PART B: SELECTED ISSUES

11 History, methods and implementation of national treatment guidelines

In Germany there are guidelines from various institutions, organisations and scientific medical societies. Problems in demarcating the borderlines between terms such as standards, guidelines and regulations/rules, overlapping of the actual content and differences in bindingness and relevance to the field of practice all combine to produce a very heterogeneous overall picture when it comes to “guidelines”.

The guidelines examined in this chapter can be broken down into three types. (I) guidelines are developed by scientific medical societies in accordance with the definition of treatment guidelines which is also used by the EMCBDDA. Work began on the preparation of treatment guidelines for substance-related disorders in 2000 under the umbrella of the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften - AWMF). The treatment guidelines of the Association of Scientific Medical Societies in Germany are developed in a standardised procedure based on the scientific state of knowledge. (II) In addition to these treatment guidelines, there have been regulations and rules on substitution treatment from the German Medical Association (BAEK) since 2001. Among other things, these are intended for the purpose of helping achieve a manageable implementation of different legal prerequisites (from the Narcotics Act, the Amending Regulation on the Prescription of Narcotic Drugs und the Medical Products Act). As regulations and rules these have a greater binding effect and are of considerable relevance to the field of practice in Germany. In terms of their actual content, they overlap with the treatment guidelines of the Association of the Scientific Medical Societies in Germany. (III) The German Statutory Pension Service (DRV) developed “Guidelines on Rehabilitation Needs in Cases of Dependency-Related Illnesses” (Leitlinien zur Rehabilitationsbeduerftigkeit bei Abhaengigkeitserkrankungen) for the first time in 2003. They are highly relevant to the field of practice in terms of quality assurance for rehabilitation services which are financed by Statutory Pension Insurance.

The three types are first of all presented in this chapter. In 11.1 the institutional background to the respective histories of guidelines past and present are discussed. The discussion within the community of informed persons and specialists who have supported the development of guidelines is also briefly outlined. A description of the guidelines themselves is provided in 11.2 along with several comments on the further development of existing guidelines. Finally, 11.3 addresses implementation, implementation strategies and impediments. By the same token, it will be taken into account in what contexts the respective guidelines bear relevance to areas of actual practice.

11.1 History and overall framework

11.1.1 Guidelines of the Association of the Scientific Medical Societies in Germany (AWMF)

The Association of the Scientific Medical Societies in Germany (AWMF) was founded as a non-profit association in 1962 by 16 societies at the time. The area of tasks of the Association of the Scientific Medical Societies in Germany, which has 153 scientific societies as members at present, includes tasks such as quality assurance the profession of physician or the electronic publication of scientific literature. Upon the instigation of the "Sachverstaendigenrats fuer die Konzertierte Aktion im Gesundheitswesen" ("Council of Experts for Concerted Action in the Health Sector"), the Association of the Scientific Medical Societies in Germany has been coordinating the guidelines for diagnostics and therapy through the individual scientific medical societies since 1995[140].

Guidelines are understood to mean "systematically developed statements to support decision-making by physicians and if need be by other health professions and patients to promote an appropriate approach to existing health problems" (AWMF & AEZQ 2008). Together with the AErztliche Zentralstelle fuer Qualitaetssicherung (AEZQ – "Physicians' Central Office for Quality Assurance"), the Association of the Scientific Medical Societies in Germany has developed the "German Instrument for Methodical Assessment of guidelines (DELBI)", which was published for the first time in 2005 and replaced the checklist "Methodical Quality of Guidelines ("Methodische Qualitaet von guidelines") from 2000. On top of additional manuals of the Association of the Scientific Medical Societies in Germany for the development of guidelines, the instrument is intended to support quality assurance in the development of guidelines (AWMF & AEZQ 2008; AWMF Online: http://www.awmf-online.de/).

Under the umbrella of the Association of the Scientific Medical Societies in Germany, treatment guidelines for substance-related problems have been developed since September 2000, with the two scientific medical societies "The German Society for Research on Addictions" (DG-Sucht) and "Deutsche Gesellschaft fuer Psychiatrie, Psychotherapie und Nervenheilkunde e.V. (DGPPN – "The German Society for Psychiatry, Psychotherapy and Neuropsychiatry") in charge. Depending on the subject of the guidelines, additional scientific societies and experts are included in the development process.

Guidelines of the Association of the Scientific Medical Societies in Germany are developed in a 3-stage procedure in accordance with "methodical standards for the development of evidence-based guidelines in Germany". Guidelines based on an informal consensus of an expert group are described as development level S1 guidelines. Non-systematic summarisation work which is based on a formal consensus procedure and which members of several groups are involved in are described as development level S2 guidelines. A systematic research of evidence is labelled development level S3 (Helou et al. 2000; Schmidt & Gastpar 2006).

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[140] See AWMF Online: http://www.awmf-online.de/

The current status of substance-related treatment was published in 2006 (Schmidt & Gastpar 2006). The guidelines have the development status of level 2 (on the further development of the guidelines at present, see chapter 11.2.8). In addition to the substance-related treatment guidelines on “Cannabis-related disorders”, “opioid-related disorders” (acute treatment and post-acute treatment), “physical and behavioural disorders due to cocaine, amphetamine, ecstacy and hallucinogens” and “medication dependency (sedatives, hypnotics, analgesics and psycho-stimulants)”, the publications also contain treatment guidelines on the substances of alcohol and tobacco.

The guidelines of the Association of the Scientific Medical Societies in Germany have a limited period of validity. The applicability of the Guidelines on the Treatment of Substance-Related Disorders expired at the beginning of 2010. The revision of the guidelines had not yet been completed at the time when this report was compiled. No point in time has been set for their completion (on the further development of the guidelines see chapter 11.2.8). In this special chapter, the most recent guidelines of the scientific medical societies, which were valid until the beginning of the year, are nevertheless taken into account in the national reporting to the EMCDDA.

11.1.2 Substitution regulations and rules of the German Medical Association

In its capacity as peak organisation of the system of physicians‘ self-administration, the German Medical Association (BAEK) represents the professional interests of physicians in the Federal Republic of Germany. A majority of substitution treatments in Germany are performed by physicians in private practice[141].

The German Medical Association was assigned by lawmakers the task of drafting rules and regulations for substitution treatment in accordance with the generally recognised state of medical knowledge for the first time in 2001 through the 15th Amending Regulation on Narcotic Law (Betaeubungsmittelrechtsaenderungsverordnung, BtMAEndV). The “Rules and Regulations on the Performance of Substitution-Supported Treatment of Opiate Addicts” was submitted for the first time in 2002. The latest revision from 2010 takes into account the statutory foundations, which changed in 2009 as a result of the 23rd BtMAEndV) and the Act on Diamorphine-Supported Substitution Treatment (BAEK 2010).

In this case, the guidelines are not treatment **guidelines**, but rather **rules and regulations** of the German Medical Association. Because these are of tremendous importance to the treatments in the field of practice, however, they are nevertheless examined in this special chapter.

11.1.3 History of the guidelines of German Statutory Pension Insurance (DRV)

Under German social security law[142], German Statutory Pension Insurance (DRV) finances rehabilitation measures for people suffering from substance abuse disorders. The reason for

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[141] Under statutory provisions, substitution treatment can only be performed by physicians who comply with the minimum requirements applying to addiction therapy qualifications, see chapter 11.2.3.

[142] The Pensions Regulatory Authority is responsible for substance abuse treatment if the prerequisites for §§ 9 – 11 Social Code VI have been met. If the requirements set out in §§ 27 and 40 Social Code V have been met, the health insurance schemes are responsibile for substance abuse treatment (DRV 2005).

the responsibility of Statutory Pension Insurance is that rehabilitation measures help enable people to return to work and thus aim to return people insured under statutory pension schemes to employment. Because this insurance is mandatory, every employee has pension insurance. The rehabilitation measures carried out for addicts, in particular alcoholics, accounted for 6% (56,393 rehabilitations for people with addiction illnesses) of all payments for medical rehabilitation (903,257) by Statutory Pension Insurance in 2007, while costs related to rehabilitation of addicts accounted for 18% (EUR 469 m. out of EUR 2,675 m.) of total costs of medical benefits from Statutory Pension Insurance (Beckmann et al. 2009b).

Statutory Pension Insurance[143] commenced projects to develop rehabilitation process guidelines in 1998. In this context guidelines are understood as "systematically developed decision-making aids for care providers and patients on the proper procedure in the case of special health problems" (Brueggemann et al. 2004; Brueggemann & Klosterhuis 2005).

Guidelines were developed in four phases, beginning with an analysis of the literature. This was followed by a comparison of the actual with the current situation in order to determine needs (the so-called "KTL-Analyse"[144]), the development of process guidelines and implementation. The first version of the "guidelines on the need for rehabilitation in the case of persons suffering from addiction illnesses" was developed in 2003. The current version was issued in 2005 (on the current further development of the rehabilitation guidelines of German Statutory Pension Insurance see 11.2.8).

As process guidelines, the rehabilitation guidelines are of major importance to the field of practice. In spite of the same term – "guidelines" – being used, a distinction needs to be made between these process guidelines and the treatment guidelines of the Association of the Scientific Medical Societies in Germany (Koch 2006). The guidelines are orientated towards rehabilitation clinics and treatment facilities, setting out the framework conditions for them. Actors involved in treatment (for example, medical personnel, therapists and social workers) are thus the target group/users of these guidelines. The guidelines stipulate what elements of treatment are to be granted in what scope to what percentage of patients. This thus places the focus on adherence to minimum standards at institutions.

11.1.4 Discussion on the development of guidelines

The development of guidelines which relate to the treatment of substance-abuse illnesses in Germany is accompanied by discussions by the informed public and experts over aspects such as the demarcation between the terms "guidelines", "standards" and "rules and regulations" (Flenker & Bredehoeft 2002), methods for developing guidelines, the applicability of guidelines and generally speaking quality assurance in the area of treatment

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[143] The Federal Pension System for Employees (Bundesversicherungsanstalt fuer Angestellte - BfA), which started up the guidelines programme in 1997, was merged with the Verband Deutscher Rentenversicherungstraeger (VDR) in 2005 to form German National Statutory Pension Insurance (Deutsche Rentenversicherung Bund - DRV).

[144] KTL-Analyse: The classfication of therapeutic services is a directory of therapeutic services compiled by the BfA (now the German National Statutory Pension Insurance - DRV) which can be performed in medical rehabilitation. The results of literature research, formulated as an evidence-based therapy module, are compared as treatment target with the actual condition (illustrated in the approval reports which have been submitted to the Bundesversicherungsanstalt fuer Angestellte (now German Statutory Pension Insurance)).

of substance abuse disorders (see Kuhlmann 2006; Schmidt & Gastpar 2002; Weissinger & Schneider 2006). The limits of application possibilities for evidence-based medicine for everyday practice, the degree to which studies conducted in countries with different health-care structures can be applied to Germany, the degree to which findings from selected populations in studies and studies settings can be applied to patients in everyday practice and the advantages of guidelines as systematically developed aids in decision-making for care providers with regard to an appropriate mode of procedure with the given problems are topics which are discussed. In this context it is frequently pointed out that the development of guidelines also has to involve a consensus among experts, at least as a low level of evidence (Schmidt et al. 2006; Fleischmann 2006; Koch 2006; Kuhlmann 2006; see. Lindenmeyer 2006; Weissinger & Schneider 2006).

The relevance of guidelines to the field of practice will probably become a subject of discussion once again as a result of the further development[145] of the guidelines of the Association of the Scientific Medical Societies in Germany at the development level with the highest degree of evidence “S3”. It would thus appear, for example, that certain criteria for excluding study populations in clinical studies (for example comorbidity) are more the rule than they are the exception in the field of practice. On the other hand, these study results are a basic prerequisite for basing guidelines on a high level of evidence (German Centre for Addiction Issues (DHS), personal communication 2010).

11.2 Existing guidelines: narrative description of existing guidelines

11.2.1 Opioid-related disorders: acute treatment

The latest guidelines of the Association of the Scientific Medical Societies in Germany on acute treatment in cases involving opioid-related disorders were published in 2006 in “Evidenzbasierte Suchtmedizin” (“Evidence-Based Addiction Medicine”) (Reymann & Gastpar 2006). These guidelines were first published in 2002 in the journal “Sucht” (Reymann et al. 2002).

Definition and aims

The objective in the treatment of treating opioid-related disorders is to ensure survival, the prevention of long-term damage to health, permanent abstinence from the use of illegal opioids and overcoming possible disorders which the addiction might be based on.

The acute treatment of opioid problems ranges over the following medical measures: the treatment of acute intoxication (detoxification), the treatment of physical withdrawal symptoms (withdrawal treatment) in reducing or discontinuing the substance, the encouragement of motivation to become abstinent, support of the motivation to make use of post-acute treatments, the termination of other possible dependencies, including medication or alcohol and the diagnostics and treatment of secondary psychiatric and somatic illnesses and the containment of negative social effects as a result of the addiction. The guidelines lay down an 8-week period of treatment.

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[145] See chapter 11.2.8.

Diagnostics

With regard to diagnostics, the guidelines contain recommendations for the case history (for example the recording of the history and pattern of consumption as well as consumption of other substances and concomitant illnesses), psychiatric examinations (in particular a record of symptoms from intoxication, withdrawal and delirium), the physical examination (e.g. examination for injection track marks, abscesses and dermatological infections), the diagnosis of withdrawal syndrome and for laboratory examinations (a comprehensive drug screening is recommended as well as testing for hepatitis viruses and HIV).

The treatment setting

Acute treatment can be provided on an outpatient basis or in day clinic addiction medicine settings. Reasons against an outpatient treatment include, for example, complications in withdrawal, suicidal tendencies, polytoxicomania as well as reasons relating to the social environment or the prior addiction history of the patient. If such reasons are present, fully inpatient treatment is performed.

Need for and planning of treatment

In the case of an acute, severe opiate intoxication, emergency medical measures should be taken. It is recommended that naloxone be used to antagonise a respiratory depression. In addition to the diagnosis of somatic and psychiatric comorbidity, collateral social damage and legal aspects should be included in the treatment planning. This necessitates a setting with support from social workers. In order to ensure the success of treatment, the motivation and in some circumstances the motivation of the patient is important. Post-acute treatment should follow upon acute treatment directly.

Pharmacotherapy of the withdrawal syndrome

Withdrawal without the administration of medication is only appropriate if the patient himself desires this. Treatment with the support of medication is generally administered with an μ-opiate receptor antagonists, with dosages then being reduced gradually.[146] Generally speaking it is recommended that D,L methadone by taken orally. If there is evidence that the patient does not tolerate this, levomethadone can be used. Buprenorphine can also be used to treat opioid withdrawal syndrome and is superior to methadone in cases involving severe depression. Clonidine can be used in Germany in inpatient treatment of withdrawal. If it is administered in combination with methadone, treatment is only supposed to occur after withdrawal from methadone. Deepen can also be used, but has considerable side-effects. It cannot be used at the same time with Clonidine.

The treatment of withdrawal symptoms with opiate antagonists (naloxone and naltrexone) is only recommended if the patient is under general anaesthesia or deep sedation or this treatment is expressly desired or several conventional attempts at withdrawal have failed. This treatment should generally speaking not be used, as withdrawal symptoms and

[146] The statutory framework conditions are set out in the Narcotics Act and the Narcotics Prescription Regulation (see chapter 1).

problems with the general well-being can be long-lasting and low compliance for a follow-up treatment is to be expected.

Dosage and period of application

The guidelines contain recommendations on the dosage and how long it is to be applied. With opioid-supported withdrawal using methadone or buprenorphine, the initial dosage is first determined. The dosage is reduced step by step or digressively in the course of the withdrawal treatment. The treatment of the withdrawal syndrome with medication being gradually reduced can last several weeks in an outpatient setting, while in an inpatient setting only 10 days can already be sufficient.

Withdrawal with the support of Clonidine can be used after the opiate effect tapers off or following methadone substitution in order to treat withdrawal symptoms. Following the withdrawal phase, a naltrexone treatment can be used in order to support the abstinence of the patient.

Information of patients and psychotherapy

It is recommended that patients be informed about risks and dangers during the treatment. Patients should be informed that a loss of opiate tolerance increases the risk of overdose if they consume opiates again. Patients should be informed about health and infection risks associated with intravenous consumption, as they should about possible vaccinations against hepatitis B and the treatment of hepatitis C. The patients should be encouraged to avoid consumption of alcohol or taking benodiazepines prior to an injection and the reasons for this communicated. Self-help groups are also recommended. Pyschotherapy in acute treatment *inter alia* helps reinforce or encourage motivation to undergo treatment and spell out treatment goals which are addressed in the post-acute treatment. Other forms of psychotherapy (e.g. cognitive therapy, behavioural theory and others) are generally considered to be helpful.

Sociotherapy

Sociotherapy is an indispensable part of the overall treatment. It helps patients reduce the negative effects of a financial and legal nature and eases their social situation. Often sociotherapy makes treatment for addiction possible in the first place, putting patients in a position to make use of longer-term treatment. If the patent agrees, the social environment of the patient should also be included in the sociotherapy.

Movement therapy procedures, which can benefit patients especially when performed in a group, are also recommended. Ergotherapy and art therapy can also be commenced during the acute treatment.

In an inpatient setting, nursing care is assigned the tasks of establishing a continuous professional relationship between the providers of treatment and care to the patient and creating a drug-free environment as the foundation for the treatment. A comprehensive assessment of the course of the treatment is performed, covering not only vital parameters and withdrawal symptoms, but also behaviour, affect and motivation.

Comorbidity

To treat hepatitis B, C and HIV, the authors cite international and national regulations and guidelines addressing this topic.[147] Because opiate addicts frequently consume additional psychotropic substances, it is recommended that the degree of consumption be determined in the screening and the patient motivated to avoid consumption of other drugs. In particular, the (gradual) elimination of alcohol and benzodiazepine consumption should take place prior to opioid withdrawal.

Neonatal withdrawal syndrome

In Germany, neonatal withdrawal syndrome is usually treated with trinctura opil or phenobarbital. The authors point out that there is a need for additional research with regard to neonatal opioid withdrawal syndrome.

11.2.2 Opioid-related disorders: post-acute treatment

The most current guidelines of the Association of the Scientific Medical Societies in Germany on post-acute treatment in the case of opioid-related disorders were published in 2006 (Havemann-Reinicke et al. 2006). These guidelines were first published in 2004 (Havemann-Reinicke et al. 2004).

Objective in post-acute treatment

Acute treatment is followed by post-acute treatment. The target groups are primarily opioid addicts (ICD 10: F11.2, F11.5-9) and persons with multiple addictions with clinical addiction to opioids predominating. Post-acute treatment aims at helping patients stop using addictive substances and minimising negative effects in all areas of life. If it is not possible for patients to completely discontinue use of addictive substances, the focal point is on minimising the negative effects (e.g. ensuring survival, partial withdrawal from other addictive substances, reduction in the risk of infection with HIV and HCV, stabilisation of health and the psychosocial situation, occupational rehabilitation and social reintegration).

Forms of treatment, indication and diagnostics

Post-acute treatment can be abstinence-orientated or substitution-supported. There are outpatient, day hospital care and inpatient forms of treatment with and without medication (e.g. psychopharmaceuticals). Psychosocial counselling and treatment definitely plays an important role here.[148]

Comprehensive diagnostics are part of the post-acute treatment. These include among other things a physical examination, clinical-chemical laboratory examinations, drug screening, psychiatric, neuropsychological and psychosocial diagnostics. The aim is to achieve an

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[147] See Reymann & Gastpar, 2006: pp. 184 et seq. In this connection the guidelines “Therapy for chronic hepatitis C in the case of intraveneous drug users“(Backmund et al. 2006) and the consensus text “HIV infection in the case of intraveneous drug addicts (IVDA)” (Deutsche Gesellschaft fuer Suchtmedizin (DGS e.V.) et al. 2008), which have been issued in the meantime, should also be cited. Both documents are available at the Internet site of the Deutsche Gesellschaft fuer Suchtmedizin (German Society for Addiction Medicine): http://www.dgsuchtmedizin.de/ueber-uns/leitlinien/

[148] For additional information on the treatment system, see chapter 5.

overall picture of the physical and psychological condition of the patient by means of the various examinations in order to be able to create as broad a foundation as possible for fine-tuned treatment decisions (and forms of treatment).

Therapies: abstinence treatment

The indication for the selection of the form of treatment and the selection of the setting is determined by the individual situation of the patient at the outset. Abstinence therapy is for patients with a high level of motivation and willingness to abstain from drug consumption, for patients with shorter periods of addiction (less than 2 years) and for younger patients (under 18). The decision of the patient determines whether an abstinence-orientated therapy is performed in an outpatient, day hospital or inpatient setting. There are no empirically validated indication criteria, but experience shows, for example, that inpatient treatment should be recommended for patients with additional psychological or psychiatric disorders.

Individual therapies are recommended at first in the case of outpatient therapy. Group therapies are only advisable after patients have achieved a certain stability, as possible relapses could jeopardise other members of the group. Group settings are fixed elements of the treatment, on the other hand, in the case of inpatient forms of treatment.

Abstinence-orientated outpatient care usually lasts one year, with less intensity in the second half of the year. Inpatient post-acute treatment generally lasts six to nine months, with a regular termination after this time producing the highest abstinence rates following treatment.

Medication therapy is used as a supportive measure within the framework of abstinence-oriented post-acute treatment in order to maintain abstinence which has already been achieved and avoid relapses.

To prevent relapses, opiate antagonists, which achieve their prophylactic effect through the blockage of opiate receptors, can be used. Naltrexon (Nemexin) is used in Germany to support withdrawal treatment following detoxification. The guidelines recommend that treatment be commenced at the end of the inpatient acute treatment and that it also be continued in outpatient post-acute treatment. A high willingness to become abstinent and compliance are needed for treatment with Naltrexon. Patients should have discontinued consumption of opioids before the mediation is administered (the length of time of the interval depends on the type of opioid used). The guidelines contain recommendations on the dosage of the medication. Severe liver insufficiency is considered to be a contraindication for the administration of Naltrexon as well as is acute hepatitis, the use of opioids, withdrawal reactions to Naloxon, unsuccessful withdrawal, acute Opioid withdrawal symptoms and if patients are under 18 years of age. The administration of Naltrexon is also contraindicated for older drug addicts.

Therapies: substitution treatment

Substitution-supported treatments are indicated as part of a comprehensive therapy strategy if the aim of discontinuing consumption of substances appears unattainable over the short or medium term in cases of lengthy addictions, attempts to achieve abstinence under the supervision of a physician have not been successful, a substitution-supported therapy has

greater prospects of success or is to be used a transition to an abstinence-orientated treatment. It can be performed in an outpatient, day hospital or inpatient setting. The overwhelming number of substitution treatments in Germany are carried out in an outpatient setting. Drug counselling and therapy facilities, physicians at private practices, psychiatric and other clinics and in some cases chemists as well refer patients to substitution treatments.

In addition to substitution in the narrower sense of the word, general medicine, psychiatric, psychotherapeutic and psychosocial treatment measures are part of the overall strategy for a substitution treatment. The overall treatment plan must be coordinated with all the actors providing treatment (e.g. the substituting physician, therapist and social worker).

The substitution treatment can take place over a longer period of time, frequently several years. If a patient achieves a certain stability (e.g. one year without any consumption of other substances) and shows motivation towards abstinence, a phase-out of the substitution should be reviewed and planned.

In Germany substances admitted for oral substitution are levomethadone (e.g. L-Polamidone), methadone (D,L methadone), buprenorphine and in justified cases of exception codein/dihydrocodein (if there is a demonstrated incompatibility of methadone and buprenophine). The synthetic opioid LAAM was licensed for substitution in Germany in 1998, but is no longer licensed as a result of massive side effects[149]. For parenteral substitution of severe opioid addicts a diamorphine-containing commercial pharmaceutical product is licensed since October 2009.

An initial dosage is determined in a search-and-find phase in order establish a suitable dosage for the substituted patients; the so-called maintenance dosage is given during the substitution phase. The medication – apart from diamorphine- is administered orally as a preparation (e.g. dissolved in orange juice) and cannot be injected.

A substitution can also take place during pregnancy if drug consumption which has been substituted in some other manner or withdrawal would pose a health risk to mother and child. An improved health condition of mother and child and a stable pregnancy can be achieved through methadone treatment with low dosages. Psychiatric treatment of the mother is urgently recommended.

Buprenorphine (Subutex©) was licensed for substitution treatment in Germany at the beginning of 2000. Buprenorphine is suited for an initial substitution therapy over a brief period of time if the addiction illness is not yet that severe. Two metaanalyses (highest degree of evidence) describe a slight tendency towards a greater effectiveness of methadone compared to buprenorphine (see Havemann-Reinicke et al. 2006, p. 216).

A legal arrangement in the Amending Regulation on the Prescription of Narcotic Drugs (§ 5 para. 8, “Take home”) stipulates that the physician providing the substitution can prescribe

[149] Diamorphine was not yet licensed at the point in time these guidelines were issued. See chapter 11.2.3. Combination preparations of buprenorphine and Naloxon (suboxene) have also been licensed in Germany (since 2006).

the required quantity of the substitute (methadone, levomethadone or buprenorphine) for 7 days and the patient can take this under his own responsibility[150].

Psychotherapy and psychosocial therapy

Psychotherapy and psychosocial therapy have high priority in the overall treatment strategy. In post-acute therapy, psychosocial therapy has proven to be effective as an abstinence therapy. It should also be part of the treatment strategy in any substitution treatment and support it. A discontinuation of therapy is generally considered to be a negative predictor of treatment success.

Different psychotherapy procedures (e.g. behavioural analysis and cognitive intervention or activity, social, communications and relapse prevention training) seek to prepare patients for a drug-free situation after the therapy as do psychosocial therapy (e.g. work and ergotherapy, occupational therapy, leisure time/experience pedagogic, sports and movement therapy, creative therapy and sociotherapy).

The guidelines stipulate that “standard psychosocial treatment” should take place during substitution on a weekly basis during the first 6 to 12 months and thereafter every 14 days. The key elements are motivating discussions and case management (coordination and referral to other psychosocial helpers), furthermore social security (dwelling, financial support), crisis intervention, drug self-management, motivation development, the solution of interpersonal problems and leisure programmes helping participants structure their everyday lives and occupational rehabilitation in the form of counselling and work projects.

It is possible to provide intensive psychosocial treatment and this should be taken advantage of if standard treatment does not suffice (any longer). The crucial parameters are comorbid disorders and pronounced problems in various areas of life. In the case of intensive psychosocial therapies, two appointments per week are offered – one individual and one in a group setting. Especially interventions and prevention of relapse are important components in intensive treatment. Psychological reference persons and family members should be involved in efforts to cope with interpersonal problems. [151]

Sociotherapy

Sociotherapy is an integral and indispensable component in abstinence and substitution treatments. Both the degree of success and the maintenance rate are increased by it. Special attention should in particular be devoted to occupational reintegration, as stable employment is a predictor of the success of a therapy.

The aim of psychotherapy is the social reintegration and the establishment of functional relationships. The patient should be prepared for a life without drugs and, to achieve this, also receive comprehensive help and support in everyday life involving the social

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[150] For the prerequisites and underlying conditions under which this “take-home substitute “ is possible, see chapter 11.2.3.

[151] As a result of different financing models and funding agencies for treatment in the 16 German *Laender,* the performance of the treatment varies in practice.

environment. The general objectives must be spelled out in detail individually in accordance with the living situation.

Measures to solidify daily structures are a boon particularly for unemployed persons. Ergotherapy and work therapy can help integrate people in gainful employment, while work and training programmes help restore, maintain and improve employability ("occupational rehabilitation" under Social Code IX: benefits to help participate in working life). This includes, for example, counselling, job placement, initial and continuous training programmes or internships.

The strategy of assisting living helps secure the living situation and make it possible to run one's own household. Social isolation can be countered through assisted living.

Patients should be offered counselling and support in various areas of life. These may be everyday chores which are related to filling out forms for government authorities (e.g. in the case of claims to unemployment benefits, housing subsidies, sickness allowances, but also criminal and civil law procedures such as the termination of an apartment lease or job, issues involving child custody or debt-handling advice).

Comorbid disorders

With drug addicts, frequently occurring comorbid disorders require consistent psychiatric-psychotherapeutic co-treatment. For treatment purposes, the use of psychopharmaceuticals are recommended as well as psychotherapeutic procedures. The guidelines contain a translation of the basic treatment principles for treating comorbid disorders of the American Society of Addiction Medicine in the annex.

The treatment of depressive disorders, psychotic disorders and personality disorders should also be handled within the framework of integrative overall treatment. This also goes for the treatment of general medical comorbid disorders, in particular types of hepatitis and HIV infections.

Incarceration and hospital treatment order

Under German law, incarcerated persons and as a rule persons undergoing hospital treatment by court order (in accordance with § 64 of the Criminal Code) are treated in an abstinence-orientated manner. The authors of the guidelines state that a substitution treatment can also be successful at these facilities if the patients meet the prerequisites for such.

After-care

Follow-up care following an abstinence or substitution treatment helps stabilise the continued motivation for abstinence, social and occupational integration, psychological stability and prevention of relapse. After-care is carried out under supervision within the framework of self-help or professionally (for example, assisted living after treatment).

11.2.3 Rules and regulations of the German Medical Association on the performance of substitution-supported treatment of opiate addicts

As a result of the revision of the Amending Regulation on the Prescription of Narcotic Drugs in 2001, § 5, section 11 assigns the German Medical Association the task of setting out the generally recognised state of medical knowledge pursuant to compliance with the prerequisites for the licensing of substitution treatment under § 5, section 2, nos. 1, 2, 4 letter c. The German Medical Association appointed a joint experts commission with the Association of Statutory Health Care Physicians (Kassenaerztliche Bundesvereinigung) in the autumn of 2001 in order to prepare rules and regulations on substitution-supported treatment of opiate addicts. The rules and regulations on the Performance of Substitution-Supported Treatment of Opiate Addicts was adopted by the German Medical Association on 22 March 2002 and published in the Deutsches Aerztebaltt on 24 May 2002. The current, revised version of the rules and regulations was issued by the Board of the German Medical Association on 19 February 2010 (BAEK 2010).

Legal foundations

In addition to the Amending Regulation on the Prescription of Narcotic Drugs, the *Betaeubungsmittelgesetz* (Narcotics Act) and the *Arzneimittelgesetz* (Medical Products Act) set out the legal foundations for substitution treatment.

The physician providing treatment must meet the minimum requirements with respect to addiction-therapy qualifications and have a substitution license in order to be able to begin performing diagnostics and determining indications with the substitution[152]. These minimum requirements are set by the medical associations. Patients may not undergo substitution treatment with another physician at the same time.

Definition and objectives

As a scientifically evaluated form of therapy for manifest opiate dependency, substitution treatment requires a comprehensive overall strategy. It seeks to ensure survival, reduce the use of opiates and other narcotic substances and achieve abstinence from addictive substances, to stabilise the health situation and treat secondary illnesses, to reduce risks during pregnancy and after birth and to help the patients participate in society and working life once again.

Manifest opiate dependency (in accordance with ICD-10 F11.2) justifies the indication of a substitution-supported treatment. It should be used after weighing out whether it would be preferable to an abstinence-orientated treatment. If the substitution treatment offers a greater chance for success, then this is indicated. In the case of younger patients who have only recently become addicts, a substitution treatment should only be considered as a transitional solution. Substitution helps reduce risks particularly in the case of pregnant women.

Therapy

[152] The exceptions (such as for example medical staff to fill in for the physicians providing substitution when they are on holiday) are set out in the Amending Regulation on the Prescription of Narcotic Drugs (BtMVV) and are contained in the regulation/rule.

The overall strategy in substitution therapy also includes identifying additional somatic and psychological illnesses and if need be the initiation of co-treatment of these. The therapy strategy also covers assistance in arranging psychosocial measures. The involvement of the professional system of aid for substance abuse disorders and psychosocial assistance help achieve the identified therapy objectives. The scope and type of measures are based on the respective individual situations. The physician providing treatment should motivate the patient to initiate contact with the respective institutions and facilities. The physician providing treatment and the facility should act in consultation to determine the individual treatment needs. The progress of both treatment elements should be coordinated and reviewed on an ongoing basis.

Before the substitution is initiated it is up to the physician to perform a host of precautionary measures. A detailed examination of the patient should be performed and communication take place with actors who have provided treatment in the past. It must be ensured that there is no multiple substitution. The physician is obligated to submit a notice to the Substitution Register in codified form.[153]

The physician is required to obtain the permission of the patient for the therapy measures, and a written agreement should be concluded over the most important arrangements. This relates, for example, to the selection of the substitution substance and informing the patient about the effect, side effects and interactions. This also goes for modalities of ingestion under supervision, the daily administration, weekend arrangements and possible take-home arrangements. Abstaining from the consumption of other substances and checks and controls on adherence should be agreed upon as should the objectives of the therapy, criteria for breaking off the therapy and the required psychosocial assistance. The patient must release the physician providing treatment from the non-disclosure obligation (e.g. vis-à-vis the psychosocial counselling office, the Medical Association or chemists) and allow the notification of the treatment to the Substitution Register in coded form.

The regulation/rule refers to applicable provisions of the Amending Regulation on the Prescription of Narcotic Drugs with regard to the selection of the substitution substance; the physician is required to take into account the effect and side-effect profile in the planning of the therapy strategy. The initial dose shall be selected so as to ensure that an overdose can be ruled out including in the case of low opiate tolerance. The oral administration of the substitution substance should be personally supervised by the physician providing treatment. The regulation/rule contains specific arrangements for exceptions (such as, for example, filling in for a physician on holiday). The patient receives the substitution substance from the physician (or whoever is filling in for the physician) or (if allowed by law) by the chemist or medical personnel commissioned by the chemist. Agreements should be made by the physician and the chemist to ensure a smooth supply of substances.

Under some conditions in the take-home arrangements, patients can be subscribed the substitution substance to take under their own responsibility. The preconditions for this are

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[153] The notes contained in the rules and regulations e.g. on examinations and drug screening correspond to a great extent to the recommendations set out in the guideline “Opoide-Related Disorders: post-acute treatment“ of the Association of the Scientific Medical Societies in Germany (AWMF), see pursuant hereto chapter 11.2.2, Therapies: substitution treatment.

that the phase of determining the right dosage of the substitution substance has been completed. The treatment must lead to a clinical stabilisation of the patient and the patient must not be consuming any additional substances. Moreover, it must be possible to rule out any hazards for the patient or other persons as a result, the patient must have maintained the contact to the physician and PSB and psychosocial reintegration must have reached an advanced stage. Under the Amending Regulation on the Prescription of Narcotic Drugs, the period of time is limited to seven days. The patient receives the substance from the chemists, no substances available at the practice may be provided.

The physician is in charge of checking and controlling the treatment. This includes checking whether the substitution substance has been taken properly and controls on abstinence from other addictive substances. The ongoing monitoring also primarily serves the purpose of deciding on “take-home prescriptions” and the initiation of measures in the case of dangerous consumption of additional substances (e.g. reducing the does or initiating inpatient withdrawal). In looking for the cause with respect to consumption of other substances, it should be checked whether the patient is experiencing a destabilisation in living conditions, the wrong dosage has been selected or there is a comorbid disorder or somatic illness.

Termination and discontinuation

A substitution can be regularly terminated in consultation between the physician and patient if it is no longer necessary or the patient no longer desires such. It is to be terminated by the physician if it no longer appears to be suitable, or if it is determined that there is an ongoing problematic consumption of other substances. The termination of substitution is to be avoided, as one must assume it to be associated with a high potential risk. All intervention possibilities (e.g. optimisation of therapy, adjustment of the dosage, a change in the facility) should be reviewed before treatment is discontinued. Only if the patient repeatedly violates agreements (e.g. does not come to appointments, refuses to undergo checks and controls) or other misconduct (e.g. use of violence against staff of the facility or endangering other persons by passing substances on to them) and a consideration of possible damage and benefits should treatment be discontinued. If it is discontinued, the patient should be provided the possibility of a regimented withdrawal, if need be in an inpatient setting.

Quality assurance

It is recommended that a manual be issued for internal quality assurance. Arrangements laid down by the regional medical associations and associations of national health care physicians apply to external quality assurance.

Diamorphine

The regulation was expanded in the version from 19 February 2010. In its new form it also covers the substitution of diamorphine, for which special arrangements exist. In order to perform treatment with diamorphine the patient has to have turned 23 and have been dependent on opiates for at least five years and currently consume opiates primarily intravenously. Serious somatic and psychological disorders must be present and the patient

must have unsuccessfully undergone two prior treatments for dependency, of which in at least one oral substitution substance was provided for at least six months.

Accompanying psychosocial treatment is mandatory during the first six months. With substitution treatment, special requirements apply to informing the patient about the effect and dangers as well as the type of intravenous application. The administration of the substitution substance and the injection as well as return of the injection instruments must be provided under the supervision of a physician; a take-home prescription is not possible and is punishable as a criminal offence. The special aspects of the substance (rapid flow and a shorter half-life) are to be taken into account in setting the dosage. Diamorphine can only be administered at facilities licensed for such by the respective regional authorities. Special requirements apply to the qualification requirements for the physician.

11.2.4 Cannabis-related disorders

The current Association of the Scientific Medical Societies in Germany guidelines on cannabis-related disorders were published in 2006 (Bonnet et al. 2006). These guidelines were first published in 2004 (Bonnet et al. 2004).

Diagnostics

Looking at the medical history of cannabis consumers, no somatic symptoms are generally evident aside from respiratory problems. Indications of increased consumption of other substances can be determined in the special addiction anamnesis. A discriminating social anamnesis is important, as many cannabis consumers are very young patients.

Indications of consumption and regular consumption can be found through urine and blood tests. A hair analysis can provide additional information on consumption e.g. the exact point in time of consumption. It is recommended to search for other substances (alcohol and illegal drugs) in the urine and blood tests.

Diagnoses are performed in accordance with the current international classification of illnesses (ICD-10) or DSM IV.

Treatment

For young patients, who have often begun consuming cannabis at a young age and also exhibit greater psychiatric comorbidity, individual treatment plans are necessary. Brief interventions with motivation-boosting goals are effective. Environment and family therapy interventions also have a major effect on adolescents.

The guidelines contain brief interventions combining motivation-strengthening and cognitive-behavioural elements of therapy along with individual counselling work along the lines of case management in accordance with current research findings[154]. Programmes for self-help groups which are based on the 12-step programme of Alcoholics Anonymous are also an effective approach, as is cognitive behavioural therapy.

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[154] The guidelines provide a summary of reviewed strategies for the psychotherapeutic treatment of cannabis addicts from the U.S. and Australia. See Bonnet et al. 2006 p.156.

Thus far there have not been any pharmaco-therapeutic strategies for preventing relapse and reducing consumption. The authors mention, however, that a recently developed antagonist (CB1 Cannabinoid Receptor Antagonist [SR141716]) could open up the possibility of treatment, similar to relapse prevention for opium addicts.

Generally the treatment of a single cannabis dependency is performed in an outpatient setting. Depending upon the severity of the withdrawal syndrome, the danger of relapse or outpatient therapy resistance and the severity of comorbid disorders, inpatient treatment may be indicated. In particular it is recommended that children and adolescents be treated as inpatients in order to be able to take into account the frequently serious psychological and social dimension of the addiction.

The treatment should comprise acute treatment (withdrawal treatment) and medical rehabilitation (rehabilitation). Treatment of an uncomplicated intoxication generally does not require any interventionary measures going beyond supportive assistance. Patients with complicated intoxications associated with panic attacks (F12.02) react to “down-talking” or, if the patient does not respond, to the administration of benzodiazepines. Benzodiazepine can also be used for transient psychotic episodes (F12.04). The use of benzodiazepines and anti-psychotics is also an option in the treatment of longer-lasting psychotic episodes (F12.50) and possible delirious syndromes.

The treatment of symptoms accompanying the withdrawal syndrome usually do not require any pharmacological treatment. Patients profit from general physical and nursing measures in a qualified withdrawal syndrome treatment.

In serious cases, sleep disturbances can be treated with hypnotics and inner agitation and irritability with low-potency neuroleptics or sedative anticonvulsants. In the case of prominent vegetative withdrawal symptoms, clonidine can be used. Benzodiazepine should be avoided as a result of its high potential for causing dependency, but may be administered for up to 3 weeks if other substances are not sufficient. Secondary psychological and somatic illnesses should be treated individually depending upon the specific disorder.

With regard to the therapeutic relevance of cannabinoids, the guidelines address the fact that in Germany synthetic cannabinoids are licensed as category III sedatives (eligible for commercial trade and sedatives subject to prescription requirements). The psychoactive cannabinoids dronabinol and nabilone, for example, are used during chemotherapy to treat nausea and vomiting. Dronabinol is moreover used to treat the “AIDS-wasting” syndrome.

11.2.5 Psychological and behavioural disorders resulting from cocaine, amphetamines, ecstasy and hallucinogens

The latest guidelines of the Association of the Scientific Medical Societies in Germany on “psychological and behavioural disorders resulting from cocaine, amphetamines, ecstasy and hallucinogens” were published in 2006 (Thomasius & Gouzoulis-Mayfrank 2006). These guidelines were first published in 2004 (Thomasius & Gouzoulis-Mayfrank 2004).

As a result of the unsatisfactory data situation, these guidelines are more based on a consensus of experts. The authors emphasise that one special feature of the guidelines is that they are characterised by a lower level of substance specificity.

Diagnostics

Comprehensive diagnostic measures to achieve as precise a picture of the patient as possible forms the basis for a treatment. These include psychodiagnostics (identification of substance-related disorders in accordance with ICD-10), addiction anamnesis, psychopathological findings and assessment of treatment motivation and establishment of comorbid psychiatric disorders (also in accordance with ICD-10) and somatic and socio-diagnostics. At the same time, special aspects of the substances and substance-related disorders need to be cleared up.

Treatment

The guidelines cover both acute treatment as well as post-acute treatment. Different recommendations are made regarding the withdrawal/detoxification treatment for the various substances in the case of acute intoxication. In addition to the treatment of withdrawal syndromes, the respective treatment of secondary illnesses and medical emergencies, psychological-psychiatric diagnostics and measures to promote the use of an abstinence therapy and supportive measures in the social area are the goals in acute treatment.

Table 11.1 Treatment of acute, substance-related disorders with medication

Substance	Type of disorder	Treatment
Cocaine	Psychotic intoxication, nervous agitation	Temporary benzodiazepine
	Withdrawal symptoms	Motivation-boosting tricyclical anti-depressives, amantadine
Amphetamines	Psychotic intoxication, induced psychological disorders	Temporary benzodiazepine and neuroleptics
	Withdrawal with rebound phenomenon	Tricyclical anti-depressives
Ecstasy	Psychotic intoxication, strong post-effects	Temporary benzodiazepine; caveat: no neuroleptica or anti-depressives antidepressants
Hallucinogens	Psychotic intoxication	Temporary benzodiazepine; caveat: no neuroleptics

Thomasius & Gouzoulis-Mayfrank 2006.

The goal in post-acute treatment is the treatment of disorders in psychological functions, treatment of physical effects, secondary and follow-up illnesses and treatment of the interactional, psychosocial and development-related disorders. Abstinence and reduction of substance consumption are partial goals of the treatment, which should ultimately make it possible for patients to run their own lives autonomously.

Post-acute treatment is possible both in an outpatient setting (in 80 to 120 individual or group meetings – with the inclusion of important reference persons – within a period of 18 months) and as short-term or long-term inpatient therapies (3 to 6 or 7 to 10 months). Additional

treatment possibilities exist in the area of inpatient psychiatrics and psychotherapy and in specialised addiction departments in child and adolescent psychiatry and psychotherapy.

In addition to basic medical care, support should also be provided in dealing with social affairs.

The selection of the treatment setting is based on the clinical features of the substance-related disorder, the motivation of the patient for a certain procedure and the regional availability of treatment possibilities. A stable social environment can be a reason to opt for an outpatient form of treatment, while inpatient treatment is recommended in the absence of stable social and/or everyday structures. Inpatient treatment lasting more than 90 days is recommended for patients with fluctuating motivation and who especially consume cocaine through inhalation or intravenously.

Psychotherapeutic treatment is assigned a key importance in the post-acute treatment of cocaine, stimulants and hallucinogenic disorders.

Behavioural therapy/cognitive therapy, supportive therapy, psychodynamic therapy and family therapy can be applied in individual and group meetings.

Patients addicted to cocaine with several psychosocial and psychiatric disorders profit from procedures aimed at avoiding relapse more than other approaches. Family therapy approaches are recommended for adolescents. Psychological education and motivational intervention should be used as additional support in the post-acute treatment.

The authors recommend a sociotherapy which enables patients to cope with everyday problems. Patients are supposed to receive support with regard to their occupational situation, financial issues (debts), legal and bureaucratic matters and the avoidance of destabilising factors in their social environment. Easy-access programmes are helpful especially to people consuming intravenously (cocaine) or who are threatened by impoverishment (cocaine consumers, crack consumers and polytoxicomaniacs). The authors recommend the continuation of socio-therapeutic assistance through outpatient or inpatient therapy.

No general recommendations can be derived for substances with respect to pharmacological treatment in post-acute treatment as a result of the state of the art in research. If a substance-induced psychosis has been ruled out in the post-acute treatment, schizophrenia in the form of psychiatric comorbidity should be treated with neuroleptics.

Mothers who are dependent on cocaine and pregnant women must receive special attention. In addition to paediatric care, new-born children should receive child-psychiatric and intensive psychosocial assistance. The mothers should be assisted by youth and family aid institutions. The care functions of mothers require professional support in order to ensure that their children are cared for.

11.2.6 Medication dependency (sedatives, hypnotics, analgesics, psychostimulants)

The latest guidelines on “medication dependency” from the Association of the Scientific Medical Societies in Germany were published in 2006 (Poser et al. 2006).

The guidelines are broken down into three chapters on hypnotics/sedatives, analgesics und psychostimulants.

Hypnotics/sedatives

The guidelines understand hypnotics/sedatives to mean the substance groups or substances of benzodiazepine, Zolpidem/Zopiclon/Zaleplon, Clomethiazol (substances similar to barbiturates), γ-Hydroxybutyrat (GHB) and γ-Butyrolacton.

Aside from the therapeutic administration of medication, consumption of these can according to ICD-10 also cause an acute intoxication (F13.0), constitute harmful use (F13.1) or a dependency syndrome (F13.2). Of all the hypnotics/sedatives, benzodiapepine is prescribed most often as a result of its therapeutic effect. While harmful use of these substances is rather rare, dependency requiring treatment occurs relatively frequently. Abuse in the meaning of DSM-IV occurs more frequently within the framework of polytoxicomania, especially in connection with illegal drugs.

There is a need for treatment when a diagnosis is made according to ICD-10 or DSM-IV. A diagnosis is a special challenge in the case of medication dependency or abuse. On the one hand, the medications are usually prescribed for therapeutic purposes, while on the other illegal acquisition and uncontrolled consumption (especially of benzodiazepines) occur as well, frequently as additional consumption of illegal drugs. If a dependency is salient in such a case e.g. of opioids, the respective guidelines should also be taken into account. A low-dosage dependency can occur with benzodiazepines prescribed by a physician if the prescribed dosage is taken over a lengthy period of time.

In the case of acute intoxications, it should be checked whether a harmful use of other substances or a dependency is present. Patients can be monitored on an outpatient basis; while in the case of severe intoxications the patient should be placed in a hospital for observation.

In the case of harmful use without dependency, the discontinuation of the medication by the therapist is possible as a form of early intervention. The physician providing treatment or the addiction therapist should win the patient over to a life without sedatives and the avoidance of long-term effects with the aid of therapeutical talks (“motivational discussions”). In the case of dependency, hypnotics/sedatives definitely must not be discontinued suddenly. They are to be phased down in a controlled, gradual manner by the physician treating the patient.

If there is a low-dosage dependency (e.g. in the case of long-term treatment with benzodiazepines), withdrawal is not generally recommended, and is, rather, dependent on a risk-benefit assessment. The execution of so-called long-term outpatient withdrawal can take place in family physicians’ practices or with general practitioners. Specialised clinics are recommended in complicated cases. The gradual reduction of dosages may take between 4 and 10 weeks in the case of long-term outpatient withdrawal.

Patients with a high-dosage dependency should be treated within the framework of a “fast inpatient withdrawal“ which is performed within a period of 3 to 6 weeks in psychiatric clinics. Withdrawal takes place through a controlled reduction in the dosage.

Benzodiazepenine dependency is frequently accompanied by alcohol dependency and polytoximania. In the case of alcohol dependency, the dosage of benzodiazepine is reduced after the alcohol withdrawal has been completed. In withdrawal from benzodiazepine, very high dosages may initially be necessary in the case of multiple dependencies. If there are multiple dependencies it is recommended that the respective guidelines on the consumed substances be taken into account.

Withdrawal treatment is urgently recommended in the case of pregnant women, as withdrawal treatment of new-born children is extremely complicated.

Treating withdrawal from benzodiazepine with medication (which can involve, for example, the administration of sedating tricyclical antidepressives against agitation and sleep disorders or anticonvulsives for seizure prophylaxis) should begin before the withdrawal so as to prevent withdrawal symptoms.

Psychological support should vary according to individual needs and can range from brief supportive interventions all the way to more cognitive or behavioural therapeutic techniques to manage anxiety and stress. Psychological education for specific additions is particularly important with regard to dependency syndrome, risks of relapse and harmful effects. Individual meetings are recommended, as these are more effective than group meetings in these cases.

In treating comorbid illnesses, it must be taken into account whether the psychological illness (frequently anxiety and depression-related disorders, borderline personality disorders, post-traumatic stress disorders and ADHS) existed prior to the dependence on hypnotics/sedatives. Such pre-existing illnesses often continue to exist during and after the dependency and require separate treatment. On the one hand, a dependency on medication can for its part set additional processes in motion which persist as follow-up illnesses following withdrawal and also justify a need for treatment.

Analgetics

Opioids and non-opioid analgetics are used as pain-killers. The authors of the guidelines state that, in spite of the inadequate data available in Germany, it can be assumed that harmful or non-intended use takes place on a relevant clinical scale. Persons who have had a previous addictive illness, particularly relating to opiates, are particularly at risk of developing a dependency on medication.

The guidelines describe signs of harmful or non-intended use (e.g. forged prescriptions, refusal to disclose sources from which such are obtained, opposition to changes in opioid therapy) and describe the special role which physicians are assigned in prevention (risks to be avoided; e.g. patients not being provided sufficient information, monodisciplinary indication, unclear therapy objectives or therapy objectives which have not been mutually agreed upon, continued prescription of opioids in spite of insufficient prospects of success for the therapy).

Psychostimulants

The guidelines describe the harmful use and dependency on psychostimulants (such as, for example methylphenidate [e.g. Ritalin©]). Because abusive consumption prevents use of psychostimulants, but these are not supposed to be withheld in the case of indicated treatment of patients (e.g. children with ADHS), the authors draw attention to the respective guidelines of the Society for Children and Psychiatric Treatment and Psychotherapy for Adolescents.

11.2.7 German Statutory Pension Insurance (DRV): guidelines on rehabilitation needs in the case of dependency-related illnesses

The 2nd version of the “Guidelines on Rehabilitation Needs in the Case of Dependency-Related Illnesses“ from German Statutory Pension Insurance comes from 2005. It replaces the 1st version from 2003 (DRV 2005).

The guidelines refer to dependency-related illnesses in general terms. Statements and recommendations are made for special substance-related aspects in sub-chapters of the guidelines. Pathological gambling and behavioural disorders resulting from intensive use of computers and the Internet are taken into account as non-substance-related disorders.

Need for rehabilitation

In general there is a need for rehabilitation if a substance abuse disorder is present and the following preconditions have been met: a withdrawal treatment must have been completed, the person must be capable of undergoing rehabilitation and it must be possible for the rehabilitation to return the patient to gainful employment.

A dependency illness is considered to be present if the person is incapable of abstinence or has lost self-control or if these two systems occur periodically. ICD-10 and DSM-IV are used as the diagnosis criteria for diagnosing a dependency syndrome.

Rehabilitation programmes and benefits

Rehabilitation can be carried out on an outpatient or inpatient basis. The guidelines refer to an agreement between the health insurance schemes and Statutory Pension Insurance which sets out the criteria which apply to the facilities (e.g. with respect to personnel, funding agency, space, therapy offers and places) (DRV 2005, "Substance Abuse Disorder Agreement" in the annex to the guidelines). What measures are suitable for the patients must be decided on an individual basis. The most important criteria are, for example, the social and occupational integration of the patient, the living situation, capability of abstinence and active cooperation in the therapy or the degree of possible psychosocial disorders.

In the case of inpatient treatment, the therapy may last up to 26 weeks, with shorter therapies lasting between 12 and 16 weeks. Outpatient rehabilitation for addictions may last up to 18 months, in which a maximum of 120 individual or group therapy meetings can take place as well as up to twelve therapeutic discussions with important reference persons.

In the after-care, services can be provided by outpatient after-care if joining a self-help group is not enough. 20 individual or group therapy meetings are held within a period of half a year. The system of benefits also covers an adaptation phase which can follow rehabilitation. In

the phase lasting up to 16 weeks patients are stabilised in their everyday lives, while the performance capability and capacities of the insured party to deal with stress are to be improved.

Aid in reintegration in working life is of central importance to rehabilitation, which is aimed at restoring the capability to work as a more general objective from the perspective of the Statutory Pension Insurance. Aid and benefits to help reintegrate insured persons help promote motivation for addiction rehabilitation and should be provided as early on as possible. A successful reintegration has a positive impact on abstinence and psychological stability.

11.2.8 Further development of guidelines

At present the guidelines of the Association of Scientific Medical Societies in Germany at development level S2 are being further developed under the auspices of the German Society for Research on Addictions (DG-Sucht) and the German Association for Psychiatry and Psychotherapy (DGPPN). The consensus process has not yet been completed, nor can it be predicted when the guidelines will be published (Fleischmann, personal communication). Work is taking place at present on a non-substance-related development of guidelines on the topic “psychosocial therapy”. Even though experts emphasise that “addiction” should be a topic in this development process, it has thus far been ignored in the drafting of this report (Fleischmann, personal communication).

The rehabilitation guidelines of German Statutory Pension Insurance are currently being revised and the publication of the new version in 2010 is considered to be probable. The Statutory Pension Insurance is endeavouring to also involve the relevant specialised societies (e.g. German Association for Psychiatry and Psychotherapy and the German Society for Research on Addictions (DG-Sucht)) in the process of developing the guidelines. The guidelines are to be brought in line with the procedures developed in the guidelines of the Association of the Scientific Medical Societies in Germany, as this procedure enjoys broad general acceptance in the science community.

11.3 Implementation process

Gastpar and Schmidt (2006) point out that studies have yet to be conducted on the applicability and use of the guidelines in practice. A review of the relevance of guidelines in everyday practice should also provide a basis to assess the needs for improvement of guidelines with regard to their viability in practice.

The guidelines of the Association of the Scientific Medical Societies in Germany drafted in Germany are supposed to contribute to an improvement in quality in addiction aid through their application. The most important preconditions for the application of guidelines are the dissemination, availability and acceptance of them by professions providing treatment. With the publication of the guidelines of the Association of the Scientific Medical Societies in Germany and their free availability in the Internet it can be assumed that the degree of awareness of the guidelines is high among the relevant groups of professions. To date no data which can be validated is available; just as little is known about the use and application of the guidelines in actual practice.

Because the development of the guidelines has to be supported by a broad consensus among experts, it must be assumed that they meet with a high level of acceptance among the relevant professional groups in spite of the discussion over applicability and viability in the state of practice (see Koch 2006; Schmidt 2006 and chapter 11.1.4).

Because the guidelines of the Association of the Scientific Medical Societies in Germany are not regulations, it is left up to clinics and treatment facilities what internal standards they want to base their treatments on. Clinics must set out in their quality management systems, however, which guidelines their treatments are based on in order to achieve certification through an external auditor. It can thus be assumed that the guidelines of the Association of the Scientific Medical Societies in Germany are applied on a broad scale at the level of the clinics. (Fleischmann, personal communication).

The guidelines of German Statutory Pension Service are implemented at the level of rehabilitation facilities by the agreement on “Dependency-Related Illnesses” between the Statutory Pension Insurance and health insurance schemes contained in the annex defining the requirements applying to facilities with regard to the performance of outpatient and inpatient treatment measures and laying down the criteria for decisions on outpatient and inpatient treatment (DRV 2005)

The guidelines of German Statutory Pension Insurance are of decisive importance in the performance of rehabilitation measures, the reason being that they stipulate what can be paid for by the Statutory Pension Insurance (or the health insurance schemes). The Evidence-based Therapy Model (ETM) which is formulated therein is made available to facilities. The Classification-of-Therapeutic-Benefits (KTL) analysis[155] determines to what extent the Evidence-based Therapy Model can be applied. An improvement in the supply of rehabilitation in actual practice is supposed to be achieved through feedback to the facilities and institutions (Brueggemann et al. 2004).

[155] KTL analysis: The Classification of Therapeutic Benefits (KTL) is a directory of therapeutic benefits drafted by the BfA (now German Statutory Health Insurance) which can be carried out during a medical rehabilitation. The results of a research of the literature, formulated as an evidence-based therapy module (ETM) are compared as treatment targets with the actual situation (as reflected in the release reports of the BfA (now the German Statutory Health Insurance) (see 11.1.3).