

**The German Diabetes Association
German College for Psychosomatic Medicine**

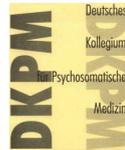
**Evidence-based Guidelines of the German Diabetes Association:
Psychosocial Factors and Diabetes Mellitus**

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1 Foreword

The prevalence of diabetes mellitus has taken on epidemic proportions and continues to grow. The illness not only poses noteworthy clinical problems and problems for social medicine, but also, most importantly, can have a serious impact on the life of every affected individual. Although great advances have been made in the care of patients with diabetes, a broad range of variation can be observed in the quality of care for those suffering from diabetes mellitus. Equally variable is the quality of the available guidelines regarding diabetes mellitus, due in large part to the differences in the quality of methodological approaches. Therefore, the Deutsche Diabetes Gesellschaft – DDG (German Diabetes Association) has taken it upon itself to create a national approach for assuring and improving the quality of care in diabetes treatment by means of evidence-based consensus guidelines.

Scientists, physicians, diabetes-trained non-physician groups, financial backers, and patient organisations were called upon to contribute to the development of the DDG Guidelines. Consequently, these guidelines should provide an orientation aid in defining what is necessary and what is superfluous when caring for those suffering from diabetes. In this regard, the DDG Guidelines make it possible to implement the precepts put forth in the German Healthcare Structure Law of 2000 for the area of diabetes care, which stipulate that the use, necessity, and cost effectiveness of a measure must be in line with the current status of scientific knowledge.

The present guidelines “Psychosocial Factors and Diabetes” were developed through an interdisciplinary process of consensus according to the principles of the DDG (see below) and is recognised by the DDG and the German College for Psychosomatic Medicine (Deutsches Kollegium für Psychosomatische Medizin) as their official guidelines. The recommendations address the following topics: patient education, behavioural medicine, and psychological disorders of particular relevance to diabetes: depression, anxiety disorders, eating disorders, and dependence on alcohol and nicotine.

2 Methods

The methodological approach in developing the guidelines follows the specifications of evidence-based medicine. It is based on nationally and internationally accepted quality criteria, as defined by and embraced as the standard of the following organizations, among others: the Agency for Health Care Policy and Research [AHCPR, 1992], the

Evidence-Based Medicine Working Group [Hayward et al, 1995], the Scottish Intercollegiate Guidelines Network [SIGN, 1999] and the Centre of German Physicians for Quality Assurance in Medicine (Zentralstelle der Deutschen Ärzteschaft zur Qualitätssicherung in der Medizin, ÄZQ, 1999). A summary of the approach is presented in the following paragraphs.

Composition of the working group

- The chairman and Guideline Commission of the DDG assembled authorities who are recognised in their respective fields into expert panels for each guideline.

Database search

- Determination of the relevant databases (e.g., MEDLINE/PubMed®, Knowledge Finder®, HealthStar®, Cochrane, EMBASE) in consultation with the expert committees.
- Determination of the keywords for the search through a consensus among the experts in a discipline, general medical practitioners and patient representatives.
- Systematic search of the scientific literature (English and German, clinical studies, no animal experiments), as well as currently available standards, guidelines, recommendations and their references.
- Checking of search results for their relevance by staff trained in the field (scientists and physicians from the expert committees).

Assessment and evaluation

- Scientists experienced in the analysis of study designs classified the studies according to their scientific evidence into levels of evidence I-IV corresponding to the AHCPR and SIGN (see Table 1). In the event of diverging opinions, classification was achieved according to consensus reached through discussion.

Compilation

- Creation of rough drafts based on the central statements of the examined and evaluated literature.
- Multiple meetings of the expert panels to discuss the content of the drafts.

- Presentation of the discussion drafts at specialist meetings, public symposia and on the Internet, as well as in pre-publications for debate and critical comment.
- Consideration of suggested amendments, corrections, and additions arising from teleconferences, small meetings, or written communications (postal and electronic).
- Conclusion of the expert versions.
- User version for practising physicians; patient versions based on the final expert versions.
- Discussion and implementation of all versions.

The draft guidelines “Psychosocial Factors and Diabetes” were first presented to the interested public in a special issue of the journal *Diabetes und Stoffwechsel* (Volume 12, 20 January 2003) and as a virtual document on the DDG’s website. This step enabled a wider audience to inspect the document critically, thus prompting others to participate actively in the creation of the guidelines by submitting comments and suggestions for additions and amendments. All suggestions for alterations received before printing began were discussed by the expert groups and incorporated as appropriate. The outcome of this process is presented below as the long version of the diabetes guidelines, which were examined again by the DDG Guideline Commission and approved by the DDG Executive Committee in May 2003. An abridged user version of the guidelines is in preparation.

Table 1 Classification of the published literature into levels of evidence according to their scientific evidence [modified after AHCPR, 1992; SIGN, 1996]

Levels of evidence (LE)

- Ia Evidence from meta-analysis of randomised controlled trials
- Ib Evidence from at least one randomised controlled trial
- IIa Evidence from at least one controlled study without randomisation
- IIb Evidence from at least one other type of non-randomised and uncontrolled clinical study, e.g., cohort study

- III Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
 - IV Evidence from expert committee reports or opinions and/or clinical experience of respected authorities
-

The weighting of the stated intervention recommendations (screening, prevention, diagnostics, therapy and rehabilitation) with grades A through C was performed by clinically trained experts based on underlying evidence **and** clinical relevance. In areas in which clinical evidence had to be weighted differently from the scientific evidence, the grade of the recommendation was determined through an interdisciplinary consensus (see Table 2). This procedure ensures that recommendations for which external evidence is insufficient or unavailable can receive the highest grade A if experience has shown them to be indispensable for the clinical course. In contrast, interventions that might otherwise be assigned evidence levels Ia or Ib can receive the lowest grade due to their minimal clinical significance. The necessary transparency is achieved by assigning both the underlying external evidence and the grade of the recommendation to the individual recommendations.

Table 2 Weighting of Recommendations

Grade	Underlying evidence
A	Evidence levels Ia, Ib or first-rate from a clinical perspective
B	Evidence levels IIa, IIb, III or second-rate from a clinical perspective
C	Evidence level IV or third-rate from a clinical perspective

3 Introduction

Somatic and psychosocial factors are important both for the treatment and long-term prognosis of diabetes mellitus. In diabetes care the patient assumes a crucial role since he must carry out the essential therapeutic measures in his daily life, in a responsible manner, and on a permanent basis. As a consequence, the prognosis for diabetes

largely depends on how successful the patient is in this endeavour, against the background of his or her social, cultural, family, and work environment. The following psychosocial factors are of importance in this context:

- Acquiring knowledge about self-treatment and skills for its implementation in daily life;
- Emotional and cognitive acceptance of one's illness;
- Coping with diabetes and its possible consequences in all affected areas of life and in various phases of the illness (e.g., diabetes-specific burdens, acute and diabetes-related complications);
- Identification and modification of behaviours that are an obstacle to successful self-treatment;
- Dealing successfully with crises and/or problems associated with the illness (e.g., mental disorders such as depression, anxiety, eating disorders).

A series of evidence-based psychosocial interventions exist that help patients with diabetes to cope successfully with the recommended treatment strategies and maintain a good quality of life (QoL). Therefore, the treatment of diabetes should always be approached from a “biopsychosocial” perspective.

The present recommendations on psychosocial interventions for diabetes are based on the best evidence available. They refer only to adult patients. Separate guidelines of the German Diabetes Association addressing the psychosocial problems of and interventions in children and adolescents with diabetes are in preparation.

4 Patient education

4.1 Definition

A diabetes education program is a systematic and goal-oriented process that imparts knowledge about the illness and skills for its treatment. The patient has to integrate the illness into his or her daily living through independent decision making, in order to avoid acute or long-term negative consequences and maintain QoL. The structured patient education program is a worldwide recognised, indispensable therapeutic measure for patients with diabetes [American Diabetes Association, 2000, **EL IV**; European Diabetes

Policy Group, 2000a, **EL IV**; European Diabetes Policy Group, 2000b, **EL IV**; Deutsche Diabetes Gesellschaft, 2000b, **EL IV**].

4.2 Results and principles of patient education

- The aim of patient education is to enable the patient to perform treatment strategies on one's own authority. Within the framework of the patient education program, patients with diabetes have to be informed about the proper form of treatment and possible risks. This instruction will place them in a position to deal with the illness in a responsible manner and as independently as possible [Assal et al., 1985, **EL IV**; Department of Health, 2001, **EL IV**] (**grade A**).
- A patient education program without adequate medical treatment of the diabetes (see the guidelines of the German Diabetes Association) is not successful [Bloomgarden et al., 1987, **EL Ib**; Korhonen et al., 1987, **EL Ib**; deWeerd et al., 1991, **EL Ib**]. The patient education program represents an integral part of the therapy of patients with diabetes and, therefore, must proceed in close coordination with the diabetes treatment (**grade A**).
- Effectiveness and efficiency (cost-benefit analysis) of educational and treatment strategies must be empirically secured [Brown, 1988, **EL Iib**; Padgett et al., 1988, **EL Iib**; Clement, 1995, **EL IV**]. Nevertheless, there are a number of unanswered questions concerning the most effective and efficient form of patient education, methods and didactics, specific target groups, and different measurements of success [Glasgow et al., 1999, **EL IV**; Norris et al., 2001, **EL Ia**].
- Despite sufficient evidence pointing to the effectiveness and efficiency of educational and treatment programs, educational practice often does not reflect these findings. Deficiencies in patient education are common, especially among patients with type 2 diabetes. Only a minority of patients undergo a structured educational program shortly after the diagnosis is made. There are still a large number of patients who have never been trained in managing their diabetes [Deutsche Diabetes- Gesellschaft, 1995, **EL IV**; Deutsche Diabetes-Gesellschaft, 2000a, **EL III**].
- Education programs with the primary goal to impart knowledge about the origins of diabetes and its treatment have a proven influence on the patient's knowledge [Korhonen et al., 1983, **EL Ib**; Fernando, 1993, **EL Ib**]. However, the increase in

knowledge does not necessarily affect treatment-relevant behaviour or glycaemic control and does not necessarily result in a reduction of diabetes-related complications [Raz et al., 1988, **EL Ib**; Arseneau et al., 1994, **EL Ib**; Small et al., 1992, **EL Ib**; Trento et al., 1998, **EL Ib**]. While diabetes-specific knowledge is necessary for successful self-treatment, it is not sufficient. Therefore, educational programs that primarily impart knowledge about the illness and its treatment should no longer be the sole component of diabetes education (**grade A**).

- In contrast, educational programs that actively involve the patients in the educational process and motivate them to develop personal treatment goals have proved to be effective. As “self-management training,” these programs offer concrete assistance in modifying behaviour and transferring the content of the program into patients’ daily living [Glasgow et al., 1996, **EL Ib**; Anderson et al., 1995, **EL Ib**; Norris et al., 2001, **EL Ia**; Task Force to Revise the National Standards, 1995, **EL IV**; American Diabetes Association, 2000, **EL IV**; Norris et al., 2001, **EL Ia**].
- Patients should be motivated to establish personal treatment goals. Moreover, they should be offered appropriate assistance to attain these goals (**grade A**).
- In addition to the type of diabetes, treatment strategies and individual prognosis, the program must take into account the patients’ individual problems, motivation levels and cognitive abilities. According to the patients’ background knowledge, information, and needs, programs should be offered that are introductory or intermediate, refresher courses or problem-specific [Kulzer et al., 2002, **EL IV**] (**grade A**).
- Both individual and group education programs have proven effective [Glasgow et al., 1996, **EL Ib**; Franz et al., 1995, **EL Ib**; Mühlhauser et al., 1987, **EL Ib**; Campbell et al., 1990, **EL Ib**; Glasgow et al., 1996, **EL Ib**; Norris et al., 2001, **EL Ia**]. A group setting is more successful in achieving changes in fundamental living habits (“lifestyle modification”) [Norris et al., 2001, **EL Ia**].

4.3 Type 1 Diabetes

- Although educational programmes for patients with type 1 diabetes are widely available, relatively few studies have evaluated these programmes. Recently published studies, however, verify the effectiveness of educational measures for

patients with type 1 diabetes [Mühlhauser et al., 1987, **EL Ib**; Pieber et al., 1995, **EL III**; Bott et al., 1997, **EL III**]. As a consequence, education of patients with type 1 diabetes represents an indispensable therapeutic measure (**grade A**).

- A structured education programme for patients with type 1 diabetes should include the following aspects [Deutsche Diabetes-Gesellschaft, 1997, **EL IV**]:
 - Assistance in accepting the illness, building up adequate motivation for treatment, empowerment;
 - Establishing and evaluating individual therapeutic goals;
 - Imparting knowledge about the fundamentals of the illness and its treatment (causes of diabetes, clinical characteristics, course of illness and prognosis, etc.);
 - Imparting knowledge and skills for treating the illness (principles of insulin therapy, adjusting the insulin dosage, etc.);
 - Learning self-monitoring techniques (measuring blood glucose levels, ketone levels, blood pressure, etc.);
 - Recognising, treating and preventing acute complications (hypoglycaemia, infections, etc.); risk factors (hyperlipidemia, hypertonia, smoking, etc.) for macroangiopathic diabetes-related illnesses (myocardial infarction/heart attack, apoplexy, etc.); diabetes-related illnesses (nephropathy/kidney disease, retinopathy, neuropathy, erectile dysfunction, diabetic foot, etc.);
 - Importance of nutrition. Imparting knowledge and skills with regard to healthful nutrition (carbohydrate content of foods, developing a nutrition plan that takes into account individual living habits and therapy strategies, etc.);
 - Importance of physical exercise. Imparting knowledge regarding the effect of physical activity on regulation of blood glucose (hypo-, hyperglycaemia, etc.);
 - Behavioural strategies in special situations (ketoacidosis, travel, etc.);
 - Assistance in managing diabetes treatment-related difficulties in daily living;
 - Pregnancy, hereditary transmission, contraception;

- Social rights of patients with diabetes (job, driver's license, insurance, etc.);
 - Check-up examinations and use of the health care system to deal with diabetes in a conscientious manner.
- It is recommended that an educational and treatment program for type 1 patients comprise at least 20 sessions (of 45 minutes each) [Deutsche Diabetes-Gesellschaft, 1997, **EL IV**].

4.4 Type 2 Diabetes

- The manifestation of type 2 diabetes is strongly linked to a lack of exercise and obesity [Ohlson LO et al., 2002, **EL III**; Edelstein et al., 1997, **EL III**]. Patients with increased glucose tolerance (IGT) carry an increased risk of developing type 2 diabetes [Eriksson et al., 1991, **EL III**; Charles et al., 1991, **EL III**]. Lack of exercise and obesity can be positively influenced by a systematic, long-term treatment and education programme (lifestyle modification) in order to prevent or delay the manifestation of the illness [Pan et al., 1997, **EL Ib**; Tuomilehto et al., 2001, **EL Ib**; Diabetes Prevention Program Research Group, 2002, **EL Ib**].
- Early identification and behavioural and medical treatment of patients with an increased risk of developing type 2 diabetes are tasks of high priority in order to reduce the continually rising incidence of type 2 diabetes. Patient education programmes that aim towards long-term assistance in modifying nutrition behaviour and physical activity can be used for this purpose (**grade A**).
- In the short and long term, patient education programmes for patients with type 2 diabetes are able to improve patients' knowledge [Ridgeway et al., 1999, **EL Ib**], nutritional behaviour [Uusitupa, 1996, **EL Ib**], weight [Rainwater et al., 1982, **EL Ib**], self-treatment [Wierenga, 1994, **EL Ib**], lipids [Kaplan et al., 1987, **EL Ib**] and glycaemic control [Anderson et al., 1995, **EL Ib**]. Despite a large number of randomised, controlled studies, at present it is difficult to point to well-founded conclusions regarding the differential indication and influencing factors of special educational strategies [Norris et al., 2001, **EL Ia**].
- Education of type 2 diabetes patients is an indispensable therapeutic measure (**grade A**).

- Educational programmes for patients with manifested type 2 diabetes must be adapted to the prognosis of the diabetes, age, and treatment strategies. A structured educational program should include the following aspects [German Diabetes Association, 2000a, **EL IV**]:
 - Assistance in learning to accept the illness, building up adequate treatment motivation, support in learning how to deal with the illness in a responsible manner, empowerment;
 - Establishing and evaluating individual therapeutic goals;
 - Imparting knowledge about the fundamentals of the illness and its treatment (causes of diabetes, clinical characteristics, course of illness and prognosis, etc.);
 - Imparting knowledge and skills for treating the illness (behaviour modification, principles of drug treatment, insulin therapy, etc.);
 - Learning self-monitoring techniques (urine tests, measuring blood glucose and blood pressure, etc.);
 - Learning strategies for self-observation, self-evaluation, and self-monitoring with regard to diabetes-relevant behavioural strategies (nutrition, physical activity, foot care, etc.);
 - Recognising, treating and preventing acute complications (hypoglycaemia, infections, etc.); risk factors (hyperlipidemia, hypertonia, smoking, etc.) for macroangiopathic diabetes-related illnesses (myocardial infarction/heart attack, apoplexy, etc.); diabetes-related illnesses (nephropathy/kidney disease, retinopathy, neuropathy, erectile dysfunction, diabetic foot, etc.);
 - Importance of nutrition. Imparting knowledge and skills needed to create a low-calorie or carbohydrate-defined diet. Developing and practising a dietary schedule that takes into account individual treatment strategies and individual lifestyle;
 - Importance of physical exercise. Developing and practising a schedule for physical activity that takes into account individual lifestyle, treatment strategies, and health status;

- Behaviour in different situations (sickness, travel, etc.);
 - Assistance in integrating diabetic therapy into daily life with all of its difficulties;
 - Social rights of patients with diabetes (job, driver's license, insurance, etc.);
 - Check-up examinations and use of the health care system to deal with diabetes in a conscientious manner.
- Middle-aged (<65-years-old) patients who have been diagnosed with type 2 diabetes and exhibit a relevant risk of developing secondary illnesses together with hypertension should undergo a patient education programme encompassing a minimum of 20 sessions (of 45 minutes each). [German Diabetes Association, 2000a, **EL IV**]. An education programme of at least eight sessions (of 45 minutes each) is recommended for patients diagnosed with type 2 diabetes who are advanced in age (> 65) and exhibit low risk of developing secondary illnesses. The content of the educational programme should be adapted to the patient's age and the prognosis of the diabetes [German Diabetes Association, 1997, **EL IV**].

5. Behavioural medicine

5.1 Definition

Behavioural medicine in diabetology aims to improve patients' cognitive, emotional and behavioural abilities so that they can cope with typical problems related to the illness and diabetes treatment.

5.2 Blood Glucose Awareness Training

Approximately 20%-30% of all type 1 diabetes patients are affected by severe, recurrent hypoglycaemia [The Diabetes Control and Complication Trial Research Group, 1997, **EL Ib**]. Severe recurrent hypoglycaemia can have various causes. The problem of a disturbed perception of hypoglycaemia has been well investigated [Gold et al., 1994, **EL III**; Pramming et al., 1991, **EL III**; Clarke WL et al., 1995, **EL III**].

- In the treatment of disturbed perception of hypoglycaemia, structured blood glucose awareness training (BGAT) has proven to be effective. Proof of effectiveness is available for the following outcome variables:
 - Reduction of severe hypoglycaemia [Cox et al., 2001, **EL IIb**];
 - Improved perception of low blood glucose values [Cox et al., 1994, **EL Ib**];
 - Improved glycaemic control [Cox et al., 1994, **EL Ib**];
 - Increase in knowledge about hypoglycaemia-induced affective and mental alterations [Cox et al., 2001, **EL IIb**];
 - Improvement of the adrenalin response to a hypoglycaemic stimulus [Kinsley et al., 1999, **EL Ib**];
 - Decrease in hypoglycaemia-related driving violations [Cox et al., 2001, **EL IIb**];
- Patients with insufficient hypoglycaemia perception and severe recurrent hypoglycaemia should be treated by means of blood glucose awareness training (**grade A**).

5.3 Interventions for reducing stress

Stress has an influence on the metabolic control of patients with diabetes [Goetsch et al., 1994, **EL III**; Herpertz et al., 2000, **EL IIa**]. However, the observable effects are not unidirectional and show great intra-individual and inter-individual variance depending on situational factors, the type and amount of stress, personal characteristics, and coping strategies [Surwit et al., 1992, **EL III**; Surwit et al., 1984, **EL III**; Peyrot et al., 1999b, **EL III**].

- Increased stress can lead to treatment problems [Gonder-Frederick et al., 1990, **EL III**] and poor glycaemic control [Kawakami et al., 1999, **EL III**].
- Studies on persons with an increased risk of manifesting type 2 diabetes [Mooy et al., 2000, **EL III**] and findings from animal experiments [Kai et al., 2002, **EL III**] indicate that stress facilitates the manifestation of type 2 diabetes. In contrast, there

is no convincing evidence for a direct influence of stress on the manifestation of type 1 diabetes [La Greca et al, 2001, **EL III**].

- The effectiveness of stress reduction strategies (e.g., progressive muscle relaxation, biofeedback) in order to improve metabolic control has not yet been conclusively verified, despite isolated indications of effectiveness [Henry et al., 1997, **EL Ib**; Surwit et al., 2001, **EL Ib**] [Aikens et al., 1997, **EL IIa**; Feinglos et al., 1987, **EL Ib**; Harris, 1980, **EL Ib**; Jablon et al., 1997, **EL Ib**; Koehler, 1981, **EL Ib**].
- Therefore, interventions for reducing stress (e.g., relaxation) with the primary goal of improving blood sugar levels and metabolic control cannot yet be recommended unconditionally for clinical routine. (**grade B**).
- In general, interventions for reducing stress (e.g., relaxation) are an effective procedure within the framework of basic psychosomatic care or psychotherapy [Stetter, 1998, **EL IIa**]. There are no counter-indications for implementation in persons with diabetes mellitus.

5.4 Interventions to facilitate coping with diabetes

Adequate coping with illness is a decisive pre-condition for effective self-treatment behaviour and for the long-term success of therapy. Diabetes-related negative emotions and other problems of coping behaviour frequently arise over the course of the illness and can negatively influence glycaemic control and patients' compliance [Polonsky et al., 1995, **EL III**; Welch et al., 1997, **EL III**; Snoel et al., 2000, **EL III**]. Patients with diabetes-related complications and/or mental disorders have many difficulties in coping with the illness [Welch et al., 1997, **EL III**; Anderson et al., 2001, **EL III**].

- A number of various individual and group therapy interventions are available to improve patients' coping behaviour, especially with regard to diabetes-associated psychosocial and medical problems (e.g., group discussions to deal with psychosocial barriers and the feeling of social stigmatism, or to plan an adequate diet). However, the majority of studies that have evaluated these types of interventions independent of educational programmes could not verify a significant effect on glycaemic control or QoL [Rabkin et al., 1983, **EL Ib**; White et al., 1986, **EL Ib**; Jones, 1990, **EL Ib**; Boehm et al., 1993, **EL Ib**; Hanestadt & Albrektsen,

1993, **EL IIa**; Anderson et al., 1995, **EL IIa**; Glasgow et al., 1997, **EL Ib**; Halford et al., 1997, **EL Ib**].

- At present, available data do not support the general recommendation of psychotherapeutic strategies in diabetes care in order to improve coping behaviour (**grade B**).
- Psychotherapeutic interventions should be considered in patients with severe coping problems, as their effectiveness has been established for chronic illnesses in general [de Ridder et al., 2001, **EL IV**] (**grade B**).

5.5 Interventions for improving interpersonal problems

Interpersonal problems and insufficient social support complicate therapy implementation and are associated with poor metabolic control. Social support contributes to improved glycaemic control (Griffith et al., 1990, **EL III**].

- Psychotherapeutic group settings [Stevens, 1983, **EL IIa**; Fosbury et al., 1997, **EL Ib**] are effective in terms of altering dysfunctional locus of control and social competence; however, a positive effect on metabolic control has not been consistently demonstrated.
- Psychotherapeutic interventions are useful in patients with severe interpersonal problems that affect diabetes care negatively (**grade B**).

6.1 Depression

6.1.1 Definition

According to the international classification of mental disorders, depressive symptomatology is classified as follows (ICD-10) (WHO, 1991):

- Depressive episode (F32)
 - mild – moderate – severe
- Recurrent depressive disorder (F33)
- Persistent mood disorder (F34)

- Cyclothymic disorder (F43.0)
- Dysthymia (F34.1)
- Other mood disorder and unspecified (F38, F39)
- Adjustment disorders (F43.2)
 - brief depressive reaction (F43.20)
 - prolonged depressive reaction (F43.21)
 - combined anxiety and depressive reaction (F43.22)

Depressive episodes are characterised by the following symptoms (ICD-10):

Main symptoms:

- depressed mood to a degree that is definitely abnormal for the individual, present for most of the day and almost every day, largely uninfluenced by circumstances, and sustained for at least two weeks.
- loss of interest or pleasure in activities that are normally pleasurable;
- decreased energy or increased fatigability.

Additional symptoms:

- loss of confidence and self-esteem;
- unreasonable feelings of self-reproach or excessive and inappropriate guilt;
- recurrent thoughts of death or suicide, or any suicidal behaviour;
- complaints or evidence of diminished ability to think or concentrate, such as indecisiveness or vacillation;
- change in psychomotor activity, with agitation or retardation (either subjective or objective);
- sleep disturbance of any type;
- change in appetite (decrease or increase) with corresponding weight change.

Somatic symptoms:

- marked loss of interest or pleasure in activities that are normally pleasurable;
- lack of emotional reactions to events or activities that normally produce an emotional response;
- waking in the morning two hours or more before the usual time;
- depression worse in the morning;
- objective evidence of marked psychomotor retardation or agitation (remarked on or reported by other people);
- marked loss of appetite;
- weight loss (5% or more of body weight in the past month);
- marked loss of libido.

The depressive episode/disorder is divided:

- a) into **mild, moderate or severe depressive episodes**, according to the number of symptoms present.
- b) according to the type of symptomatology. If at least four somatic symptoms are present, one speaks of **depression with somatic syndrome**. In the case of severe **depression with psychotic symptoms**, additional delusions or hallucinations are present.
- c) according to the course of the illness, into **depressive episodes (F32)** and **recurrent depressive disorders**. Relapsing forms of depressive disorders can be **unipolar (monopolar F33)** or **bipolar (F31)**. In the unipolar form, the patient experiences recurring depressive episodes; in bipolar forms, manic and depressive episodes can alternate.

The depressive episode lasts at least two weeks, and the patient's case history shows no evidence of manic or hypomanic symptoms. There have been no hypomanic or manic symptoms sufficient to meet the criteria for hypomanic or manic episode (F30.0) at any time in the individual's life. The episode is not attributable to psychoactive substance use (F10-F19) or to any organic mental disorder (in the sense of F00-F09).

Dysthymia (F34.1) is a milder variant of depression that, however, lasts at least two years, during which time the criteria for depression are not, or only rarely, fulfilled (“double depression”).

Adjustment disorders (F43) manifest themselves within the context of an adjustment process subsequent to a decisive change in living circumstances or following distressful life events or severe physical illnesses. They can be categorised as a **brief depressive reaction** (duration less than one month) (F43.20), **prolonged depressive reaction** (duration up to two years) (F43.21), or as a **mixed anxiety and depressive reaction** (F43.22). The present guidelines do not address the bipolar affective disorders or manic episodes.

6.1.2 Epidemiology

- Compared with the normal population, persons with diabetes are roughly at twice the risk of developing depression [Anderson et al., 2001, **EL III**].
- The prevalence of depression among individuals with either type 1 or type 2 diabetes ranges between 6% and 26.7% in controlled studies, depending on the population studied, the definition of the disorder, and the instruments implemented [Anderson et al., 2001, **EL III**].
- Higher prevalences arise in clinical samples [Anderson et al., 2001, **EL III**].

6.1.3 Interaction between diabetes mellitus and comorbid depression

- Patients with diabetes mellitus and comorbid depression have poorer metabolic control than patients who have diabetes without comorbid depression (HbA1c) [Lustman et al., 2000a, **EL III**]. This connection, however, is dependent on the type of diabetes, sex, and the population studied [Pouwer et al., 2001, **EL III**]. Depressive patients with diabetes comply with the therapeutic and medical recommendations to a lesser extent [Ziegelstein et al., 2000, **EL IIa**], in particular with regard to dietary recommendations [Ciechanowski et al., 2000, **EL III**].
- Overweight patients with both type 2 diabetes and a lifetime diagnosis of a depressive episode tend to break off from weight reduction programs more frequently than patients who never became depressed [Marcus et al., 1992, **EL III**].

Smoking and nicotine abuse is more frequent in depressive patients with diabetes [Marcus et al., 1992, **EL III**].

- Depression is an independent risk factor for the development of not only diabetes, but also coronary heart disease [Forrest et al., 2000, **EL IIa**]. Depression influences the mortality rate following a myocardial infarction [Bush et al., 2001, **EL IIa**].
- Depression and depressive mood considerably reduce QoL and satisfaction with therapy [Hanninen et al., 1999, **EL III**; Kohen et al., 1998, **EL III**].
- The costs of medical care are distinctly higher in patients with diabetes and comorbid depression as compared with patients who have diabetes but no depression [Ciechanowski et al., 2000, **EL III**].
- The risk of depression increases with the development and number of diabetes-related complications [de Groot et al., 2001, **EL III**]. Acute diabetes-related complications are associated with a higher depression rate compared with chronic diabetic lesions [Peyrot & Rubin, 1999a, **EL III**].
- During the first 30 days after a severe episode of hypoglycaemia, patients show increased depressive symptomatology [Strachan et al., 2000, **EL III**].
- The studies by Eaton et al. [1996, **EL IIb**] and Kawakami et al. [1999, **EL IIb**] suggest that patients who suffer from depressive symptomatology show an increased risk of developing type 2 diabetes.
- The issue of whether depressed patients with diabetes experience a less favourable course of the diabetes (higher rate of relapse, longer phases of illness) than patients who have diabetes but no depression is controversial. [Kovacs et al., 1997, **EL III**; Wells et al., 1993, **EL III**].

6.1.4 Diagnostics and Screening

- Patients who suffer from depressive symptomatology often consult a physician for unspecific physical ailments and play down the psychological symptomatology. Weakness, increased fatigue, apathy, irritability, anxiety, sexual problems, sleep disorders, loss of appetite, and weight loss (in addition to the characteristic complaints) all can be symptoms of depression. When presented with these unspecific complaints, depression should be taken into consideration in terms of

differential diagnostics. In cases of severe ketoacidosis or hypoglycaemia, differential diagnostic procedures should check whether these conditions stem from an attempted suicide or other expressions of depressive disorders or self-destructive behaviour.

- The primary physician plays a key role in the early recognition of the depressive disorder. Fifty percent to seventy percent of depressive disorders are not recognised in primary care; an even larger number of patients are not adequately treated [Kruse et al., 1999, **EL III**; Lustman & Harper, 1987, **EL III**].
- The central diagnostic instrument is the physician-patient dialogue. As part of screening questions for depressive disorders, the physician should enquire about depressive mood (despondency, hopelessness), loss of interest and pleasure in activities, and reduction in drive. If signs of depression are present, the physician should always actively bring up the possible danger of suicidal tendencies in the patient, and enquire about suicidal thoughts, impulses and preparatory actions. The sensitivity of the diagnostic judgement grows as the physician-patient interaction becomes more patient-oriented [Davenport et al., 1987, **EL III**; Goldberg et al., 1993, **EL III**; Kruse, 2002, **EL III**].
- Questionnaires on depressive symptomatology allow depression screening based on the patient's own responses. Especially questionnaires such as "Hospital Anxiety and Depression Scale, HADS" [Zigmond and Snaith 1983], the "Patient Health Questionnaire, PHQ" [Spitzer et al. 1999], the "Center for Epidemiologic Studies-Depression Scale, CES-D" [Radloff, 1977] and the "Beck Depression Inventory, BDI" [Beck and Beamesderfer 1974] have proven themselves to be valid and reliable instruments that can be implemented as screening instruments and as therapy controls.
- Structured clinical interviews such as the CIDI [WHO 1993] and SCID [First et al. 1996] provide a reliable diagnostic assessment of depressive disorders. Due to the considerable amounts of time involved, they are suitable primarily for scientific studies and for monitoring the course of psychotherapies.
- From a differential-diagnostic standpoint, the depressive syndrome is to be distinguished from depressive symptoms in schizophrenic disorders (F20), personality disorders (F6), post-traumatic stress disorders (F43.1), and schizoaffective disorders (F25). Depressive symptoms can also manifest themselves

within the framework of organic mental disorders. Likewise, depressive symptoms can occur in connection with infections, postoperatively, in metabolic disorders, in intoxication and insufficiency diseases, and as an abnormal reaction to drugs and medications.

6.1.5 Therapy

- While a multitude of studies verify the effectiveness of therapies in affective disorders, only a few scattered studies exist that specifically examine the therapy for depression in patients with diabetes mellitus.
- Cognitive behavioural therapy reduces the depressive symptomatology of patients with type 2 diabetes and leads to an increase in the rate of remission of the depression. These results are accompanied by an improved metabolic control [Lustman et al., 1998, **EL Ib**].
- Antidepressants have been shown to be effective among patients with diabetes in reducing the depressive symptomatology [Lustman et al., 1997, **EL Ib**; Lustman et al., 2000b, **EL Ib**; Goodnick et al., 1997, **EL IIb**]. Tricyclic antidepressants lead to a deterioration of metabolic control and to a considerable gain in weight [Lustman et al., 1997, **EL Ib**], while an antidepressant psychopharmacological therapy with SSRI inhibitors can lead to hypoglycaemia, which can necessitate an adjustment in the insulin therapy [Lustman et al., 2000b, **EL Ib**; Goodnick et al., 1997, **EL IIb**; Wise, 1992, **EL III**].
- There is some evidence that stress management and stress reduction programs reduce depressive symptoms of patients with diabetes mellitus [Henry et al., 1997, **EL Ib**; Spiess et al., 1995, **EL Ib**; Grey et al., 1998, **EL Ib**; Gilden et al., 1992, **EL Ib**]. Also, regular telephone calls by a nurse within the framework of “automated telephone disease management” might reduce the depressiveness of patients [Piette et al., 2000, **EL Ib**].

6.1.6 Recommendation

- The evidence-based psychotherapies for treating depression also are effective among patients with diabetes. In particular, psychotherapeutic counselling, specialised psychotherapy, psychopharmacological therapy, and sociotherapy should be integrated into treatment (**grade A**).

- According to the guidelines of the German Association of Psychiatry, Psychotherapy and Neurology (DGPPN) [Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde, 2001a, **EK IV**], antidepressant therapy comprises basic psychotherapeutic therapy, specialised psychotherapy, antidepressant psychopharmacological therapy, and social therapy. In special cases additional therapies, such as phototherapy, sleep-deprivation therapy, and electroconvulsive therapy, can be implemented. The treatment can be on an outpatient, inpatient, or partial inpatient basis. The differential indication for the individual therapy strategy depends on severity, subtype and course of the depression, comorbidity, ability of therapy to influence the symptoms, and the patient's wishes (**grade A**).

6.1.6.1 Psychosomatic treatment in primary care

- If the patient is not suicidal, there is no acute crisis, and prior attempts at therapy were not a failure, then the attending physician can administer basic psychosomatic treatment in order to reduce symptoms. This treatment encompasses (**grade A**):
 - Building a trusting, reliable, constant relationship with the patient;
 - Active, flexible and supportive behaviour;
 - Providing detailed information and education about the illness (i.e., depression), developing a common concept of the illness, psychoeducation;
 - Conveying hope and encouragement, relieving feelings of blame, guilt and failure;
 - Acceptance of the patient's behaviour (including complaining);
 - Positive reinforcement of non-depressive cognitions;
 - Anticipating the patient's vulnerability;
 - Activating and motivating the patient, without overwhelming him or her;
 - Taking notice of and addressing suicidal tendencies (actively mentioning suicidal tendencies if suspicion exists, protecting the patient);

- If the symptoms are not alleviated within a certain time or if the pre-conditions are not met, then specialised psychotherapy and/or pharmacological therapy should be introduced (**grade A**).

6.1.6.2 Psychotherapy

- The following psychotherapeutic procedures are scientifically and empirically based and recommended for the treatment of depression by the DGPPN [Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde, 2001a, **EL IV**] and should be implemented according to a differential indication (**grade A**):
 - Interpersonal Psychotherapy
 - Cognitive Behavioural Therapy
 - Psychodynamic Psychotherapy

6.1.6.3 Pharmacological therapy

- The following antidepressant drugs are used in the acute treatment of unipolar depressive disorders (**grade A evidence**):
 - Tricyclic and tetracyclic antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRI)
 - MAO inhibitors
 - Atypical and new antidepressants
 - Adjuvant administration of benzodiazepine and low-potency neuroleptics.
- When selecting an antidepressant for patients with diabetes, Selective Serotonin Reuptake Inhibitors (SSRI) are preferred over tricyclic antidepressants because the use of tricyclic antidepressants can lead to weight gain and hyperglycaemia, thereby worsening metabolic control. In other respects, the psychopharmacological treatment of depression should comply with the guidelines of the DGPPN [Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde, 2001a, **EL IV**], taking into account side effects relevant to diabetic metabolic control (**grade A**).

6.2 Anxiety Disorders

6.2.1 Definition

The majority of anxiety disorders in patients with diabetes are not diabetes-specific and can be classified according to the International Classification of Mental Disorders (ICD-10) [World Health Organization, 1991]. Yet, in part they are closely tied to diabetes-related issues, making it necessary to devote special attention to these aspects (for example, obsessive diabetes management can be a symptom of an obsessive-compulsive disorder). Moreover, there are anxiety disorders exclusively related to diabetes, such as fear of hypoglycaemia, which cannot be classified per se into a particular ICD-10 category since they could fulfil the criteria for various anxiety disorders depending on their specific symptoms.

According to the International Classification of Mental Disorders (ICD-10) of the World Health Organization (WHO, 1991) anxiety disorders are classified as follows:

- Agoraphobia with/without panic disorder (F 40.0)
- Social phobia (F 40.1)
- Specific phobia (F 40.2), esp. injection phobia
- Panic disorder (F 41.0)
- Generalised anxiety disorder (F 41.1)
- Mixed anxiety and depressive disorder (F 41.2)
- Obsessive-compulsive disorder (F 42)
- Post-traumatic stress disorder (F 43.1)
- Adaptation disorder, mixed anxiety and depressive reaction (F 43.22)

Agoraphobia with/without panic disorder (F 40.0): Anxiety about, or avoidance of, places and situations in which escape might be difficult or embarrassing, or in which no help would be expected in the event of a panic attack or panic-like symptoms. Agoraphobia can manifest itself with (F40.01) or without (F40.00) a panic disorder. All the following criteria must be fulfilled for a diagnosis:

- Psychological and vegetative symptoms must be the primary manifestation of anxiety;
- Anxiety must arise in at least two of the following situations: e.g., in crowds, public places, journeys far from home, or journeys alone;
- The avoidance of the phobic situation must be, or has been, a determining symptom.

Social phobia (F 40.1): Anxiety about negative appraisal by others that is triggered by confrontation with certain social situations and performance situations, usually leading to avoidance behaviour. All the following criteria must be fulfilled for a diagnosis:

- The psychological, behavioural, or vegetative symptoms must be the primary manifestation of anxiety;
- Anxiety must be confined to certain social situations or predominate therein;
- Avoidance of the phobic situation, when possible.

Social anxieties in patients with diabetes may be related to their illness and have a negative effect on the diabetes management (e.g., for fear of attracting negative attention, patients with diabetes refrain from measuring blood sugar or injecting insulin when eating in public).

Specific phobia (F 40.2): Anxiety that is triggered by confrontation with certain feared objects or situations (e.g., heights, certain animals, blood) and frequently leads to avoidance behaviour. All the following criteria must be fulfilled for a diagnosis:

- The psychological or vegetative symptoms must be the primary manifestation of anxiety;
- Anxiety must be confined to the presence of a certain phobic object or a specific situation;
- The phobic situation is avoided, whenever possible.

In patients with diabetes who require insulin injections, injection phobia in particular should be taken into consideration, where insulin injection is feared and is accompanied by strong vasovagal reactions.

Panic disorder (F 41.0): Disorder exhibiting unexpected, repeatedly occurring panic attacks. The attacks occur suddenly, are accompanied by intense anxiety and predominantly vegetative symptoms (e.g., tachycardia, sweating, tremors, dyspnoea) with fear of an imminent disaster (e.g., “going mad”, loss of control, heart attack). Typically, there is unremitting apprehension about future panic attacks (“anxiety about the anxiety”). Diagnosis can be made only in the presence of several severe vegetative anxiety attacks, when they have taken place within a period of roughly one month and:

- in situations in which no objective danger exists;
- when the anxiety attacks are not confined to known or predictable situations;
- between the attacks there are periods largely free of anxiety (anticipatory anxiety is frequent, however);
- A panic disorder should be diagnosed only in the absence of a phobia.

Generalised anxiety disorder (F 41.1): Unremitting, pronounced anxiety and apprehension that extends over various areas of life and is accompanied by persistent motoric tension and overexcitability. Primary symptoms of anxiety must be present on most days over a period of at least several weeks, usually even several months. As a rule, the following individual symptoms can be observed:

- Fears (worries about future misfortune, nervousness, difficulty with concentration, etc.);
- Motoric tension (physical unrest, tension headaches, trembling, unable to relax);
- Vegetative overexcitability (dizziness, sweating, tachycardia or tachypnoea, upper abdominal pain, dizziness, dry mouth, etc.).

Excessive anxiety and worry about illness can manifest itself within the bounds of a generalised anxiety disorder. To make a diagnosis, however, further anxieties must be present that relate to other areas of life.

Mixed anxiety and depressive disorder (F 41.2): This category should be applied in the joint presence of anxiety and depression. The following criteria are necessary for the diagnosis to be made:

- Presence of anxiety and depression in mild to medium-grade form, with no predominance of one or the other;
- At least temporary manifestation of vegetative symptoms (e.g., tremors, heart palpitations, dry mouth, stomach ailments, etc.);
- Neither of the two disorders reaches a magnitude that would justify the respective individual diagnosis.

Obsessive-compulsive disorder (F 42): Disorder characterised by intruding compulsive thoughts that trigger anxiety and/or unease and/or compulsive actions performed to neutralise the aversive emotions. To make this diagnosis, compulsive thoughts or actions, or both, should be present on most days over a period of at least two weeks. Symptoms must demonstrate the following characteristics:

- They must be recognisable to the patient as his or her own thoughts or impulses.
- The patient must offer resistance to at least one thought or action, even if he or she is unsuccessful.
- The thought or action may not itself be pleasant.
- The thoughts, ideas, or impulses occur frequently in an unpleasant manner.

Compulsive symptoms may interfere with diabetes and associated treatment strategies, causing serious problems (e.g., blood sugar is measured with excessive frequency due to compulsive perfectionism about the desired blood sugar values, sometimes resulting in severe hypoglycaemia).

Post-traumatic stress disorder (F 43.1): A disorder caused by intruding memories of a very traumatic experience (e.g., severe accident, rape, sexual abuse). The memories are accompanied by symptoms of increased agitation and avoidance of stimuli associated with the trauma. This disorder should be diagnosed only when it

- manifests itself within six months following a traumatic event of unusual severity. A “probable” diagnosis can be made when the time between the event and the onset of the disorder exceeds six months, provided that the clinical features are typical and no other diagnosis exists (such as anxiety disorder, compulsive disorder, or depressive episode).

- In addition, the patient must experience recurrent and intrusive recollection of the event (including images, thoughts or perceptions) or dreams of the event.
- Distinct emotional withdrawal, emotional numbness, avoidance of stimuli that could evoke a memory of the trauma are frequently observed, but not essential for diagnosis. The vegetative disorders, impairment of mood and abnormal behaviour all contribute to the diagnosis, but are not of singular importance.

The initial manifestation of diabetes does not, as a rule, represent a traumatic experience that could lead to a post-traumatic stress disorder, and therefore does not justify the diagnosis.

Adaptation disorder, combined anxiety and depressive reaction (F 43.22): States of subjective suffering characterised by anxiety and depressive reactions following a decisive change in life. The following criteria are necessary to make this diagnosis:

- Both anxiety and depressive symptoms are present, but not more intense than in the combined anxiety and depressive disorder (F 41.2).
- The symptoms usually do not last for more than six months.

In terms of the patient with diabetes, adaptation disorders could arise principally within the context of the initial diagnosis.

In addition, anxiety disorders, such as hypoglycaemia anxiety may be exclusively related to diabetes. Such disorders cannot be classified per se into a particular ICD-10 category since they may fulfil the criteria for various disorders depending on their different clinical manifestations. This anxiety symptomatology may be classified under various ICD-10 diagnoses:

- fear of hypoglycaemia (F 40.0 or F 41.0 or F 40.1)
- Anxiety about the consequences of diabetes (F 41.1 or F 41.2 or F 42 or F 43.22)

Fear of hypoglycaemia (F 40.0 or F 41.0 or F 40.1): Excessive anxiety about potential hypoglycaemia in the future. Typically there are difficulties in distinguishing between physical symptoms of anxiety and those of the adrenergic phase of hypoglycaemia. To avoid possible hypoglycaemia, the patient usually accepts high values of blood glucose.

Depending on the clinical manifestation of hypoglycaemia anxiety, the criteria for a panic disorder, agoraphobia, or social phobia could be fulfilled.

Anxiety about the consequences of diabetes (F 41.1 or F 41.2 or F 42 or F 43.22):

Disorder characterised by excessive anxiety and worry about possible effects and complications of diabetes. Depending on the different clinical manifestations of anxiety, the criteria for a “generalised anxiety disorder”, “anxiety and depressive disorder, combined”, “adaptation disorder”, or “mixed anxiety and depressive disorder” may be fulfilled.

6.2.2 Epidemiology

- Point prevalence of anxiety disorder in the general population is 9% [Wittchen et al., 1999, **EI III**]. Despite inconsistent data, there is no convincing evidence of an increased prevalence of anxiety disorders in patients with diabetes as compared with the normal population [Berlin et al., 1997, **EL III**; de Groot et al., 1999, **EL III**; Lustman et al., 1986, **EL III**].
- Injection phobias rarely occur [Snoel et al., 1997, **EI III**; Mollema et al., 2002, **EL III**]. Only one study reported a high rate (28%) of injection-related anxieties [Zambanini et al., 1999, **EL IV**].
- Anxiety about diabetes-related complications and fear of hypoglycaemia are the two most important diabetes-associated psychological burdens. These two hardships may lead to considerable emotional impairment and problems with coping with the illness [Cox et al., 1987, **EL IV**; Irvine et al., 1992, **EL IV**; Zettler et al., 1995b, **EL IIb**; Snoel et al., 2000, **EL III**; Welch, 1997, **EL III**].

6.2.3 Interaction between diabetes mellitus and comorbid anxiety disorders

- Anxiety disorders or subclinical anxieties can cause poor metabolic control [Mazze et al., 1984, **EL III**; Lustman et al., 1986, **EL III**; Berlin et al., 1997, **EL III**], though study results are inconsistent [Metsch et al., 1995, **EL III**; Spiess et al., 1994, **EL III**; Friedman et al., 1998, **EL III**].
- Patients who have diabetes and an anxiety disorder are not only impaired by their mental disorder, but also have an above-average burden with regard to coping with the diabetes and generic QoL [Kohen et al., 1998, **EL III**].

6.2.4 Diagnostic instruments and screening

- Because the symptomatology usually lacks any specificity, diagnosis of an anxiety disorder in patients with diabetes cannot be made easily. For this reason, the physician's anamnestic interview is of considerable importance. According to the DGPPN guidelines [Dengler et al., 2000, **EL IV**] the following questions should be clarified: Are somatic or psychological symptoms of anxiety present? Are anxiety attacks or chronic anxiety involved? Do the anxiety attacks manifest themselves unexpectedly? To what extent do anticipation anxiety, avoidance behaviour, or social impairments exist?
- The German version of the Beck Anxiety Inventory is suitable to attain an initial orientating assessment [Margraf et al., 2002]. For screening purposes, the complete German version of the "Patient Health Questionnaire" (PHQ-D) is appropriate [Spitzer et al., 1999; Löwe et al., **EL III**]. This comprehensive inventory provides screening for the most frequent mental disorders in primary care, in addition to a specific screening of anxiety disorders.
- Questions on diabetes-related anxieties, such as excessive anxiety about the consequences of diabetes or hypoglycaemia, should be asked as screening strategies (**grade A**). Furthermore, screening instruments for the occurrence of hypoglycaemia, for example, the "Hypoglycaemia Anxiety Inventory" [Kulzer, 1995, **EL III**] proved to be effective in clinical practice. The "Questionnaire on Stress in patients with diabetes" (QSD-R) (FBD-R) [Herschbach et al., 1997, **EL III**] can provide clues to excessive diabetes-associated stress (**grade B**).
- Standardized psychiatric interviews, such as the DIPS [Margraf et al., 1991], M-CIDI [Wittchen et al., 1997] or SKID-I [Wittchen et al., 1997], provide a precise differential diagnostic classification according to the ICD-10 criteria.
- Anxiety symptoms may be of varying origins and have to be distinguished from one another. They may result from psychological stress associated with diabetes; however, they also may be due to different illnesses (e.g., hyperthyreosis, pheochromocytoma, vestibular syndrome, seizures, arrhythmia and supraventricular tachycardia). Suitable laboratory tests (blood count, electrolytes, blood glucose, transaminases, gamma-GT, TSH, FT₃ and FT₄) should be performed (including ECG and EEG). So as not to foster hypochondriac anxieties, additional diagnostic procedures should proceed only upon founded suspicion of certain physical illnesses or in the event of treatment resistance. Moreover, anxiety

disorders must be distinguished from anxieties associated with other psychological disorders (somatoform disorder, disorders due to psychoactive substance use, or psychotic disorders), according to the DGPPN guidelines [Dengler et al., 2000, **EL IV**] (**grade A**).

6.2.5 Therapy

- There are very few specific, methodically sound research findings with regard to psychotherapy of anxiety disorders in adult patients with diabetes. These findings do not allow definite statements on specific intervention strategies and effects in order to reduce anxiety symptoms (**grade B**).
- Four case studies reported successful psychotherapeutic treatments of insulin injection phobia. Nonetheless, the number of studies is too small for any generalization or treatment recommendation to be made [Kolko & Milan, 1980, **EL IV**; Bell et al., 1983, **EL IV**; Steel et al., 1986, **EL IV**; Zambanini et al., 1997, **EL IV**]. Nor has the effectiveness of behavioural therapy or blood-glucose awareness training been sufficiently verified for the reduction of fear of hypoglycaemia or anxiety about diabetes-related complications [Fröhlich et al., 1992, **EL IIa**; Zettler et al., 1995a, **EL IIb**; Cox et al., 1991, **EL Ib**; Cox, 2001, **EL IIb**].
- Anxiety treatment interventions are generally an effective procedure within the framework of psychotherapy. There is no counter-indication for their use in patients who have diabetes (**grade A**).

6.2.6 Recommendations

- If a comorbid anxiety disorder needs to be taken into consideration in a patient with diabetes, adequate diagnostic procedures must be performed; established diagnostic procedures and differential diagnostics should be performed. In cases of doubt or in cases with severe symptomatology, diagnostic clarification and possibly continued treatment by a specialist should be arranged (psychologist, physician specialising in psychosomatic medicine or psychiatry) (**grade A**).

6.2.6.1 Psychosomatic treatment strategies in primary care

- In subclinical anxieties or low-grade symptomatology, basic psychosomatic treatment strategies may be performed: **(grade A)**
 - Diagnostics and differential diagnostics of the anxiety disorder
 - Clarification of diabetes-specific anxieties
 - Counselling and psychoeducation
 - In mild phobias: encouragement and guidance for exposure to feared situations
 - Self-help manuals
- If the symptomatology does not improve after roughly four weeks, then psychotherapy with and without pharmacological intervention should be initiated **(grade A)**.
- If evidence arises that points to diabetes-specific anxieties (e.g., hypoglycaemia anxiety, insulin injection phobia), then treatment should proceed with a psychotherapist experienced about diabetes, whenever possible **(grade A)**.

6.2.6.2 Psychotherapy

- If a patient with diabetes has a moderate or severe anxiety disorder or a satisfactory improvement was not achieved within the bounds of the described basic psychotherapeutic interventions, then procedures should be implemented that have been scientifically validated for patients with anxiety disorders but without diabetes. Such procedures include cognitive behavioural therapy, psychodynamic psychotherapy, and, possibly in combination with these procedures, pharmacological interventions. The guidelines of the DGPPN should be consulted [Dengler & Selbmann, 2000, **EL IV**] **(grade A)**.
- If there is evidence of diabetes-specific anxieties (e.g., fear of hypoglycaemia, insulin injection phobia), then the method of first choice should be behavioural therapy with a psychotherapist experienced in treating patients with diabetes. If this treatment remains unsuccessful, then a psychodynamic therapy should be recommended as second choice **(grade A)**.

6.2.6.3 Pharmacological therapy

- In the treatment of anxiety disorders, the following drugs are primarily used (**grade A**):
 - Benzodiazepine
 - Beta-blockers
 - MAO inhibitors
 - Buspiron
 - Neuroleptics
 - Serotonin reuptake inhibitors (SSRI)
 - Tricyclic antidepressants
- Of all the antidepressants, the SSRI's are preferred over the tricyclic antidepressants due to their better profile of side effects for patients with diabetes (**grade A**).

6.3 Eating disorders

6.3.1 Definition

Eating disorders are classified as follows, according to the International Classification of Mental Disorders (ICD-10) published by the World Health Organization (WHO, 1991):

Anorexia nervosa (AN): [The ICD-10 Classification of Mental and Behavioural Disorders – Clinical descriptions and diagnostic guidelines, World Health Organization, Geneva, 1992]. For a definite diagnosis, all the following are required:

1. Body weight is maintained at least 15% below that expected (either lost or never achieved), or Quetelet's body-mass index is 17.5 or less
2. The weight loss is self-induced by avoidance of "fattening foods". One or more of the following may also be present: self-induced vomiting; self-induced purging; excessive exercise; use of appetite suppressants and/or diuretics.

3. There is body-image distortion in the form of a specific psychopathology whereby a dread of fatness persists as an intrusive, overvalued idea, and the patient imposes a low weight threshold on himself or herself.
4. A widespread endocrine disorder involving the hypothalamic-pituitary–gonadal axis is manifest in women as amenorrhoea and in men as a loss of sexual interest and potency. (An apparent exception is the persistence of vaginal bleeding in anorexic women who are receiving hormone replacement therapy, most commonly taken as a contraceptive pill.) There may also be elevated levels of growth hormone, raised levels of cortisol, changes in the peripheral metabolism of the thyroid hormone, and abnormalities of insulin secretion.

Bulimia nervosa (BN): [The ICD-10 Classification of Mental and Behavioural Disorders – Clinical descriptions and diagnostic guidelines, World Health Organization, Geneva]. For a definite diagnosis, all the following are required:

1. There is a persistent preoccupation with eating, and an irresistible craving for food; the patient succumbs to episodes of overeating in which large amounts of food are consumed in short periods of time.
2. The patient attempts to counteract the “fattening” effects of food by one or more of the following: self-induced vomiting; purgative abuse, alternating periods of starvation; use of drugs such as appetite suppressants, thyroid preparations or diuretics. When bulimia occurs in patients with diabetes, they may choose to neglect their insulin treatment (“insulin-purging”).
3. The psychopathology consists of a morbid dread of fatness; the patient sets herself or himself a sharply defined weight threshold, well below the premorbid weight that constitutes the optimum of healthy weight in the opinion of the physician. There is often, but not always, a history of an earlier episode of AN, the interval between the two disorders ranging from a few months to several years. This earlier episode may have been fully expressed, or may have assumed a minor cryptic form with a moderate loss of weight and/or a transient phase of amenorrhoea.

Binge eating disorder (BED): [DSM-IV, APA, 1994] Besides anorexia and bulimia nervosa, the 4th edition of the American Psychiatric Association classification scheme “Diagnostic and Statistical Manual of Mental Disorders” [DSM-IV, APA, 1994] introduced the category of “Eating Disorder Not Otherwise Specified” (EDNOS). Parallel to this, the

10th edition of the ICD [Dilling et al., 1991] distinguishes between “atypical bulimia nervosa” (F50.3), “eating attacks associated with other psychological disorders” (F50.4), and “eating disorders not otherwise specified” (F50.9). The BED is not explicitly listed in the ICD-10 [Dilling et al., 1991].

Eating Disorder Not Otherwise Specified (EDNOS): [DSM-IV, APA, 1994] The EDNOS category is applied to disorders of eating that do not meet the criteria for any specific eating disorder. Examples include:

1. For females, all the criteria for AN are met except that the individual has regular menses.
2. All the criteria for AN are met except that, despite significant weight loss, the individual’s current weight is in the normal range.
3. All the criteria for Bulimia Nervosa are met except that the binge eating and inappropriate compensatory mechanisms occur at a frequency of less than twice a week or for a duration of less than three months.
4. The regular use of inappropriate compensatory behaviour by an individual of normal body weight after eating small amounts of food (e.g., self-induced vomiting after the consumption of two cookies).
5. Repeatedly chewing and spitting out, but not swallowing, large amounts of food.

BED – Research criteria: [DSM-IV, APA, 1994]

A. Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following:

1. eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances.
2. a sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating).

B. The binge-eating episodes are associated with three (or more) of the following:

1. eating much more rapidly than normal

2. eating until feeling uncomfortably full
3. eating large amounts of food when not feeling physically hungry
4. eating alone because of being embarrassed by how much one is eating
5. feeling disgusted with oneself, depressed, or very guilty after overeating

C. Marked distress regarding binge eating is present.

D. The binge eating occurs, on average, at least two days a week for six months.

E. The binge eating is not associated with the regular use of inappropriate compensatory behaviours (e.g., purging, fasting, excessive exercise) and does not occur exclusively during the course of AN or BN.

6.3.2 Psychological comorbidity

- With regard to psychological comorbidity, BN and AN are most commonly associated with depressive disorders (ICD F31) [Bushnell et al., 1994, **EL III**; Pollice et al., 1997, **EL III**].
- In contrast to obese persons without an eating disorder, a high prevalence of mental disorders has been observed in obese persons with a **BED** [Yanovski et al., 1993, **EL III**], with the highest rate being that of comorbid depressive disorders [Marcus et al., 1990, **EL III**]. The average caloric consumption of obese patients with a BED is increased, even between hunger attacks, as compared to obese persons without an eating disorder [Yanovski & Sebring, 1994, **EL III**]. The case histories of the former group show great fluctuations in body weight, alternating with phases of strict dieting [Brody et al., 1995, **EL III**].

6.3.3 Epidemiology of eating disorders

6.3.3.1 Population-based data

- Numbers on the incidence of AN vary between 4.2 [Turnbull et al., 1996, **EL III**] and 8.2 [Lucas et al., 1991, **EL III**] in a population of 100,000. The highest age-specific incidence rate of 56.7 per 100,000 has been observed among young women

between the ages of 15 and 19 [Lucas et al., 1991, **EL III**]. The prevalence rate of AN varies depending upon how strictly the criteria are applied. Note the frequency of illness in the following groups:

- Among adolescent girls between the ages of 15 and 19, the prevalence is 0.3% [Lucas et al., 1991, **EL III**]; other studies report 0.7% to 2.1% [Pope et al., 1984, **EL III**].
 - High-risk groups, such as female ballet students or models who are subject to extreme “slimness pressure”, show a prevalence of 7%.
 - The prevalence of eating disorders in males is markedly lower than in females; depending on the study and diagnostic criteria, it ranges from 5% to 10% of all persons with eating disorders [Hsu, 1990, **EI IV**].
- According to Hoek [1991, **EL III**], {Is “HoEL” correct? It looks strange to me.}the incidence of **BN** was 11.4 per population of 100,000 in the Netherlands during the years 1985 to 1989, and the prevalence was 1.5%. The prevalence of BN in young women is 2% to 4.5% [Cooper & Fairburn, 1983, **EL III**; Bushnell et al., 1990, **EL III**]. The peak of illness is at age 18. Epidemiological investigators attribute the rise in eating disorders in the industrialised countries of the world mainly to the increase in BN [Hsu, 1990, **EL IV**; Turnbull et al., 1996, **EL III**].
 - In terms of the **BED**, we can assume that there is a prevalence of 2.0% in the normal population, 30% in therapy groups aimed at weight reduction, and 71.2% in Overeaters Anonymous [Spitzer et al., 1992, **EL III**]. These findings support the assertion that the prevalence of binge eating is high, particularly in samples of obese persons who suffer from their obesity and seek out medical or psychological help for weight reduction. This eating disorder is 1.5 times more common in women than in men.

6.3.3.2 Patients with type 1 diabetes mellitus

- None of the controlled studies on the prevalence of AN in patients with type 1 diabetes mellitus--studies that were based, among others, on a (standardised) psychiatric interview--diagnosed a single case of AN in the patients examined (point prevalence) [Popkin et al., 1989, **EL III**; Robertson & Rosenvinge, 1990, **EL IIa**; Fairburn et al., 1991, **EL IIa**; Peveler et al., 1992a, **EL IIa**; Striegel-Moore et al.,

1992, **EL IIa**; Engström et al., 1999, **EL IIa**; Jones et al., 2000, **EL IIa**]. Thus, the comorbidity of diabetes mellitus and AN is judged to be extremely rare.

- The prevalence of **BN** in patients with type 1 diabetes mellitus is higher than that of AN, varying between 0.0% [Striegel-Moore et al., 1992, **EL IIa**; Peveler et al., 1992b, **EL IIa**; Engström et al., 1999, **EL IIa**] and 3.0% [Fairburn et al., 1991, **EL IIa**]. However, in their systematic review of all controlled studies, Nielsen & Mølbak [1998, **EL Ia**] were unable to verify the assertion of a higher prevalence of BN in type 1 diabetic patients as compared with the general population.
- In controlled studies among patients with type 1 diabetes, the statistics on the mean frequency of the **EDNOS** vary between 3.0% [Fairburn et al., 1991, **EL IIa**] and 9.0% [Jones et al., 2000, **EL IIa**]. In particular, the study by Jones et al. [2000, **EL IIa**] on adolescent girls with type 1 diabetes mellitus pointed to a higher prevalence of principally “eating disorder not otherwise specified” as compared to metabolically healthy subjects. Therefore, we must assume that this age and sex group represents a population at risk for EDNOS.

6.3.3.3 Patients with type 2 diabetes mellitus

- Despite the greater epidemiological significance of type 2 diabetes mellitus, the comorbidity of diabetes mellitus type 2 and eating disorders has been the subject of little empirical research. The controlled study by Kenardy et al. [1994, **EL IIa**] on the prevalence of BED in patients with type 2 diabetes was unable to demonstrate an increased prevalence of this eating disorder. In a comparison of samples of patients with type 1 diabetes vs. those with type 2 diabetes, Herpertz et al. [1998, **EL III**] was not able to determine any difference in the prevalence of eating disorders, although the BED predominated in patients with type 2 diabetes.

6.3.3.4 Prevalence of “insulin purging”

- The statistics on the mean frequency of “insulin purging” vary, according to study, from 5.9% [Herpertz et al., 1999, **EL III**] to 39.0% [Stancin et al., 1989, **EL III**]. The large mean variation can be explained neither by the different age groups nor by the different survey instruments (questionnaires, interviews).

6.3.4 Metabolic control in diabetes mellitus patients with eating disorders

- Regarding the question as to whether an eating disorder in a patient with diabetes is accompanied by deterioration in metabolic control, the majority of controlled studies have compared eating-disturbed patients who have type 1 diabetes mellitus with non-eating-disturbed ones. In comparison with non-eating-disturbed patients who have diabetes, the metabolic control of eating-disturbed patients with diabetes was significantly poorer in all studies [Birk & Spencer, 1989, **EL III**; Rodin et al., 1991, **EL III**; Fairburn et al., 1991, **EL IIa**; Peveler et al., 1992, **EL IIa**; Jones et al., 2000, **EL IIa**] with the exception of the study by Herpertz et al. [1998, **EL III**]. Neither in the study by Crow et al. [2001, **EL III**] nor in that of Herpertz et al. [1998, **EL III**] did a significant difference in the HbA1c exist between eating-disturbed and non-eating-disturbed patients with type 2 diabetes mellitus.
- The prospective, controlled investigation by Rydall et al. [1997, **EL IIa**] came to the conclusion that pathological eating behaviour that fulfils the criteria of neither a clinical eating disorder (AN, BN) nor a subclinical eating disorder (EDNOS) but is characterised by frequent “feeding attacks” also goes hand in hand with poorer metabolic condition.

6.3.5 Diabetes-related complications in patients with eating disorders

- The meta-analysis by Nielsen & Mølbak [1998, **EL Ia**] indicates a three-fold increased risk of retinopathy in patients with type 1 diabetes mellitus and BN.
- Pathological eating behaviour that does not exhibit the full picture of an eating disorder according to the ICD criteria [WHO, 1992] likewise represents an increased risk of diabetic microangiopathy [Rydall et al., 1997, **EL IIa**].

6.3.6 Anorexia nervosa as a risk factor for patients with type 1 diabetes mellitus

- If a patient with type 1 diabetes mellitus develops AN, there is a significant rise in mortality [Nielsen et al., 2002, **EL IIb**]. In light of the rarity of this coincidence, there is a paucity of empirical investigations into the cause of death.

6.3.7 Diagnostics

- The comorbidity of diabetes mellitus and **AN** is extremely rare, and due to the poor nutritional condition of the anorexic patient, it is generally easy to diagnose.
- In every instance of diabetes mellitus that requires insulin and remains difficult to bring under control – particularly among adolescent girls and young female adults – one should consider early on whether a combination with **BN** and/or “**insulin purging**” might possibly be present. What points to this kind of comorbidity is above all the frequent, seemingly inexplicable decompensation of the diabetes mellitus [Feiereis, 1988, **EL IV**; Copeland & Anderson, 1995, **EL IV**].
- In obese patients who have type 2 diabetes as well as considerable fluctuations in weight and highly variable blood glucose values, the differential diagnosis of a **BED** should be considered early on.
- To diagnose the eating disorder, a biographical case history is often necessary, as it helps the patient overcome the threshold of shame and a longstanding tendency to deny the eating disorder.
- Various standardised questionnaires screen for eating disorders. Questionnaires such as the Eating Disorder Inventory (EDI) [Garner, 1991], in particular, have proven to be valid and reliable instruments that can be implemented as screening instruments and as a therapy control.
- With the aid of the Structured Interview for Anorexia and Bulimia nervosa (SIAB) or clinical interviews such as the DIPS [Margraf et al., 1991], M-CIDI [Wittchen et al., 1997], or SKID-1 [Wittchen et al., 1997], reliable and valid diagnoses of eating disorders according to the criteria of DSM-IV (APA, 1994) and ICD-10 (WHO, 1992) can be performed.

6.3.8 Therapy

6.3.8.1 Patients with type 1 diabetes mellitus

- Up to the present time, hardly any treatment intervention studies have been carried out on eating-disturbed patients with type 1 diabetes mellitus. Therefore, we are unable to draw conclusions based upon empirical data. Nevertheless, a series of case study contributions (**EL IV**) exist that show predominantly positive therapeutic

results in the principally inpatient treatment of anorexic and bulimic patients with type 1 diabetes [Feiereis, 1988, **EL IV**; Peveler & Fairburn, 1989, **EL IV**; Ramirez et al., 1990, **EL IV**; Herpertz & von Blume, 1995, **EL IV**; Jacobson, 1996, **EL IV**; Walsh et al., 2000 **EL IV**].

- Specialised psychotherapeutic treatment of these patients is urgently needed because of the increased risk of mortality, the danger to health from the eating disorder, the frequently encountered comorbid depressive disorder, as well as the negative effect on the diabetes therapy [Copeland & Anderson, 1995, **EL IV**; Peveler & Fairburn, 1989, **EL IV**]. Psycho-educative approaches alone are not sufficient, nor will they help to achieve their objective (**grade A**).
- Psychotherapeutic interventions for the treatment of eating disorders are effective. There is no counter-indication for their use among patients with diabetes mellitus. Consequently, the treatment of eating-disturbed patients with type 1 diabetes mellitus should proceed according to the guidelines of the DGPPN [DGPPN, 2001b, **EL IV**].
- For psychotherapy to be successful, it is necessary to understand the patient's life situation in general and that of the diabetes mellitus patient in particular. Therefore, the attending psychotherapist needs to know about the therapy regime and any possible association with the eating behaviour/eating disorder (e.g., hypoglycaemia, physical activity, etc.) (**grade A**).
- Specialised psychotherapeutic treatment should be given particular consideration in the presence of the diagnosis "insulin purging" since these counter-regulatory measures, characteristic for patients with type 1 diabetes, as a rule are accompanied by poor metabolic control and very often represent an expression of self-destructive behaviour (**grade A**).
- Early start of therapy and sufficient duration are important for treating eating-disturbed patients (**grade A**).

6.3.8.2 Patients with type 2 diabetes mellitus

- No treatment intervention study exists on eating-disturbed patients with type 2 diabetes. Integrated psychotherapeutic interventions are generally effective for the treatment of eating-disturbed patients. There are no counter-indications for their

implementation in patients with diabetes mellitus. As a consequence, treatment of eating-disturbed patients with type 2 diabetes mellitus should proceed according to the guidelines of the DGPPN [DGPPN, 2001b, **EL IV**] (**grade A**).

- As a rule, eating-disturbed patients with type 2 diabetes suffer from BED and obesity, requiring that considerations about all three illness entities be taken into account for the treatment. Consequently, a multimodal treatment concept is necessary, whose integral parts comprise psychotherapy and weight management (**grade A**).
- According to the guidelines of the German Obesity Society [1998, **EL IV**], the basic program for weight management rests on three foundations: nutrition therapy, behavioural therapy, and movement therapy [Hauner, 1997, **EL IV**]. One should bear in mind, though, that the medical demand for weight reduction and the unavoidable, restrictive eating behaviour it requires pose an obstacle to the dynamics of the BED. The hunger attacks involved in this disorder are discussed as being a consequence of pronounced cognitive control behaviour and its collapse (loss of control), inter alia [Abbott et al., 1998, **EL IIa**]. In terms of weight management in patients with BED, emphasis should be placed initially on normalising eating behaviour, as opposed to restricting eating behaviour, in order to break the vicious circle of cognitive loss of control (binging) followed by fasting.

6.4 Disorders due to the use of alcohol and nicotine

6.4.1 Definition

The neutral term “dependency” nowadays is used in place of the older term “addiction”. Under the category “F1 Mental and behavioural disorders due to psychoactive substance use” of the ICD-10 [WHO, 1991], the substances are coded separately in second position, following the point covering the various processes of dependency: acute intoxication (F1x.0), harmful use of substances (F1x.1), dependency syndrome (F1x.2), and, finally, the withdrawal syndrome (F1x.3). The following substances appear in the position of the “x”:

- Alcohol (F10)
- Opioids (F11)

- Cannabinoids (F12)
- Sedatives or hypnotics (F13)
- Cocaine (F14)
- Stimulants, including caffeine (F15)
- Hallucinogens (F16)
- Tobacco (F17)
- Volatile solvents (F18)
- Multiple drug use and use of other psychoactive substances (F19)

Due to insufficient data on disorders involving the use of other psychotropic substances, the present guidelines address only the harmful use of and/or the dependency on alcohol and tobacco as they relate to diabetes mellitus.

Harmful use (F1x.1) is defined as a consumption pattern of psychotropic substances that damages a person's health. This damage can take the form of a physical or psychological disorder and should be able to be clearly defined. The pattern of use should have existed for at least one month or have occurred repeatedly during the past twelve months.

For **dependency syndrome (F1x.2)** to be diagnosed, three or more of the following criteria must have existed for at least one month or have occurred repeatedly within a twelve-month period:

- a strong desire to consume the substance
- decreased control over the use of the substance
- physical withdrawal syndrome upon reduction or cessation of substance use
- development of tolerance to the substance's effects
- life centred around use of the substance
- continued consumption despite clear presence of damaging consequences and an awareness of the extent of the damage

6.4.2 Alcohol-related disorders

6.4.2.1 Epidemiology

- Alcohol abuse currently exists among 2.65 million persons (4% of the population aged 18 and older) in Germany; 1.6 million persons (2.4% of the population aged 18 and older) are acutely alcohol dependent. Ten to twelve percent of German citizens consume alcohol to a degree (men > 40g pure alcohol/d; women > 20g pure alcohol/d) that may not be acutely dangerous but carries with it a high long-term risk of health and social damage. [Breitenbach, 2000, **EL IV**; Bühringer et al., 2000, **EL IV**]. Alcohol dependence does not occur with any greater frequency among individuals with diabetes than in the general population [Spangler et al., 1993, **EL III**; Jacobson et al., 1997, **EL IIb**], and some studies showed lower prevalence rates [Wells et al., 1989, **EL III**; Gavfels, 1997, **EL III**].

6.4.2.2 Interaction between diabetes and alcohol-related disorders

- Alcohol abuse increases the risk of manifestation of type 2 diabetes [Carlsson et al., 2000, **EL III**; Rimm et al., 1995, **EL IIb**].
- Chronic alcohol abuse can lead to manifestation of diabetes through an alcohol-related pancreatitis [Carlsson et al., 2000, **EL III**; Rimm et al., 1995, **EL IIb**].
- In addition to the general physical and psychosocial consequences of alcohol dependency, metabolic control is negatively influenced by the direct effect of alcohol on glucose metabolism and indirectly due to the negative effect of alcohol consumption on self-treatment behaviour. There is specifically increased risk for diabetes-associated secondary illnesses, such as hypertonicity [Loenzo et al., 2002, **EL IIb**], hyperlipidemia [Laws et al., 1993, **EL IIb**], and/or diabetes-related complications, for example, the development of polyneuropathy [Adler et al., 1997, **EL IIb**], diabetic foot syndrome [Kästenbauer et al., 2001, **EL III**], erectile dysfunction [Martin-Morales et al., 2001, **EL III**] or severe hypoglycaemia and ketoacidoses, which may result in death [Stepka et al., 1993, **EL III**; Cusi et al., 1994, **EL IV**; Balkau et al., 1991, **EL IIb**; Keilman, 1983, **EL IV**; Lindegard et al., 1987, **EL IIb**].

- Insufficient, discontinuous medical care frequently makes diabetes treatment very difficult in patients with alcohol dependency. Poor care results largely from a lack of motivation for treatment, faulty self-treatment, and chronic effects on health from the alcohol abuse (e.g., gastrointestinal disorders) [Balkau et al., 1991, **EL IIb**; Greenhouse et al., 1996, **EL IV**].

6.4.2.3 Diagnostics

- Early diagnosis is important because of the negative effects substance dependencies have on diabetes therapy. Due to the problems of dependency, patients often exhibit a tendency to deny their alcohol dependency; such denial should be taken into consideration during the diagnostic process (**grade A**).
- Diagnosis requires a thorough review of the drinking habits and attendant physical and psychological problems, a physical examination, and special laboratory tests [American Psychiatric Association, 2000, **EL IV**]. Frequently those affected have additional psychological disorders (depression, anxiety disorders) and cognitive impairments that likewise require in-depth diagnosis and treatment [Wittchen et al., 1999, **EL III**].
- Questionnaires on alcohol-related dependency allow screening for alcohol dependency based on responses made by the patient about himself or herself. Suitable for use are valid and reliable German-language instruments such as the “Lübeck Alcohol Dependency and Abuse Screening Test” (LAST) [Rumpf et al., 2001], the Trier Alcoholism Inventory [Funke et al., 1987], and the “Munich Alcoholism Test” (MALT) [Feuerlein et al., 1999].
- Structured clinical interviews, such as DIPS [Margraf et al., 1991], M-CIDI [Wittchen et al., 1997] and SKID-1 [Wittchen et al., 1997] allow reliable diagnoses of alcohol dependence.

6.4.2.4 Therapy

- There are no studies on the treatment of alcohol-dependent patients who have diabetes. Therefore, the interventions recommended in the guidelines of the American Psychiatric Association [American Psychiatric Association, 2000, **EL IV**] should be applied for the treatment of alcohol dependency (**grade A**).

- Because of the increased danger to health resulting from dependency and its negative effect on diabetes therapy, the treatment of the dependency illness in patients with diabetes carries special importance. Therefore, every alcohol-dependent patient should undergo a structured therapeutic programme to treat his or her dependency (**grade A**).
- The diabetes therapy must be oriented towards the dependency, as long as the patient is unsuccessful in breaking the habit or this prospect seems unrealistic [Rollnick et al., 1999, **EL IV**]. The demands of therapy should be adapted to the abilities of the patient. As much as possible, addiction counsellors and relatives should be involved in the diabetic care of the patient (**grade A**).

6.4.3 Smoking-related disorders

6.4.3.1 Epidemiology

- Nicotine dependence is the most widespread form of substance dependence in Germany. Altogether, 28.3% of the population over 15 years of age (men, 34.7%; women, 22.2%) smoke in Germany; of that 28.3%, 96% consume cigarettes. Eighty-seven percent of the cigarette smokers are regular smokers who consume 15.4 cigarettes a day on average. According to the ICD-10 criteria for dependence, roughly 70% to 80% of the smokers are nicotine dependent, so that a total of approximately 8-9 million men and 5-6 million women can be classified as tobacco dependent in Germany [Herbst et al., 1997, **EL III**; Batra et al., 1997, **EL IV**; Statistisches Bundesamt, 1998, **EL IV**]. The prevalence of tobacco dependence in patients with diabetes does not differ, on average, from that of the general population, despite an increased risk for developing diabetes-related or -associated effects and complications [Gafvels et al., 1997, **EL III**; Wakefield et al., 1995, **EL III**; Malarcher et al., 1995, **EL III**; Ford et al., 1994, **EL III**; Ford et al., 1991, **EL III**]. In fact, several studies found higher rates in patients with diabetes [Dierkx et al., 1996, **EL IV**], especially in younger patients [Wakefield et al., 1995, **EL III**; Ford et al., 1991, **EL III**; Newman, 1990, **EL III**] and patients with a low level of education [Ford et al., 1991, **EL III**].

6.4.3.2 Interaction between diabetes and tobacco-related disorders

- With rising tobacco consumption, smoking increases the risk of manifestation of type 2 diabetes [Will, 2001, **EL IIb**; Ko et al., 2001, **EL III**; Manson et al., 2000, **EL IIb**; Rimm, 1995, **EL IIb**; Kawakami et al., 1997, **EL IIb**].
- Smoking is an important additional risk factor for developing diabetes-related or – associated effects and complications. It is well established that smoking increases the risk of cardiovascular diseases, diabetes-related neuropathies, peripheral vascular disease, erectile dysfunction, strokes and hypertonia [Dierkx et al., 1996, **EL IV**; Beach et al., 1982, **EL III**; Wei et al., 1998, **EL IIb**]. Smoking significantly increases the risk of diabetic nephropathy [Sawicki et al., 1993, **EL III**; Chaturvedi et al., 1995, **EL IIb**; Holl et al., 1998, **EL III**; Uchimoto et al., 1999, **EL IIb**; Mehler et al., 1998, **EL III**; Biesenbach et al., 1997, **EL IIb**; Ikeda et al., 1997, **EL III**]. Nicotine abstinence can improve an existing proteinuria [Chasse et al., 1991, **EL III**]. In the case of terminal kidney disease, smoking is an important risk factor for increased mortality [Biesenbach et al., 1996, **EL IIb**; Stegmayr et al., 1990, **EL III**]. The findings on diabetic retinopathy are controversial [Moss et al., 1996, **EL IIb**; Chaturvedi et al., 1995, **EL III**; Eadington et al., 1991, **EL III**].
- Patients who have diabetes and smoke have an increased risk of mortality as compared to persons who have never smoked. The risk depends on the duration of smoking and the number of cigarettes smoked [Chaturvedi et al., 1997, **EL IIb**; Al-Delaimy, 2001, **EL IIb**].
- Increasingly, nicotine dependence has been associated with problems in carrying out diabetes therapy [Spangler et al., 1993, **EL III**]. Broadly, one can assume a negative association between smoking and metabolic control [Chaturvedi et al., 1995, **EL IIb**; Bott et al., 1994, **EL IIb**; Lundman et al., 1990, **EL III**]. However, the data on this connection are contradictory [Stenstrom et al., 2000, **EL III**; Sinha et al., 1997, **EL IIb**; Mathiesen et al., 1984, **EL III**]. Smoking can represent a predictor variable for poor self-treatment behaviour [Bott et al., 1994, **EL IIb**; Gay et al., 1994, **EL III**].
- Patients with diabetes who are tobacco dependent have an increased comorbidity with depression [Spangler et al., 1993, **EL III**; Sullivan et al., 1998, **EL IV**].

6.4.3.3 Diagnostics

- Those affected by nicotine dependency often deny dependency [Bodmer et al., 1990, **EL III**; Ardron et al., 1988, **EL III**] and underestimate the negative effects in terms of the risk of developing diabetes-related or –associated complications [Wakefield et al., 1995, **EL III**].
- Besides a general case history survey, enquiries should be made specifically about secondary illnesses and complications. The degree of dependency is contingent on the number of cigarettes (or cigars or pipes) smoked daily, the time when the morning cigarettes are smoked, and the smoker's daily profile, depth of inhalation, and brand of cigarette smoked, inter alia [Arzneimittelkommission der Deutschen Ärzteschaft, 2001, **EL IV**].
- To determine nicotine dependence, the Fagerström Test is recommended [Fagerström et al., 1989, **EL IV**]. It can evaluate the degree of dependency based on six questions.
- Structured clinical interviews such as the DIPS [Margraf et al., 1991], M-CIDI [Wittchen et al., 1997] and SKID-I [Wittchen et al., 1997] allow reliable diagnoses of nicotine dependency.

6.4.3.4 Therapy

- Randomised studies have shown varying rates of success for the therapy of tobacco dependent patients who have diabetes [Canga et al., 2000, **EL Ib**; Sawicki et al., 1993, **EL Ib**]. Various authors indicate that the treatment of tobacco dependency is particularly difficult in young adults [Ismail et al., 2000, **EL III**; Wilkes et al., 1999, **EL III**; Fowler et al., 1989, **EL III**; Ardron et al., 1988, **EL III**]. Very heavy smokers rarely achieve nicotine abstinence [Sinha et al., 1997, **EL Iib**].
- For treatment of tobacco dependency, the interventions recommended by the evidence-based guidelines of the WHO [WHO-Europe 2001, **EL IV**], the American Psychiatric Association [American Psychiatric Association, 2000, **EL IV**], the American Diabetes Association [Haire-Joshu et al., 1990, **EL IV**] and the therapeutic recommendations of the Drug Commission of the German Board of

Physicians [Arzneimittelkommission der Deutschen Ärzteschaft, 2001, **EL IV**] should be implemented (**grade A**).

- Treatment of tobacco dependency takes on particular importance in patients with diabetes due to the increased danger to health caused by the dependency and its negative effects on diabetes therapy [Haire-Joshu et al., 1999, **EL III**]. Consequently, the problem of the relationship between smoking and risk of diabetes-related or –associated complications should be adequately addressed in a structured diabetes education programme. Every nicotine-dependent patient with diabetes should undergo a structured therapy programme to treat his or her dependency within the framework of that individual's diabetes therapy (**grade A**).
- In instances of patients rejecting smoking cessation programmes, short interventions have proven effective in increasing motivation to stop smoking [Rollnick et al., 1999, **EL IV**; der Fiore et al., 2000, **EL IV**]. As a consequence, measures for increasing motivation to abstain from smoking should be repeatedly implemented within the framework of diabetes treatment (**grade A**).

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Appendix 1:

Register of the catalogue of the search criteria for the literature search

Definition/classification

- diabet*
- insulin-dependent
- insulin*
- IDDM
- juvenile
- jugendlicher
- type 1-diabet*
- type I-diabet*
- Typ-1-Diabet*
- Typ-I-Diabet*
- non-insulin-dependent
- nicht insulin*
- NIDDM
- type 2-diabet*
- type II- diabet*
- Typ 1-Diabetes
- Typ I-Diabetes
- maturity-onset diabetes
- mody
- impaired glucose tolerance
- gestörte Glukosetoleranz

Publications

- clinical trial*
- guidelines
- incidence

- inzidenz
- klinische Studie*
- leitlinie*
- meta-anal*
- prävalanz
- prevalence
- randomisiert*
- randomized controlled trial
- study
- studie*
- sytematic review
- trial*
- uebersichts*

Patient management, monitoring and education

- patient education
- education
- teaching program
- self-treatment
- self care
- management
- selfmanagement
- selfmanagement training
- empowerment
- patientenschul*
- schulung*
- diabetesschulung*
- schulungsprogramm
- selbstbehandlung
- selbstmanagment

Interventions/therapy:

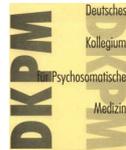
- behandlung
- behavior
- behavior-therapy
- behaviour
- behaviour-therapy
- beratung
- bgat
- biofeedback
- blood glucose awareness training
- case-management
- cognitive-behavior-therapy
- cognitive-behaviour-therapy
- cognitive-therapy
- combined-modality-therapy
- coping
- counseling
- crisis-intervention
- entspannungstherapie
- family-therapy
- familientherapie
- group therapy
- gruppentherapie
- hypoglykämiewahrnehmungstraining
- hypnotherapie*
- interperso*
- intervention
- kognitive Verhaltenstherapie
- krisen*
- management
- marital-therapy

- multimodal*
- psychotherap*
- psychotherapie
- psychoanalysis
- psychoanalyse
- psychiatric*
- psychodynami*
- relaxation-therapy
- social*
- soziale*
- stress*
- support
- therap*
- training
- treatment
- unterstützung
- verhaltensmodifikation*
- verhaltenstherapie

Comorbidity:

- abhängigkei*
- abuse
- addict*
- angst*
- affective disorder
- affektive*
- alcohol
- alkohol
- angst*
- anorexia
- anorexia nervosa

- anxiety*
- binge eating*
- bulimia
- bulimia nervosa
- bulimie
- comorbidity
- depend*
- depression*
- dysthymi*
- eating disorder*
- essstörung*
- eßstörung*
- fear*
- furcht
- gesundheitsbezogene Lebensqualität
- health related quality of life
- hypoglycemi*
- komorbidität
- lebensqualität*
- missbrauch*
- multiple-substance abuse
- nicotine*
- nikotin*
- obsession
- obsessive compulsive disorder
- panic*
- panik*
- phobia
- phobic*
- phobie
- phobisch*



- post traumatic stress disorder
- posttraumatische Belastungsstörung
- ptsd
- quality of life
- rauch*
- smoking
- substance-abuse
- substanzabusus
- substanzmißbrauch
- tabak*
- tobacco*
- worry
- zwang*

Appendix 2

Cited and evaluated publications

Evaluated publications: n = 493

Cited and included publications: n = 273

Psychosocial issues and diabetes

