Diabetes therapy goals

Diabetes is a chronic disease that poses considerable challenges for people with diabetes in their daily therapy. In addition to drug therapy, the therapy behaviour of the person with diabetes plays a significant role in the prognosis of the disease. In diabetes therapy, it is therefore important to define therapy goals together with the person with diabetes, taking into account a multitude of biological, somatic, social and behavioural factors, and to support those affected as best as possible in implementing therapy goals into their personal living environment and their self-management.

The most important superordinate therapy goals for diabetes are described in the evidence-based guidelines for type 1 and type 2 diabetes [1, 2], as well as in the Disease Management Program (DMP) requirements guideline (DMP-A-RL) [3].

- **Maintaining or improving the quality of life limited by diabetes:** For people with diabetes, maintaining the quality of life is the most important goal of diabetes therapy [4]. This means remaining as physically and psychologically healthy as possible despite and with diabetes, being able to realise one’s own life goals and being socially integrated – without being limited in areas of life that are important for people, such as family/relationship, job, interests, leisure time, etc. Study results show relatively consistently that these goals, which are important for people with diabetes, have not yet been achieved worldwide [5, 6].

- **Preventing symptoms of the disease:** Elevated, decreased or even highly-fluctuating glucose levels (increased glucose variability) can lead to symptoms such as an increased urge to urinate (polyuria), a strong feeling of thirst (polydipsia), fatigue, weakness and tiredness. Symptoms that should be avoided during therapy also include dry or itchy skin, neuropathic symptoms and fluctuations in lens refractive power due to osmotic effects of increased glucose levels.

- **Preventing acute complications:** It is important to prevent side effects of antihyperglycaemic therapy, in particular hypoglycaemia – especially severe hypoglycaemia in which the affected person is dependent on external help (e.g., by relatives or medical staff). As well, it is important to prevent severe hyperglycaemic metabolic derailments (e.g., diabetic ketoacidosis) because of the associated burdens and dangers for the person with diabetes, as well as the associated health risks, which can be lethal in some cases.
**Preventing diabetes-associated diabetes complications:** This mainly concerns the prevention of micro- and macrovascular sequelae, in particular retinopathy with severe visual impairment or blindness, renal insufficiency with the need for renal replacement therapy, coronary heart disease, peripheral arterial occlusive disease and ischaemic stroke. The goal is also to prevent neuropathies and diabetic foot syndrome with neuro-, angio- and/or osteoarthropathic lesions and amputations.

**Preventing diabetes-associated increased morbidity and mortality:** One major goal is to reduce the increased risk of cardiac, cerebrovascular and other macroangiopathic morbidity and mortality associated with diabetes. Using data from 65 million insured persons in Germany, the excess mortality due to diabetes in Germany could be estimated at 174,627 people. Overall, 21 % of all deaths in Germany were associated with diabetes in this study [7].

In the case of a chronic disease such as diabetes mellitus, the therapy goals should always be set in consultation with the person affected. It must be taken into account that the therapy goals may differ between people with diabetes and the physician of the diabetes team. While people with diabetes often name “maintenance of quality of life” and “preventing acute complications” as the most important therapy goals, physicians often focus on “preventing diabetes-associated increased mortality” and “preventing diabetes complication”. The therapy goals agreed individually with the people with diabetes should be evaluated regularly and as needed during the course of treatment and followed up or adjusted according to the results [2].

**Different categories of therapy goals**

According to Elwyn et al. [8], the guideline group of the Type 2 Diabetes [2] guideline suggests dividing the therapy goals into three categories:

- **Fundamental goals:** These are general goals of people such as autonomy, self-determination, participation in life, maintaining health or quality of life. A possible question on the superordinate life goals could be: “When you think about your diabetes, what is particularly important to you for your life?”

- **Functional goals:** These are goals that aim to prevent or reduce functional impairments that interfere with a self-determined and healthy life, such as the treatment of a functional impairment, the promotion of activities of daily living, the improvement of sporting activities, cognitive performance or also the ability to work, keeping a job. A question about function-related goals could be formulated, for example, as follows: “What drives you to take good care of your diabetes – what do you want to achieve with it in your daily life?” or “Which activities in your life are so important that you do not want to jeopardise them through poor diabetes control?”.

- **Disease-specific goals:** These include all goals that are directly associated with the treatment of diabetes and its complication. This refers to somatic goals (e.g., preventing complications, less pain, better sleep) as well as psychological (e.g., preventing diabetes-related stress, anxiety, depression) and social goals (e.g., safe participation in road traffic). “In concrete terms, what would you like to achieve if you make maintain your diabetes therapy well, what would you get out of it?” could be a question about the disease-related goals.

When agreeing on individual therapy goals, the authors of the Type 2 Diabetes guideline recommend starting with the higher-level life goals, as these influence the function-related and disease-specific goals (“top-down approach”). If patients find it difficult to formulate higher-level life goals, more concrete, function-related and disease-specific goals can also be worked out together first. Building on this, it can then be easier to derive higher-level life goals from them (“bottom-up approach”). Since the prioritisation of therapy strategy goals can change, in practice the question of individual therapy strategies should be asked again at regular intervals [2] and this should also be recorded in writing.

**Role of people with diabetes in therapy**

In diabetes therapy, people with diabetes play the decisive role, as they are permanently responsible for implementing the essential therapy measures in their personal everyday life. Therefore, the prognosis of diabetes depends primarily on the extent to which those affected succeed in coming to terms with their diabetes emotionally (emotional level), in gaining a positive attitude towards their disease as well as in acquiring sufficient knowledge and skills for self-treatment (cognitive level), and in implementing the diabetes therapy in the best possible way with the support of the diabetes team (behavioural level). One of the main goals of diabetes therapy is motivating people to deal with their disease as well as possible and with personal responsibility. These goals are to be realised to the extent that the cognitive and emotional conditions of the respective affected person allow. The diabetes teams must accept it if people with diabetes pursue goals that deviate from the goals and recommendations of the diabetes team.

In view of the central importance of the people with diabetes for the therapy of diabetes, modern treatment concepts feel committed to the “self-management” or “empowerment approach”:

- **Empowerment:** Strategies and measures aimed at increasing the autonomy and self-determination of people with diabetes in order to enable them to deal with diabetes on their own authority and responsibility (“help for self-help”).

- **Self-management:** This is understood as the competence to independently shape one’s own life (with diabetes as a chronic disease) according to one’s own goals, values and beliefs. Important self-management skills include the ability to set meaningful personal goals, to develop a strategy for the successful implementation of these goals and to implement them consistently. In addition, the implementation should be observed and controlled, and reflected conclusions should be derived from the results of one’s own actions.

In terms of content, the two terms are closely linked; the term “self-control” is also frequently used. In relation to diabetes, the consequence of this approach is to take seriously the individual goals of people with diabetes regarding their lives and their management of diabetes, and to enable them to cope as independently as possible with the disease-specific demands and problems associated with diabetes. People with diabetes should be empowered to make informed decisions for their own life and management of diabetes.
Often, "shared expertise" is also spoken of in this context: The person with diabetes is the "expert" for his or her life, values and beliefs and knows best how the daily routine of therapy looks based on the background of his or her social, cultural, family and professional environment. The diabetes team, on the other hand, are the "experts" for diabetes therapy and medical aspects of diabetes, diabetes counselling and education. A successful therapy should be based on the foundation of a good relationship between the physician/diabetes team and the person with diabetes and result in joint therapy planning [9].

**Shared decision-making**

The concept of empowerment/self-management also has implications for defining the therapy, which should be a shared responsibility between the physician/diabetes team and the person with diabetes and then put into an agreement on the appropriate medical treatment. The term "shared decision-making" (SDM) is usually used for this. This means that possible treatment options are discussed and a jointly responsible, informed decision is made with the equal, active participation of the diabetes team and the people with diabetes.

This participatory approach is also advocated in a joint statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) [10] as the standard of modern diabetes therapy, and described in an extra chapter of the type 2 diabetes guideline [2]. It is also in line with the current Patients’ Rights Act, which stipulates the patient’s right to self-determination, information and education about the expected health development and therapy. Studies also show that most patients, as well as physicians, favour shared decision-making and that this promotes autonomy, the ability to self-manage, therapy satisfaction, motivation and adherence, especially in chronic diseases such as diabetes [11].

In upcoming health-related decisions regarding type 2 diabetes, the discussion should be conducted according to the concept of shared decision-making [2]. The individual steps of shared decision-making are shown in ▶Fig. 1.

**Communication with people with diabetes**

In a chronic disease such as diabetes, a good relationship between the physician/diabetes team and the people with diabetes is an important factor for a successful working alliance for the treatment of diabetes. The goal of successful communication between physicians and people with diabetes is to create a good, caring inter-personal relationship that facilitates conversation as well as the exchange of information about therapy, and provides the basis for shared decision-making.

Core competencies for successful communication are:
- **The authenticity of the relationship** (congruence)
- **And an empathetic understanding of the other** (empathy). This is particularly important in diabetes therapy, as it is a crucial prerequisite for people with diabetes to open up in conversation with the diabetes team and also report on the difficulties, problems, but also successes and challenges of diabetes therapy in everyday life.

- **Good communication between physicians and people with diabetes** also has the advantage that people with diabetes understand medical information more easily because they dare to ask. Based on a population-based German study (Kora study), it was shown that a positive relationship between people with diabetes and physicians is associated with increased adherence and quality of life in the people studied [12].
- **It is also important that the person and his/her background, needs, perceptions and expectations are recorded in the context of diabetes therapy, as this is crucial for successful communication between the diabetes team and the person affected.**
- **The perception of successful communication is often evaluated differently by the physician and people with diabetes. This was exemplified in the DAWN study. While the majority of physicians stated that they had discussed the impact between physicians and people with diabetes, this was only stated by one in five people with diabetes [5].**

For the conversation between physicians and people with diabetes, the questions in ▶Tab. 2 can be used to reflect on successful communication and interaction.

**Personalised diabetes therapy, precision medicine**

Since diabetes therapy depends on a wealth of different influencing factors, these should be implemented in the sense of a patient-centred, individualised or personalised therapy plan. This is also emphasised in the statement of the ADA/EASD [10] on the therapy of type 2 diabetes.

When jointly determining a therapy, a number of factors should be taken into account in the decision. In this context, a positive relationship between the benefit (e.g., risk reduction of complications) and possible harm (e.g., severe hypoglycaemia, strains due to overtreatment) must be expected, taking into account the planned or implemented therapeutic measures. In addition, the effects on participation in all relevant areas of life must be taken into account [2].

The following are the most important factors to consider:
- **Characteristics of the disease or therapy**: duration of disease, risk factors, concomitant diseases in the context of diabetes (e.g., hypertension, hyperlipidaemia), extent of insulin secretion or resistance, side effects (e.g., hypoglycaemia, hyperglycaemia, drug side effects, interactions, intolerances, skin irritations due to plasters, devices).
- **Physical functions**: genetic factors, immune system, complications of diabetes, comorbid diseases, frailty, motor deficits (e.g., complications in handling insulin pens and aids), pain, visual impairment (maculopathy, retinopathy).
- **Psychological factors**: state of mind, psychosocial problems, comorbid mental illnesses, coping with illness, acceptance of illness, self-efficacy, motivation for diabetes therapy.
- **Characteristics of the person**: age, expected life expectancy, cognitive abilities or limitations, health literacy, language and language comprehension, disease-related knowledge and skills, attendance of diabetes training.
**Social context factors**: social, occupational environment, cultural background, education level, diabetes support, poverty, health insurance.

**Medical care context factors**: availability of medication, mobility to visit medical institutions, health insurance

In order to weigh these different influencing factors, there are various tools and treatment heuristics that can serve as decision-making aids in practice

A working group of Inzucchi et al. [13], for example, has developed a scheme in which the factors age, duration of disease, life expectancy, comorbidities, vascular diseases, motivation/adherence, resources/support are correlated with stricter or not so strict efforts to reduce the HbA1c value in the therapy of type 2 diabetes, depending on the degree of severity.

Increasingly, risk scores, algorithms based on artificial intelligence (AI), are also being used in clinical practice to determine the individual risk of developing diabetes complication or a mortality risk [14, 15]. Based on the respective factors important for the analysis, the personal risk is thus determined, which is an important prerequisite for personalised treatment in the sense of precision medicine. Research using AI has helped to identify subtypes of the disease that are different in terms of aetiology, clinical features and prognosis.
Integrated, personalised diabetes management

Several working groups [18–20] have developed models of integrated, personalised diabetes management. Common to all approaches is that a structured decision-making process starts with an assessment of the most important patient characteristics and the most important factors influencing the therapy. In the subsequent process of shared decision-making, a treatment plan is then developed jointly between the physician/diabetic team and the person with diabetes, and suitable treatment goals are derived from this. In the subsequent implementation process, the person with diabetes and the physician jointly analyse to what extent the implementation of the therapy is successful and the agreed goals are achieved or whether the therapy needs to be adjusted.

The procedural course of this diabetes management process ensures that, on the one hand, the individual contextual factors are always taken into account in therapy planning and adjustment and, on the other hand, that therapy adjustment is regularly carried out with the involvement of people with diabetes. The procedure described in the EASD/ADA position paper [10] is intended to support both the physician and the person with diabetes at all levels of this feedback process (assessment—diagnostics – documentation – systematic analysis – shared, personalised decision – monitoring and, if necessary, adjustment of the therapy). Due to the increasing digitalisation of diabetes therapy, this process also serves as a heuristic framework for possible digital applications to automate and optimise this feedback process. For clinical practice, the action steps outlined in ▶ Tab. 1 have proven to be useful.

Tab. 1  Meaningful steps in practice with regard to shared decision-making.

1. Agreement between physician and patient that a decision is pending (e.g., “We should talk today about whether insulin therapy is useful and necessary in addition to tablets in your diabetes therapy”).
2. Emphasising the equality of partners in the decision-making process (e.g., “I think this would be a good treatment option for you for a number of reasons, but of course the decision is yours”).
3. Describing the different treatment options and information about their advantages and disadvantages (“Let me briefly explain to you the advantages and disadvantages of the previous therapy and of a possible insulin therapy”).
4. Ask for the understanding, thoughts, concerns, open questions and expectation of a person with diabetes (“What do you think about possible insulin therapy, do you have any concerns or questions for me?”).
5. Clarifying available treatment options (“I understand that you would prefer to continue taking only tablets, but unfortunately in your situation there are no other medications that will normalise your elevated glucose levels as you lack insulin. Or are you still thinking of other treatment options?”).
6. Clarifying the preferences of a person with diabetes and leading toward making the decision (“I sense that you are not yet fully convinced about insulin therapy, but also concerned about your significantly-elevated glucose levels. Shall we show you how insulin injection works so that you can get a better idea?”).
7. Negotiating the decision-making options (“If I have understood you correctly, you would like to try insulin therapy once in order to find out more precisely whether you feel confident about injecting and whether it also works in everyday life. If you want, you can try it out right after our conversation”).
8. Reaching an agreement on decision implementation (“Then I am curious to hear what you will report next time and whether you are satisfied with the insulin therapy. I would suggest that you make an appointment for the next few weeks. A member of staff will give you an initial briefing on injecting insulin and insulin therapy straight away”).

Tab. 2  Questions to reflect on successful communication and interaction between the diabetes team and people with diabetes.

- Did I adopt an accepting, appreciative, person-centred and empathic attitude in the conversation?
- Did I listen to the patient’s concerns and adjust the content of the conversation accordingly?
- Did I take up the patient’s wishes, expectations and ideas, but also possible concerns and problems in the conversation?
- Did I ask open questions during the conversation and encourage the patient to ask questions or inquire?
- Did I actively encourage the patient’s own initiative in the conversation?
- Did I correctly assess the patient’s possibilities to implement his or her diabetes therapy on his or her own?
- Have I discussed the concrete therapy goals – especially milestones with the patient and reached an agreement with the patient about them?
- Have I asked the patient, if necessary, what is preventing him/her from achieving the therapy goals and whether or, in his/her opinion, how I can provide support?
- Have I asked the patient about his/her successes so far and appreciated them?
- Did I make a concrete agreement with the patient at the end of the discussion or did I agree on a specific topic of discussion for the next appointment?
Important factors that have turned out to be particularly significant in the treatment history to date.

**Step 2: Consideration of specific factors that influence the choice of therapy**

The second step refers to the recording of influencing factors that very specifically affect the therapy, such as the joint definition of the individual therapy goal or a scheme for titration or dosage self-adjustment of the insulin therapy. The side effect profile and possible effects on other parameters (e.g., body weight, risk of hypoglycaemia, allergic skin reactions with continuous glucose monitoring [CGM]) should also be discussed. In particular, the aspect of adherence and persistence of therapy should be taken into account not only when choosing a therapy, but especially during its implementation [21].

**Step 3: Joint decision-making for the preparation of a therapy plan**

Before a joint decision is made, an analysis of the glucose values or other important parameters such as blood pressure values, exercise or nutrition data is usually carried out in advance between the physician/diabetic team and the people with diabetes. It is very helpful that a lot of data is now available digitally. When all relevant information and influencing factors for a decision are available, the third step is making a joint decision for the initiation or adjustment of a therapy or a measure which accompanies the therapy (e.g., logging of dietary behaviour, weight reduction). It is important to perform a realistic assessment of the possibilities the person with diabetes has in implementing the therapy – while taking into account any barriers (e.g., due to lack of abilities, lack of motivation...
or the dominance of other life circumstances that currently make it difficult to implement the therapy which may exist.

**Step 4: Joint agreement on therapy plan**

In the next step, realistic goals must be set jointly by the physician/diabetic team and the person affected in order to implement the jointly-determined therapy plan. The essential scientific findings for the formulation of realistic goals are summarised in the word SMART: Good goals should be specific, measurable, attractive, realistic and timely (▶ Tab. 3).

**Step 5: Implementation of the therapy plan**

It is favourable to set a time frame for the implementation of the therapy plan and to plan the next check-ups. In practice, it has proven useful that patients who do not reach mutually-agreed goals are seen at least every 3 months.

**Step 6: Monitoring and support**

There are now a number of ways to monitor the course of therapy and offer support when needed. This can be based on agreements between the physician/diabetic team and the person with diabetes, agreeing on criteria for when to call on the help of the diabetes team (definition of yellow, red flags). Specific events (e.g., severe hypoglycaemia, weight gain above a predefined threshold, transient ischemic attack (TIA)s) can also be cause for targeted support. With modern technologies, the monitoring of certain events and body conditions is much easier.

**Step 7: Review and approval of the therapy plan**

In the last step, the therapy plan to-date is analysed and a decision is made together with the person with diabetes whether it needs to be changed or adapted, or other measures need to be initiated to optimise the therapy (e.g., training, referral to foot care).
Adherence is a significant variable for the success of treatment and is named by the World Health Organization (WHO) as one of the most important non-specific measures to not only improve the prognosis of diabetes, but also to save costs. This is particularly true for diabetes, which often involves polypharmacy with changing dosages, times of intake, side effects and interactions, and where the implementation of dietary and exercise regimens is often poor [22]. Adherence in diabetes is often overestimated by treatment providers and should therefore receive more attention in clinical practice [21]. Systematic reviews have found that adherence rates for oral antidiabetics are only between 60 and 85 %, and for antihypertensives and antidepressants less than 60 %. Adherence to insulin therapy is also below 80 %. Patients with lower adherence have poorer metabolic control (HbA1c, blood pressure, lipids), higher mortality and higher hospitalisation rates [23].

- The behaviour of treatment providers (e.g., little empathy, poor communication skills, too little time for contact with the person affected, incorrect therapy decisions, etc.).
- And also, the general framework conditions of the health care system (e.g. co-payments, poor accessibility of practitioners, high co-payments, lack of reimbursement, etc.).

If a therapy goal has been agreed upon in the context of shared decision-making between people with diabetes, it can happen for various reasons that those affected deviate from the agreement in their actual behaviour (non-adherence). In the German program for disease management guidelines (Nationale Versorgungsleitlinien [NVL]) Type 2 Diabetes guideline, it is suggested to proceed according to the following scheme (Fig. 2, and 3) in order to analyse whether an agreed therapy strategy was implemented or not and for what reason. This is not meant to be an evaluation in the sense of assigning blame or failure, but rather to identify potentially remediable reasons or to check the joint goals and strategies for suitability for everyday use.

In clinical practice, regular enquiries about adherence and possible reasons for non-adherence, the use of combination therapies, electronic medication plans and digital tools such as apps with reminder functions can increase adherence.

Clinical Inertia

One major reason for not achieving treatment goals and for sub-optimal glycaemic control is referred to as “clinical inertia”. This means that a therapy plan is not adapted or intensified accordingly if certain treatment goals are not achieved. Often, this is because adjustment of the therapy which took place was either too late or omitted despite having exceeded the limits for therapy escalation described in guidelines or having failed to recognise or overcome barriers to therapy. From a health care perspective, this is an important problem as health care research shows that the implementation of therapy measures in everyday life is different than in clinical studies [24, 25].

Physician-related causes are primarily responsible for “clinical inertia”. In a systematic review article [26], the physician’s share is estimated at approx. 60 %, approx. 20 % of the causes/reasons lie in the practice organisation and only approx. 30 % of the causes/reasons lie on the part of people with diabetes. Lack of knowledge and negative attitudes towards evidence-based guidelines, insufficient involvement of the person concerned in therapy decisions and poor organisation of the practice (e.g., lack of reminder systems, lack of team agreements, lack of routines for monitoring the success of treatment) are major causes of clinical inertia.

Multi-professional cooperation

The treatment of people with diabetes and also the agreements on therapy decisions often take place in a team consisting of different treatment professions. A prerequisite for good diabetes care is functioning teamwork with clear agreements. Responsibilities coordinated within the team and good communication structures are a prerequisite for successful teamwork. In addition, many other

<table>
<thead>
<tr>
<th>Tab. 3</th>
<th>Smart goals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Specific: A goal should never be formulated in a vague and unspecific way, but rather in a very precise way and should specifically name all aspects that are part of the goal (example: instead of: “I will measure my glucose more frequently in the future”, it would be better to say, “I will measure my glucose at least 5 times a day and activate a reminder function in my smartphone for the first time. I will definitely measure my glucose after getting up, before the main meals and before going to bed”).</td>
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<tr>
<td>▪ Measurable: A good goal should be measurable and contain a quantitative unit for goal achievement (e.g., days, km, calories, hours, frequency, kg, etc.). (Example: Instead of: “I will transfer my glucose values to my computer and evaluate them with a programme”, it would be better to say, “I will install the evaluation programme on my computer tomorrow and deal with my glucose values next Sunday. If my ‘Time in Range’ does not reduce by at least 5 % within the next 3 weeks, I will make another appointment with you”).</td>
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<tr>
<td>▪ Attractive: Goals should be attractive and as motivating as possible. (Example: Instead of: “I will try to exercise more because of my weight”, it would be better to say, “I will send you an email with a screenshot of my smartphone with the analysis of my steps when I have managed to walk more than 10,000 steps every day for the first week”).</td>
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<tr>
<td>▪ Realistic: The goals should be formulated so realistically that they are also achievable (example: instead of: “From now on I will always wear my orthopaedic shoes”, it would be better to say, “From now on I will also wear my orthopaedic shoes at home, which I have not done so far”).</td>
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<tr>
<td>▪ Timely: A good goal should not only be generally measurable, but also timely. (Example: Instead of: “Why don’t you see how well you get along with the medication xxxx in everyday life?”, it would be better to say, “I suggest we make an appointment in 4 weeks and then evaluate together how well you have gotten along with the medication and what experiences you have had with it”).</td>
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</tbody>
</table>

Tab. 3 Smart goals.
professions, some with special further training from the German Diabetes Society (DDG), are involved in the treatment of diabetes and also need important information and need to communicate regarding the results. For this purpose, an electronic patient record (ePA), supplemented by the diabetes-specific electronic medical record (eDA), can offer great advantages in the future, especially in the treatment of diabetes [27] (▶ Tab. 4).

### Conflict of interest

Bernhard Kulzer: Advisory Boards: Bayer, Becton Dickinson, Berlin Chemie, Novo Nordisk, Sanofi, Roche. Lectures, study projects


### References


### Tab. 4  Multi-professional treatment of diabetes.

<table>
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<th>Profession</th>
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<td>Anaesthesiology</td>
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<td>Vascular diseases</td>
</tr>
<tr>
<td>Biochemistry</td>
<td>Metabolic diseases; translation of research results into practice</td>
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<td>Cardiology</td>
<td>Cardiovascular diseases</td>
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<td>Psychological disorders in type 1 diabetes in childhood and adolescence</td>
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