Scientifically accompanied project to improve the treatment of patients with type 2 diabetes in family practice

Project management:
Association QualiCCare, under the scientific responsibility of Prof. Dr. med. Emanuel Christ, Prof. Dr. med. Michael Brändle, Dr. med. Christian Häuptle, Dr. rer. nat. Astrid Czock

Dear Madam, Dear Sir,

We ask you herewith if you would participate in a research project. In the following, the planned research project is described:

1. Aim of the project

With this project, we want to investigate how the application of a checklist of criteria affects the quality of treatment of patients with type 2 diabetes.

2. Patient selection

All persons who have diabetes mellitus type 2 can participate.

3. General information about the project

The association QualiCCare (www.qualiccare.ch) has adopted the criteria for "Good diabetes management in primary care" of the Swiss Society of Endocrinology and Diabetology (www.sgedssed.ch) and, as an implementation partner, is supporting 30 different family practices in eastern Switzerland in introducing these criteria into their daily practice routine. The aim is to ensure that your family doctor treats you as a patient with type 2 diabetes comprehensively and according to the newest scientific findings. To ensure this, your family doctor and his practice team will be given a sort of checklist.
When evaluating the documentation, not the individual patient is assessed, but always the entirety of all patients with diabetes mellitus type 2 in a practice. In total, we expect that in all 30 participating practices the treatment of about 1'500 patients with diabetes will be recorded.
The documentation important for the evaluation includes a patient number, your year of birth and your sex. However, your name, address or other personal data will not be filed. At no stage can any conclusions be drawn to your person. All patient data remains accessible only by your doctor and his team.

This project will be carried out in accordance to the Swiss law. The responsible ethics committee has examined and approved this project.

<u>Procedure</u>

A member of the practice staff responsible for the project takes your patient file and retrospectively documents your last year's treatment in accordance to the given checklist. The following points are included in this checklist:
At least 3 times a year regular check-ups regarding diabetes by the family doctor
1x annual lifestyle consultation (diet, exercise for BMI >25, smoking cessation for smokers)
2x annual HbA1c determination
2x annual blood pressure measurement
1x annual cholesterol measurement
1x annual renal function examination
An eye examination every 2 years
1x annual foot examination

Furthermore, your medication and the flu vaccination will be recorded.

At each new doctor's appointment in the current year, a record is made of the points on the checklist that have been fulfilled. After 12 months, the practice has a second list of treatments on file, which can be compared with last year's. Ideally, the second list will show an improvement, as the practice team and your family doctor have the list of diabetes management points at hand and can use it as a reminder. Apart from these criteria, which would have to be fulfilled for the optimal treatment of patients with type 2 diabetes, there are no further examinations that you will have to undergo. On the other hand, your doctor may decide in your case that one of the above criteria is not relevant to you and therefore will not collect it.
If you do not wish this to happen, please speak to your family doctor.

2. Benefit

You will not personally benefit from participating in the project. If you participate in this project, it may help you to have a high quality of life for a long time in spite of your diabetes, as certain negative issues may occur later or can even be prevented. For example, regular foot checks can detect reduced nerve sensitivity at an early stage and appropriate precautions (regular professional foot care) can be taken to avoid serious problems.

3. Rights

You participate voluntarily. If you do not wish to participate or later withdraw your participation, you do not need to give reasons for your decision. Your medical treatment/care is guaranteed, regardless of your decision. You may ask questions about your participation and the project at any time. Please contact the person named at the end of this information.

4. Duties

As a participant, you need to adhere to the necessary specifications and requirements given by the practice. Inform your family doctor about the course of the illness and report new symptoms, new complaints and changes in your state of health.
Inform your family doctor about simultaneous treatment and therapies prescribed by and discussed with another doctor.

5. Risks

You do not take any additional risks because participating in this project.

6. Results

Your family doctor will inform you during the project of any new findings that may affect the benefits, your safety and your consent to participate. If you do not wish to be informed, please talk to your family doctor.

7. Confidentiality of data

For this project, your personal and medical data will be filed. Only employees in the practice of your family doctor will see your unencrypted data. People involved in the study project will only see your encrypted data. Encryption means that all references that could identify you (name, date of birth) will be deleted and replaced with a key (code). Persons who do not know the key can therefore not draw any conclusions to who you are. The key-list remains at all times in the family doctor's office. All persons, who have access to your data are strictly bound to the professional code of confidentiality. As participating individual, you have the right to view your data at any time.

The collected data of each practice will be encrypted and sent to QualiCCare, where it will be stored for 10 years. The evaluation of the data collected per practice is carried out by the QualiCCare Association or by a scientific institution commissioned by the Association.
Only your family doctor has access to the encryption. The scientific advisory board of the study is responsible for compliance with the Swiss guidelines on data protection.

There is a possibility that this study project will be reviewed by the responsible ethics committee or by the institution that initiated the project. The project manager may have to disclose your personal and medical data for such controls. We comply with all data protection regulations. At no time, will your name be made public.

1. Resignation

You can stop and withdraw from the study at any time if you wish. The data collected up to that point will still be evaluated in encrypted form; as the whole project would lose its value.
After the evaluation, your key allocation will be destroyed, so that no one can know that the data and samples originally came from you.

2. Compensation

If you participate in this project, you will not receive any compensation, as there are no additional costs for you or your health insurance company due to your participation.

3. Liability

The Swiss Law regulates the conditions and procedures.

4. Financing

The pharmaceutical company Sanofi-Aventis, the medtech company Roche Diabetes Care, both members of the interprofessional association QualiCCare, as well as QualiCCare itself, support the project.

5. Contact person(s)

In the event of any uncertainties, fears or emergencies that arise during or after the project, you can always contact your family doctor.

Declaration of consent

Written Declaration of consent to participate in a project study

Please read this form carefully. Please ask if you do not understand or have questions.

BASEC-number (after submittance):	
Study title **(scientific and layman's language)**:	QualiCCare Accompanying research to optimize the treatment of chronic patients with diabetes mellitus type 2 in primary care practice Scientifically accompanied project to improve the treatment of patients with type 2 diabetes in family practice
Responsible institution **(Projektmanagement with address)**:	**Association QualiCCare** **Rütistr. 3a, 5400 Baden**
Place of performance:	**General practioner's office / primary care practice**
Projectmanager of study: name and surname in block letters.	**Prof. Dr. med. Emanuel Christ**
participant: Name and surname in block letters: date of birth:	☐ female ☐ male

- I was informed verbally and in writing by the undersigned family doctor about the purpose, the course of the project, possible advantages and disadvantages as well as possible risks.
- I am participating in this project voluntarily and accept the content of the written information provided on the above-mentioned project. I had sufficient time to make my decision.
- My questions in connection with my participation in this project have been answered. I keep the written information and receive a copy of my written consent.
- I agree that the responsible experts of the project management / the principal investigator of the study and the ethics committee responsible for this project may inspect my unencrypted data for testing and control purposes, but under strict confidentiality.
- I will be informed in case of study results or accidental findings that directly affect my health. If I do not wish this, I will inform my family doctor.
- I am aware that my health-related and personal data can only be passed on in encrypted form for research purposes for this study project.
- I can withdraw my participation at any time and without giving reasons, and without any disadvantages for my further medical treatment/care. The data collected until then will be still used for evaluation of the study.
- I am aware that the obligations mentioned in the information for participants must be observed. In the interest of my health, my family doctor can exclude me at any time.

Place, date	Signature participant

Confirmation from the family doctor:

I hereby confirm that I have explained the nature, significance and scope of the project to this participant. I assure to fulfil all obligations in connection with this project in accordance with the applicable law. Should I learn at any time during the implementation of the project of any aspect, that could influence the participant's willingness to participate in the study, I would inform him/her immediately.

Place, date	Name and surname of informing family doctor in block letters Signature of family doctor / general practioner