

DIABETES MELLITUS TYPE 2 PROTOCOL

CELLO

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Introduction

CELLO, the cooperation of primary health care practitioners in Leiden and surroundings, is an organisation of independently working general practitioners. Currently 13 general practitioners are affiliated with Cello. Together they are responsible for the care of approximately 30.000 patients. The cooperation started on the 1st April 2009. The objective is to provide care for patients with Diabetes Mellitus according to the latest guidelines, in the most optimal way.

Cello counts five (part time) practice nurses and three (part time) administrative workers. They work at a separate location (Doezastraat 1, 2311 GZ Leiden). Two (part time) dieticians are also located here, as well as a physiotherapist and pedicure. In addition to caring for patients with diabetes, the cooperation has also extended into caring for patients with (risk of) pulmonary disease COPD and cardiovascular diseases.

Every target group has their own commission within Cello in which at least two general practitioners and two practice nurses take part. There is an official Diabetes Commission that specifically guarantees and protects the interests of the diabetes care of Cello.

The NHG (Dutch General Practitioner Association) Standard for Diabetes Mellitus type 2 forms the basis for the care that is given. It contains the official guidelines for diagnosis, treatment and guidance of adult patients with Diabetes Mellitus in the general medical practice.

This protocol has been composed by Cello and is present at the location and forms a basis for the care given. In the near future the DM-protocol of ROH-West Netherlands will also be published, under which Cello sits. This will elaborate further on the care.

For more information on Cello, please visit our website www.cello-hazorg.nl

1. Way of working at CELLO for patients with Diabetes Mellitus

The general practitioner reports a new patient to Cello via the chain care computer programme Citokis. The patient is then invited, in writing, to the diabetes consultation. The letter is accompanied by a form to take a blood sample.

A standard control takes place every three months. During these consultations lifestyle, blood pressure, weight, medicine use and other possible factors that may influence wellbeing or the disease are discussed. Three out of four of the planned consultations are conducted by the practice nurse on the Doezastraat. Once a year the patient's own general practitioner conducts the checkup. This is three months after the annual checkup. The annual checkup itself is conducted by the practice nurse. This checkup consists of an extensive blood examination, foot examination and (referral for) an eye examination¹ is organized. The blood pressure is also measured as well as the height, weight and abdominal circumference.

¹ If the patient is already under treatment at an ophthalmologist, the eye examination (fundoscopy) will take place there.

For people that are not able to come to the Doezastraat, like those who have a movement limitation, house visits are possible. Also, at the request of a general practitioner, the consultation of the practice nurse can be organized at a different location for a temporary or longer period.

After every consultation with the practice nurse (and after every visit) the patient receives an instruction to contact the general medical practice within ten days. This is so that the patient can learn what the policy is, i.e. if something will be changed, such as an increase or reduction of medicine use.

All relevant information is processed by the computer programme Citokis. The communication between general practitioner and practice nurse about the consultation also takes place through Citokis. This concerns lab results, measures such as blood pressure and weight, any foot examinations, the individual points of attention and the policy to be followed. Of course, communication by telephone is always possible.

For general practitioners, it is possible to consult the medical specialist (internist) that is connected to Cello.

Tasks that are not delegated to the practice nurse are:

- Making the diagnosis
- Defining or changing the treatment policy
- Signing prescriptions

The final responsibility stays with the general practitioner (due to WGBO – Law on medical policy agreement), who therefore has to keep control of the way the practice nurses executes the delegated tasks. This control can also be seen as guidance of the practice nurse.

The practice nurses will, after consultation with the Diabetes Commission, follow the necessary extra training in order to provide optimal care. Practice nurses can do proposals to improve the care, such as adjustments to the lifestyle and/or medication. Additionally, every general practitioner can indicate their preferences for this care, i.e. what they do and do not expect from the practice nurse.

The target group consists of all patients with (risk of) Diabetes Mellitus. The objective is to improve the care for diabetes patients, by providing modular guidance by the practice nurse, adjusted to the individual patient.

The objective of practice nurse support is to maintain health benefits, or where possible, improve them. A form of (teaching the patient) effective self-management is essential.

The patient will be asked the following:

- Wellbeing and lifestyle
- Complaints (e.g. hypo or hyperglycemia)
- Medication (patient compliance)
- Self control of blood glucose values
- Eye problems such as visus complaints
- Cardiovascular complaints (angina pectoris, claudicatio intermittens, heart failure, cerebrovascular disease)
- Neuropathic complaints (sensibility loss, pain/tingling sensation and numbness in the extremities)
- Autonomous neuropathy (gastric emptying problems or diarrhoea)
- Sexual problems (erectile dysfunction, reduced sexual desire or reduced lubrication)

2. Diagnosis

The diagnosis may be made after measuring (*venous*) fasting plasma glucose of >6.9 mmol/l in the patient on two different days; or when a random blood glucose concentration of >11.0 mmol/l is measured in combination with complaints that fit hyperglycemia. With a non-fasting value between 7.8 and 11 mmol/l, *no* clear conclusion is possible. Measure a fasting plasma glucose after several days.

Reference values

Reference values for diagnosis of Diabetes Mellitus and disrupted fasting plasma glucose (mmol)			
		Capillary glucose	Venous glucose
Normal	Fasting glucose	<5.6	<6.1
	Non-fasting	<7.8	<7.8
Disrupted	Fasting glucose	>5.6 and <6.0	>6.0 and <7.0
Diabetes Mellitus	Fasting glucose	>6.0	>6.9
	Non-fasting	>11.0	>11.0

Risk profile

The NHG Standard advises to evaluate the health risks for a patient who has been diagnosed with Diabetes Mellitus type 2. These data should be actualized every year. Also see the CVRM (Cardio-Vascular Risk Management) protocol.

The current risk profile can be determined through:

- Checking the medical file for cardiovascular pathology: myocardial infarction, angina pectoris, heart failure, CVA, TIA and peripheral vascular disease
- Asking the patient about cardiovascular disease in parents, brothers or sisters before the age of 60
- Lifestyle such as smoking, alcohol usage and psychological factors
- Blood pressure and BMI

- The following laboratory measurements:
 - HbA1C, fasting glucose
 - Cholesterol-, HDL- and LDL-cholesterol-, triglyceride level (fasting)
 - Sodium and potassium
 - Creatinine, glomerular filtration rate (GFR)
 - albumine/ creatinine-ratio or the albumin concentration in the first morning urine
 - ALAT

2.1 Disrupted glucose tolerance

If fasting glucose is disrupted (capillary: >5.6 and <6.0 and venous: >6.1 and <6.9), the measure should be repeated after 2 weeks. If it is too high, after 3 months the fasting glucose and HbA1c should be measured again. If the diagnosis of Diabetes Mellitus is still not possible, the patient should be checked annually by the diabetes service.

When a patient is diagnosed with a disrupted glucose tolerance, determine the risk profile and conduct additional diagnostics and evaluation.

2.2 Detection (possibilities) in the general medical practice

Determine blood glucose levels for:

- people with complaints or disorders that can be caused by Diabetes Mellitus, e.g. thirst, polyuria, weight reduction, pruritus vulvae at an older age, mononeuropathy, neurogenic pains and sensibility disorders.

- Every three years for persons older than 45 years who are at risk:

- Hypertension
- Manifest cardiovascular disease
- Fat metabolism disorders
- BMI>27
- Parents, brothers or sisters with DM type 2
- Women that have suffered from pregnancy diabetes
- Persons from Turkish, Moroccan or Surinam origin (Hindus: from 35 years onwards)

3. Treatment of Diabetes Mellitus

3.1 Target values

Target values of glycemic parameters

	Capillary	Venous
Fasting glucose (mmol/l)	4-7	4.5-8
Glucose 2 hours postprandial (mmol/l)	<9	<9
HbA1c (%)	<53 mmol/mol (former value <7%)	

3.2 Information and education

These form the basis of the treatment.

Objectives diabetes reduction:

The patient gains insight into:

- The target values for the glycemic parameters, lipids and blood pressure
- (self)regulation of achievable targets regarding weight, smoking behaviour, alcohol usage, exercise and medication compliance
- Recognition of the signs of hyper- and hypoglycemia and how to react
- (possible) control and regulation of the patients own blood glucose levels
- Daily inspection of the feet when risk of an ulcer is medium to high, and wearing suitable shoes and socks with thick seams
- Regular control of the eyes (funduscopy)
- Reacting adequately to illness, fever, vomiting and long distance trips

3.3 Non-medical treatment

- stop smoking
- sufficient exercise
- nutrition
- if BMI>25: lose weight

Referral to a dietician:

- new patients with Diabetes Mellitus
- as a preparation for insulin therapy
- overweight

3.4 Medical treatment

If the patient's lifestyle change does not result in achieving the target values (HbA1c) after 3 months, medicinal therapy is started. The general practitioner decides this and prescribes the medication.

Possible options to switch to medication sooner:

- If fasting glucose value is diagnosed >10mmol/l, oral medication can be started sooner
- If fasting value >20mmol/l insulin can be issued faster

Build-up scheme

Step 1	Start with metformin
Step 2	BMI > 27: Add a SU derivate to metformin Concerning addition of TZD in this scheme: this had to be adjusted due to the recent decision in Europe to withdraw the TZD rosiglitazon from the market. The NHG has not announced its decision on pioglitazon yet. The NHG website states: <i>A modest position remains for pioglitazon (on basis of Pro-active trial). It can be considered as a 2nd medicine next to metformin for patients with obesitas and a history of cardiovascular disease.</i> Contra indicator remains heart failure
Step 3	Add insulin to oral blood glucose decreasing agents once a day
Step 4a	NPH insulin twice daily
Step 4b	Insulin four times a day

- For all drugs, start with a low dosage
- If necessary, increase the dosage every 2 to 4 weeks
- Proceed to the next step if increasing the dosage, due to side effects or having reached the maximum dosage, is not possible any longer, if also the glycemic control (HbA1c) is insufficient
- Switch to another drug in case of contra indications or side effects

If the target value is not met with the maximum achievable oral treatment, it is advised to start with insulin (please see protocol insulin therapy).

If BMI < 25 the scheme (table 4) will often be advanced more quickly

Dosage oral glucose decreasing drugs

	Generic Name	Preparation	Min-Max daily dosage	Advice for dosage and use
Step 1	Metformin (biguanide)	Tablet 500/850/1000 mg	500-3000 mg	1-3 daily after meals
Step 2	Tolbutamide	tablet 500/1000 mg	2x1000 mg	1-2 daily before breakfast/ dinner
	Glyclazide	tablet 80 mg	3x80 mg	1-3 daily before meals
	Glimepiride	tablet 1/2/3/4 mg	1-6 mg	1 daily before breakfast
	<i>Insulin secretagogues</i>			
	And:			
	Pioglitazon <i>Thiazolidinediones</i>	Tablet 15/30/45mg		1 daily before breakfast, during or after meal

Always give metformin in the build-up scheme to prevent side effects; start with 1x500mg daily and increase slowly if necessary.

After the publication of the NHG standard in 2006 several new drugs for Diabetes Mellitus have been launched.

Regarding DPP-4 inhibitors and GLP-1 agonists the NHG (May 2010) states:

Conclusion for the daily practice:

DPP-4 inhibitors and GLP-1 agonists are new medical treatment options for type 2 diabetes that cause a modest decline in HbA1c compared to a placebo, but, in the case of DPP-4 inhibitors, show a less strong decline in HbA1c than metformin, insulin secretagogues or glitazones.

No results of studies with clinical outcomes (micro- or macrovascular complications and mortality) are known.

Together with the absence of data on effectiveness and safety on the long term these new drugs do not form a direct reason to change the current scheme for medicinal treatment in the NHG Standard for Diabetes Mellitus type 2.

4. Complications due to Diabetes Mellitus

In the ROH protocol this is addressed at length.

In short:

4.1 Cardiovascular risk factors

See CVRM protocol

4.2 Nefropathy

Beware of renal complications:

- Creatinine clearance <60 ml/min (moderate renal failure). Consultation of an internist can be considered.
- Creatinine clearance <30 ml/min (severe renal failure). The patient should be forwarded to secondary health care.

4.3 Foot problems

Regular checkup of feet, e.g. look for position disorders, vascular and neurological disorders.

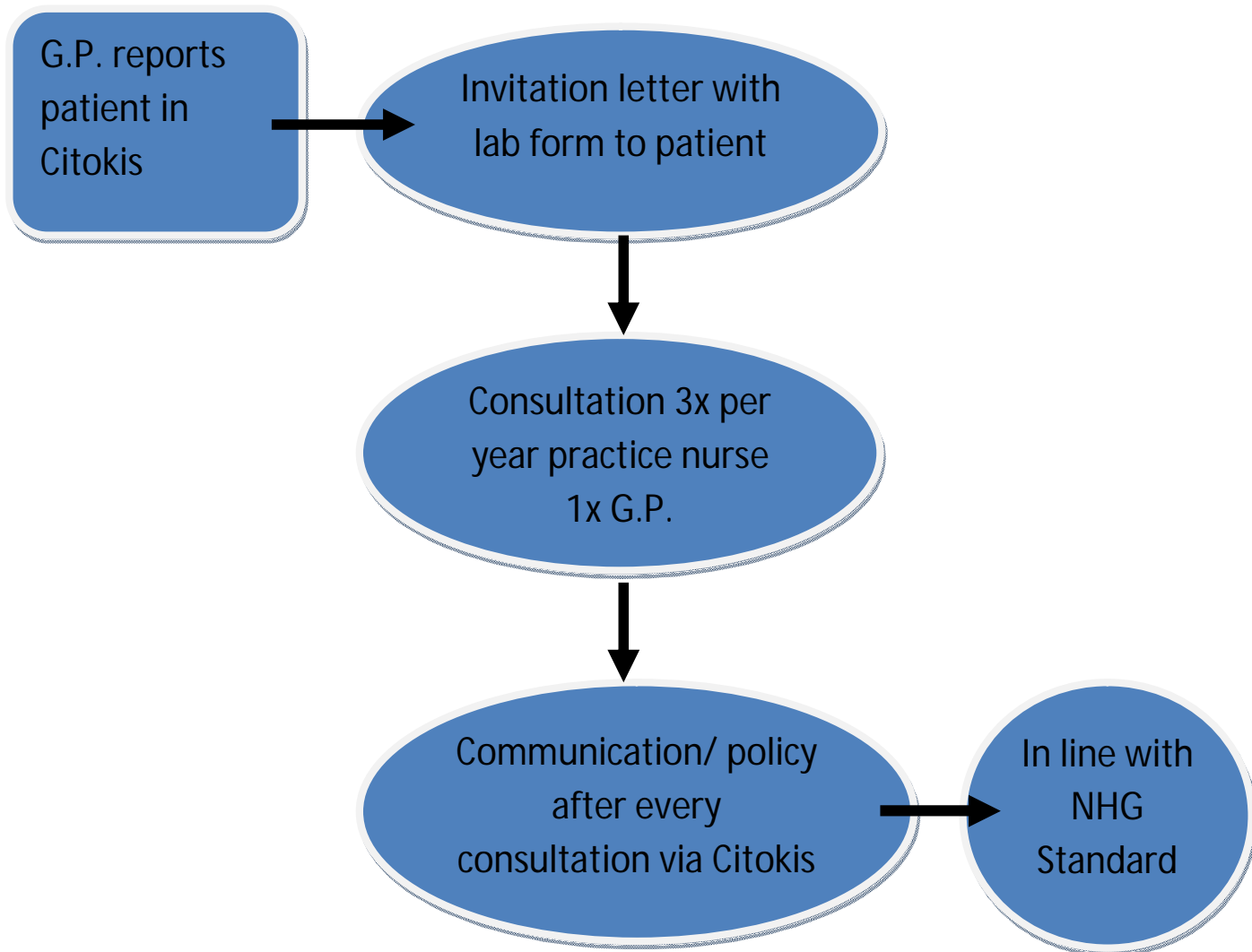
4.4 Neuropathy

Pay attention to complaints / disorders of the neuropathic and/or autonomous nervous system

4.5 Retinopathy

Pay attention to complaints / disorders of the neuropathic and/or autonomous nervous system. Periodic eye checkup (funduscopy)

5. The Cello route for patients with Diabetes Mellitus



Literature:

- NHG Standard Diabetes Mellitus type 2
- NHG Practice guide for practice nurses
- Protocol Diabetes Care edition 2010/2011, Houweling S.T., Kleefstra N., Verhoeven S., Ballegoie van E., Bilo H.J.G.