants.

Any concomitant abuse of narcotic substances, alcohol or dependence-producing pharmaceuticals must be treated concurrently with other treatment.

In active drug abusers there is as a main rule no indication for treatment with central stimulants. Treatment with central stimulants may, however, be initiated for opioid dependent persons in stable substitution treatment. Such treatment must be carefully monitored because of the risk of development of abuse of central stimulants.

Drug abusers in acute psychiatric danger, e.g. suicidal ideas/threats or manifest psychotic symptoms, who pose a danger to themselves or others, should be assessed and treated acutely in a psychiatric setting.

In the individual course of treatment for drug abuse with concurrent mental disease, the doctor who is in charge of municipal drug abuse treatment must contribute to securing the best possible course of treatment involving the municipal drug abuse treatment system, the primary health care sector and the psychiatric system.

In Annex 4 a further description is found of the clinical problems in connection with assessment and treatment of drug abusers with mental disorders.

8 Medical substitution treatment of opioid dependence

Substitution treatment of opioid dependence must be accompanied by comprehensive treatment initiatives that address the drug abuser's somatic and mental health problems as well as the social problems that the drug abuser has. For most opioid dependent individuals substitution treatment for short and long periods will be a precondition for taking part in social treatment initiatives.

Drug abusers in substitution treatment have lower mortality than untreated drug abusers. Furthermore there is a reduction of risk behaviour in relation to blood-borne diseases and reduced occurrence of other abuse related diseases. Finally, drug abusers in substitution treatment are known to commit fewer property offences and to some extent they are more often in employment.

The outcome of treatment depends both on correct dosage and on the extent and the quality of concurrent psycho-social treatment. If dosage is correct and provided that the patient does not engage in other abuse or receive other treatment with sedatives, there is no appreciable influence on psychomotor or cognitive functions including reaction time and memory.

Concerning the right to prescribe dependence-producing pharmaceuticals as part of drug abuse treatment, cf. Section 2.2

8.1 Indications

The decision to offer substitution treatment must be assessed in the light of whether substitution treatment is relevant with regard to achieving the aims that have been set up in the social action plan. In addition to these general considerations, the following criteria must be met:

- There must be dependence on opioids (F11.2) as defined in WHO ICD-10: Mental disorders and behavioural disorders
- The drug abuser must want this treatment. In the first place this means that treatment is voluntary, and secondly it means that the wish for this form of treatment (substitution treatment) must be expressed with some weight

- Other relevant treatment alternatives must have been considered. Substitution treatment is a demanding form of treatment where the dependent individual and the treatment institution commit themselves to binding cooperation for an unknown but most often fairly long duration
- Pregnant drug abusers that want to go through with their pregnancy should be offered substitution treatment if detoxification is not realistic.

Buprenorphine or buprenorphine/naloxon and methadone, are the preparations that are used in substitution treatment. In the following the designation buprenorphine covers both buprenorphine on its own and the combination drug buprenorphine/naloxon.

Buprenorphine should be the first-line treatment because of its low toxicity and a presumed lower risk of developing dependence. The combination drug buprenorphine/naloxon was registered in 2006, and because of its superior safety profile it should be attempted to use buprenorphine/naloxon rather than buprenorphine to the widest possible extent.

The principles for initiation of treatment with buprenorphine and methadone respectively differ decisively and can be seen in the table below:

| | Buprenorphine | Methadone |
|---|--|---|
| Clinical condition on the initiation of treatment | Incipient withdrawal symptoms (in order to avoid precipitated withdrawal symptoms) | No intoxicated presentation (in order to avoid methadone poisoning) |
| Start dose | Start dose (test dose) 4 mg, hereafter dose increase over 24 hours | Low, 20-30 mg for 24 hours |
| Dosage | Rapid dose increase Steady state achieved after 2-3 days | Slow dose increase Steady state achieved after 2-6 weeks |

8.2 Buprenorphine

Buprenorphine is a partial agonist on the μ -opioid-receptor with high affinity for this.

Buprenorphine is found in two types of preparation:

- Buprenorphine on its own
- Buprenorphine in combination with naloxon (buprenorphine/naloxon).

Naloxon is an antagonist to the μ -opioid-receptor.

The purpose of the naloxon component is to limit intravenous abuse and reduce diversion to the illegal market.

When buprenorphine/naloxon is taken sublingually, buprenorphine is taken up over a relatively short period whereas there is little uptake of naloxon sublingually. If on the other hand buprenorphine/naloxon is taken intravenously, the naloxon component will lead to the development of withdrawal symptoms or lack of effect of the substance.

Naloxon does not influence the opioid effect of buprenorphine, for which reason the treatment regimen is the same for buprenorphine and for buprenorphine/naloxon.

Both buprenorphine and buprenorphine/naloxon are administered sublingually and usually as one daily dose. The degree of supervised administration and dispensing depends on the patient's functional level.

For patients in stabilised buprenorphine treatment and especially in the case of treatment with buprenorphine/naloxon, the dispensing regimen may be organised with less restriction than in the case of methadone.

Buprenorphine represses other opioid agonists from the receptors, and the taking of buprenorphine therefore releases withdrawal symptoms in drug abusers who are being treated with methadone and morphine as well as in heroin abusers. In drug abusers who are in buprenorphine treatment, buprenorphine will also block the effect of other agonists, and to a wide extent it therefore protects against poisoning with these substances.

The respiratory-depressing and sedative effects of buprenorphine are less severe than in the case of full agonists such as morphine and methadone. The risk of fatal poisoning is minimal even for non-habituated individuals.

Because of the greater safety of buprenorphine compared to methadone, as many opioid dependent patients as possible should be treated with buprenorphine both in cases of slow withdrawal and for maintenance treatment. Buprenorphine should be the first-line drug for opioid dependent patients who have not received treatment before. When treating a long term abuse of opioids with a long half-life (e.g. methadone), immediate initiation of treatment with buprenorphine may be difficult because of high doses of methadone. In such cases it may be appropriate initially to substitute with methadone with a view to a later change to buprenorphine. The methadone dose should be reduced to a maximum of 40 mg prior to any shift to buprenorphine.

8.2.1 Initiation of treatment

It is a precondition for initiation of treatment with buprenorphine that the patient is in the initial phase of withdrawal following the most recent taking of opioids, i.e. in a condition in which the μ -receptors are free from opioids. When discontinuing the use of heroin, initial withdrawal symptoms are seen after about 8 hours. When discontinuing the use of methadone, initial withdrawal symptoms are only seen after 1 or 2 days.

Day 0: It is important for successful initiation of treatment with buprenorphine that the patient is informed of the way buprenorphine functions, the requirement of having achieved opioid abstinence and the ways in which medication is to be given on the following day. Brief treatment of symptoms with benzodiazepine may be appropriate in order for the patient to tolerate withdrawal symptoms for the initial 24 hours.

When treatment is initiated in due time, the patient may expect withdrawal symptoms to disappear in the course of 24 to 36 hours.

Day 1: The normal beginning dose (test dose) is 4 mg, to be increased by 2 mg about every second hour until the patient no longer complains of withdrawal symptoms/craving. If there is any doubt as to the risk of developing withdrawal symptoms, an initial test dose of 1-2 mg may be used. The normal saturation dose is between 8 and 16 mg per 24 hours, but doses up to 24 mg during the first 24 hours may be necessary. It may be suitable to give the patient 2-4 mg for self-administration during the first 24 hours in order to treat possible withdrawal symptoms.

Because of the safety profile of buprenorphine it may alternatively be considered to give the patient the first dose (2-4 mg, possibly repeated) to start treatment in the home in the case of onset of withdrawal symptoms with a view to immediate follow-up by a doctor.

It is decisive for successful initiation of treatment that sufficient dosage is given during the initial days. Many failed courses of treatment with buprenorphine are due to low dosage so that the patient continues unnecessarily to have withdrawal symptoms because of insufficient medication.

Day 2: Same dose as day 1, possibly further supplemented with 2-4 mg if needed.

Days 3-4: Stabilisation has been achieved when there are no withdrawal symptoms and no use of opioids except medication with buprenorphine. Most patients are in suitable treatment when given doses of between 8 and 24 mg, but a few may need higher dosage.

Day 5 and onwards: Maintenance treatment or slow withdrawal may be planned from this stage.

During the first 2 weeks' treatment patients will often complain of temporary discomfort in the form of dysphoria, anxiety and sleep problems. Symptomatic treatment may be required.

8.2.2 Precipitated withdrawal symptoms

If the first dose of buprenorphine is taken before the onset of clear withdrawal symptoms, buprenorphine will act as an antagonist.

Precipitated withdrawal symptoms should be treated by increasing the already prescribed buprenorphine dose in order to achieve full saturation with buprenorphine on the receptors.

8.2.3 Dosage intervals

When there is satisfactory stabilisation, dosage intervals may be increased to every second day with twice the daily dose. Dosage intervals may be increased to three times weekly, e.g. Monday, Wednesday and Friday. Doses on Mondays and Wednesdays should be twice the individually adjusted daily dose, and Friday's dose should be three times the individually adjusted daily dose. Dose for a single day should normally not exceed 24 mg, but in some cases there may be a need for larger doses.

8.2.4 Slow withdrawal

At the earliest slow withdrawal may be commenced when appropriate stabilisation has been achieved. It should not be undertaken at a rate exceeding 1/2 -1 mg per day, and the patient's general condition should be monitored. It is advisable to agree with the patient beforehand whether it should be possible to prolong withdrawal. Because of the long half-life of buprenorphine, withdrawal symptoms during slow withdrawal and also at discon-

tinuation are modest. Symptomatic treatment may be required.

8.2.5 Change from methadone to buprenorphine

There should be no change to buprenorphine at doses higher than 40 mg methadone.

If there is a need to change to buprenorphine at methadone doses over 40 mg, it is always advisable to await the onset of withdrawal symptoms. When buprenorphine treatment is initiated, the effect of a buprenorphine test dose of 4 mg should be established prior to any further increase of dose.

8.2.6 Change from buprenorphine to methadone

When discontinuing buprenorphine, slow withdrawal is not required regardless of dosage. When discontinuing buprenorphine, methadone treatment may be initiated after about 24 hours with 10-30 mg methadone to be increased slowly while the patient's condition is monitored.

8.2.7 Acute pain treatment

When supplementing opioid is required for acute pain in a patient who is in substitution treatment with buprenorphine, an increase of buprenorphine dosage will only have limited effect. Instead the possibility of regional anaesthesia should be considered. If this is not possible, buprenorphine may be discontinued and treatment with high doses of morphine may be required. Attention should be given to the fact that ordinary dosage of morphine is not sufficient as long as buprenorphine continues to be present on the receptors. It is recommended to consult an anaesthesia specialist/pain specialist. When acute pain is over, the patient may be changed back to buprenorphine following a standard regimen for initiation of treatment.

8.2.8 Antagonist treatment in the case of overdose

Administration of naloxon results in withdrawal symptoms. The trigger dose is about 10 times higher in drug abusers who are in treatment with buprenorphine than in drug abusers being treated with methadone or morphine. The most important treatment in the case of overdose is to secure free respiratory passage and to assist ventilation.

8.3 Methadone

Methadone is a complete opioid agonist.

Methadone may prevent withdrawal symptoms for more than 24 hours. For the majority of drug abusers methadone can reduce or eliminate craving. At correct dosage methadone may block the euphoriant effect of the ordinarily used dose of heroin without affecting psycho-motor functions.

When deciding dosage of methadone, the principle is on the one hand to give so much that craving is reduced to the extent possible and that withdrawal symptoms are blocked for 24 hours and on the other hand so little that normal psycho-motor functions are not affected appreciably.

8.3.1 Initiation of treatment

When treatment is initiated, the drug abuser's tolerance of opioids (which may be zero) is normally not known, and therefore treatment should always be initiated with a low dose of 20–30 mg per day. Fatal poisoning has been described when doses of 40 mg per day have been administered. Because of the risk of accumulation, dose increase should be gradual with an increase not exceeding 5-10 mg every second day until the patient's condition is stable so that there are neither withdrawal symptoms nor symptoms of overdose. Dosage is fixed for a period of 2 to 3 weeks or more. Usually maintenance dose will not exceed 120 mg.

Methadone is normally administered once per day. During slow withdrawal, at doses under 40 mg per day, administration two times per day may be required in order to achieve sufficient 24-hour coverage.

The form of administration may be suspension, tablets or dissolution for intravenous use. Depending on the drug abuser's stability and functional capacity, medicine may be taken daily and under supervision (in practice 5 days a week) or several 24-hour doses may be dispensed for self-administration.

8.3.2 Heart rhythm disorders

The doctor should be aware that high doses of methadone may cause the development of cardiac conduction disorders. Severe heart rhythm disorders (ventricular tachycardia, ventricular fibrillation, torsade de pointes) and continuing abnormal ECG (QT-prolongation) have been observed in drug abusers in methadone treatment. ECG should be taken routinely in connection with treatment with 120 mg methadone or more and in the case of dizziness and cases of fainting in patients treated with methadone as well as in the case of known cardiac disease.

8.3.3 Slow withdrawal

At the earliest, slow withdrawal may be initiated after appropriate stabilisation. Withdrawal should not exceed 5 mg per day and should include regular monitoring of the patient's general condition. It is advisable to agree with the patient beforehand whether there should be a possibility of prolonging the withdrawal process. Many patients that discontinue or try to discontinue methadone treatment complain of definite and long term withdrawal symptoms. There is hardly any doubt that this is a real problem and that it is re-

lated to the long duration of the effect of methadone as well as to the fact that drug abusers in methadone treatment get higher opioid doses than it is usually possible to acquire and take as an illegal drug abuser. It is, however, not more difficult for drug abusers in methadone treatment to become drug free than it is for heroin abusers.

8.4 Pain treatment

Substitution treatment for opioid dependence does not relieve pain for which reason attention should be paid to securing sufficient pain treatment for this group of patients.

Drug abusers in substitution treatment have normal or reduced pain tolerance which means that they should be treated along the same guidelines as other patients with pain. At the same time there should be a change of substitution treatment primarily by dividing the daily dose into 3 to 4 doses.

When pain treatment is initiated, a plan should be established for this treatment.

For further information cf. National Board of Health Guidance on prescription of dependence-producing pharmaceuticals (9)

8.5 Treatment with injectable methadone

Treatment with injectable methadone is not standard treatment, but should comply with a defined protocol following the criteria below.

8.5.1 Indication for treatment

Treatment with injectable methadone may be used for patients who in spite of long term substitution treatment and psychosocial support continue to have massive intravenous abuse of prescribed or illegal opioids, and who have or are threatened by serious health complications for this reason. Thus the aim of the treatment is in the first instance to prevent deterioration of the patient's health condition and in the long term to achieve improvement of the patient's quality of life both with regard to health and socially.

Treatment with injectable methadone may not be used for pregnant women. If there has been a pause of more than 3 months in the patient's treatment with intravenously administered methadone, indication for treatment should be reassessed.

Indication for treatment with injectable methadone must be recorded including the relevant mental and somatic conditions as well as WHO ICD10-diagnoses.

8.5.2 Medical examination

Prior to initiation of treatment:

Before treatment with injectable methadone is initiated, medical examination should be undertaken including registration of possible injection injuries, ECG and screening of blood samples for HIV and hepatitis if infection has not already been established.

During treatment:

Regular examination is required to establish whether the patient gets injection injuries, including phlebitis, ulcers, endocarditis etc. During the initial year examination must be undertaken every 3 months and thereafter every 6 months. Screening of blood samples for HIV and hepatitis must be repeated at least every 6 months unless infection has already been established.

Observations and results of examinations must be documented currently.

8.5.3 Dosage, type of administration, organisational and physical environment etc.

Injection is taken care of by the patient. Treatment with injectable methadone presupposes that the patient has intravenous access. It should be noted that veins in the neck may not be used.

There are considerable differences in bio accessibility of oral and intravenous methadone. Furthermore many patients in oral methadone treatment have a concurrent side abuse of methadone or heroine. In general terms, the principle for change from oral methadone to intravenous methadone are:

$$\text{Injectable methadone (mg)} = 0,8 \times \text{oral methadone (mg)}$$

In general a dose corresponding to about 85 per cent of the dose for oral administration is appropriate.

The form of administration is injectable methadone 10 mg/ml. The patient may at any time be given the equivalent doses for oral administration.

The form of administration must be documented currently including the daily doses of injectable and oral methadone respectively.

In general injection must be carried out at the place of treatment. It must be possible to call a doctor in case of need. In order to secure the required level of discretion and hygiene, injection must be undertaken separately from dispensing of other medication.

During the first two weeks injection must be undertaken under supervision

by a health care person, and during this period patients may not be given methadone to take home. This period should be used for any adjustment of dosage as well as for education in hygiene, injection technique, risks etc.

If after this period the doctor estimates that the patient is able to administer medication properly, the patient may be given doses to take home. Special attention is required in connection with dispensing of injectable methadone for holidays and trips abroad.

8.5.4 Monitoring of treatment through questionnaires

With a view to evaluation of the form of treatment, systematic registration of the treatment is required, and this registration must currently be reported to the National Board of Health.

At the initiation of treatment and on a regular basis throughout the course of treatment the patient must be interviewed concerning health condition using the SF-36 questionnaire and the National Board of Health questionnaire concerning abuse problems.

During the first year an interview must be undertaken every 3 months and thereafter every 6 months.

Reporting is done by digital means via the National Board of Health web page <http://www.sst.dk/Formular/Methadone/Formular.aspx>

Reported data will form part of a register in the National Board of Health following the guidelines for storage of confidential information. Data are used solely for the purpose of national assessment of this form of treatment and will be deleted in 2010 when an evaluation has been carried out.

The forms may also be printed from the National Board of Health web page.

8.6 Acute initiation of treatment of withdrawal symptoms in cases of opioid dependence in persons who are unknown or very little known by the doctor

Great cautiousness must be exercised in connection with acute prescription of methadone to persons who are unknown or very little known by the doctor, e.g. persons in police custody.

Methadone treatment must not be initiated until the doctor has made certain that

- Clear withdrawal symptoms are present
- No intoxication presentation.

Initiation of treatment of withdrawal symptoms under these conditions also follows the general guidelines for initiation of treatment with buprenorphine and methadone respectively, see Sections 8.2 and 8.3.

Generally great caution is required in connection with prescription of psychoactive substances if adequate observation cannot be secured.

8.7 Control of treatment

All medical treatment presupposes control as to whether treatment has the desired effect. In connection with substitution treatment of drug abusers, the overall aim is to secure that substitution treatment supports the achievement of the treatment aims set for the individual drug abuser. Thus the purpose of control is primarily to secure the quality of treatment and is not directed at the drug abuser. Administration of medical treatment should, however, be organised in such a way that the risk of resale of substances prescribed is reduced to the extent possible.

8.7.1 New courses of treatment

In all new courses of treatment the prescribed substitution preparation should as a general rule be taken daily and under supervision until adjustment of an appropriate dose for the drug abuser has been achieved and the drug abuser's compliance with the treatment has been secured. The least possible amount of medicine should be dispensed for self-administration on non-working days.

8.7.2 Stable course of treatment

When treatment has been stabilised, medicine for self-administration may be dispensed. As a general rule medicine should not be dispensed for more than one week at a time and such administration must be carefully assessed in relation to the drug abuser's current capacity for self-administration. There may be exceptions to this, e.g. in connection with holidays.

Supervised taking of medicine should be resumed at any point during the course of treatment if the doctor considers this to be appropriate with a view to achieving the agreed aims of the treatment.

8.7.3 Control measures

Urinalysis and clinical assessment may be used for current assessment of whether treatment aims are achieved. Urinalysis as part of substitution treatment must be prescribed by the doctor responsible for the treatment. Concerning the use of urinalysis, cf. Chapter 10.

Substitution treatment and control may never stand alone, but must be part

of an overall treatment plan.

The character and extent of control vary and depend on the aim of the concrete treatment. The decisive element is that only such control requirements are set up as are necessary to achieve the individual treatment aims. Control measures must be adjusted according to the resources and capacity of the individual drug abuser and consideration should be paid to the drug abuser's possibilities for leading a normal life to the extent possible.

8.7.4 Discontinuation of substitution treatment

A decision to discontinue substitution treatment prematurely against the wish of the drug abuser requires careful consideration. A decision to discontinue substitution treatment prematurely because it is useless must be based on a medical assessment. Treatment should always be resumed when the drug abuser is motivated and agreement can be reached concerning a treatment plan.

Drug abusers with threatening or violent behaviour towards the staff or towards others in the treatment institution may be refused treatment. This option does, however, require cautiousness, and to the widest extent possible the drug abuser should be offered other services including services that secure continued medical treatment.

8.8 Substitution treatment and driving licence

Usually the National Board of Health recommends a one-year time limit for driving licences for motorbike, car, truck and bus without fare paying passengers (all categories including the use of trailer) for applicants who are in continued maintenance treatment with methadone if daily dose does not exceed 120 mg and under the conditions that there are no other health related indications against the issuing of a driving licence.

When assessing whether individuals are fit to have a driving licence, individuals in buprenorphine treatment will, regardless of dosage, be considered as individuals in treatment with less than 120 mg methadone.

The National Board of Health does not recommend driving licence for individuals who are treated with strong analgesics either as a suppository or via injection.

Concerning guidelines on doses of other types of strong analgesic medicine and maximum daily doses for individuals with a driving licence, cf. National Board of Health Guidance on prescription of dependence-producing pharmaceuticals (9).

The National Board of Health does not recommend driving licences for taxi and bus with fare paying passengers for persons in treatment with methadone or strong analgesics.

If in connection with his activity a doctor becomes aware of a drug abuser in substitution treatment that exposes the life or health of others to imminent danger by driving a motor vehicle while intoxicated, the doctor is under obligation to seek to avert this danger by contacting the patient or if necessary the National Board of Health medical officer, cf. Section 44 of the Authorization Act.

Concerning the general rules on dependence-producing pharmaceuticals and driving licences otherwise, cf. National Board of Health Guidance on prescription of dependence-producing pharmaceuticals (9).

9 Multiple abuse in individuals in substitution treatment for opioid dependence

9.1 Prevalence, complications etc.

When registering for treatment of opioid abuse, the greater part of drug abusers use other substances in addition to opioids. Opioid abuse is, however, often the most noticeable problem out of the total set of problems.

Concurrent abuse of 2-3 intoxicants is frequent. In connection with registration for substitution treatment for opioid abuse, concurrent abuse of cocaine, benzodiazepines and alcohol is often seen and in addition the greater part of clients abuse cannabis.

It is important that also abuse of/dependence on non-opioid intoxicants is diagnosed and is treated in a relevant manner.

Treatment of conditions involving multiple abuse is complicated, and often intensive treatment efforts are required, possibly admission as an inpatient. Often it will be appropriate to maintain substitution treatment for opioid dependence while treatment of other abuse is taken care of.

Medical substitution treatment of opioid dependence is not directly aimed at other abuse than opioid abuse. But individuals who are stabilised on an adequate dose of methadone or buprenorphine are less likely to have other abuse than individuals whose medication is inadequate.

The prevalence of multiple abuse is higher in the group of persons with psychiatric comorbidity.

In Denmark on average 2-3 substances are registered as a contributing cause of death in cases of poisoning.

9.2 Alcohol

Fatal overdoses are seen in connection with large amounts of alcohol in connection with substitution treatment for opioid abuse where the overall sedative effect is greater than when solely alcohol or methadone/buprenorphine respectively is used.

Concurrent alcohol abuse reduces compliance with substitution treatment for opioid abuse and reduces the benefits from substitution treatment.

Drug abusers in substitution treatment with concurrent alcohol abuse often abuse benzodiazepines.

Drug abusers in substitution treatment for opioid abuse with concurrent alcohol abuse have more somatic and mental health problems, they commit more crime and socially they function less well.

Alcohol abuse aggravates liver conditions caused by chronic hepatitis and complicates any antiviral treatment.

Alcohol related damage is among the main causes of the high rate of mortality found among drug abusers in substitution treatment for opioid dependence both during treatment and in connection with discharge from treatment.

9.2.1 Treatment of alcohol abuse

Alcohol abuse in persons in substitution treatment for opioid dependence must be treated in accordance with established principles and it is recommended that treatment of alcohol abuse is taken care of by the agency that is responsible for substitution treatment.

Insufficient opioid substitution treatment with inadequate dosage of methadone or buprenorphine may be a contributing cause of alcohol abuse in situations when alcohol is used for self-medication of opioid withdrawal symptoms.

If a person in substitution treatment for opioid dependence is assessed to be severely intoxicated by alcohol, methadone or buprenorphine should not be given to this person. Medication with opioids must be postponed until the person is no longer under the influence of alcohol. If this is not possible, admission for alcohol detoxification should be considered if substitution treatment for opioid dependence is to be continued.

Treatment of potential life threatening alcohol withdrawal symptoms in persons in substitution treatment for opioid dependence cannot be carried out using opioids but must follow general principles using anticonvulsants.

Ambulatory treatment of alcohol withdrawal symptoms in persons who are in substitution treatment with buprenorphine or methadone may be undertaken with Chlordiazepoxide in monitored treatment. Withdrawal symptoms should be treated effectively for 1-2 days followed by 1-2 weeks' slow

withdrawal. Dosage and duration of withdrawal are individually adjusted depending on the severity of alcohol abuse and other individual variables (weight, liver function etc.).

9.3 Benzodiazepines

Concerning general guidelines for treatment with benzodiazepine, cf. National Board of Health Guidance on prescription of dependence-producing pharmaceuticals (9).

It is not unusual for patients who are in treatment for opioid abuse to use medically prescribed benzodiazepines. Moreover benzodiazepine is a substance commonly abused. It is estimated that more than half of all drug abusers have used benzodiazepine for several years acquired either through legal prescription or on the illegal market. Usually benzodiazepines are taken by drug abusers in much larger doses than normally recommended.

It is important that the doctor who treats the patient for drug abuse also takes decisions concerning the patient's use of benzodiazepine, so that these prescriptions are not taken care of by other doctors without any relation to the drug abuse treatment.

Abuse of large doses of benzodiazepine together with opioids is related both to a high risk of unintended events, possibly fatal accidents, as well as to serious cases of poisoning, possibly fatal overdoses, because of sedation and respiratory depression. This also occurs in persons who are being treated for drug abuse with opioids and who have otherwise developed tolerance of the respiratory depressive effect of opioids.

Treatment of benzodiazepine poisoning may be provided through intravenous administration of the specific benzodiazepine antagonist flumazenil. Abuse of large doses of benzodiazepine considerably complicates compliance with substitution treatment for opioid dependence.

In principle benzodiazepine should not be prescribed for drug abusers because of the dependence potential and the negative effect on cognitive functions which weaken the outcome of psychosocial treatment. If in exceptional cases there is indication for such treatment, the doctor should always carefully consider advantages and disadvantages of the treatment, and indications and considerations must be recorded. Initiation of treatment with benzodiazepine should normally only take place in connection with personal consultation. An exception to this principle is acute treatment of withdrawal convulsions.

The most suitable benzodiazepine for treatment of drug abusers is characterised by slow absorption, low lipophilicity and a long half-life and it is without any accumulation of pharmacologically active metabolites. Clonazepam for instance distinguishes itself by meeting the above criteria and should therefore be chosen if treatment with benzodiazepine is unavoidable. Prescription must be limited to maximum 4 weeks.

Drug abusers should not be given long term treatment (more than a few weeks) with benzodiazepine. The recommended doses for short term treatment should not be considerably exceeded.

Generalised anxiety, panic disorder and anxiety related to posttraumatic stress-syndrome, (PTSD) are primarily treated with antidepressives.

Benzodiazepine should be avoided altogether in the treatment of sleep problems in drug abusers. Alternatively a high-dose antipsychotic may be chosen for night treatment, possibly a benzodiazepine analogue from the cyclopyrrolon group (zolpidem, zopiclon, zaleplon) for 1–2 weeks.

9.3.1 Treatment of benzodiazepine withdrawal symptoms

If a person has taken benzodiazepines only for a period of 4 to 6 weeks, discontinuation may be undertaken over a few days.

For drug abusers who have developed physical dependence after abuse of benzodiazepine over a long period of time, slow withdrawal should be undertaken with a benzodiazepine preparation with a long half-life (e.g. Chlordiazepoxide). A dose corresponding to diazepam 30 mg effectively prevents withdrawal convulsions regardless of the person's current use of benzodiazepine. The daily dose is reduced by 10–20 % at intervals of 1–2 weeks. Controlled administration should be aimed for. Too quick withdrawal may result in unpleasant withdrawal symptoms. The pace of slow withdrawal is an individual issue, but it may be appropriate to stretch this period over several months. The decisive thing is that withdrawal progresses. If the patient arrives at a difficult point, the same dose may be maintained for a couple of weeks, but in so far as this is possible, a dose increase should be avoided. If sleep problems occur during withdrawal, there should be no medication with any type of benzodiazepine or cyclopyrrolon.

9.4 Cocaine and cannabis

Concurrent abuse of cocaine and/or cannabis in persons in substitution treatment for opioid dependence considerably complicates compliance with treatment. Concerning the specific intoxicating and harmful effects of the substances see Chapter 7.

There is no specific medical treatment for neither cocaine nor cannabis but only symptomatic medical treatment. Concerning various psychotherapeutic methods that have been found useful in the treatment of cocaine and cannabis abuse, reference is made to the specific literature on this.

A certain reduction over time of concurrent cocaine abuse is often seen in connection with a comprehensive treatment for opioid dependence.

Often there is little focus on concurrent cannabis abuse in connection with treatment although the consequences of extensive and long term cannabis abuse contribute to reduced effect of substitution treatment for opioid dependence. Attention should also be paid to the fact that cannabis may be used for self-medication of anxiety or depressive conditions that would benefit from regular psychotherapeutic or pharmacological methods.

10 Use of urinalyses for euphoriant substances and medicine in connection with treatment of opioid abuse/dependence

Urinalyses may be used as part of substitution treatment for diagnostic purposes or for assessment of ongoing treatment. Urinalyses must be ordered by the doctor in charge of treatment or by an individual that the doctor has authorised to do this.

If urinalyses are part of diagnostics or treatment, a doctor must assess the result in relation to information on consumption of intoxicants and medicine, available medical information and the method used.

The doctor must inform the patient of the purpose of the urinalysis. The patient must be told that the result of urinalysis cannot lead to any sanctions in the form of discharge from treatment.

If the patient does not want to provide a urine sample, this should not prevent the patient from receiving treatment, but in order to secure proper treatment in these cases, the doctor must organise treatment taking into account the missing information.

The result of urinalyses is covered by the provisions of the Health Care Services Act on confidentiality and disclosure and obtaining of health information and other confidential information in connection with the treatment of patients.

Concerning further details on indication, analysis methods and use etc., see Annex 5.

11 Prevention of unwanted pregnancy

The municipal treatment institutions for drug abuse must secure that a systematic effort is made in this area so that counselling and provision of contraception are included in the medical part of drug abuse treatment.

When registering a female drug abuser for treatment, the doctor in the municipal drug abuse treatment system must take a gynaecological history and assess status for contraception. If there is a need for contraception, the doctor must secure that the woman gets the necessary counselling and is offered contraception. There should be a regular follow-up of this.

Principles for choice of contraceptive method:

- A bilateral contraceptive effort is recommended through which women are protected both against pregnancy and venereal diseases through
 - A method with a long term effect that does not depend on intercourse: implant, injection, intrauterine device
- and*
- condom when with a new partner for protection against venereal diseases.

The doctor in the municipal drug abuse treatment system should advise female drug abusers on easy access to pregnancy testing and emergency contraception (“morning-after-pill”).

Sterilisation should be discussed with women over 25 who already have the number of children that they want and with women who have long term and severe abuse problems and who are severely vulnerable with regard to health and mental and social problems.

When female drug abusers are admitted to gynaecological and obstetric departments, e.g. in connection with induced abortion

- the doctor in the municipal drug abuse treatment system or the general practitioner should secure, with the woman’s consent, that the specialised hospital department is informed of any need to initiate contraception in connection with admission, and
- the doctor in the gynaecological and obstetric department must secure that the woman has been advised on contraception and must aim to secure the establishing of contraception prior to discharge.

12 Treatment of pregnant drug abusers

The National Board of Health guidelines for antenatal care (17) establish that specifically targeted prevention and treatment must be provided for pregnant women whose living conditions or life style involve specific risks for mother and/or child. The group of pregnant women with special needs includes among others:

- Pregnant women with use/abuse of intoxicants
- Pregnant women with mental disease or who are mentally vulnerable
- Pregnant women who are severely vulnerable from a social point of view.

12.1 Early contact, referral to specialised hospital department

It is important as early as possible to secure speedy, possibly acute, contact between a pregnant drug abuser and an obstetric hospital department affiliated to a neonatal department that can assess the need for treatment (possibly treatment as an inpatient) and relief measures. Often a pregnant drug abuser finds it difficult on her own initiative to use the ordinary prophylactic services within antenatal care and thus has neither seen her general practitioner nor been to a pregnancy examination at a midwifery centre or contacted a hospital.

As this is a high risk group with poor living conditions and a varying degree of motivation to seek treatment,

- any doctor who treats a pregnant drug abuser must secure that contact to a specialised obstetric department has been established or take steps to establish this contact, and
- any doctor may directly refer a pregnant drug abuser to assessment at an obstetric hospital department.

12.2 Abortion counselling

When the first interview takes place at an early stage of pregnancy, the pregnant drug abuser should be advised on the possibilities of abortion. At the same time the woman must be informed of available opportunities for support during pregnancy and for support after giving birth, cf. Section 100,

Subsection 2 of the Health Care Services Act. Until the twelfth week of pregnancy the woman may choose to have an abortion, cf. Section 92 of the Health Care Services Act. If the pregnant woman has exceeded the twelfth week, she must be informed of the opportunities for applying to the regional joint council on abortion for permission to have a late abortion, cf. Chapter 25 of the Health Care Services Act. As early as possible the pregnant drug abuser should be referred to a specialised hospital department with a view to counselling on any need for supplementing examinations, i. e. risk assessment and foetal diagnostics as well as screening for infectious diseases. The woman may have a need for further counselling before she is ready to decide whether she will go through with the pregnancy or have an abortion. The woman must also be informed of cooperation with the social authorities, confidentiality, communication and notification obligations, cf. Section 100 of the Health Care Services Act.

If the woman decides to have an abortion, the hospital department must make sure that the woman has been informed of the services in the municipal drug abuse treatment system with a view to follow-up treatment after discharge. The various possibilities of contraception are discussed with the woman prior to intervention so that, to the extent possible, contraception has been established before discharge from hospital.

12.3 Cross-sectoral and multidisciplinary antenatal care

In connection with referral of the pregnant drug abuser to the obstetric hospital department, responsibility for continued coordination of cross sectoral and multidisciplinary antenatal care is placed within the framework of the obstetric department. In cooperation with the obstetric hospital department the municipal drug abuse treatment system may take care of drug abuse treatment of the pregnant drug abuser including substitution treatment.

Compared to ordinary antenatal control, a pregnant drug abuser is seen more often for control:

- Pregnant drug abusers in stable treatment including stable substitution treatment in the municipal drug abuse treatment system are usually seen for obstetric control every 2 to 3 weeks until the 35th or the 36th week of their pregnancy and from then on they are seen every week.
- A pregnant drug abuser with an unstable abuse pattern and unstable contact to the municipal drug abuse treatment system is invited to accept admission to an obstetric department, and if this proposal is turned down, she will usually be seen for obstetric control every 1 to 2 weeks until the 35th or the 36th week and from then on every week.
- Treatment is, furthermore, always provided on the basis of individual assessment.

12.4 Substitution treatment of opioid dependent women during pregnancy and confinement

Treatment of opioid dependence in pregnant women should be undertaken in cooperation with an obstetric hospital department. Initiation of methadone treatment of a pregnant opioid abuser must always involve consultation with a specialised obstetric hospital department.

Initiation of substitution treatment should, to the extent possible, be undertaken during admission in an obstetric hospital department that is responsible for substitution treatment during pregnancy. If the pregnant woman in substitution treatment is then seen on an outpatient basis, the doctor in the municipal treatment system may take care of substitution treatment in cooperation with the obstetric hospital department.

If the doctor in the municipal drug abuse treatment system finds indication for initiation of substitution treatment in the municipal system, this must always be undertaken in consultation with the specialised obstetric hospital department.

Continuation of substitution treatment initiated prior to pregnancy must also be taken care of in cooperation with the specialised hospital department.

If the doctor in the municipal drug abuse treatment system finds indication for changes in the medical part of substitution treatment (e.g. withdrawal, phasing out or other dosage change), this must always be conferred with the obstetric hospital department.

When initiating substitution treatment of a pregnant woman who has not been in substitution treatment during pregnancy, methadone is recommended as the first-line preparation.

It is important that the pregnant opioid abuser is stabilised as soon as possible on methadone, either with a view to dose reduction/detoxification during pregnancy or with a view to stabilisation on methadone throughout pregnancy.

Pregnant women who were in stable substitution treatment with buprenorphine when becoming pregnant, should be recommended to continue this treatment during their pregnancy.

For further description of substitution treatment of pregnant women with opioid dependence, cf. Annex 6

12.5 Treatment of pregnant women with alcohol and benzodiazepine withdrawal symptoms

Treatment of alcohol and benzodiazepine withdrawal symptoms in pregnant women must be undertaken in cooperation with an obstetric hospital department, preferably during hospital admission.

12.6 Legal basis, confidentiality, notification obligations etc.

The legal basis and the most significant rules a doctor or other health care person must be aware of when having a pregnant drug abuser as a patient are briefly described in the following.

12.6.1 The Health Care Services Act

Antenatal care is regulated by the Health Care Services Act (Act no. 95546 of 24 June 2007), in which access to services in the health care sector in connection with pregnancy are regulated.

The Executive Order on preventive health care services for children and young people (18) lays down that the municipal council may decide that pregnant women with special needs should be offered special services including additional counselling, assistance and possibly further examination by a doctor or health visitor. It follows from this that there is a possibility of providing for antenatal home visits by a health visitor and for strengthened cooperation between midwife, doctor and health visitor for pregnant women with special needs.

12.6.2 The legal status of pregnant drug abusers

Assistance to a pregnant woman must be based on the pregnant woman's wishes and needs and her right of self-determination must be respected, cf. Chapter 2.

As a general rule the pregnant drug abuser gives tacit consent when she visits a clinic for antenatal examination. If the pregnant woman does not want to take part in antenatal examination, this is an expression of her right of self-determination. Pursuant to the legislation in force consideration for the unborn child cannot lead to forced treatment.

Only when the initiatives of the health care staff in connection with antenatal care have not resulted in cooperation being established with the pregnant drug abuser, may reporting to the social authorities be relevant according to the Social Services Act.

12.6.3 Confidentiality and notification obligation

Health care staff play a central role in relation to protection of the unborn child. Often lack of awareness of rules pertaining to notification and communication of information may act as a barrier against their use. When a doctor or another professional is in doubt as to whether he or she may or has to communicate information about the conditions of a pregnant drug abuser, the consequence may be that this is not done - out of fear of violating confidentiality rules or because of misplaced regard for the pregnant woman. The result may be that the pregnant woman and thus the unborn child do not get necessary help in due time.

The rules on confidentiality are set aside for a health care person in cases when a health care person is under a notification obligation. Such an obligation is laid down in the Section 153 Subsections 1-3 of the Social Services Act. Pursuant to this provision an Order has been issued on notification obligations vis-à-vis the municipal authorities (19).

According to this order the following persons are under obligation to notify the municipal authorities when as part of their activity they acquire knowledge of conditions pertaining to a child or a young person under 18 that may lead to the presumption that the child or the young person in question needs special support or when in connection with their activity they acquire knowledge of expectant parents with problems that lead to the presumption that the child will need special support immediately after birth:

- Public sector staff and others that work for the public sector.
- Doctors who are not covered by a) above.

There is also a notification obligation when conditions pertaining to expectant parents lead to the presumption that after birth the child will have difficulties in relation to its everyday environment or otherwise be living under unsatisfactory conditions.

The notification obligation applies when there is no reasonable possibility to remedy the difficulties in due time through one's own activity, including through counselling of and advice to the parents.

12.7 Other provisions

12.7.1 Special support for expectant parents

If it is assumed that special support for a child is needed immediately after birth or if the expectant parents' conditions give rise to worries with the regard to the unborn child, the municipality must in detail examine the conditions of the expectant parents in consideration of the need for early and

targeted initiatives (20). Decisions in this regard must be taken with the parents' consent.

During a pregnancy the municipal council must decide on the initiation of assistance measures (e.g. counselling, support in the home, relief arrangements, institutional care) when this is regarded to be decisive out of regard for the child's special needs for support after birth (21). Decisions in this regard must be taken with the parents' consent.

In addition to children and adolescents the municipality's supervision obligation also includes expectant parents.

12.7.2 The right of pregnant drug abusers to be offered a contract on treatment of drug abuse with the possibility of being detained in treatment

Pursuant to legal provisions on the detaining of drug abusers in treatment (22), the municipal council must offer a pregnant drug abuser who is receiving institutional treatment pursuant to the Social Services Act (23) the possibility of entering into a contract on treatment involving the possibility of detainment. The pregnant drug abuser is free to decide whether she wants to enter into a contract on treatment involving the possibility of detainment at the place of treatment. In principle institutional treatment (live-in care) is provided in an open treatment environment, and the measures that can be used in connection with the initiation and upholding of detainment must be adapted to relevant conditions. Solitary confinement in a locked room, whether for a short time or a long time, is not allowed.

Coercion must be adapted to the individual situation and must not exceed what is strictly necessary. Physical coercion is allowed to the extent that this is required in order to prevent the drug abuser from exposing him or herself or others to imminent danger or physical or mental harm. By physical coercion is understood for instance physical restriction of an individual. Solitary confinement, by which is understood confinement in a locked room whether for a short or a long period, is not allowed, neither is immobilisation. By immobilisation is understood the use of mechanical means of restraint in the form of belts, straps, straitjacket or other type of mechanical immobilisation.

A contract on treatment with the possibility of detainment of the pregnant drug abuser may be entered into for a period not exceeding 6 months from the time of its being concluded.

The pregnant drug abuser may, however, at any time revoke a contract on treatment with the possibility of detainment, though detainment may be

practiced, cf. especially Section 5 in the Consolidated Act (22) when there is reason to assume that the pregnant drug abuser is going to break off the agreed treatment and it would be unjustifiable not to detain the person in question because

- the prospect of ceasing abuse or of a considerable and decisive improvement of the condition otherwise would be considerably weakened, or
- the drug abuser exposes himself or herself or others to imminent danger.

Detainment may only occur if gentler measures are insufficient.

Detainment must cease when the above conditions no longer apply. The individual case of detainment may not exceed 2 weeks from the time the decision is taken, and the total period of detainment may not exceed 2 months within a period of 6 months.

Decisions on detainment and its discontinuation are taken by the leader of the treatment institution.

For drug abusers other than pregnant drug abusers, the municipal council must decide whether the municipality is to make use of the provisions of this act (22). So far there have been no instances of concrete use of treatment contracts with the possibility of detainment although a few municipalities have decided that in principle the act should be made use of.

13 Repeal of legal provisions

The National Board of Health Guidance no. 9710 of 25 July 2006 on the use of injectable methadone for drug abuse treatment is repealed as well as Guidance no. 9881 of 8 June 2007 on prescription of dependence-producing pharmaceuticals and substitution treatment of persons with opioid dependence Chapter 7.

14 Coming into force

This Guidance comes into force on July 1st 2008.

National Board of Health, July 1st 2008

Anne Mette Dons

Helle Petersen

15 References

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2. Executive Order no. 1373 of 12 December 2006 on patient records kept by doctors, dentists, chiropractors, midwives, clinical dieticians, clinical dental technicians, opticians and contact lens opticians (keeping, storage, disclosure and transfer etc.)
3. The Health Care Services Act, Consolidated Act no. 95 of 7 February 2008
4. Act on Authorization of Health Care Professionals and on Professional Health Care Practice, Act no. 451 of 22 May 2006
5. The Social Services Act, Consolidated Act no. 1117 of 26 September 2007
6. Consolidation Act on Legal Protection and Administration in Social Matters, Consolidated Act no. 1047 of 27 August 2007
7. National Board of Health Guidance no 9429 on Prescription and Handling of Pharmaceuticals of 30 June 2006
8. National Board of Health Guidance no.9229 of 25 April 2005 on nursing records
9. National Board of Health Guidance no.38 on prescription of dependence-producing pharmaceuticals of 18 June 2008
10. National Board of Health Guidance no. 11053 on Diagnosing and Treatment of Sexually Transmissible Diseases, 1 April 1999
11. National Board of Health Guidance on prevention of viral hepatitis, June 2002
12. National Board of Health Guidance on Human Immuno Deficiency Virus HIV and Prevention of Blood-Borne Infection, October 1992
13. National Board of Health National Action Plan for the Prevention of Hepatitis C among Drug abusers, August 2007
14. National Board of Health Guidance no.11053 on Diagnosing and Treatment of Sexually Transmissible Diseases, 1 April 1999
15. Ministry of the Interior and Health Order no. 746 of 29 June 2006 on Hepatitis Vaccination free of charge for Specially Exposed Groups
16. Order no. 1102 of 20 September 2007 on Doctors' Notification of Infectious Diseases etc

17. National Board of Health, 1 July 1998: Maternity Care: Guidelines and status. Health care services in connection with pregnancy, child-birth and maternity
18. Order on Preventive Health Care for Children and Adolescents, no. 1183 of 28 November 2006
19. Order no.1336 on Notification Obligations vis-à-vis the Municipality pursuant to the Social Services Act, 30 November 2007
20. The Social Services Act, Consolidated Act no.1117 of 26 September 2007, Section 50, 10
21. The Social Services Act, Consolidated Act 1117 of 26 September 2007, Section 52, 6
22. Act on Retention of Drug abusers in Treatment no.190 of 27 February 2007, Section 1, 1 as amended by Act no. 542 of 6 June 2007
23. The Social Services Act, Consolidated Act no. 1117 of 26 September 2007, Section 107, 2, 2
24. National Board of Health: “Counselling of individuals found to be infected with HIV on health promotion and prevention of infection. Advice to health care persons.” September 2007

1. Annex to Chapter 4

1. Diagnoses

According to the WHO ICD-10 criteria for classification and diagnosis the most significant mental diseases or behavioural disorders caused by intoxicants are covered by an overall diagnostic demarcation and grouped according to the individual intoxicant and with regard to harmful use, dependence syndromes and unspecified mental disease or behavioural disorder.

Table 1: Basis of diagnoses

| Diagnosis (ICD-10) | Description |
|--------------------|--|
| F10.1 | Harmful use of alcohol |
| F10.2 | Dependence syndrome resulting from alcohol |
| F10.9 | Unspecified mental disease and behavioural disorders resulting from alcohol |
| F11.1 | Harmful use of opioids |
| F11.2 | Dependence syndrome resulting from opioids |
| F11.9 | Unspecified mental disease and behavioural disorders resulting from opioid abuse |
| F12.1 | Harmful use of cannabis |
| F12.2 | Dependence syndrome resulting from cannabis |
| F12.9 | Unspecified mental disease and behavioural disorders resulting from cannabis |
| F13.1 | Harmful use of sedatives or hypnotics |
| F13.2 | Dependence syndrome resulting from sedatives or hypnotics |
| F13.9 | Unspecified mental disease and behavioural disorders resulting from sedatives or hypnotics |

| | |
|-------|--|
| F14.1 | Harmful use of cocaine |
| F14.2 | Dependence syndrome resulting from cocaine |
| F14.9 | Unspecified mental disease and behavioural disorders resulting from cocaine |
| <hr/> | |
| F15.1 | Harmful use of central stimulants |
| F15.2 | Dependence syndrome resulting from central stimulants |
| F15.9 | Unspecified mental disease and behavioural disorders resulting from central stimulants |

For further details, cf. Annex 1 and the WHO ICD-10 classification.

2. Annex to Chapter 5

2.1 Introduction

Drug abusers have increased somatic morbidity which is caused especially by intravenous abuse, but lack of care for own health and life style diseases are contributing factors.

General knowledge on concomitant diseases and injuries due to drug abuse is scarce among drug abusers. Most often medical treatment is only sought in connection with severe acute disease. Often drug abusers will have untreated diseases for a long time, and insufficiently treated chronic diseases are often seen. The health problems that follow from drug abuse lead to a great number of hospital admissions and emergency room visits. They also result in many cases of disability pension and are a contributing cause of increased mortality among drug abusers.

2.2 Diseases that are especially frequent among intravenous drug abusers

Many diseases that drug abusers contract are caused by non-sterile and technically inadequate intravenous administration of the substances used. Other frequently occurring diseases are related to the special life style that is often seen in connection with active drug abuse.

Table 2: Frequent disease conditions among drug abusers

| Injection related diseases | Life style diseases |
|---|--|
| Local infections in and around the site of injection | Dental diseases |
| <i>Cellulitis, abscess</i> | COPD, pneumonia, (TB) |
| <i>Erysipelas</i> | Traumas |
| Systemic infections | Gynaecological infections and/or sexually transmissible infections |
| <i>Bacterial</i> | |
| <ul style="list-style-type: none">• Bacteraemia/sepsis• Endocarditis | |

| | |
|--|--|
| <ul style="list-style-type: none"> • Organ abscesses <p><i>Viral</i></p> <ul style="list-style-type: none"> • Hepatitis • HIV <p>Vascular lesions</p> <p><i>Deep venous thrombosis</i></p> <ul style="list-style-type: none"> • Post-thrombotic syndrome • Chronic leg ulcers | |
|--|--|

2.3 Injection related diseases

2.3.1 Local infections at or around the area of injection

A light flush is often seen around the area of injection which does not in itself require treatment, but if there is any sign of phlegmonous spread, antibiotics treatment should be initiated to reduce the risk of further spreading of infection or abscess formation. The bacteria most frequently seen are streptococcus and staphylococcus. Development of erysipelas is often seen. As for choice of antibiotic, an easily applicable dosage regimen should be selected with a view to minimising compliance problems.

Abscesses are treated according to ordinary guidelines with incision, possibly under antibiotics cover.

When treating ulcers and injection injuries it is important to consider status for tetanus cover.

2.3.2 Systemic infections

Bacterial

In connection with non-sterile injection naturally occurring skin bacteria are spread via the blood stream and infection may occur in all organs. The most frequent places are cardiac valves, lungs and bones, but infections in the central nervous system and in the kidneys are also seen. Many of these infections follow a slow course of development and clinical manifestations may be scarce.

Intravenous drug abusers have increased risk of heart valve infection *and* consequences thereof in the form of damaged heart valves. Symptoms such as continuing subfebrilia, tiredness and general weakening should lead to suspicion of endocarditis. If the drug abuser has had endocarditis earlier or has undergone heart valve surgery, the risk of renewed infection is big other things being equal. Treatment requires hospital admission for 4 to 6 weeks in connection with parenteral antibiotic therapy. In connection with dental treatment, abusers who have had endocarditis and/or have undergone heart valve surgery should be given prophylactic antibiotics.

Viral

Concerning hepatitis and HIV, see Annex 3.

2.3.3 Vascular lesions etc.

Injection of substances involves a great risk of tissue damage in and around the veins used. Often the abused substances have not been produced for intravenous use or impurities have been added in connection with the abuser's preparation of the substance for injection, which may lead to tissue damage. Long term intravenous abuse reduces the number of usable veins, and often the drug abuser will have to use big veins in the groin or in the neck. Attention should also be paid to damage of vessels, nerves or tendons in connection with paravenous administration which often happens to inexperienced intravenous abusers or to intravenous abusers with long term and large scale intravenous abuse.

Drug abusers have a great risk of thrombophlebitis in the deep veins. It is difficult to establish the diagnosis, but whenever there is swelling of leg/arm, deep venous thrombosis should be considered, and if a suspicion of deep venous thrombosis is maintained, the patient must be referred to a hospital for examination. If diagnosis is established in time, treatment with anticoagulants may reduce the risk of pulmonary embolus or chronic circulatory disturbance. Oral anticoagulant treatment of drug abusers frequently involves compliance problems leading to considerable risk of bleeding complication as a result of overdose and inadequate handling of the anticoagulants.

Post-thrombotic syndrome is frequent in intravenous abusers and is characterised by chronic oedema and possibly pain and brown pigmentation of the leg. Because of the oedema, skin circulation is compromised and even commonplace minor scratches may develop into big leg ulcers that require treatment over long time. Often the condition is complicated by erysipelas. Drug abusers with compromised venous circulation in the legs should be recommended permanent use of compression stockings in order to reduce the risk of developing chronic leg ulcers.

More *indirect* tissue damage may result from unintended compression of peripheral cells and nerves which may occur in connection with strongly sedative intoxication if for instance the intoxicated drug abuser falls profoundly asleep and compromises blood supply for instance to an extremity. Paralysis of the innervation area of the compromised nerve may occur in this way, e.g. as a "drop hand" or "drop foot". Treatment is temporary support bandage and intensive physiotherapy. Total restitution is often achieved but frequently there are also consequences in the form of loss of sensibility, asynergy and contractures.

2.4 Life style diseases

2.4.1 Chronic obstructive pulmonary disease (COPD)

Smoking of tobacco and cannabis is widespread among drug abusers and many also relatively young drug abusers have chronic obstructive pulmonary disease (COPD) in an advanced stage. Exacerbations and pneumonia are often seen. Prior to prescription of inhalation steroids or systemic steroid treatment in cases of COPD, the possibility of tuberculosis should be ruled out.

2.4.2 Tuberculosis

Coughing, weight loss, fever and possibly night sweats should lead to suspicion of tuberculosis. Patients that do not respond to ordinary antibiotics treatment of pneumonia should be conferred with a pulmonary/-infection department. X-ray examination of thorax should be undertaken on the basis of wide indications. Extrapulmonary tuberculosis should be considered in the case of weight loss or long term symptoms of general weakening especially in patients with immune depression. In connection with anti tuberculosis treatment attention should be paid to the frequently occurring compliance problems.

2.4.3 Dental diseases

Often a drug abuser's health and quality of life is reduced because of the person's dental state. At an early point attention should be drawn to the fact that caries, parodontosis and dental traumas are widespread among drug abusers. Cooperation with dentists should be given some priority as part of health care provision for drug abusers.

It is often difficult for drug abusers to eat normal food because of chewing problems either resulting from lacking teeth or toothache. Special food habits involving increased consumption of sugar are frequent. Dental hygiene is often inadequate. Opiates and certain psychotropic drugs reduce saliva secretion which further increases the risk of dental diseases.

Pain in the teeth may lead to added drug abuse or may start during withdrawal. Damaged teeth may be the starting point of infections with a risk among other things of developing endocarditis.

3. Annex to chapter 6

3.1 Hepatitis A, hepatitis B, hepatitis C and human immunodeficiency virus (HIV)

Drug abusers are to a wide extent infected with the blood-borne viral diseases hepatitis B, hepatitis C and HIV, and they are infected at an early stage of intravenous drug abuse.

Intravenous abusers who state that they have never shared syringes/needles with others are infected to the same extent as others and infections are also found among those who state that they have never engaged in intravenous abuse.

The incidence of HIV antibody positive drug abusers is falling and it is low, which is probably due to limitation of risk behaviour. But drug abusers still get infected and the limitation of risk behaviour that has resulted in reduced HIV incidence has not been sufficient to reduce the high incidence of hepatitis B and C. Drug abusers are infected with hepatitis C at a very early point in their abuse careers and a little later with hepatitis B so that in the course of ten years almost all of them are infected with HCV, HBV or HIV.

The high incidence of hepatitis C is especially disturbing, and after few years' intravenous abuse there is a prevalence of about 70-80 per cent. At least two thirds develop chronic infection and may thus pass on infection. Chronic infection leads to a risk of chronic hepatitis with a risk of cirrhosis and a further risk of developing liver cancer.

Especially hepatitis C is a severe threat to the drug abuser's health and is a contributing factor to a situation where more and more drug abusers no longer die from overdoses, but along with an increase of their average age they die from disease.

The great number of undiagnosed drug abusers, the seriousness of the diseases and the fact that now there are reasonable treatment opportunities mean that a targeted and systematic effort to uncover the patients' infection status is important, partly to curb infection, but also in order to be able to initiate relevant treatment.

Experience shows that handling of viral infection in drug abusers is difficult both because of the relatively high complexity of these diseases but also because of the complex problems of the drug abusers and not least because of great differences in the professional background of the doctors that take care of drug abuse treatment . In order to facilitate medical efforts in municipal drug abuse treatment and also in general practice, and in order to strengthen cooperation with hospital infection departments, this chapter includes a further description of conditions relating to viral infections in drug abusers:

- An overview of prevalence, infection risk and routes of infection, course of disease, diagnostics and treatment of hepatitis A, B and C as well as HIV in drug abusers
- Guidance on vaccination against hepatitis A and hepatitis B
- Examination programmes concerning the blood samples to be taken and the interpretation of results
- Check list for counselling of drug abusers on transmission of infection and measures to be taken in case of hepatitis B and C as well as HIV
- Guidance on tracking of infection and prophylaxis after exposure to infection risk

Concerning the nomenclature used, see the list in Section 3.9 of the present Annex.

3.2 Overview of prevalence, infection risk and modes of transmission, course of disease, diagnostics and treatment of hepatitis A, B and C and HIV in drug abusers

3.2.1 Hepatitis A, B and C

Acute viral hepatitis:

Clinically many cases of acute hepatitis are asymptomatic or only associated with mild general symptoms that do not immediately lead to suspicion of liver disease. Hepatitis C (HCV) infections are more often asymptomatic than hepatitis A (HAV) or hepatitis B (HBV) infection. Classical manifestation is jaundice preceded by days or weeks of prodromal symptoms in the form of a general feeling of illness, tiredness, muscle pain, nausea, loathing of food, pain below the right costal margin and vomiting. There is little or no fever in the icteric phase. Over some days the clinical condition usually improves but full recovery may take months.

Diagnosis of acute hepatitis:

- HAV infection: Positive anti-HAV IgM
- HBV infection: Positive HBsAg and/or positive anti-HBcIgM
- HCV infection: Positive HCV-RNA and negative anti-HCV

Complications:

- Development of chronic hepatitis.
- Fulminant viral hepatitis. Seen in less than 1 per cent. Defined as liver deficiency with encephalopathy that occurred within 8 weeks of the onset of the icteric phase of the disease. The first symptoms of liver insufficiency are often lethargy, confusion, behavioural change.

Chronic viral hepatitis:

Chronic viral hepatitis is defined as infection with HBV or HCV for more than 6 months. Hepatitis D virus (HDV) infection may occur at the same time as or in connection with already established chronic HBV infection, but this is very rarely seen in Denmark. Hepatitis A does not develop into chronic hepatitis

Symptoms:

Most patients with chronic viral hepatitis have few or very unspecific symptoms until possible development of liver cirrhosis or hepatocellular carcinoma. Therefore the diagnosis is often made at random when blood samples show heightened transaminases or when persons in risk groups undergo serological examination.

Diagnosis of chronic hepatitis:

> 6 months:

- HBV infection: Positive HBsAg and positive anti-HBc IgG
- HCV infection: Positive HCV RNA and positive anti-HCV

3.2.2 Hepatitis A

Prevalence

In Denmark hepatitis A mainly occurs when infection has been imported from endemic areas and the greater part of patients notified as having hepatitis A are believed to have been infected while travelling abroad.

About 10 per cent of hepatitis A cases in Denmark are seen among intravenous drug abusers among whom outbreaks have also been seen.

Infection risk and modes of transmission

Infection is primarily transmitted faeco-orally and occurrence therefore depends on hygienic standards. Infection most often occurs through water and food that has not been sufficiently heat-treated but may also occur through direct contact with an infected person. Transmission may also be blood-borne though this is rare. Sexually transmitted infection is seldom seen in Denmark but is known from outbreaks both in this country and abroad. The risk of infection is biggest when there is close contact and is increased if hygienic conditions are poor.

Course of disease

Incubation period: 2-6 weeks

Clinically it is not possible to distinguish between hepatitis A and other types of hepatitis. Clinically acute hepatitis is seen in more than 50 per cent of infected persons. Hepatitis A seems to follow a more severe course in patients with chronic HCV infection. Hepatitis A is almost always fully cured and does not lead to chronic infection. A fulminating course is seldom seen.

Diagnostics

Table 3: HAV

| Clinical issue | Test | Result | Interpretation |
|--------------------------------|--------------|--------|---|
| Suspicion of acute hepatitis A | Anti-HAV IgM | Pos | Acute hepatitis A |
| | | Neg | Non-acute hepatitis A |
| Examination of HAV immunity | Anti-HAV IgG | Pos | Hepatitis A immune |
| | | Neg | Hepatitis A susceptible Indication for vaccination |

Treatment

No specific treatment. Nutrition and time in bed according to the patient's needs. Abstention from alcohol in the acute phase is recommended. There is no evidence to support strict prohibition of alcohol in the months following recovery from disease.

Vaccination

Hepatitis A vaccination: Havrix®, may be requested from Statens Serum Institut Administration: 1 ml intramuscular in musculus deltoideus.

Immunity commences 1-2 weeks after the first vaccination dose and lasts at least 12 months.

Through vaccination 6 to 12 months after first dose, immunity will be achieved for 20 years or maybe longer.

If there is also a need for hepatitis B vaccination, the following preparation should be used:

Combined Hepatitis A + B vaccination: Twinrix®: see Section 3.3

Prevention

Stressing the importance of washing one's hands before eating and before

preparing food as well as after going to the lavatory and to the extent possible sterile conditions in connection with intravenous drug abuse.

3.2.3 Hepatitis B

Prevalence

Earlier this disease primarily occurred in Denmark as sexually transmitted infection especially among men who have sex with men. Since the 1990s it has predominantly been among intravenous drug abusers that infection has been established, but sexual transmission does account for a considerable proportion. About 100 cases of acute hepatitis B are notified in Denmark every year.

The number of persons with chronic hepatitis B in Denmark is estimated at about 15,000. Chronic hepatitis B is most frequently seen among immigrants from endemic areas primarily South Eastern Asia and Africa, among intravenous drug abusers, among men who have sex with men and among persons with multiple heterosexual partners.

Among intravenous drug abusers in treatment in Denmark recent studies have found the prevalence to be 43 to 64 per cent.

Modes of transmission and infection risk

In an infected person the presence of HBV may be established in blood, semen and other secretions. Hepatitis B virus is primarily transmitted parenterally via blood, through intravenous abuse, needle stick accidents, unprotected sex, and vertically from mother to child during delivery or horizontally during childhood probably through skin scratches.

Nose secretion, sweat, tears, urine, faeces and vomit are ordinarily not considered infectious unless visible blood is involved.

There is a risk of infection via toothbrushes, shaving equipment, feeding bottles, toys etc. when there is contact with the blood stream or mucous membranes.

Course of the disease

A great part of the primary HBV infections are asymptomatic or show few symptoms. Icterus is seen in about one third of cases.

In most cases of acute hepatitis B the symptoms are the same as the symptoms of hepatitis A. In rare cases there may be a long phase of prodromal symptoms characterised by arthralgia, fever and rash.

The course of acute hepatitis B is more serious than the course of acute

hepatitis A in that about 0.5 per cent develop fulminating liver insufficiency. In cases of chronic hepatitis B there are usually no specific symptoms until the possible development of complications in the form of cirrhosis and possibly hepatocellular carcinoma.

Among immuno competent young adults with acute hepatitis B the risk of developing chronic infection is on average 3-5 per cent. Among HIV infected persons the risk is described as being 20-40 per cent before introduction of antiretroviral treatment and 7 percent after.

The course of a case of chronic HBV infection may be divided into four phases which can be seen in the table below:

Table 4: Chronic HBV

1st phase, immuno tolerance-phase: The patient is HBsAg and HBeAg positive with pronounced viraemia, i.e. a high level of HBV-DNA in blood, but without biochemical (normal ALAT) and histological disease activity. The condition is highly infectious.

2nd phase, immuno reaction-phase: There is immunological response but not always enough to keep the infection down. The patient is HBsAg and HBeAg positive with moderate viraemia, and there are signs of biochemical and histological activity. The condition is highly infectious.

3rd phase, the inactive phase: The immunological response has meant that full or part control of infection has been achieved. The patient is still HBsAg positive but has formed antibodies against HBeAg (seroconversion from HBeAg to anti-HBe) and there is low viraemia (HBV-DNA < 10⁶ copies/ml). There are no signs of biochemical or histological activity. The condition is only slightly infectious.

4th phase, the immune phase: Few patients enter this fourth phase where they become HBsAg negative and anti-HBs positive, are not infectious and are considered to be cured.

Spontaneous seroconversion: In cases of chronic hepatitis C spontaneous seroconversion is very rarely seen, but among hepatitis B patients up to 10 per cent per year become HBe antigen and /or HBV DNA negative, and in 2 per cent per year further disappearance of HBs antigen is seen.

Incipient cirrhosis can be seen already after 5 years of active hepatitis and after 20 years about 20 per cent have developed cirrhosis. The risk of hepatocellular carcinoma is biggest among patients who have already developed cirrhosis (1-3 per cent per year).

Diagnostics

Table 5: HBV

| Clinical issue | Analyses | Outcome | Interpretation |
|----------------------------------|-----------------------------|---------------------------------|--|
| Acute hepatitis B | HBsAg and/or Anti-HBcIgM | HBsAg pos Anti-HBcIgM pos | Acute hepatitis |
| Chronic hepatitis B | HBsAg | HBsAg pos for > 6 months | Chronic hepatitis B |
| Clarification of HBV immunity | HBsAg Anti-HBs | 1) HBsAg pos Anti-HBs neg | 1) Hepatitis B virus- infection No indication for vaccination |
| | | 2) HBsAg neg Anti-HBs pos | 2) Earlier hepatitis B virus infection or vaccinated |
| | | 3) HBsAg neg Anti-HBs neg | 3) Susceptible to hepatitis B virus- infection. Indication for vaccination |

Treatment

Referral to specialised hospital department

All patients with chronic hepatitis B should be referred to a specialised hospital department (infection medicine or gastroenterology) with a view to further examination, counselling and assessment of treatment indication.

Control

Regardless of where the patient is seen, the following blood samples should be taken every year:

HBsAg, HBeAg + anti-HBe*, HBV-DNA, ALAT and alfa-fetoprotein

* only if the patient has been HBeAg positive at the preceding blood test
Patients who have recovered from hepatitis B, are HBsAg negative and anti

HBs positive, cf. Table 5, and they just need to be informed that having recovered from HBV infection they have life long immunity.

Treatment of acute hepatitis B

No specific treatment. Nutrition and time in bed according to patient's needs. Alcohol abstinence is recommended.

Treatment of chronic hepatitis B

Treatment of hepatitis B is a specialist task that should be offered all patients with chronic hepatitis B where liver biopsy has shown moderate to severe inflammatory alterations and/or fibrosis or where repeated liver biopsies have shown progression in the histological alterations.

Treatment is daily oral nucleoside/nucleotide analogue for 12 months, possibly longer, and possibly in combination with pegylated interferon as subcutaneous injection 1 time every week for 24 weeks. Nucleoside/-nucleotide analogue treatment involves few or slight side effects. In the majority of patients pegylated interferon has side effects in the form of flu like symptoms, weight loss, emotional volatility, impotence, pruritic rash, bone marrow depression (leucopenia and thrombocytopenia) and thyroid disorders (which are irreversible in 5-10 per cent of cases), most pronouncedly during the first months of treatment.

Patients who have had severe psychosis or depression that has required treatment should be assessed by a psychiatrist prior to any treatment.

Drug abusers in stable drug abuse treatment are not excluded from treatment. Active substance and/or alcohol abuse may influence the patient's compliance to such an extent that the patient may not register possible symptoms of side effects which could develop into life-threatening conditions and that after having gone through treatment in a satisfactory manner there is a risk of reinfection. Compliance with treatment should be assessed individually in cooperation with a specialised hospital department and the municipal treatment institution for drug abuse.

Persons in treatment should optimally be advised to totally abstain from alcohol or alternatively to limit alcohol consumption as much as possible.

Effect of treatment

Eradication of hepatitis B virus is not possible (contrary to the treatment of hepatitis C), and therefore the primary aim of treatment is to suppress the virus as much as possible and for as long as possible in the hope of avoiding histological and clinical consequences in the long term.

Vaccination: See Section 3.3 of the present Annex.

3.2.4 Hepatitis C

Prevalence

It is estimated that about 15,000 people in Denmark have chronic hepatitis C infection.

In accordance with international studies it has so far been assumed that about 90 per cent of intravenous drug abusers in Denmark have hepatitis C infection. Recent Danish studies do, however, indicate a falling incidence.

Hepatitis C is the most frequent (60 per cent) cause of hepatocellular carcinoma, 40 per cent of terminal liver cirrhoses are due to hepatitis C, and hepatitis C virus is now the most frequent cause of liver transplantation in the USA. It is estimated that in Western Europe and the USA respectively there will be an increase of deaths from at present 10,000 per year to 30,000 per year during the next 10 to 20 years unless effective treatment can change this.

Infection risk and modes of transmission

Hepatitis C virus is primarily transmitted via blood in connection with needle sticks. In the industrialised part of the world intravenous drug abuse is the most frequent mode of transmission. It is estimated that half of all individuals that have commenced intravenous drug abuse are infected with hepatitis C within a year. After around 3 to 5 years about 90 percent have been infected.

HCV RNA has been detected in blood, saliva, tear fluid, semen, ascites fluid, cerebrospinal fluid, but in spite of this there does not seem to be extensive transmission otherwise than through blood and blood products. Transmission via blood contamination of mucous membranes has, however, been seen.

Sexual transmission of hepatitis C is extremely rare, and hepatitis C discordant couples (where one person has hepatitis C and the other one does not) are not recommended to use condoms at all times. It is, however, recommended not to have unprotected sex in connection with periods, outbreak of genital herpes or anal sex.

Vertical transmission from a mother with chronic hepatitis C infection to a child in connection with delivery is rare (< 5 per cent), it is a little higher for HCV/HIV co-infected mothers and does not lead to recommendation of caesarean. Mothers are not advised against pregnancy and breast feeding.

In most studies it is still up to between 10 and 40 per cent of transmission that is listed as unknown. It is significant to focus on this “unknown” group which may contain a number of already known modes of transmission as well as some new ones that have not yet been uncovered. Piercing and tattooing are probable sources of infection, but no studies have documented

this. Persons who have had short term abuse which later they do not acknowledge, may be part of the group listed as unknown sources of infection.

Course of the disease

On average the incubation period from the time of infection to the onset of symptoms in the case of acute hepatitis C is 7 weeks, but 50 to 75 per cent of cases of acute hepatitis C follow an asymptomatic course. If the infection leads to symptoms, the clinical picture is most often lethargy and it is uncharacteristic with tiredness, nausea, vomiting, possibly icterus with slight elevation of transaminases levels. Fulminating hepatitis is rare.

Most infected persons (60-80 per cent) develop chronic infection which is defined as demonstrable anti-HCV and HCV RNA for more than 6 months. Once chronic infection has been developed, spontaneous cure is rarely seen. In the greater part of patients with chronic hepatitis C there are no symptoms until the possible development of cirrhosis. About 20 per cent of patients with chronic infection develop cirrhosis over a period of 20 years. Following this there is a risk of developing hepatocellular carcinoma in 1-4 per cent per year of patients with established cirrhosis.

With regard to those that are not chronically infected, it is important to be aware that the presence of anti-HCV does not result in immunity so that re-infection may occur if there is new exposure to hepatitis C virus.

Diagnostics

As hepatitis C virus infection seldom gives characteristic symptoms until chronic active hepatitis is complicated through cirrhosis, it is important to be observant and undertake examination for HCV based on suspicion alone. Anti-HCV cannot be demonstrated until about 8 weeks after exposure, and in immuno depressed persons it may take considerably longer.

Table 6: HCV

| Clinical issue | Analyses | Outcome | Interpretation |
|---------------------|---------------------|---|--------------------------------|
| Acute hepatitis C | HCV-RNA Anti-HCV | HCV-RNA pos Anti-HCV pos > 8 weeks after exposure | Acute hepatitis C |
| Chronic hepatitis C | HCV-RNA Anti-HCV | HCV RNA pos for > 6 months Anti-HCV pos for > 6 months | Chronic hepatitis C |
| Cured hepatitis C | HCV-RNA Anti-HCV | HCV-RNA neg Anti-HCV pos | Cured hepatitis C infection |

Treatment

Referral to specialised hospital department

All patients that are found to be anti-HCV and HCV RNA positive should be referred to a specialised hospital department (infection medicine or gastroenterology) for further diagnosis, counselling and assessment with a view to treatment.

Control

Regardless of where the patient is seen, the following blood tests should be taken every year: **HCV RNA, ALAT and alfa-fetoprotein**

At ALAT > 2 x the upper limit, liver biopsy should be undertaken if it is estimated that the patient will be able to undergo treatment.

In cases of advanced cirrhosis ultrasound scanning for liver carcinoma should be undertaken every 6 months.

Medical treatment

Acute hepatitis C

A single study has shown that early treatment of acute hepatitis C with interferon means that 98 per cent are permanently virus free after 24 weeks' treatment. At present, therefore, treatment of acute hepatitis C with pegylated interferon 1 x week for 24 weeks is recommended. For persons who are also HIV infected, treatment should be supplemented with ribavirin. Most persons who are infected with HCV and get over the infection do this within 12 weeks from the time of infection for which reason it is recommended that treatment is not initiated until 12 weeks after the presumed time of infection.

Chronic hepatitis C

Treatment is offered patients with chronic hepatitis C when liver biopsy has shown moderate to severe inflammatory changes and/or corresponding fibrosis, or when repeated liver biopsy has shown progression of the histological alterations. At present treatment is a combination of pegylated interferon in the form of subcutaneous injection 1 x weekly and oral ribavirin. The time of treatment varies according to genotype so that patients with genotypes 1 and 4 are treated for 48 weeks and patients with genotypes 2 and 3 for 24 weeks. Regarding side effects of pegylated interferon, see above: Treatment of chronic hepatitis B. The most frequent side effect of treatment with ribavirin is anaemia, blood parameters must, therefore, be followed closely during treatment.

Pregnancy: Ribavirin must not be used during pregnancy. There must be a negative pregnancy test before women are treated. Safe contraception must be used during treatment and for 6 months after treatment has been

finalised. Regarding male patients their female partners must use safe contraception during treatment and for 6 months after treatment has been finalised. Male patients with pregnant partners must use condoms in order to minimise possible transmission of ribavirin to their partners.

Drug abusers in stable treatment are not excluded from treatment. Active substance or alcohol abuse may influence patients' compliance to such an extent that the patient may not register possible symptoms of side effects which may develop so as to become life threatening or that after having been treated satisfactorily there is a risk of reinfection. Compliance with treatment is assessed individually through cooperation between the hospital department and the municipal treatment system for drug abuse.

The best thing is to advise persons in treatment to totally abstain from alcohol consumption or alternatively to limit alcohol consumption as much as possible.

Effect of treatment

Lasting effect of treatment (cure) is defined as negative HCV RNA 24 weeks after treatment has been finalised, and it is achieved in about 40 per cent of patients with genotypes 1 and 4 and about 80 per cent of patients with genotypes 2 and 3.

Vaccination

No vaccine has been developed against hepatitis C.

3.2.5 Human immunodeficiency Virus (HIV) infection

Prevalence

About 0.1 per cent of the Danish population are infected with HIV. Certain groups have an especially high prevalence, and in Denmark this concerns especially men who have sex with other men and intravenous drug abusers.

Intravenous drug abusers account for about 5 per cent of new cases of HIV infection found every year.

HIV prevalence among intravenous drug abusers in Denmark is very low, about 4-6 per cent, compared to other European countries and the USA, e.g. in New York there is a prevalence of 50 per cent.

Infection risk and modes of transmission

Infection is blood borne and occurs e.g. in connection with risk behaviour related to intravenous drug abuse, sexual contact and vertical infection from mother to child. There is no certain knowledge as to the risk of infection through sexual intercourse. It is estimated to be on average about 0.5 per

cent. The risk of infection from mother to child is 25-30 per cent and occurs most frequently during pregnancy or in connection with breast-feeding. Medical treatment (see below), delivery through caesarean and omission of breast-feeding reduces the risk of infection to < 1 per cent. It cannot be determined in advance whether a person is highly infectious or is only slightly infectious, but there is a relation between the risk of infection and the amount of virus in semen and vaginal secretion. A person who is in effective combinatory treatment and has low virus levels will be less infectious than a person who is not in treatment. But a person whose treatment is not effective might transmit a virus that is resistant to treatment.

The risk of infection from needle stick incidents with an HIV contaminated syringe is approximately 0.3 per cent.

Course of the disease

Primary (acute) HIV infection is seen 1-3 weeks after infection in about half of those who are infected with HIV. The symptoms are flu-like involving muscle pain and fever, rashes, glandular enlargement and pharyngitis. Because the symptoms are similar to those of an unspecified virus infection, primary HIV infection is seldom recognized as such. The symptoms disappear spontaneously and after this 5-10 years may pass without the patient having any symptoms of HIV infection. Gradually as the immune system is affected and the number of CD4 cells drops, the patient will be susceptible to infections which in persons with a normally functioning immune system do not cause disease. These infections are called opportunistic infections. In cases of concurrent HIV and opportunistic infection the patient is defined as having AIDS (Acquired Immuno Depressive Syndrome). Instances of opportunistic infections are Pneumocystis Carinii Pneumonia (PCP), Tuberculosis, Atypical Mycobacteriosis, Toxoplasmosis, Candida-Oesophagitis, Cytomegalovirus-infections and other diseases such as Lymphoma, Kaposi sarcoma and Cervical Cancer. The latter is the reason that all HIV infected women should be examined at least once every year through a cervical smear test.

Diagnostics

< 3 months after infection (primary HIV infection): Positive HIV RNA in plasma, positive HIV DNA in cells
> 3 months: anti-HIV positive

Referral to specialised hospital department

All persons with established HIV infection must be referred to specialised hospital department.

Treatment

In Denmark there is indication for treatment if:

- CD4 level is below 300/Ål
- The patient has clinical symptoms of HIV
- The patient has acute HIV infection
- The patient is pregnant

The treatment consists of 3 antiretroviral substances from at least two different groups, typically two nucleoside analogues and either a non-nucleoside analogue or a protease inhibitor. The antiretroviral preparations used at present are nucleoside reverse transcriptase inhibitors and non-nucleoside reverse transcriptase inhibitors, which both in different ways inhibit reverse transcriptase, and protease inhibitors, which inhibit HIV protease by binding itself directly to the enzyme. The effect of treatment is monitored through control every three months of CD4 levels and HIV RNA. The optimal treatment effect is maximally suppressed HIV RNA and as a result of this an increasing CD4 level within reference value.

It is extremely important that all pregnant women who have a potential risk of having been exposed to HIV infection (including former or active drug abusers and persons from - or with partners from – areas with a high endemic incidence of HIV) are tested for HIV. If they are not already in retroviral treatment, pregnant women should start treatment from the 14th week of pregnancy in order to prevent transmission from mother to child. The woman should be treated with intravenous zidovudine during confinement. The child should be given medicine for 4 weeks following birth and may not be breast fed. Treatment of HIV infected women in connection with pregnancy, delivery and breast feeding is a specialist task to be taken care of in cooperation between departments of infection medicine, gynaecology and paediatrics at Hvidovre Hospital, Odense University Hospital and Skejby Sygehus respectively.

For updated guidelines consult the web page of the Danish Infectious Diseases Society- DSI: www.dsinfm.dk.

Side effects: There are several side effects of antiretroviral treatment of which the most frequent at present are altered fat distribution and increase of cholesterol and triglyceride levels in the blood. It is as yet not clear whether these alterations result in increased risk of cardiovascular sequelae.

Vaccination

No vaccine against HIV has been developed.

3.3 Vaccination against hepatitis A and B

According to Ministry of the Interior and Health Order no. 746 of 29 June 2006 on free hepatitis vaccination of especially exposed groups,

- intravenous abusers who have not been infected with hepatitis B may be vaccinated free of charge against hepatitis B. The vaccine is given in the form of a combined vaccine that also protects against hepatitis A infection unless the use of combination vaccine is considered unsuitable from a medical point of view, and
- persons who live together with a person with chronic hepatitis B infection as well as the regular sexual partners of a person with chronic hepatitis B, may be vaccinated free of charge against hepatitis B infection, but cannot be vaccinated free of charge against hepatitis A.

Serological testing prior to vaccination is recommended in order to determine whether the drug abuser already has or has had hepatitis A and/or B infection. Examination and vaccination of family and relations are organised accordingly. If a person has already had hepatitis B, the combined vaccine should not be used (Twinrix), and the person should only be vaccinated against hepatitis A (Havrix).

Drug abusers have a high incidence of HBV and low compliance with vaccination. Therefore a quick regimen should be selected depending on the stability of contact with the concrete patient.

Vaccination with combined Hepatitis A + B vaccination: Twinrix®.

Administration: 1 ml intramuscularly in musculus deltoideus at 0, 1 and 6 months. If speedier immunisation is wished, the three doses may be given at 0, 7, 21 days and a fourth dose is then given after 12 months.

If the drug abuser has had hepatitis A, only vaccination against hepatitis B is used: Engerix-B®, 20 microgram/ml. Administration: 1 ml intramuscularly in musculus deltoideus at 0, 1 and 6 months. If speedier immunisation is wished, the three doses may be given at 0, 7, 21 days and a fourth dose is then given after 12 months.

When vaccination has been completed, protection for at least 15 years may be expected in > 90 per cent.

In cases of interrupted vaccination a booster is given Engerix-B®, 20 microgram/ml 1 ml or Twinrix® respectively, depending on vaccination regimen, at intervals of one month until the patient has been given altogether 3 doses.

According to Ministry of the Interior and Health Order no. 746 of 29 June 2006 expenditure for hepatitis B vaccines (Twinrix®, Engerix-B®) is to be paid by the regions. The vaccine is requested free of charge from Statens Serum Institut stating the doctor's health security reimbursement number and the patient's civil registration number. If the doctor performing the

vaccination does not have a reimbursement agreement with the health authorities, Statens Serum Institut will – if so requested by the doctor in question – forward a separate invoice to the doctor requesting the medicine who will then forward the invoice to the relevant municipal authority.

Expenditure for hepatitis A vaccination, (Havrix®), is not covered by the order on reimbursement by the authorities. It is recommended that this problem is solved at the local level.

3.4 Counselling of drug abusers on transmission of infection and measures with regard to hepatitis B and C as well as HIV

Counselling interviews with drug abusers may be difficult. The relatively complicated issues regarding blood-borne viral infections may be difficult for the doctor to explain and they may be difficult to understand, accept and not least to remember for the patient. Fear of the severity of these diseases may act as a barrier against taking in information. Often the drug abuser’s life situation is characterised by more or less acute problems that dominate the agenda during consultation and that may concern anything from medication, somatic and mental problems to social issues. And in addition the drug abuser may be under the influence of various intoxicants.

The checklist below for counselling of drug abusers concerning transmission of infection and precautions relating to hepatitis B and C as well as HIV is a tool for use by the doctor in connection with counselling interviews with drug abusers. Any drug abuser in treatment should receive the information on the list, preferably also in writing.

Table 7: Checklist for counselling of drug abusers with regard to transmission of infection and precautions relating to hepatitis B and C as well as HIV

| | Hepatitis B | Hepatitis C | HIV |
|---|-------------|-------------|-----|
| Avoid infection by always using only personal and clean tools, i. e always use sterile needles and syringes. Only use personal scoops, filters, rinsing water, sniffing tubes etc. and never share with others. | + | + | + |

| | Hepatitis B | Hepatitis C | HIV |
|--|-------------|---|---|
| Provide information on concrete possibilities of access to clean needles, syringes and rinsing water as well as the handling and disposal of used tools. | + | + | + |
| Secure knowledge of insufficient effect of chlorine for cleaning of needles/syringes | + | + | + |
| Avoid sharing toothbrush and shaving equipment with others as infection may be transmitted via small volumes of blood. | + | + | + |
| Avoid sexual practices that involve contact between mucous membranes and semen/blood. | + | (+) | + |
| Recommend condom for all sexual activity | + | (-) | + |
| | | It is recommended, however, not to have unprotected sex in connection with periods, outbreak of genital herpes or anal sex. | It is an offence to have unsafe sex for a person who is aware of being HIV infected and who does not inform a partner of this fact. |

| | Hepatitis B | Hepatitis C | HIV |
|--|--|-------------|--|
| Examination of sexual partners and household | <p>+</p> <p>In cases of chronic hep. B</p> <p>Vaccination free of charge</p> | - | - |
| Special restrictions on contact in the family with regard to hygienic measures | - | - | - |
| Drug abusers may not donate blood | + | + | + |
| Transmission from mother to child | <p>+</p> <p>Routine screening in connection with the first pregnancy examination with a view to vaccination and passive immunisation of the newborn infant few hours after delivery</p> | + | <p>+</p> <p>Taking care of HIV infected women in connection with pregnancy/delivery/breast-feeding is a specialised task (infection medicine, obstetric and paediatric departments)</p> |

3.5 Screening programmes for hepatitis A, B and C and HIV

The aim of screening programmes for hepatitis and HIV in drug abusers is to determine whether a drug abuser is infected and if so whether this infection is a thing of the past or is a chronic infection and then to take action on the basis of findings.

Table 8: Infected or not infected?

| | |
|---|---|
| <p>Drug abuser not infected Is there indication for vaccination?</p> | <p>Drug abuser infected Has the infection been cured? Is there chronic infection? Is there indication for referral to specialised hospital department?</p> |
|---|---|

Efforts should be organised in such a way as to secure easy and quick access to the taking of blood samples from newly admitted patients either taken care of locally by doctor or laboratory technician or through referral to a laboratory – possibly supported by staff to secure implementation.

The forms below list what blood samples should be taken and how results should be interpreted.

3.5.1 Guidelines on serological testing for hepatitis A, B and C and HIV

Table 9: Hepatitis A

| | |
|--|---|
| <p>The following blood tests are prescribed: Total HAV</p> | <p>HAV total</p> <p>If negative: The patient has not/has not had hepatitis A Indication for vaccination (Havrix or Twinrix, depending on hepatitis B status)</p> <p>If positive:</p> <ul style="list-style-type: none"> ■ IgM positive/IgG negative: Acute/recent (3-6 months) infection ■ IgM negative/IgG positive: Earlier infection or immune |
|--|---|

Table 10: Hepatitis B

The following blood tests are prescribed:

HBsAg, anti-HBs (HBs-antibody)

Anti-HBs

If **positive**: Either earlier hepatitis B infection or immunised (> 10 U/ml)

If **negative**:

- And at the same time HBsAg positive: Acute or chronic infection.
- And at the same time HBsAg negative: The patient has not had hepatitis B infection. Indication for vaccination

HBsAg:

If **positive** > 6 months: Chronic hepatitis.

Referral to specialised department

If **negative**: Not hepatitis B. Control 1 x per year

- And at the same time anti-HBs positive: Immunised

Table 11: Hepatitis C

The following blood tests are prescribed:

HCV- antibodies

HCV-antibodies:

If **positive**: Hepatitis C (earlier/current). HCV RNA should be prescribed

If **negative**: Patient has not hepatitis C. Further blood tests not required. Control 1 x per year

HCV RNA

If **positive** > 6 months: Chronic hepatitis C.

Referral to specialised department

If **negative**: Earlier hepatitis, cured. Control 1 x per year

Table 12: HIV

| | |
|---|---|
| The following blood tests are prescribed: | HIV-antibodies |
| HIV-antistof | <p>If positive: The patient is infected with HIV virus. <i>Referral to specialised hospital department</i></p> <p>If negative: The patient is not infected with HIV virus or the patient is infected with HIV virus but has not yet developed antibodies.</p> <p>Control 1 x per year</p> |

3.6 Referral to specialised hospital department

Cooperation between infectious disease departments and treatment institutions for drug abuse is very important so that infected persons can be referred quickly to a specialised hospital department for further diagnosis, counselling and assessment with a view to continuing control and treatment. Referral to treatment and control may be supplemented with further support and accompanied hospital visits to secure implementation.

3.7 Tracking of infection

When it has been established that a person is infected with a sexually transmissible disease, in the present context HIV and hepatitis B, the doctor must look into whether tracking of infection is possible. Together with the patient the doctor must consider both who may be the source of infection as well as what persons may have been exposed to infection and should be invited to undergo examination.

The patient may decide to inform his or her partners or may choose to request assistance for this. Some will refuse to give information on names/-refuse to cooperate. When the patient has been informed during the interview and attempts have been made to motivate cooperation, a decision not to cooperate must be respected. In these cases a follow-up interview with the patient should be arranged at a later point in time.

For further details on the above, cf.

- National Board of Health guidance on diagnosis and treatment of sexually transmissible diseases (14).
- National Board of Health advice to health care staff on counselling of persons who have been found to have HIV infection with regard to health promotion and prevention of infection (24).

3.8 Post Exposure Prophylaxis, "PEP"

Exposure to hepatitis B, C and HIV may occur in connection with:

- Handling of contaminated needles and syringes in connection with drug abuse and tattooing/piercing.
- Accidents that lead to skin being penetrated by material that is likely to be infected (needle sticks).
- Squirt of blood that is likely to be infected on mucous membranes or non-intact skin.
- Unprotected sex with an infected partner.

The risk of infection after needle stick injury with contaminated needle with regard to HIV is about 0.3 per cent, for HCV about 3 per cent and for HBV about 30 per cent.

First aid: Washing down of exposed skin or mucous membranes with water and soap and disinfection of possible skin lesions with 2.5 per cent tincture of iodine or alcohol solution.

Hepatitis B: If possible the source of infection is examined for HBsAg.

If the source of infection or the infection status of the person in question is unknown or known to be positive, vaccination of the exposed person must be immediately undertaken. To the extent possible blood samples are also drawn from the exposed person with a view to assessing immunity (anti-HBs, HBs Ag).

It is not possible to fix a time span following which vaccination is not assumed to have any protective effect, and for this reason vaccination may also be initiated 1 week after a given accident. The initial vaccination dose is given regardless of whether the injured person has been vaccinated against hepatitis before. If it turns out later that an injured person who has been vaccinated before has anti-HBs > 10 IU/l, further vaccination is omitted.

In case of vaccination following exposure 4 doses are given at 0, 1, 2 and 12 months.

Hepatitis C: A person who is known to have been exposed to hepatitis C virus should be examined for anti-HCV as soon as possible after exposure and again after 4-6 months. If earlier diagnosing of possible hepatitis C infection is wished, HCV RNA is measured 4-6 weeks after exposure. Several studies indicate that treatment with interferon reduces the risk of developing chronic infection. It is recommended to postpone treatment until 12 weeks after the presumed time of infection.

HIV: In cases of possible HIV exposure a specialised hospital department must be contacted immediately with a view to counselling and guiding the person in question. Retrospective studies have shown that post-exposure prophylaxis with zidovudin reduces the risk of infection by about 75 per cent (from 0.3 per cent to 0.1 per cent). Treatment which consists in 4 weeks' oral combinatory treatment must be initiated as soon as possible and preferably within 24 hours following the accident in order to have effect.

3.8.1 Organisation of counselling and vaccination in connection with accidents that involve exposure to hepatitis B, C and HIV

Immediately after presumed exposure persons may be referred for risk assessment and treatment at the emergency room of the nearest hospital that cooperates with an infectious diseases department, blood bank and clinical microbiology department.

3.9 Terminology

Hepatitis A

| | |
|--------------|--|
| HAV | Hepatitis A virus |
| Anti-HAV | Antibodies directed against hepatitis A virus |
| Anti-HAV IgM | Antibodies of IgM class directed against hepatitis A |

Hepatitis B

| | |
|-------------|---|
| HBV | Hepatitis B virus |
| HBV DNA | Hepatitis B virus DNA |
| HBsAg | Hepatitis B virus "surface" antigen |
| Anti-HBs | Antibodies directed against hepatitis B virus "surface" antigen |
| HBeAg | Hepatitis B virus "e" ("matrix") antigen |
| Anti-HBe | Antibodies against hepatitis B "e" ("matrix") antigen |
| HBcAg | Hepatitis B virus "core" antigen |
| Anti-HBc | Antibodies against hepatitis B virus "core" antigen |
| Anti-HBcIgG | Antibodies of IGg class directed against hepatitis B "core" antigen |
| Anti-HBcIgM | Antibodies of IgM class directed against hepatitis B virus "core" antigen |

Hepatitis C

| | |
|----------|---|
| HCV | Hepatitis C virus |
| Anti-HCV | Antibodies directed against hepatitis C virus |
| HCV-RNA | Hepatitis C virus RNA |

4. Annex to Chapter 7

4.1 Incidence of mental disease in connection with drug abuse

Psychiatric comorbidity in drug abusers, as defined by WHO in 1995, means "concurrent occurrence in the same person of disorders caused by use of psychoactive substances and other mental disorders".

Generally it is difficult to distinguish between primary and secondary psychiatric comorbidity in cases of intoxicant abuse/dependence. Most often the conditions and problems seen are complex and causal relations are multifactorial.

Studies in recent years have shown that some 60-70 per cent of drug abusers in treatment have some psychiatric disorder, and the life time prevalence of psychiatric disease for drug abusers is around 90 per cent.

Psychiatric disease may make it difficult to carry through treatment for abuse problems and consumption of intoxicants may deteriorate the course of a mental disease, e.g. by worsening symptoms or hindering treatment.

Frequent psychiatric conditions are serious behavioural and personality disorders, typically of a dissocial or emotionally unstable kind, but conditions related to nervousness and stress are also seen often as well as affective mental disorders in connection with drug abuse. The prevalence of schizophrenia and other psychotic conditions among drug abusers is about 10 per cent. There is considerable overlap of the dominant diagnostic categories in patients with mental disorders and drug abuse, and the frequency of the individual diagnosis categories stated in various clinical studies covers a considerable range. The great variations are among other things due to the use of different diagnostic criteria and lack of comparability of the studies in questions.

There is an increased frequency of suicide attempts among drug abusers, and the life time risk of suicide among drug abusers is 10-15 per cent.

ADHD (Attention-Deficit Hyperactivity Disorder) is the DSM-IV designation, and internationally it is the most common designation of the psychiatric disorder in children which in Danish and according to the WHO ICD -10 classification is called hyperkinetic disorder. In about 50 per cent of cases the condition persists with more or less noticeable symptoms in adult life. In adults psychiatric comorbidity (behavioural disorders, depression,

anxiety, abuse) is frequent for which reason differential diagnostics may be difficult. In recent years international studies have found the condition to be frequently associated with drug abuse in adults.

The prevalence of drug abuse among persons with mental disease is well-known, and it is much higher than in the general population. Thus the prevalence of drug abuse in persons with mental disease is found to be about 20 per cent. The most recent estimate of the number of drug abusers made by the National Board of Health shows that in 2007 there are about 27,000 drug abusers among the general population in Denmark. The figure does not include experimental use of substances but is an estimate of the number of persons who have a continuing use of narcotics that leads to somatic, mental and/or social harm, cf. National Board of Health yearly report on the situation with regard to narcotics in Denmark 2007.

4.2 Psychiatric symptoms/disorder induced by intoxicants

Psychiatric symptoms induced by intoxicants range from mild states of anxiety and depression (most frequent) to actual psychotic conditions (rare). In spite of the different chemical effects and mechanisms of the intoxicants, a great part of psychiatric symptoms are common to the different intoxicants. Acute withdrawal symptoms after abuse of sedative intoxicants such as alcohol and benzodiazepine are typically fidgetiness, agitation, anxiety and tremor, while acute withdrawal symptoms after abuse of central stimulants such as cocaine and ecstasy are tiredness, depression and seclusion. In fact all intoxicants when consumed in sufficient amounts and for a certain length of time, may lead to psychotic disorder.

There are great individual differences in reactions to a given intoxicant both regarding intoxication, poisoning and withdrawal. This is further complicated in cases of multiple abuse. Therefore it is always necessary *over some time* to assess the psychiatric symptoms and their relation to abstinence or continuing abuse.

Most psychiatric symptoms induced by intoxicants will remit or improve within hours or days after consumption of the intoxicant has been discontinued unless the symptoms in question are untreated long term withdrawal syndrome, depression, psychotic conditions or chronic brain damage (dementia, amnesic syndrome). Depressive symptoms are often seen in the months following cessation of alcohol use although the patient does not suffer from an actual depression.

Abuse of intoxicants has changed in recent years. In certain social circles - especially among young people - it has become popular to mix sedative

intoxicants with central stimulants. The most popular combinations are alcohol, cannabis and opioids consumed along with cocaine, amphetamine or ecstasy. Among severely vulnerable opioid abusers with a long abuse career, it is most common to combine benzodiazepine, alcohol and cocaine.

Depending on different half-lives and the abuser's tolerance levels there may be considerable changes of the intoxicating effect during an observation period. Cocaine for instance has a half-life of about 30 minutes and will thus disappear from the blood sooner than alcohol. After a few hours' observation a patient who has consumed both alcohol and cocaine will thus suddenly appear to be under increased influence of alcohol solely because the central stimulating effect of cocaine has ceased.

When assessing a patient who is under the influence of intoxicants, it is important to establish what substances the patient has consumed. What the patient believes that he or she has consumed, is not always what has actually been consumed. Various diluents may have been added to illegal intoxicants, and the diluents may be more dangerous than the actual intoxicant. And sometimes various substances have been added in order to intensify the effect of an intoxicant. The use of urinalysis may be a diagnostic tool that helps determine what reactions may occur and what is thus to be expected during a period of observation, for further details see Annex 5.

Table 13: Clinical profile of psychoactive substances.

| Effect | Psychoactive substances | | | | | |
|---------------------------------------|-------------------------|---------|----------|----------------|-----------|---------------|
| | Alcohol | Opioids | Cannabis | CNS-stimulants | Sedatives | Hallucinogens |
| Acute toxicity | ++ | +++ | 0 | ++ | ++ | 0 |
| Withdrawal symptoms | ++++ | ++++ | + | + | ++++ | 0 |
| Withdrawal convulsions | ++++ | 0 | 0 | 0 | ++++ | 0 |
| Intoxication psychosis | 0 | 0 | ++ | ++++ | 0 | +++ |
| Delirious withdrawal state | ++++ | 0 | 0 | 0 | ++++ | 0 |
| Amnesic syndrome | ++ | 0 | 0 | 0 | (+) | 0 |
| Substance induced psychosis | ++ | 0 | ++ | +++ | 0 | +++ |
| Substance induced depressive symptoms | + | + | + | +++ | + | + |
| Substance induced anxiety | + | + | + | +++ | + | +++ |
| Dementia | +++ | 0 | 0 | 0 | (+) | 0 |

"Substance induced" means that the condition is not limited to the phase of intoxication. Alcohol has been included for comparison.
+ means 'present' and the number of + signifies degree of severity

4.3 Description of the most significant intoxicant induced psychiatric conditions according to the WHO-ICD 10 criteria

The codes listed below are the diagnosis categories use in ICD-10 where x refers to psychoactive substance used (e.g. opioids F 11, cannabinoids F12). For further classification see WHO- ICD 10, mental diseases and behavioural disorders.

F1x.0: Acute intoxication

A condition following use of a psychoactive substance that leads to disorders with regard to consciousness level, cognitive functions, perception, affect, behaviour or other psychological functions and reactions. The disorders are directly linked to the acute pharmacological effects of the substance and will in time cease totally except in cases of tissue damage or other complications such as vomit in the air passage, trauma, delirium, coma, convulsions. The nature of complications depends on the pharmacological character of the substance and the mode of administration.

F1x.3: Withdrawal state

A group of symptoms of varying type and severity that occur after total cessation or relative reduction of the use of a psychoactive substance following continuing use over some time. The onset and course of withdrawal state is limited in time and has to do with the type of psychoactive substance in question and the amount or dose that has been used immediately prior to discontinuation or reduction of use. Withdrawal state may be complicated by convulsions.

F1x.4: Withdrawal state with delirium

Abstinence condition as defined in F1x.3 and complicated through delirium as defined in F05, organic delirium. Convulsions may also occur.

F05: Delirium (delirious condition, clouding of consciousness)

Organic cerebral syndrome characterised by concomitant disturbance of consciousness and attention, perception, thinking, memory, psychomotor performance, emotions and sleeping/waking rhythm.

- A. Clouding of consciousness in the form of reduced perception of environment and impaired attention
- B. Cognitive disorders
 - a. Impaired short time memory
 - b. Disorientation as regards time and place and own personal data
- C. Psychomotor disorder with > 1 of the following:
 - a. Quick changes from hypo - to hyper activity
 - b. Increased reaction time

- c. Increased or reduced flow of speech
- d. Tendency to startle
- D. Disturbed sleep at night with > 1 of the following:
 - a. Sleeplessness or inverted sleep rhythm
 - b. Deterioration of symptoms during the night
 - c. Anxious dreams and nightmares
- E. Acute onset and fluctuating course of development

F1x.5: Psychotic disorder

A group of psychotic phenomena that occur during or immediately after use of a psychoactive substance but which can be explained neither by acute intoxication alone nor as part of a withdrawal state. This substance induced condition is characterised by hallucinations, perceptive distortions, delusion (often paranoid), psychomotor disorders (excitation or stupor) and abnormal affective condition which may vary from intense fear to ecstatic condition. Sensorium is usually clear but a certain degree of clouding of consciousness may be seen though not pronounced confusion.

- A. During or within 2 weeks after discontinuation
- B. Psychotic symptoms continue for more than 48 hours
- C. Duration not more than 6 months

F1x.6: Amnesic syndrome induced by alcohol or other psychoactive substances

A syndrome combined with chronic distinct impairment of memory as regards recent and old data. Sense of time and sequence of earlier events is usually disturbed and learning ability with regard to new material is impaired. Confabulation may be pronounced. Most often other cognitive functions are well preserved and the amnesic disorders are much more pronounced than the other disturbances.

- A. (1) Impaired short time memory to a degree that interferes with every-day activity
- (2) Reduced long term memory
- B. Absence of:
 - (1) impaired immediate recall (1-3 minutes)
 - (2) disturbed consciousness
 - (3) dementia
- C. No objective or amnesic evidence of relevant organic cerebral disease except alcoholic encephalopathy.

F02.8: Dementia in connection with intoxication

Disease in the brain caused by poisoning usually of a chronic or progressive nature involving weakening of a number of higher cortical functions includ-

ing memory, orientation, perceptive and thinking capacity, learning capacity, judgement. No clouding of consciousness. Impaired emotional control, social behaviour or motivation. May be accompanied by paranoid symptoms, hallucinations and depressive symptoms.

4.4 Overview of the most significant clinical manifestations in relation to abuse of substances and pharmaceuticals and treatment principles

Concerning the contents of illegal intoxicants confer National Board of Health monitoring of narcotics in the illegal market in Denmark. Results of forensic analyses of illegal substances at street level are published in the reports "Narkotika på gadeplan" (Narcotics at street level).

4.4.1 Opioids

Includes: Heroin, morphine, methadone, buprenorphine, ketobemidon

Mode of consumption: Orally, sniffing, smoking, injection, rectally

Acute intoxication

Opioid intoxication provides a state of euphoria, mental tranquillity, well-being, moderation of anxiety, sedation, emotional disinhibition, decrease of attention, apathy and impaired judgement. Opioid intoxication does *not* lead to toxic psychosis. *The somatic symptoms* are miosis and there may be nausea and vomit. In addition to the analgesic effect opioids have a constipating effect and a suppressing effect on the cough reflex and the respiratory centre.

Severe intoxication ("overdose") of opioids leads to central respiratory insufficiency (bradypnoe or Cheyne-Stokes' respiration), pronounced miosis, hypotension and decreased level of consciousness to varying degrees on the way to coma. There is cyanosis, cold and moist skin, hypothermia. Only at severe anoxia will there be dramatic fall in blood pressure. At the same time pupils become dilated. Cardiac arrhythmia may be seen when there is anoxia. Poisoning may result in respiratory failure, cardiac arrest and death. Lack of cough reflex may lead to aspiration and obstruction of respiratory passages at an early stage.

Withdrawal symptoms

After a short time of opioid abuse there may be withdrawal symptoms that may be seen as restlessness, irritability, anxiety, gloom, sleeplessness. The somatic withdrawal symptoms are pupil dilatation, feelings of heat and cold, "gooseflesh" (piloerection), nausea, vomit, diarrhoea, stomach pain, yawning, sneezing, tears and runny nose, muscle pain, increased pulse, slight hypertension and slight temperature increase.

Because of differences in half-life, opioid withdrawal symptoms occur at varying time intervals:

- Heroin or morphine abuse: Onset 6-8 hours after latest dose, maximum intensity on day 2 or 3, symptoms disappear after 7 days
- Methadone use: Onset 1-4 days after latest dose and continues for 10 to 14 days

After long term opioid abuse there may be symptoms such as restlessness, troubled state of mind, irritability, gloom, loss of energy and sleep problems for several months.

Acute treatment

Acute intoxication

In cases of overdose antidote is given: Inj. Naloxon 0.4 mg/ml, ds. 2 ml intravenously, if necessary intra-muscularly, possibly to be repeated. Antidote may trigger withdrawal symptoms. Otherwise ordinary principles for treatment of respiratory and cardiac insufficiency are followed.

Abstinence treatment

Treatment of opioid withdrawal symptoms follows the general guidelines for initiation of treatment with buprenorphine and methadone respectively, see Chapter 8, Section 8.6.

Abstinence treatment in cases of multiple abuse

See Chapter 9.

4.4.2 Cannabis; Tetra-hydro-cannabinol (THC):

Includes: Cannabis, marihuana

Mode of consumption: Smoking, orally

Acute intoxication

Intoxicating effect appears in the form of a sense of well-being, relaxation, euphoria, reduced anxiety and less aggression. There is a reduction of cognitive functions expressed in reduced concentration capacity, lack of ability to extend scope of attention, reduced short term memory and learning capacity. There is a reduced ability to carry out complicated actions and reaction time is reduced. There are perception disturbances in some ways similar to the effect of hallucinogens but less pronounced. Sensory impressions are distorted, body perception may be distorted and sense of space and time may be altered. Cannabis intoxication leads to delusions of reference, pseudo hallucinations and sudden changes of mood.

Somatic symptoms of cannabis consumption are tachycardia, vasodilatation, conjunctival injection, increased appetite, dryness of mucous membranes

and possibly orthostatic hypotension and fainting. Large doses may lead to coordination disturbances. Cases of death from acute cannabis poisoning among somatically healthy persons have never been described.

Severe poisoning with high doses of cannabis may cause *toxic delirious psychosis* with clouded consciousness, disorientation, impaired short term memory, disturbed time perception, euphoria or dysphoria, fragmented and incoherent thinking and quickly changing hallucinations and delusions. Toxic delirium usually disappears after some hours or a few days.

Chronic intoxication

Amotivation syndrome is a consequence of chronic abuse and is seen in cases of chronic consumption of cannabis. It manifests itself as apathy, passivity, lack of energy, slight cognitive disturbances in the form of impaired concentration and memory.

Withdrawal symptoms

Withdrawal state may be seen after ceasing cannabis abuse involving restlessness, anxiety, sleeplessness, irritability, increased aggression loss of appetite, diarrhoea, increased pulse, slight hypertension and sweating. Onset of symptoms about 10 hours after the latest dose and maximum intensity reached after 48 hours. May persist for weeks up to months.

Mental diseases caused by cannabis

The most frequently occurring side effects of cannabis are *anxiety, dysphoria, passing paranoia, brief pseudo hallucinations and memory problems*.

In addition to toxic delirium cannabis may induce *acute, passing paranoid-hallucinatory psychosis*, the so-called "cannabis psychosis", which may be developed by predisposed and vulnerable persons. It is presumably relatively rare. There is no certainty as to whether "cannabis psychosis" is an independent phenomenon or should be seen as part of a more chronic psychotic condition in the long term.

In predisposed and vulnerable persons cannabis use may constitute an increased risk of developing schizophrenia and other long term psychoses later in life. Cannabis use may also worsen symptoms pertaining to an existing schizophrenic condition. Cannabis is often used for self-medication by persons that suffer from schizophrenia.

Acute treatment

Acute intoxication wears off in the course of three to five hours. Treatment consists mainly in providing a peaceful environment and reassuring the patient that the condition will improve quickly as acute poisoning decreases.

There is no specific medical treatment but small doses of benzodiazepine may be indicated when there are anxiety, agitation and sleep problems.

Cannabis induced paranoid hallucinatory psychosis that does not disappear after few days may indicate treatment with antipsychotics.

4.4.3 Benzodiazepines

Includes: Sedatives, hypnotics, anxiolytics

Mode of consumption: orally, injection, (smoking)

Acute intoxication

Slight to moderate intoxication: Reduced anxiety, release from inhibition, well-being, feeling of relaxation that may develop into varying degrees of decreased level of consciousness involving decrease of attention, apathy, reduced learning ability and possibly *anterograde amnesia* (similar to alcoholic "black-out"), reduced ability to undertake complicated movements, prolonged reaction time, ataxia, dysarthria, unsteady gait and difficulty in standing.

The so-called "paradoxical effect" characterised by aggression, hostility, violence (including murder, rape and unmotivated offence against property) and altogether chaotic behaviour with following loss of memory is observed with increasing frequency after the introduction of highly potent fluorobenzodiazepine preparations (flunitrazepam). Persons who are under heavy influence of benzodiazepines must be treated with the outmost caution and confrontation should be avoided to the extent possible as long as the influence persists.

Severe poisoning: Brief unconsciousness occurs after ten times the therapeutic dose in non-habituated persons. At a 100 times therapeutic dose unconsciousness is still not deep and blood pressure and respiration are only slightly affected. Lethal dose is often more than 200 times therapeutic daily dose. But combination of benzodiazepine poisoning and poisoning with another substance, e.g. alcohol may be life threatening. If benzodiazepine is administered intravenously, there will be a risk of respiratory failure.

Withdrawal symptoms

Tremor, increased pulse, orthostatic hypotension, sweating, sleeplessness, anxiety, tiredness, malaise, psychomotor agitation, nausea, vomiting. There may be passing sight and auditory hallucinations or tactile hallucinations, illusions and delusions. Withdrawal convulsions occur in about 25 per cent. There can be clouding of consciousness and the condition may develop into *withdrawal state with delirium*.

The risk of severe withdrawal symptoms increases with the volume of the daily dose and the duration of use.

For benzodiazepines with a short half-life (< 10 timer) withdrawal symptoms may occur 6-8 hours after the latest dose and reach a maximum after 48 hours.

For benzodiazepines with a long half-life (e.g. diazepam), 7 days may pass after the latest dose until the onset of withdrawal symptoms and these reach maximum intensity 10-12 days after the latest dose.

Acute treatment

Acute poisoning

Poisoning solely with benzodiazepine is rarely a life threatening condition. Antidote is flumazil (Lanexat ®) 0.3 ml given slowly intravenously, possibly repeated after 1 minute, maximum administration 2 mg.

Respiratory insufficiency is treated according to ordinary principles.

Abstinence treatment

- When benzodiazepine has been taken within 4-6 weeks, discontinuation may be effected over a few days
- Following abuse over a longer period:
 - Slow withdrawal using a preparation with a long half-life (e.g. Chlordiazepoxide). Daily dose is reduced by 10-20 per cent at 1-2 weeks' intervals. For more detailed instruction see Chapter 9 Section 9.3.1
- Fully developed withdrawal state may be treated with:
 - Chlordiazepoxide (Risolid®) 50-100 mg 3-4 times daily, maximum 600 mg per day. Phased withdrawal over 10 days. Observation required for changes of consciousness and convulsions.

4.4.4 Central stimulants

Includes:

1. **Cocaine, crack**; Mode of consumption: Sniffing, smoking, injection, orally.
2. **Amphetamine**; Mode of consumption: Sniffing, injection, orally.
3. **Ecstasy (3,4-methylenedioxymethamphetamine, MDMA)**; Mode of consumption: Orally, injection.
4. **Khat**; **Mode of consumption:** Orally by chewing leaves from the plant *catha edulis* or drinking.

Acute intoxication

Intoxication leads to sensations of well-being, exaltation, optimism, increased energy, initiative, restlessness, gregariousness, talkativeness, increased self-confidence, increased attention, increased sensitivity, release from inhibition and impaired judgement. There may be tension, irritability, aggression, anxiety, hyper attention as regards the behaviour of others, vigilance, delusions of reference and confusion.

Symptoms and objective findings in cases of slight, moderate and severe acute intoxication are listed below. The conditions seen in cases of poisoning

are closely related to the symptoms seen in cases of serotonin-syndrome, malign hyperthermia and malign neuroleptic syndrome.

Table 14: Symptoms and objective findings in cases of poisoning with central stimulants.

| Slight intoxication | Moderate intoxication | Severe intoxication |
|--------------------------------|------------------------------|---|
| Nausea and vomit | Hyperactivity | Delirium |
| Mydriasis | Insomnia | Muscle rigidity |
| Xerostomia | Confusion | Coma |
| Trismus | Increased body temperature | Convulsions |
| Tremor | Increased muscle tonus | Hyponatraemia |
| Restlessness | Aggression | Hypotension |
| Paleness | Panic disorder | Cardiac arrhythmia |
| Bruxism (gritting one's teeth) | Visual hallucinations | Intracerebral haemorrhage |
| Hyperreflexia | Tachypnea | Hyperthermia (>40 °C) |
| Irritability | Tachycardia | Metabolic acidosis |
| Palpitations | Hypertension | Renal insufficiency |
| | | Rhabdomyolysis |
| | | Hepatotoxicity |
| | | Respiratory distress syndrome |
| | | Disseminated intra-vascular coagulation |

Chronic intoxication

Long time use of central stimulants often leads to the stimulating effect being replaced by a depressive effect on mental and somatic functions. There will be gloom, reduced feeling of pleasure, tiredness, psychomotor inhibition or agitation, apathy, passivity, tendency to isolation.

Withdrawal symptoms

Few hours or up to days after use there will be dysphoria, restlessness, tiredness, psychomotor inhibition or agitation, sleep problems (insomnia or hypersomnia). No somatic withdrawal symptoms.

Mental diseases caused by central stimulants

- Paranoid-hallucinatory psychosis
- Toxic, delirious psychosis
- Anxiety conditions
- Depression

Acute treatment

Acute intoxication of *slight and moderate degrees* will often improve spontaneously in quiet surroundings without treatment.

Anxiety, agitation, dysphoria, aggression and sleeplessness may indicate treatment with benzodiazepine.

Psychotic symptoms are treated in the acute phase with benzodiazepine. Intoxication with central stimulants leads to great sensitivity vis-à-vis the side effects of antipsychotics. There is a risk of severe extra-pyramidal side effects, malignant neuroleptic syndrome or status epilepticus. If treatment with antipsychotics cannot be avoided, a high dose of non-typical neuroleptics should be used. The condition will always have to be taken care of within a psychiatric setting.

Convulsions and cardiovascular and respiratory insufficiency are treated according to ordinary principles.

Treatment of delirium may also be carried out following ordinary principles. Substance induced mental diseases (paranoid-hallucinatory psychoses, depressive conditions, anxiety) may indicate specific treatment if they do not disappear spontaneously within a few days.

4.4.5 Hallucinogens

Includes: LSD (Lysergic acid-diethylamide), mescaline (type of cactus), psilocybin (type of fungus), ketamin (anaesthetic)

Mode of consumption: Orally

Acute intoxication

Intoxication from hallucinogens leads to changes in perception and disturbance of thought and emotions. Sensory impressions become intense, sharp and detailed. The structuring of sensory impression changes, sense of time disappears. There will be illusory experiences. There may be 'out-of-body experiences', depersonalisation and derealisation experiences. Thinking is characterised by lively associations, imagination flows freely. Lability of mood, constant changes between e.g. euphoria and dysphoria. Anxiety that may develop into acute panic reaction, so-called "bad trip", characterised by fearful fantasies and paranoid fantasies. Acute panic reaction usually lasts only 2-6 hours.

Somatic symptoms during intoxication are tremor, pupil dilatation, tachycardia and slight hypertension, sweating, blurred sight and ataxia. Lethal dose of LSD is not known, and survival has been seen after very big doses of LSD.

Withdrawal symptoms

There are no physical withdrawal symptoms.

Hallucinogen induced mental diseases

Toxic psychosis. Psychotic symptoms may last for days or weeks after acute intoxication.

”Flashback” is a spontaneous intoxication that may occur several months after the latest intake of hallucinogens and it occurs without any intake of hallucinogen. Flashbacks are often provoked by tiredness, somatic illness, stress experiences, anxiety and nervousness.

Acute treatment

Acute panic reaction is treated with benzodiazepine.

Toxic and post hallucinogen psychosis most often disappear in the course of hours, days or a couple of weeks. If psychosis does not disappear spontaneously after a few days, the patient is treated with antipsychotics.

Convulsions and cardiovascular and respiratory insufficiency is treated according to ordinary principles.

4.4.6 Gamma hydroxybutyrate (GHB), ”Fantasy”

Mode of consumption: Orally in fluid form

Acute intoxication

The substance GHB was originally introduced as an anaesthetic, but it has been withdrawn because of serious side effects (e.g. convulsions, vomit, paralysis of cough reflex and aspiration).

Intoxication gives a feeling of well-being, reduction of anxiety, sedation, release from inhibition and impaired judgement. Intoxication resembles intoxication resulting from alcohol or benzodiazepine. There is a very little interval between the doses that result in intoxication and impairment of consciousness respectively. This is even more pronounced if other intoxicants, primarily alcohol, are consumed at the same time. Deep unconsciousness and possibly respiration failure is a special risk associated with GHB.

Withdrawal symptoms

Regular use is rare but withdrawal symptoms have been described. They are dramatic and potentially life threatening. Anxiety, sleep problems and tremor occur after 1 to 6 hours and in serious cases there are nausea, circulatory disturbances and psychotic symptoms with hallucinations and violent agitation.

Acute/long term treatment

Symptomatic. No specific medical treatment

4.4.7 Alcohol

See Chapter 9.

4.5 Check list for brief psychiatric examination

The list below may be useful for systematic interviewing in connection with psychiatric examination.

Table 15: Check list for psychiatric examination

1. Disturbances of consciousness

Impaired consciousness (decreased level of consciousness)

- Somnolence (patient may be awakened to full consciousness but falls asleep or dozes off if left alone)
- Sopor (patient cannot be awakened to full consciousness but reacts and answers with monosyllables)
- Coma (patient does not react to pain stimuli)

Unclear consciousness (clouding of consciousness)

- Reduced perception of environment and impaired attention, reduced ability to focus during interview, is easily distracted, "loses the thread", is not caused by the actual impact of the intoxicant. Is always seen in connection with delirious conditions

2. Mode of thought

Formal disturbances (disconnected, incoherent, unintelligible)

Content (delusions)

3. Disorientation (seen in delirious conditions among other things)

Autopsychic disorientation: Lack of orientation as to own personal data (name, date of birth, occupation, marital status)

Allopsychic disorientation: Lack of orientation as to time, place and formerly known persons

4. Psychomotor pace

Depression: Inertness and under-activity such as slowness of thought, lack of thoughts, lack of spontaneous speech, response latency, emotional numbness, rigid facial expression, little movement

Stupor: Severe degree of psychomotor inhibition where the patient is almost motionless

Increased motor pace: Restlessness, agitation, hyperactivity without purpose. Often seen in withdrawal state with delirium, e.g. delirium tremens.

Increased mental pace: Quick lively associations, talkativeness, lively facial expressions, increased emotionality, quick movements and hyperactivity

5. Mood (basic frame of mind)

The emotional condition (mood) that characterises the patient over some time.

May be neutral, low, raised. May be accompanied by symptoms of anxiety.

A. Depressive symptoms

Depressive condition (ICD-10):

| | |
|---|--|
| I. Core symptoms of depression | <ol style="list-style-type: none">1. Dejection2. Reduced level of desire/interest3. Reduced energy/increased fatigability |
| II. Accompanying symptoms of depression | <ol style="list-style-type: none">1. Reduced self-confidence/self-respect2. Self-reproach/feelings of guilt3. Thoughts about death or suicide4. Difficulties of thinking and concentration5. Agitation/inhibition6. Sleep problems7. Appetite – and weight changes |

The diagnosis depression presupposes at least: 2 weeks of symptoms, 2 core symptoms and 2 accompanying symptoms

Slight degree: At least 2 symptoms under I + at least 2 symptoms under II

Moderate degree: At least 2 symptoms under I + at least 4 symptoms under II

Severe degree: All 3 symptoms under I + at least 5 symptoms under II

B. Elation

Raised or irritable mood, increased activity or restlessness, concentration difficulties or easily distracted, increased talkativeness, reduced need for sleep, increased sexual drive.

C. Anxiety symptoms

Palpitation, sweating, tremor, troubled state of mind, dizziness, difficulty in breathing, choking sensation, fear of death, loss of control.

6. Psychotic/non-psychotic

Delusions (paranoid ideas): Misconceptions that are considered to be true and which are maintained with unshakeable conviction.

Hallucinations: Hallucinations related to hearing, sight, taste, smell or touch.

7. Memory

Short term memory: Ability to recall experiences after 2-3 minutes.

Long-term memory: Ability to recall events from memory after some time.

Differentiation between long-term memory as regards recent data (hours, days and weeks) and long-term memory as regards older data (months, years).

8. Suicide risk

Signs of acute suicide risk:

The person has recently undertaken suicide attempt or has had insistent suicidal ideas

The person puts forward continued ideas and wishes regarding suicide and is not able to dissociate him or herself from these

The person makes active attempts to commit suicidal acts

The person is characterised by a strong feeling of hopelessness

The person has depressive delusions

The person has expressed a wish to die vis-à-vis relatives

"The staff" has a sense that the patient (the person) has strong suicidal impulses although the person in question denies this.

Concerning the taking of abuse history see Chapter 4.

Concerning urinalysis see Chapter 10 and Annex 5.

4.6 Treatment strategy

Possibilities for local cooperation between psychiatry, municipal drug treatment system and general practitioner should be adapted to the individual course of treatment, in the best possible manner.

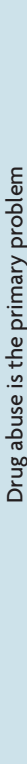
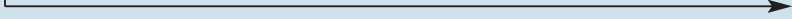
Quotation from Guidance on Medical Treatment of Drug Abusers in Substitution Treatment for Opioid Dependence, Chapter 7:

“Drug abusers who are in acute psychiatric danger, regardless of aetiology (acute intoxication, withdrawal or primary psychiatric condition) e.g.

suicidal thought/threats or manifest psychotic symptoms that involve a danger to self or others, must be assessed and treated acutely in a psychiatric setting.”

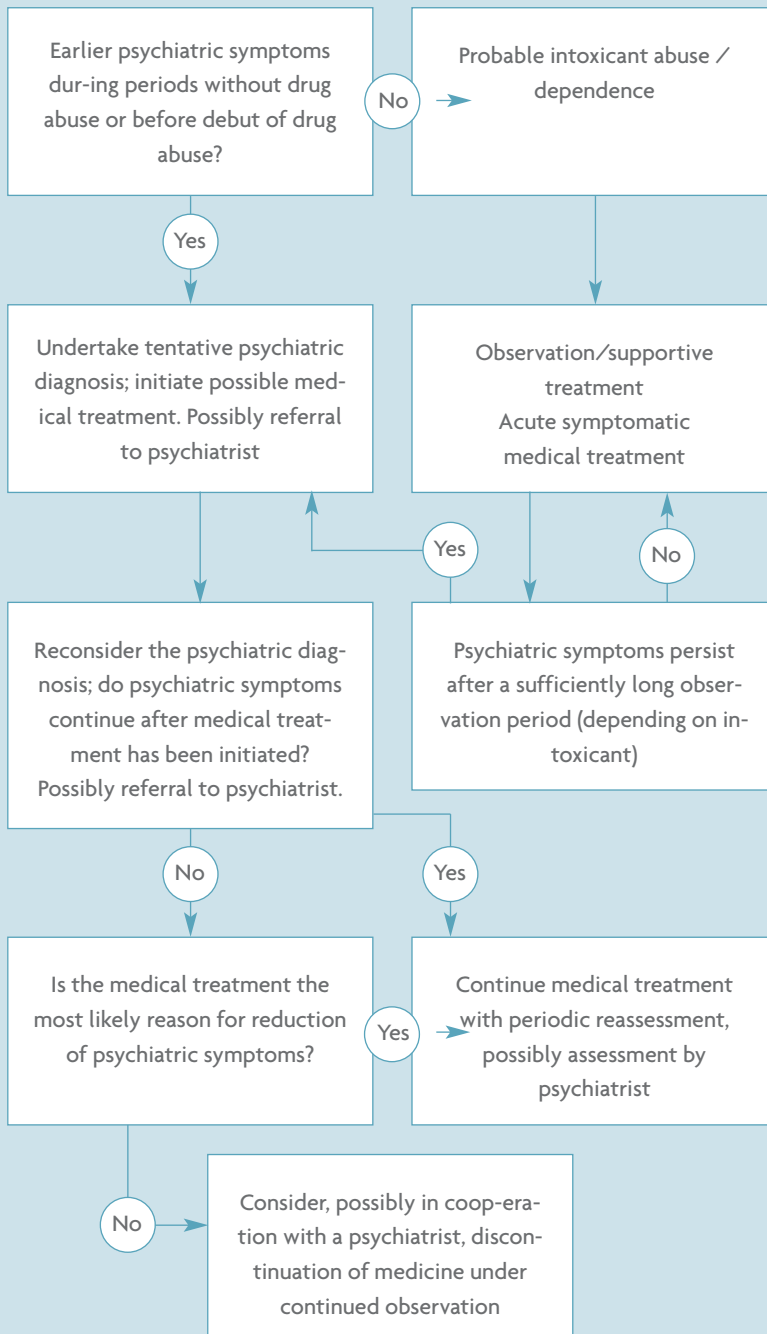
The table below is a guide to the general principles for treatment of drug abusers with psychiatric comorbidity.

Table 16: General principles for treatment of drug abusers with mental diseases. layout

| | | |
|--|--|--|
| Drug abuse is the primary problem  | Category III Patients with non-psychotic diseases (anxiety, slight/moderate affective disorders and personality disorders) and chaotic drug abuse Treatment: Municipal drug abuse treatment system | Category IV Patients with chronic psychoses who have severe behavioural disorders and comprehensive chaotic abuse Treatment: Psychiatric setting ("dual diagnosis setting") |
| | Category I Patients with non-psychotic diseases (anxiety, slight/moderate affective disorders and personality disorders) and stabilised/well-treated drug abuse Treatment: Municipal drug abuse treatment system Possibly delegation to patient's general practitioner | Category II Patients with chronic psychoses with reasonably adjusted behaviour and stabilised/well-treated drug abuse Treatment: Primary: Psychiatric setting, (community psychiatry) Secondary: Municipal drug abuse treatment system |
| | Mental disease primary problem  | |

The algorithm below is indicative for diagnostic examination and treatment of any concurrent mental disease in connection with treatment of drug abuse in the municipal treatment system for drug abusers.

Table 17: Diagnostic examination, treatment strategy



5. Annex to Chapter 10

5.1 Introduction

Quotation from Guidance on Medical Treatment of Drug Abusers in Substitution Treatment for Opioid Dependence, Chapter 10:

“Urinalyses may be used as part of substitution treatment with a view to diagnosing or assessment of ongoing treatment.

If urinalyses are part of diagnostics or treatment, a doctor must assess the result in relation to information on consumption of intoxicants and medicine and available medical information and the method used”.

In order to secure appropriate use of urinalyses for euphoriant and medicine in connection with substitution treatment of opioid dependent persons, the following chapter provides a description of fundamental principles concerning on the one hand indication for use of urinalyses and on the other hand the most significant procedures and analysis methods that a doctor must be aware of when prescribing urinalyses.

Finally the chapter explains legal and patient safety aspects in connection with the taking and the use of urinalyses as part of drug abuse treatment.

5.2 Indication

Urinalysis is the most objective tool to assess the occurrence of intoxicant use. Self reported use of intoxicants may give the same results as urinalyses but this is not always the case.

Urinalysis may increase diagnostic certainty in several situations:

- Suspicion of opioid dependence
- Unclear conditions in connection with drug abuse treatment as regards e.g.
 - Initiation of substitution treatment
 - Multiple abuse
 - Psychiatric conditions

- Suspicion of other drug abuse in connection with current clinical control of substitution treatment.
- All life-threatening conditions where substance use may be suspected to be a contributing cause.

5.3 Demonstration of substance and medicine use in urine samples

Clinical chemical analyses of urine for content of substances and medicine are not unequivocal. There are risks of errors with regard to the taking of samples and with regard to false negative and false positive results.

Urinalysis only provides a reliable picture of substance use during a few days prior to the sample being taken.

5.3.1 Securing the quality of urine samples

Before the urine is analysed for euphoriant/medicine, the quality of the urine sample should be secured *immediately* when the sample is taken through assessment of the appearance of the sample, establishing of its temperature, pH-value and density or creatinin (urine sticks).

Table 18: Normal values for fresh non-manipulated urine

| Urine parameter | Normal values |
|-----------------|--------------------|
| Temperature | 32-38° C |
| pH | 5 – 8,5 |
| Density | 1,005 – 1,030 g/ml |
| Creatinin | 4,2-17,5 mmol/l |

If the quality of the urine does not correspond to the values in the above table, a following analysis will in most cases be worthless.

In special cases when the doctor is still uncertain as to the character of the urine sample, the patient may be supervised by health care staff or another person who assists the doctor, when the sample is produced.

5.3.2 Analysis methods

Urine screening for substances and medicine is a primary analysis which is used to separate negative samples from possibly positive samples. Screening is carried out through the use of *immunological* methods that are not necessarily 100 per cent specific to relevant groups of substances. Positive results should always be *confirmed* through the use of specific methods such as e.g. *gas chromatography-mass spectrometry* (GC/MS).

Screening tests may be carried out using *on-site tests* (quick- test) or through the sending in of urine samples for *screening at clinical biochemical departments /laboratories*.

There are several on-site tests on the market in the case of which the quality of the method is more or less equivalent to a corresponding laboratory-screening. In practice safety levels will be somewhat lower when on-site tests are used because of the risk of errors in connection with insufficient handling of samples, faulty storage of sticks or erroneous interpretation of analysis results. When using on-site tests it is, therefore, important to be familiar with the quality of the method and procedures for use in accordance with the description of the preparation and the instructions provided.

Table 19: Instances of uncertainty when interpreting on-site tests

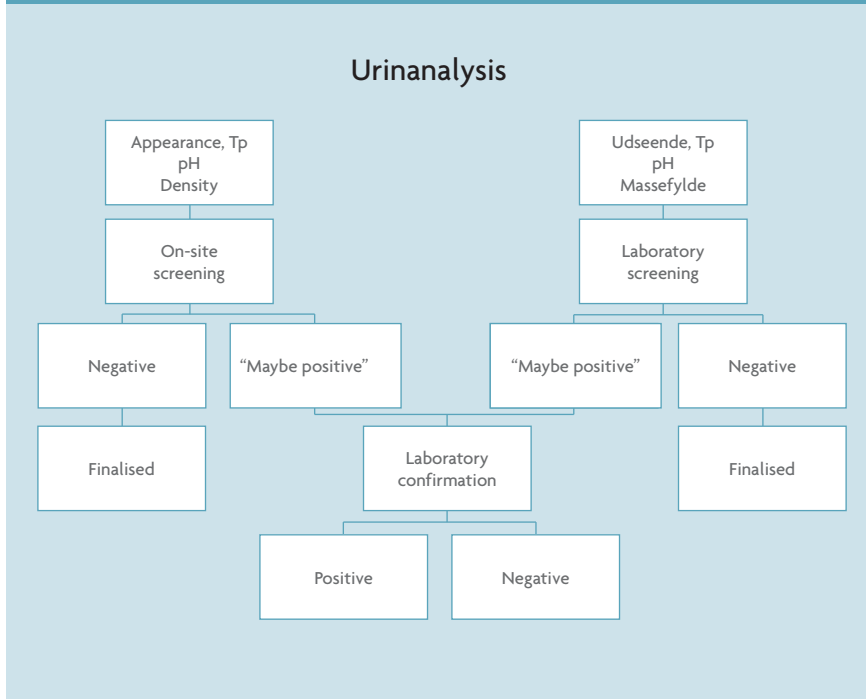
A: A urine sample is analysed for amphetamine using an on-site test, and the test indicates that the presence of amphetamine cannot be demonstrated, i.e. the test is "negative". There is no need for further action.

B: Another sample is also analysed using an on-site test, and the test shows the presence of amphetamine, i.e. the sample is "possibly positive". The results of on-site test are not sufficiently specific to stand alone, and the sample should be re-analysed at a laboratory using a more specific method. It may turn out that actually there is amphetamine in the sample, and it may now be labelled "positive". Another possibility is that it is not possible to demonstrate the presence of neither amphetamine, methamphetamine, ecstasy nor ephedrine, which are the "amphetamines" the presence of which is specifically analysed using a confirmatory laboratory method. What has influenced the result of the on-site test is thus a substance which resembles amphetamine but which is not amphetamine. In the case of some on-site tests, it has turned out that large amounts of nicotine in urine may influence the outcome of the test which may indicate the presence of amphetamine. Mostly it will, however, not be possible to determine what substance has caused a "non-negative" sample. The sample will then be described as "negative".

The use of on-site tests may be a sensible alternative to laboratory screening in situations when the advantage of an immediate response outweighs the risk of erroneous results. On-site tests may be used to distinguish between negative and non-negative ("maybe positive") samples. In order to determine if the latter are really positive, confirmation is required from a laboratory that uses more specific methods.

When using urinalyses in substitution treatment, it is recommended that the procedures outlined in Table 20 are used.

Table 20: Routine procedures for use urinalyses



If the patient denies a positive screening result, confirmation using a more specific analysis method should always be sought.

5.3.3 Detection time

Detection time is the period following the consumption of a given substance during which the substance can be demonstrated in a given urine sample. Detection time varies greatly for the individual substances and depends on the individual decomposition and discharge rates for the various substances, the size of the doses consumed, concentration of the urine and the analysis methods used.

Table 21: Detection times (indicative) for euphoriants/medicine in urine samples

| Urinalysis | Substance/ pharmaceutical | Detection time after first intake | Detection time after latest intake: Up to |
|---|--|--------------------------------------|---|
| Amphetamine | Amphetamine Methamphetamine MDMA/Ecstasy | 6-8 hours | 3 days |
| Cocaine | Cocaine Crack | 4 hours | 4 days; but up to 4 weeks at chronic abuse |
| Benzodiazepine* | It cannot be deter- mined what benzodia- zepine has been taken | 6-8 hours | 5 days, but up to 4 weeks at BZ with a long half-life |
| Methadone | Methadone | 6-8 hours | 2 days; but up to 1 week at high doses |
| Opioids** | Heroin (morphine) Codeine | 6-8 hours | 3 days |
| Ketobemidon | Ketogan, Ketodur | 6-8 hours | 1 day; though 2-3 days at large doses |
| Buprenorphine | Subutex/Suboxon | 6-8 hours | 2 days |
| Cannabis (tetra- hydro-cannabi- nol, THC) | Cannabis Marihuana Marinol (medicine) | 6-8 hours | 3 days; but up to 6 weeks for chronic abusers |

*Benzodiazepine: Normal (small) therapeutic doses cannot be demonstrated.

**Opioids: Intake of large amounts of poppy seed (food article, e.g. on bread) may give positive result for opiates.

6. Annex to Chapter 12

6.1 Introduction

In Denmark an estimated 1500-2000 children are born every year by mothers who are dependent on intoxicants and/or dependency producing medicines.

Cooperation about pregnant women with abuse is a specialist task that requires extraordinary interdisciplinary and cross sectoral efforts both in the primary and in the secondary sectors. As abuse is often connected with considerable social problems, it is recommended that the social authorities are involved at an early stage of cooperation. Efforts should be made to achieve total abstention, alternatively to reduce harm through controlled use by initiating and retaining the woman in drug abuse treatment. The aim is to reduce and preferably eliminate risk factors with regard to damage in the unborn and the newly born child.

It is of decisive significance for the unborn child's growth, development and health and for the family's health, well-being and future that a coordinating initiative is launched as soon as possible. The initiative is comprehensive and concerned with prevention of pregnancy complications and congenital malformation against the background of abuse.

Concerning a more comprehensive description and guidance for interdisciplinary and cross-sectoral handling of pregnant women with substance related problems and their children, see National Board of Health publication "Omsorg for gravide og småbørnsfamilier med rusmiddelproblemer", 2005. (Care for pregnant women and families with children with substance related problems)

This chapter covers only the most significant areas which the municipal doctor or the general practitioner must be aware of when treating female drug abusers.

6.2 Target group

Pregnant women with drug abuse

Problems in the life of the pregnant drug abuser constitute risk factors in

relation to the course of pregnancy and delivery and the growth of the unborn child, its development and health.

The pregnant drug abuser's life is often characterised by a problematic childhood and she is often in a vulnerable psychosocial situation (typically poor housing conditions, crime, prostitution, partner with substance problem, violence, child placed outside the family).

The woman's health and general condition is often characterised by under nourishment/malnutrition, anaemia, abuse related viral infections (hepatitis, HIV) and other somatic and mental diseases. Often the women neglect their health problems. Frequently pregnancy is detected fairly late. Calculation of time of confinement is often uncertain because of menstrual irregularity and a doctor/midwife is only seen at a late stage.

The specific effect of intoxicants and the woman's abuse pattern which often varies between overdoses and withdrawal in combination with her health condition and life situation constitutes considerable risks for foetus development and the child's health condition after birth.

Children of pregnant intoxicant users

Children born by socially vulnerable women have a higher frequency of premature births, stillborns, low birth weight and infant mortality. Moreover children of intoxicant dependent mothers risk other serious pregnancy and birth complications such as e.g. placental separation, intrauterine asphyxia, congenital malformations and neonatal withdrawal symptoms.

The effect of intoxicant use during pregnancy on the children's long term prognosis is very little known. Follow-up examination of children of opioid dependent mothers in Denmark have shown a high prevalence of brain damage, developmental damage, behavioural and psychic problems, deprived family conditions and negligence.

6.3 Effect of intoxicants on pregnancy, birth and the child's development

A child's development is determined by multiple factors, and it is not possible to distinguish between the specific effects of the individual intoxicants on foetus development, on the course of pregnancy and birth or on the child's condition after birth and its further development. All intoxicants easily pass placenta, and in principle they have the same effect on mother and foetus with regard to intoxication and withdrawal. In cases of untreated intoxicant dependence the condition of the pregnant woman will alternate between intoxication and withdrawal and this will also be the case for the

foetus. The two extremes – intoxication and withdrawal - release intra-uterine asphyxia in the foetus with a risk of retarded weight development and premature birth and increased perinatal mortality.

Alcohol

In the western world alcohol is considered to be the most frequent cause of mental retardation in children. Alcohol damage is caused early in pregnancy often before the pregnant woman is seen for antenatal care. Congenital alcohol damage covers a wide range from minor and insignificant damage to severe multiple handicaps and death. The most serious damage is foetal alcohol syndrome (FAS), which includes the triad: special facial features, brain damage and stunted growth. About half of the children with FAS also have congenital malformations in other organs e.g. organic heart disease, cleft palate, clubfoot. It is estimated that there are about 75 cases of FAS in Denmark per year (1.3 per 1000 births).

Opioids

Opioids do not result in malformations but have a growth-inhibiting effect (symmetric) on the foetus.

Heroin

Children of heroin dependent mothers are born with low birth weight. Moreover, there is a risk of spontaneous abortion, foetal death, brain damage and neonatal withdrawal syndrome.

Methadone

Methadone is less growth-inhibiting to the foetus than heroin. It is well-documented that methadone treatment in combination with prenatal care and psychosocial support can improve the course of pregnancy and birth considerably and thus improve the child's condition at birth and reduce morbidity and mortality for mothers and children. Neonatal withdrawal symptoms in the case of methadone may, however, be stronger and last longer than withdrawal symptoms after heroin use. Withdrawal symptoms as such do not, however, lead to physical damage to the child's development provided they are treated correctly.

Buprenorphine

Studies so far have found buprenorphine to be safe and effective for the treatment of pregnant women and their unborn/newly born children. Though the data material available is still less extensive than in the case of methadone, it has shown that buprenorphine is fully comparable with methadone in relation to perinatal morbidity and neonatal withdrawal syndrome.

Central stimulants (Cocaine, amphetamine, ecstasy)

Central stimulants have a pronounced vasoconstrictive and hypertensive effect which may lead to reduced placental passage with a risk of intrauterine growth-inhibition, placental separation and premature birth. Cocaine and amphetamine may have a damaging effect on the foetus with a risk of malformation of the foetus, reduced head volume and disturbances of cardiac function. There is no documentation for the development of neonatal withdrawal symptoms. There is, however, a risk of neurological symptoms such as irritability, motor unrest, increased muscle tonus, convulsions. Studies have shown that 50 per cent of cocaine exposed newborns have abnormal EEG though this is normalised in the course of the first months of life.

Cannabis

In consideration of the wide prevalence of this substance also among pregnant women, knowledge about its effect on foetal development, pregnancy, birth and a child's further development is scarce. Several studies have shown a connection between low birth weight and premature birth, other studies have not confirmed this connection. Children exposed to cannabis may develop neonatal withdrawal symptoms which are often less severe than withdrawal symptoms from other intoxicants.

Benzodiazepine

After long term abuse, benzodiazepine may have a damaging effect on the foetus with a risk of malformation of the brain and nervous system as well as intrauterine growth inhibition. There is a risk of neonatal withdrawal symptoms because of the long half-life of this substance.

Sniffing

Sniffing of organic solvents (glue, lighter gas, petrol) damages the foetus and may have effects similar to the ones that result from alcohol with a risk of malformation, low birth weight and brain damage.

6.4 Early contact, referral to specialised hospital department

It is important that a pregnant intoxicant using woman is not seen primarily as a "drug abuser" but as a "pregnant woman" who wants the best for her child to the same degree as other women. It is important to use neutral, professional and objective terminology that cannot be perceived as discriminating or moralising especially in relation to intoxicant use, prostitution etc. The aim is that the woman becomes able to enter into cooperation with the relevant professionals for the sake of both the pregnant woman herself and the health and development of the unborn child. When in contact with pregnant substance users, general ethical dilemmas will often be on the agenda in situations where the woman's legally safeguarded right to take

decisions with regard to her own body involves a risk for the life, health and prognosis of the unborn child.

Quotation from Guidance on medical Treatment of Drug Abusers in Substitution Treatment for Opioid Dependence, Chapter 12:

“It is important as early as possible to secure speedy, possibly acute, contact between a pregnant drug abuser and an obstetric department affiliated to a neonatal department that can assess the need for treatment (possibly admission as an inpatient) and relief measures. Often a pregnant drug abuser finds it difficult on her own initiative to use the ordinary prophylactic services within antenatal care and thus has neither seen her general practitioner nor been to a pregnancy examination at a midwifery centre or contacted a hospital.

As this is a high risk group with poor living conditions and a varying degree of motivation to seek treatment,

- Any doctor who treats a pregnant drug abuser must secure that contact to an obstetric hospital department has been established or take steps to establish this contact, and
- Any doctor may directly refer a pregnant drug abuser to assessment at an obstetric hospital department.”

The obstetric hospital department should undertake an overall assessment and planning of the interdisciplinary initiatives (doctor - midwife - social worker and psychologist) and the network that is to be adapted to the individual pregnant substance user. The course of development and the interdisciplinary initiatives in the professional networks that may already have been established (municipal drug abuse treatment system, social services, general practitioner etc.). vary considerably and depend on the overall vulnerability of the pregnant woman, functional level and the duration of pregnancy at the time of admission.

6.5 Pregnant drug abusers with somatic and psychiatric comorbidity

6.5.1 Hepatitis and HIV

Hepatitis B and C and HIV may be transmitted from mother to child in connection with pregnancy, birth and breast feeding. It is important to inform the pregnant woman and her partner about these diseases and make sure that both undergo serological screening as early as possible in the course of pregnancy, cf. Chapter 6.

Pregnant women who are hepatitis B/C or HIV positive are referred to a department of infection medicine.

Hepatitis B

If the pregnant woman is hepatitis B antigen positive, and her partner is hepatitis B antigen/antibody negative, it is recommended that he is vaccinated against hepatitis B. If there are children in the home and/or more adults, these should also be examined and vaccinated in case of need. When the pregnant woman is hepatitis B antigen positive, the newborn child should commence vaccination against hepatitis B immediately after birth and should be given an injection of gamma globulin. The patient's own doctor follows up on these vaccinations.

A pregnant woman who is not infected with hepatitis B, may *not* be vaccinated against hepatitis B during pregnancy regardless of whether her partner is a disease carrier.

Mothers who are hepatitis B antigen positive may breast feed.

Hepatitis C

In the case of hepatitis C antigen positive pregnant women no special measures are required during pregnancy and birth or with regard to the newborn child. Regarding the child, follow-up blood tests may be made at the latest when the child reaches 18 months.

Mothers who are hepatitis C antigen positive may breast feed.

HIV

All HIV-positive pregnant women are referred to give birth at one of the hospitals that take care of treatment of HIV-positive pregnant women and their children. The pregnant woman is given prophylactic antiretroviral treatment from the 14th week of pregnancy and this treatment continues until delivery.

Caesarean section is recommended 2 weeks before stipulated confinement. But vaginal delivery is possible if CD-4 cell count is above 300 and HIV RNA levels are low (under 20) at delivery. During delivery retrovir is administered parenterally to the mother and antiretroviral treatment of the child is initiated immediately after birth and continues during the first 4 weeks of life. Paediatric department follows up on this treatment.

An HIV-positive woman is recommended not to breast feed. If an HIV-positive mother insists on breast feeding and/or is against the child being treated with retrovir, the social authorities should be informed of this.

6.5.2 Mentally sick pregnant drug abusers

Children of mothers with dual diagnosis, concurrent abuse and mental disorder, are doubly vulnerable and exposed to more risk factors than children of intoxicant users without mental disease. As described in Chapter 7 the mental diseases in the pregnant drug abuser may be primary or secondary in relation to intoxicant use and often it will not be possible to distinguish.

If there is suspicion of mental disease in a pregnant woman with intoxicant related problems, it is therefore important to secure that a psychiatric assessment is undertaken and that relevant treatment is initiated including decision as to whether treatment should be provided in a psychiatric or community psychiatric setting.

Medical treatment of mental disease in a pregnant woman with intoxicant problems should always be undertaken after consultation with an obstetric specialist out of regard for the possible harm to the foetus that may be caused by the individual medical product.

Under all circumstances it is necessary to secure close cooperation between the psychiatric system, the obstetric hospital department as well as the social authorities and the drug abuse treatment system in the municipality.

If it is not possible to establish sufficient contact with the pregnant woman prior to delivery, it is important that the obstetric hospital department secures that an action plan for the child and the mother is made immediately after birth in cooperation with the municipality.

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