From indication statement to implementation

A multidisciplinary guideline about self-monitoring of blood glucose values by people with diabetes

National guideline

Colophon

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National guideline

Digital version with appendices on www.eadv.nl and www.diabetesfederatie.nl

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- Diabetes Fonds
- Diabetes GPs Advisory Group (DiHAG)
- Diabetes and Nutrition Organization (DNO)
- Diabetes Association the Netherlands (DVN)
- EADV, the professional organisation for diabetes care providers
- Royal Dutch Society for Physical Therapy (KNGF)
- Royal Dutch Association for the Advancement of Pharmacy (KNMP)
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Summary

In diabetes care, there is a lack of clarity in the recommendations in the area of self-monitoring. For this reason, EADV started the Self-Monitoring Guideline project within the National Diabetes Action Programme. Five relevant questions were formulated based on a sticking point analysis. These have been answered by means of a literature study and with input from experts in diabetes care. This concerns the diabetes care of adult diabetes patients.

Initial questions

The five questions formulated concern:

1. **the benefit of self-monitoring by diabetes patients who do not use insulin;**
2. **the frequency and timing of self-monitoring to be recommended for diabetes patients who use insulin once or twice a day;**
3. **the effective frequency of self-monitoring for diabetes patients who have an intensive insulin programme or insulin pump therapy;**
4. **the education necessary for self-monitoring;**
5. **recommendations in the area of the implementation of self-monitoring to improve the reliability of the test results.**

The conclusions from the scientific literature available, particularly (Cochrane) reviews and major analyses, are recorded in the text. Considerations were formulated from the workgroup's reflections on the literature findings. Together the conclusions and other considerations form the basis for the set of recommendations. Summarised briefly, these are:

Recommendations on question 1

1. **There is no evidence that self-monitoring in people with type 2 diabetes without insulin therapy leads in general to improvement of clinically relevant outcomes. Self-monitoring for people with type 2 diabetes without insulin therapy may only be worthwhile in special circumstances.**

These special circumstances are situations in which it is desirable, in consultation with the diabetes practitioner, to gain insight into the blood glucose values:

- on suspicion of dysregulation, evaluation after an agreed period (for example at most three months)
- for desired pregnancy, to at most two years
- when using other glucose-affecting medication (such as corticosteroids[1]), for as long as the dysregulation lasts
- in preparation for insulin therapy
- with pregnancy and previously experienced diabetes gravidarum

Recommendations on question 2

1. **For people with type 2 diabetes with once- or twice-daily insulin injection therapy, self-monitoring under conditions is considered worthwhile.**

2. **Agreements with respect to self-monitoring must be recorded and evaluated in a care plan prepared jointly by patient and care provider.**

3. **The patient's individual goal, established in discussion with the practitioner, must be determining for the number of measurement moments and the times when these are done.**

Specific situations may require extra measurements.

As a guideline, the following is recommended, largely following the NDF Guideline 2003:

- **upon initiation of once- or twice-daily insulin therapy:**
  - daily fasting[2] until stable blood glucose values are established
  - weekly or fortnightly a four-point curve: before the three main meals and before bed
  - on indication weekly or fortnightly a seven/eight-point curve: before and after each meal, before bed, and in case of suspicion of night-time dysregulation, a check during the night
- **modify the frequency as necessary during follow-up appointments between patient and diabetes care provider**

1 For other blood glucose-affecting medication, please see: KNMP Diabetes Mellitus Guideline (2010 draft) § 4.2.2.

2 Also in accordance with NHG standard on diabetes mellitus type 2 (March 2006).

Recommendations on question 3

Despite the absence of robust justification from the literature, the workgroup states that

1. **For people with diabetes with an intensive insulin programme of three or more injections per day or insulin pump therapy, targeted self-monitoring with an average of four to five times a day is to be recommended.**

Self-management is vital in this regard.

In incidental cases and/or when more insight is needed, a greater number of measurements per day may be necessary. In the NDF Guideline (2003) it is proposed if necessary: weekly or fortnightly a seven- or eight-point curve (before and after meals and if desired during the night).

Also, there are conceivable situations where less-frequent monitoring would be sufficient. The diabetes care provider and patient can decide this in mutual agreement.

Recommendations on question 4

1. **Structured education is an essential part of diabetes care and must be offered to all people with diabetes, in any event at the time the diagnosis is made.**

Structured education ought to be offered to diabetes patients annually and must be evaluated.

2. **Conditions with which structured education must comply and which can also be used as evaluation criteria:**
   - Education must link up with the individual needs and goals of the diabetes patient and be clear for the patient to understand. It must be available locally and be integrated into the conventional care.
   - Education programmes must be *evidence-based* with a structured plan of approach, contain clearly formulated goals and learning subjects, and be presented by adequately trained educators. Group education is preferred because it appears more effective than individual education. An equivalent alternative must however be available for patients who cannot/do not want to participate in group education.

- The NDF Standard of Care should serve as basis for the content.
- The outcomes of the programme must be evaluated, both under participants and as a programme itself.

Recommendations on question 5

In follow-up to the NVKC-KNMP-NVZA Guideline, the workgroup recommends:

1. giving individual instruction at the start of self-monitoring and to repeat it annually;
2. having patients' blood glucose meters checked and recorded annually by a CCKL-accredited laboratory, or a care provider under supervision of such a lab;
3. as standard advice, having patients wash their hands before conducting the test;
4. allowing patients to use the first drop of blood for their measurements providing their hands have been washed and properly dried;
5. if handwashing is not possible, the first drop may be wiped away and the second may be used, incidentally and under conditions;
6. avoiding applying pressure when obtaining the blood drop.

General introduction

Background and definition

The measurement and recording of their own blood glucose level by people with diabetes mellitus, and its progression in time, abbreviated to 'self-monitoring' in this report, is considered to be a cornerstone in the self-care and the guidance of such people. In self-monitoring, the person with diabetes conducts measurements and collects these for the purposes of his/her treatment. In this way the practitioner, in consultation with the person with diabetes, is better enabled to modify their treatment if necessary. Self-regulation goes a step further. In this, the person with diabetes is able to modify the treatment based on the results of the measurements.

In 2003, this text was the introduction to the NDF (Netherlands Diabetes Federation) Guideline 'Advice on self-monitoring of the blood glucose content in diabetes mellitus'. Self-monitoring may still be considered as an important factor in diabetes care. New technologies, such as continuous glucose monitoring, are in the ascendant, but are not as yet making the self-monitoring of blood glucose values superfluous. Self-monitoring also includes the recording of the values measured.

Benefit and aim

ADA (the American Diabetes Association) states that self-monitoring may be seen as a part of effective diabetes treatment. Self-monitoring helps diabetes patients to gain insight into the effect of their treatment versus their lifestyle and puts something into their hands to anticipate this.

In the Diabetes Type 2 Care Standard[3], self-monitoring is mentioned as a part of diabetes-related education and it is stated that it can make a contribution to the self-management of the condition. 'It offers more insight into the factors that determine blood glucose values and can thus lead to adequate blood

3 NDF guideline 'Advice on self-monitoring of the blood glucose level in diabetes mellitus' (2003).

glucose regulation. Self-monitoring can also postpone the use of extra medication or the switch to insulin, and prevent, defer or reduce complications.'

Self-monitoring has the immediate objectives:

- the diabetes-related education of people with diabetes mellitus, where self-monitoring can give insight into the nature and progression of the clinical picture
- the establishment of effects on the blood glucose level of potentially dysregulating influences, such as:
  - deviations in mealtimes
  - exertion including sport
  - physical and/or mental stress
  - related conditions
- the determination or adjustment of the insulin dose, the nature of the insulin to be used, and the distribution of the insulin administrations through the day
- the tracking down of acute dysregulations, particularly hypo- and hyperglycaemia, with or without symptoms

And, not derived from the NDF guideline mentioned:

- support in certain situations, such as when driving or after resolution of a hypoglycaemic incident

There is still much obscurity about the measurement of blood glucose values, a procedure with which a lot of money is involved and to which both the individual diabetes patient and practitioner attune a major part of their policy.

The situation in the Netherlands

In 2007, GPs in the Netherlands registered 740,000 people with diabetes. This number continues to grow by an estimated 70,000 people per year. Of all those with diabetes, over 90% have diabetes type 2[4].The average age of the group is just under 70, and more than half use only blood glucose-lowering tablets[5].

4 www.nationaalkompas.nl

5 In one region in the east of the Netherlands, 91% of the 8300 diabetes patients have diabetes type 2. Of these, 90% are treated by their GP and over 60% with only blood glucose-lowering tablets. The average age of the group as a whole is 68; more than 30% are over 75.

It is estimated that over 200,000[6] insulin-using diabetes patients[7] in the Netherlands measure their blood glucose values more or less regularly. The frequency at which this happens varies, as does the time at which the procedure is conducted, the interpretation of the values found and the way in which the procedure is conducted. The 2003 NDF guideline mentioned earlier only gives limited and non-scientifically justified advice. To reiterate, there is little clarity about a procedure with which a lot of money is involved, and to which both the individual diabetes patient and practitioner attune a major part of their policy.

During the sticking point analysis prior to the development of this guideline, professionals and diabetes patients were asked what questions about self-monitoring need to be answered. From this survey it emerged that the major need is for recommendations in the areas of the indication statement, conditions, frequency, times and implementation of self-monitoring. Not only in the Netherlands, but worldwide, there is a lack of recommendations on the optimum use of self-monitoring. This statement led to the development of an up-to-date multidisciplinary guideline on self-monitoring for care professionals with recommendations for daily practice. A patients' version derived from this will be included at a subsequent stage.

Objective

This guideline was developed to support the daily, practical diabetes care for adult patients with diabetes mellitus. The guideline is envisaged as contributing to care professionals' choices and considerations. The recommendations are based on conclusions from the scientific literature, combined with other considerations from the workgroup members. The patient perspective was included in these considerations, and the findings from the mostly foreign literature were laid alongside the Dutch practice.

The guideline should form part of the entirety of (scientific) justifications of the (NDF) Diabetes Care Standard.

6 An estimate of the number of diabetes patients who are treated with insulin, which usually implies self-monitoring.

7 Rather than 'patient' the designation 'person with diabetes' is usual. For the sake of brevity and readability, in the rest of the document, the designation 'patient' is usually used, by which a diabetes patient is meant naturally.

Target group

The guideline was written primarily for care providers in diabetes care: GPs, practice support staff, internists, dieticians and diabetes nurses.

There is a wider group for whom the guideline may be relevant, varying from diabetes patients to care personnel in different settings (nursing and care homes, hospitals, psychiatry, home care, etc.), pharmacists, healthcare insurers, diagnostic companies and other organisations that in one way or another have to do with the self-monitoring of blood glucose values.

Multidisciplinary workgroup

A workgroup was set up in the third quarter of 2010 with representatives from a number of relevant professional organisations, the Dutch Diabetes Association (DVN) and a scientific employee from TNO/CBO (the Dutch Institute for Healthcare Improvement). Various workgroup members, as well as being expert on details in the diabetes field, have a scientific foundation and have been involved in such projects previously. The workgroup then jointly established the contents of this guideline.

Conflict of Interest

The workgroup members signed a declaration in which they indicate whether and if so what connections they have with the pharmaceutical industry. In this, no possible conflicts of interest were notified.

Working method and structure of the study

In order to provide answers to questions that are current in practice, the work-group started by assessing sticking points affecting various involved parties in the Netherlands. A list of who was approached for this is included in Appendix 12. The reactions were processed and clustered into five main subjects, which were converted into five initial questions that form the basis for this guideline. Using these questions, search terms were developed, and an extensive exploration of the literature was done.

This document is built up from the five initial questions, each represented by its own chapter. Each chapter begins with a brief introduction, followed by the formulated question and a description of the method used in the literature research. A more extensive description of the literature found is included in the relevant appendix, as is the methodological quality of the studies. To determine this, use was made of the categorisation of methodological quality of individual studies.

Classification of methodological quality of individual studies			
	Intervention	Diagnostic accuracy of research	Damage or side-effects, etiology, prognosis (*)
A1	Systematic review of at least two studies of level A2 conducted mutually independently		
A2	Randomised double-blind comparative clinical study of good quality and of sufficient extent	Study with respect to a reference test (a 'golden standard') with cutoff levels defined in advance and independent assessment of the results of the test and golden standard, concerning a sufficiently large series of successive patients who have all had the index and reference tests	Prospective cohort study of sufficient extent and follow-up, in which adequate checks are made for 'confounding' and selective follow-up is sufficiently excluded
B	Comparative study, but not with all the characteristics as listed under A2 (also included here are the patient-control study and the cohort study)	Study with respect to a reference test, but not with all characteristics that are listed under A2	Prospective cohort study, but not with all characteristic as listed under A2 or retrospective cohort study or patient-control study
C	Non-comparative study		
D	Opinion of experts		

* This classification is only applicable in situations where for ethical or other reasons controlled trials are not possible. If these are indeed possible then the classification for interventions applies.

(Source: http://www.cbo.nl/thema/Richtlijnen/EBRO-handleiding/5-Literatuuronderzoek)

Then the most important findings are summarised in a conclusion. Each conclusion was assigned a level of evidential value, based on the categorisation generally used:

Level of evidential value of the conclusions
1. Study of level A1 or at least two studies of level A2 conducted mutually independently
2. One study of level A2 or at least two studies of level B conducted mutually independently
3. One study of level B or C
4. Opinion of experts

There then follows a part in which the workgroup sets the literature findings out against the Dutch situation, puts the sometimes absent and often somewhat weak evidence under the spotlight, and presents a reflection on it from their own knowledge and expertise in the matter. The conclusion and considerations then lead to the final recommendations for practice.

An important part of these considerations, as well as the patient and professional perspectives and the costs, is the balance between the desirable (mainly health care gain) and undesirable effects (mainly side-effects).

To formulate the recommendation, the workgroup did not use formal methods (such as the Delphi method), but rather employed informal methods to reach a consensus.

The workgroup identified a number of key recommendations. These are recommendations of which the workgroup strongly believes that their application would be to the patients' advantage. The workgroup considers it important that the key recommendations are easy to recognise, and has therefore prepared a separate, recognisable and plasticised summary card featuring these recommendations. This card can be used as an aid to support the implementation of the recommendations.

Particularly the key recommendations lend themselves to investigation of whether the most important recommendations are followed in practice.

Authorisation

The guideline was sent in draft form to a wide readers' panel, comprising relevant parties in diabetes care (see Appendix 12). After processing their observations, a final version was presented for authorisation to the Netherlands Diabetes Federation (NDF). Final remarks were included and the end product was accepted into NDF's guideline file.

Updating of the guideline

The guideline will be tested every three years against scientific developments by a multidisciplinary committee still to be assembled.For important developments, this committee may decide to make intermediate electronic amendments and to distribute these to relevant professional groups. If necessary, a new workgroup will be instituted to review (parts of) the guideline.

Note from the workgroup

In this guideline, the HbA1c value is often used as an outcome measure for the effect of interventions. HbA1c is presented in mmol/mol along with the statement of the 'old' value (%).

The interpretation of a difference between two values measured in one patient should happen with care, taking into account the biological variation in the variable concerned, and the analytical variation in its determination. As a rule, the requirement is placed on a measurement method that the analytical variation may be at most half of the biological variation[8]. The HbA1c value has a biological variation coefficient of 3.4%.It can be calculated that an HbA1c value of 53 mmol/mol (7%) would have a confidence interval of 49-57 mmol/mol (6.6-7.4%) if the correlation coefficient of the laboratory method is not greater than 1.7%.

8 1. Fraser CG, Petersen PH. Desirable standards for laboratory tests if they are to fulfill medical needs. Clin Chem 1993;39:1447–53 (discussion), 1453–5 (review).
2. Stockl D, Baadenhuijsen H, Fraser CG, Libeer JC, Petersen PH, Ricos C. Desirable routine analytical goals for quantities assayed in serum. Eur J Clin Chem Clin Biochem 1995;33:157–69.

1. Self-monitoring in type 2 diabetes patients without insulin therapy

1.1 Introduction

Between 1990 and 2007, the point prevalence for men with diabetes mellitus has approximately doubled, while for women it has risen by around 40%.

Of these people, 90% have diabetes type 2. The increase was greatest in the period 2000-2007, according to the National Compass on Public Health[9].

Of the people with diabetes type 2, 80-90% are treated without insulin therapy[10]. By number, the group of type 2 diabetes patients without insulin therapy is thus by far the largest group of Dutch diabetes patients and this will remain so for the time being.

Adequate regulation of blood glucose values is important for preventing or postponing the complications of diabetes type 2, which include peripheral vessel disease, eyesight degradation and kidney failure. In the Netherlands, it is usual to have the fasting glucose determined once every three months, and the HbA1c once a year[11]. This however provides the patient with no information about the blood glucose's daily level. Self-monitoring by means of a finger prick and test strips[12] can indeed provide this information. This in turn can help or encourage the patient to modify his/her diet and/or level of physical activity based on the glucose values measured. The questions that arise here are:

9 Version 4.2, 9 December 2010.

10 LHV Advisory Groep on Integrated Care, National Association of Healthcare Centres: Transparency of Integrated Care for diabetes mellitus, Care Groups Report 2010. February 2012.

11 1. NHG Standard on Diabetes Mellitus, 2006 version. Rutten GEHM, Grauw de WJC, Nijpels G, Goudswaard AN, et al. 2. NHG standard on Diabetes mellitus type 2 (second revision). 3. Huisarts Wet 2006;49:137-152 4. NDF Care Standard for diabetes, http://www.diabetesfederatie.nl/ndf-zorgstandaard-2.html pp 40-41.

12 Under the designation 'test strips' also come the test sets that are supplied in rolls rather than as individual strips.

1. whether there is evidence for the effectiveness of self-monitoring; and
2. whether there are also undesirable effects from the self-monitoring of blood glucose values.

1.2 Question

The above led to the following question:

Question 1: Does the self-monitoring of blood glucose values by people with diabetes type 2 without insulin therapy in combination with conventional monitoring by the diabetes practitioner lead to different outcomes as regards HbA1c, quality of life, hypo- and hyperglycaemic dysregulations or medication usage, compared with conventional monitoring by the diabetes practitioner (in the Netherlands four times a year fasting blood glucose and once a year HbA1c)[13]?

1.3 Method

Recently (2010), an overview of the published systematic reviews of RCTs was written by the CVZ (Healthcare Insurance Board) with the title 'Self-monitoring in people with type 2 diabetes who do not use insulin'.[14] In this, eleven systematic reviews were cited, all published since 2005. Also in 2010, a *health technology assessment report* appeared from the Aberdeen Health Technology Assessment Group under the title *'Self-monitoring of blood glucose in type 2 diabetes: systematic review'*. This yielded yet another systematic review (AHRQ, 2007).

A literature search conducted by the workgroup in February 2011 (Appendix 1.1) revealed no new systematic reviews, but did find two relevant RCTs (Kleefstra et al, 2010; Polonsky et al, 2011) and one academic review from one of the members of the SMBG International Working Group (Kolb et al, 2010).

13 1. NHG Standard on Diabetes Mellitus, 2006 version. Rutten GEHM, Grauw de WJC, Nijpels G, Goudswaard AN, et al. 2. NHG standard on Diabetes mellitus type 2 (second revision). 3. Huisarts Wet 2006;49:137-152 4. NDF Care Standard for diabetes, http://www.diabetesfederatie.nl/ndf-zorgstandaard-2.html pp 40-41.

14 Source: http://www.cvz.nl/binaries/live/cvzinternet/hst_content/nl/documenten/standpunten/2010/sp1009+zelfcontrole+diabetes.pdf (checked on 21 February 2011).

In a later literature search in February 2012, an updated version of a Cochrane review about self-monitoring was also discovered. The outcomes of this review are in line with the literature listed previously.[15]

1.4 Literature discussion

The number of RCTs included in the systematic reviews vary from five to twelve. A significant proportion of the RCTs were not of high methodological quality. Besides this, the interventions were varied. The studies thus differ markedly in how frequently and on what days self-monitoring was done (twice a day, three times a day, at least six times a day). In most RCTs, a difference between the intervention and control groups in the change in HbA1c before and after the intervention was taken as yardstick for the effectiveness of self-monitoring. Other outcomes of self-monitoring such as (change in) medication usage, quality of life, fasting glucose or hypoglycaemic incidents were only investigated incidentally.

A comprehensive discussion of the literature can be found in Appendix 1.1.

1.5 Conclusion (level 2)

Most systematic reviews indicate a beneficial effect of modest extent of self-monitoring on HbA1c. The effect of self-monitoring would appear greater the higher the baseline HbA1c is, but it cannot be excluded that this effect was caused by a single study with a steep fall in HbA1c (see Figure 1.1).[16] There is insufficient evidence to make a statement about a possible positive effect of self-monitoring on hypo- or hyperglycaemic incidents, quality of life or medication usage. Undesirable effects of self-monitoring, such as an increase in anxiety or depression, cannot be excluded.

15 Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. The Cochrane Library, 2012, Issue 1.

16 In a meta-analysis of individual patient data that appeared after the comments round no relationship was found between HbA1c level and effect of self-monitoring. This meta- analyse confirmed the effect size of HbA1C reduction of 0.2-0.3%. Farmer et al (2012) calculated 0.25% in a follow-up of three months. *Farmer AJ, Perera R, Ward A, Heneghan C, Oke J, Barnett AH, Davidson MB, Guerci B, Coates V, Schwedes U, O'Malley S. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. BMJ. 2012 Feb 27;344:e486.*

1.6 Other considerations

In the literature found, it is difficult to establish whether conventional care, as this is administered in the Netherlands (usually according to NHG (Dutch College of General Practitioners)/NDF standards), differs from the conventional care in the countries where the studies were conducted. Conventional care in the Netherlands, specifically targeted at blood glucose monitoring, comprises: a three-monthly fasting blood glucose and in any event one annual HbA1c determination. Most studies mention an HbA1c check every quarter.

The workgroup emphasises that HbA1c is the best singular approach to the glycaemic status of patients with type 2 diabetes.

1.6.1 Clinical relevance of effect of self-monitoring

The clinical relevance of a drop in HbA1c of 2.2 to 3.3 mmol/mol (0.2 to 0.3%), as is found in the literature, can be described as doubtful. Neither do the other outcomes indicate a positive recommendation with regard to the use of self-monitoring in people with diabetes type 2 without insulin usage.

1.6.2 Attitude of the professionals

The workgroup considers that from the perspective of care providers, self-monitoring under certain clinical conditions may be worthwhile for motivated patients with whom a care plan is jointly prepared. Examples of these situations are suspicion of dysregulation, use of medication that can have an unintentional effect (such as corticosteroids[17]), in preparation for pregnancy, with previously suffered diabetes gravidarum, or for evaluation with suspicion of hypoglycaemic incidents.

If the patient is capable of an adequate reaction to the blood glucose values found, self-monitoring might contribute to the patient's well-being and quality of life. A condition is that the care provider would have to provide education and guidance. Self-monitoring without education or self-management would seem to be a not very worthwhile intervention.

17 For other blood glucose-affecting medication, please see: KNMP Diabetes Mellitus Guideline (2010 draft) § 4.2.2.

1.6.3 Patients' perspective

From the patient's perspective, self-monitoring and self-management could contribute to a greater feeling of autonomy and the possibility of starting behaviour modification based on the blood glucose values found. For the patient too, education is a condition for the insight into the factors affecting the blood glucose pattern and knowledge of adequate reactions to this. Given the increased involvement of patients in their own treatment, denial of the opportunity to self-monitor might be poorly received by certain patients. This might concern patients who were shocked by the diagnosis and who are motivated to modify their lifestyle to prevent (more) medication usage.
Self-monitoring helps to evaluate the effect of lifestyle modifications.

From the patients' perspective, self-monitoring and self-management could contribute to a greater feeling of autonomy.

Patients also cite disadvantages such as the lack of opportunity for self-management, a lack of interest by the care provider and negative feelings (anxiety, discouragement, failure) from seeing high blood glucose values.

The indication for self-monitoring and the frequency and times of measurement must be defined in consultation with the patient. The goal that is envisaged with self-monitoring must be formulated; the indication and objective must be established together with the patient in a care plan with agreements about evaluation.

1.6.4 Costs

The indications formulated below form an expansion of the current indications for self-monitoring. This is associated with an increase in costs. Theoretically, cost-effectiveness is conceivable through

1. postponement of (more) medication usage.
2. a reduction in HbA1c and thus postponement/prevention of the occurrence of diabetes-related complications.
3. actively participating patients with better health perspectives.

Against this are costs, which in a recent Cochrane review were estimated at €361 in the first year[18].

About the cost-effectiveness of self-monitoring for these indications however, no opinion can be stated based on the evidence available.

Also, without a formal cost-effectiveness calculation, it could however be suspected that, even with marginal effectiveness, the costs per gained life year would be very high.

It is supposed that, partly given the average age of the diabetes patients concerned and the usually limited opportunities to intervene for abnormal values, only a small proportion of patients would want self-monitoring.

1.7 Recommendations

With limited justification from the literature, the workgroup arrived at the following recommendations:

There is no evidence that self-monitoring in people with type 2 diabetes without insulin therapy leads in general to improvement of clinically relevant outcomes. Self-monitoring for people with type 2 diabetes without insulin therapy may only be worthwhile in special circumstances.

18 Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. The Cochrane Library, 2012, Issue 1.

These special circumstances are situations in which it is desirable, in consultation with the diabetes practitioner, to gain insight into the blood glucose values:

- on suspicion of dysregulation, evaluation after an agreed period (for example at most three months)
- for desired pregnancy, to at most two years
- when using other glucose-affecting medication (such as corticosteroids[19]), for as long as the dysregulation lasts
- in preparation for insulin therapy
- with pregnancy and previously experienced diabetes gravidarum

Patient and care provider must agree and record how often and when measurement is done, what the expected result is, and when evaluation will happen. In general, and following the NDF self-monitoring guideline (2003) it could be advised:

- weekly or fortnightly a four-point curve: before the three main meals and before bed
- on indication weekly or fortnightly a seven/eight-point curve: before and after each meal, before bed, and in case of suspicion of night-time dysregulation, a check during the night

Conditions, besides the patient's motivation, are a care provider motivated for this and the ability of the patient and care provider to take action based on the values found. Recording of the values measured by the diabetes patient is vital to this. This could be in the form of a diary and/or electronically. A jointly prepared care plan helps to support the formulation of the individual objectives. In the evaluation of this care plan, the benefit of self-monitoring can be discussed.

The provision of a blood glucose meter with associated materials could be permitted under the conditions stated.

19 For other blood glucose-affecting medication, please see: KNMP Diabetes Mellitus Guideline (2010 draft) § 4.2.2.

2. Self-monitoring with once- or twice-daily insulin therapy

2.1 Introduction

Despite a lack of supporting literature, there is usually agreement in the guidelines about the possible benefit of self-monitoring. Its necessity differs for each individual, as does the frequency at which a patient must check his/her blood glucose value. As yet, no consensus exists on this.

According to NICE's guideline (2008), *'The frequency of monitoring that is useful to someone with diabetes is highly individual and it is inappropriate to put an artificial restriction on this.'* (2008; p. 50).

The NHG standard (2006) only provides summary information about the timing and frequency of self-monitoring:

Step 3: add daily insulin to oral blood glucose-lowering agents. (…) The level is based on fasting glucose monitoring; day curves are unnecessary. (…).

The German guideline states the following (p. 540): *'The time and frequency of such blood glucose self-checks must be defined individually and depend largely on the type of insulin therapy in question. For patients undergoing conventional insulin therapy, one or two measurements per day are usually sufficient – when metabolic control is stable and nutrition is constant, the number of readings can also be reduced further.'* This is not underpinned by literature.

According to the ADA guideline (2010; pp S17-S18) *'The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient.'* There is only a recommendation given for patients with type 1 diabetes and pregnant women who use insulin: *'SMBG is recommended three or more times daily.'* As regards timing, the ADA guideline considers: *'To achieve postprandial glucose targets, postprandial SMBG may be appropriate.'* This recommendation is presented as an expert opinion and is not justified by literature.

2.2 Question

From the above, the workgroup came to the following question:

Question 2: To what extent does self-monitoring of blood glucose values *more or less frequently* or *at different times* by people with diabetes with once- or twice-daily insulin injection therapy affect HbA1c, quality of life, number of hypo- or hyperglycaemic dysregulations or a reduction in medication usage?

2.3 Method

The systematic reviews that were used for initial question one were screened for studies that are relevant to the above initial question.

The following studies were found: Bajkowska-Fiedziukiewicz (2008); Capelson (2006); Evans (1999); Franciosi (2001); Joy (2003); Karter (2001); Schiel (1999); Schütt (2006) and Secnik (2007).

2.4 Literature discussion

Most studies found were what are known as cross-sectional studies and not experimentally comparative research. These studies have a relatively slight evidential weight. The size of the studies varied markedly. Without exception, these studies reported only HbA1c as outcome measure, while generally only the effect of different frequencies was investigated and not that of different timing. A more comprehensive discussion of the literature can be found in Appendix 2.1.

2.5 Conclusion (level 3)

In a little over half of all the studies, a higher frequency of self-monitoring is associated with a lower HbA1c. Insofar as a relationship was found between different frequencies of self-monitoring and HbA1c, the effect could be in the order of magnitude of a 2.2 mmol/mol (0.2%) fall in HbA1c per additional self-check per day.

One study demonstrated no difference from the timing of self-monitoring on HbA1c. No evidence was found about the effect of differences in the frequency and timing of self-monitoring on outcome measures other than HbA1c.

2.6 Other considerations

Based on clinical expertise it is also not possible to establish how often and at what times self-monitoring should be done in order to realise a fall in HbA1c. There are too many factors that might affect the blood glucose values and thus the HbA1c. Unfortunately no findings were discovered in the literature about outcome measures other than HbA1c.

2.6.1 Widely employed current policy

There is a maximum of one hundred measurements per quarter imposed (source: CVZ), based on the number of insulin injections per day (one hundred measurements with once- or twice-daily injection), separate from the action that should be taken or the effect of the measurements.

There is a diversity of recommendations about the time when measurement is done. The recommendations all lead to the use of around one hundred strips per quarter:

1. measurement once daily, for example fasting.
2. a three-point curve twice a week, usually fasting, before the evening meal and before bed.
3. a four-point curve twice a week, for example fasting, before lunch, before the evening meal and before bed.
4. postprandial curves: a four-point curve twice a week with a fasting measurement and measurements 90 minutes to two hours after each meal.
5. a combination of curves in which values are measured before and after the meals.

The recommendations mentioned are either supplemented or not with a single comprehensive day curve prior to the consultation with the diabetes practitioner.

2.6.2 Current policy versus findings from literature

The scientific findings, as presented in this chapter, do not clearly endorse a positive effect of self-monitoring on HbA1c. A drop of 2.2 to 3.3 mmol/mol (0.2-0.3%) cannot be called clinically relevant. No effect was measured on other parameters either, or no effect was investigated. However, it cannot always be clearly derived from the studies what kind of actions the study participants themselves took based on their measured blood glucose values.

It can be assumed that diabetes patients who themselves opt for active regulation of their blood glucose values achieve better results for the outcome parameters such as HbA1c, well-being, hypo- or hyperglycaemic dysregulation, and possible medication usage.

2.6.3 Desirable situation from practitioner's perspective

Self-monitoring does not in itself lead to an evident improvement in the diabetes status; the intervention that follows ought to have an effect.

Treatment goals must be defined with the patient. In this, medical considerations are important as well as questions such as 'Will and can the patient regulate the blood glucoses him/herself?', 'Do hypoglycaemic incidents occur?', 'How does the patient perceive high values that cannot be adjusted?', and 'How painful is the patient's experience of the finger pricks?'. These considerations will lead to a policy to be defined together, recorded in a jointly prepared care plan.

Self-monitoring does not in itself lead to an evident improvement in the diabetes status; the intervention that follows based on the measured values ought to have an effect. This requires sufficient knowledge and insight from the patient and his/her practitioner in order to be able to manage the results from the self-monitoring.

A once-daily injection of medium- to long-acting insulin, usually added to oral medication, can improve mainly the fasting blood glucose value. For high values during the day, a second injection can be added to this and a check of the

blood glucose values during the day might possibly be worthwhile. Also with a twice-daily 'mixed' programme, a mix of short-, medium- and long-acting insulin with breakfast and evening meal, a combination of measurement times through the day is usually desirable. This therapy possibly causes more hypoglycaemic incidents than a once-daily long-acting insulin dose.

The values measured and recorded by the patient are used in principle for:

1. evaluation with the practitioner: the patient brings the diary with the blood glucose values along and assesses together with the practitioner the progression and the influencing factors.In general, a low frequency of self-monitoring is sufficient in this situation, for example only a number of day curves prior to the visit to the practitioner.

2. self-regulation by the patient: based on the values measured the patient him/herself modifies
   a. the insulin dose according to the agreement with the practitioner.
   b. his/her living pattern, such as eating and physical activity.

2.6.4 Patients' perspective

With the increased patient emancipation, the desire to gain a grip oneself on the illness is growing.

Patients indicate various experiences with self-monitoring in the studies investigated. The values found can be disheartening, because right at the moment itself, no action can be taken. On the other hand, only the use of medication itself without insight into its effect is for many patients not or no longer desirable; with the increased patient emancipation, the desire to gain a grip oneself on the illness is growing.

For diabetes patients, different considerations often apply than for practitioners. The burden of measurement on the one hand and for example the need for extra measurements in case of doubt on the other count in the formation of a joint policy. Based on the patient's motivation and stated goals, this self-monitoring policy can be defined and if necessary, generally applicable recommendations can be deviated from.

2.6.5 Costs

Through tightening up the conditions for self-monitoring on the one hand (only self-monitoring if self-regulation is also done) or on the other through widen-

ing them (in order to be able to self-regulate it will possibly be necessary to measure more often – temporarily), it cannot be stated on balance what the economic effect of the recommendations would be. By gaining insight into the effect of certain foodstuffs, medicines and physical activity and thus the achievement of the stated goals, the number of measurements can be reduced in the course of time. Currently, agreements apply for reimbursement for strips without evaluation of the effect. It is possible that a shift of the costs will occur when the use of a jointly prepared care plan and self-management are linked to self-monitoring.

2.7 Recommendations

1. **For people with type 2 diabetes with once- or twice-daily insulin injection therapy, self-monitoring under conditions is considered worthwhile.**

2. **Agreements with respect to self-monitoring must be recorded and evaluated in a care plan prepared jointly by patient and care provider.**

3. **The patient's individual goal, established in discussion with the practitioner, must be determining for the number of measurement moments and the times when these are done.**

Specific situations may require extra measurements.

As a guideline, the following is recommended, largely following the NDF Guideline 2003:

- **upon initiation of once- or twice-daily insulin therapy:**
  - daily fasting[20] until stable blood glucose values are established.
  - weekly or fortnightly a four-point curve: before the three main meals and before bed.
  - on indication weekly or fortnightly a seven/eight-point curve: before and after each meal, before bed, and in case of suspicion of night-time dysregulation, a check during the night.
- **modify the frequency as necessary during follow-up appointments between patient and diabetes care provider.**

20 Also in accordance with NHG standard on diabetes mellitus type 2 (2006).

3. Self-monitoring with intensive insulin and insulin pump therapy

3.1 Introduction

There is no clear agreement in the Netherlands about the frequency of measurement of blood glucose values. Healthcare insurers have imposed rules with regard to the reimbursement for the number of test strips. Roughly this comes down for people on intensive insulin therapy or insulin pump therapy to four to five measurements a day, without conditions on self-management.

According to the ADA guideline (2010; pp S17-S18) *'SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy'*. This recommendation is presented as one with strength 'A', so a 'firm' recommendation. One of the arguments for this recommendation is that *'for these populations significantly more frequent testing may be required to reach A1C targets safely without hypoglycemia.'*

The German guideline (update 2008, p. 540) states the following: *'For patients undergoing intensified insulin therapy, as a rule at least three-four measurements should be taken per day.'* This recommendation is, as they themselves admit, based on expert opinion. This led the workgroup to question three.

3.2 Question

From the above, the workgroup came to the following question:

Question 3: Does the frequency of blood glucose measurement by people with diabetes and intensive insulin injection or pump therapy have an effect as regards improvement in HbA1c, reduction in the number of hypo- or hyperglycaemic dysregulations, improvement in quality of life, or reduction in medication usage?

3.3 Method

With a search strategy in PubMed, 35 studies were found, of which three were considered relevant. Besides this, a further specific search was done for relevant literature in Medline and Cochrane. This yielded one non-systematic review. The various search strategies and results are described in Appendix 3.1.

3.4 Literature discussion

The studies found were all correlation studies and not comparative experimental studies, so that no statements can be made in terms of causal relationships. They were indeed large studies with thousands of study subjects. The outcome measure investigated was HbA1c as a rule. Other outcomes such as hypo- and hyperglycaemia, quality of life or reduction in medication usage were hardly investigated.

A more comprehensive discussion of the literature can be found in Appendix 3.1.

3.5 Conclusion (level 3)

The studies found suggest a positive association between more frequent measurement of blood glucose and a fall in HbA1c.

No evidence was found that offers sufficient indications for the determination of an optimum frequency of self-monitoring in people with diabetes mellitus and intensive insulin injection/pump therapy.

The studies found suggest a positive association between more frequent measurement of blood glucose and a fall in HbA1c; measurement over five times daily seems to achieve no further gain in terms of HbA1c reduction.

3.6 Other considerations

Based on the literature available, it seems that the frequency of self-monitoring has an effect on the level of HbA1c. Per extra check per day, up to a maximum of five measurements, an improvement in the HbA1c of 2.2 to 3.3 mmol/mol (0.2 to 0.3%) can be expected. This applies to people with diabetes who use an intensive insulin programme, in other words insulin therapy at least

four times daily or an insulin pump. From the literature as regards this effect it emerges that there is no difference between people with diabetes types 1 and 2.

3.6.1 The effect of self-monitoring

The evidential power of the studies with regard to the effect of self-monitoring in an intensive insulin regime can be termed modest.

ADA states in its Position Statement 2010:

'Major clinical trials of insulin-treated patients that demonstrated the benefits of intensive glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved.'

Just as in the studies found for this guideline, ADA too gives no specific advice about the recommended frequency of blood glucose measurement in combination with actions linked to it.

No possible negative effect of self-monitoring were reported in the studies found. An explanation for this could be that patients with an intensive insulin programme or an insulin pump themselves possess possibilities for self-regulation and are therefore able to correct bad values.

3.6.2 Attitude of the professionals

The number of hypo- and hyperglycaemic incidents possibly reduces with frequent self-monitoring.

Experience from daily diabetes practice teaches that the successful achievement and maintenance of a target value of HbA1c < 53 mmol/mol (7%) proceeds more quickly with frequent measurement. The number of hypo- and hyperglycaemic incidents also reduces with frequent self-monitoring and thus the risk of hypo-unawareness and the occurrence of long-term complications as well.

Self-monitoring cannot be disassociated from self-management here. The measurement of blood glucoses without being able to intervene based on the values found will have little or no effect on the effects mentioned above.

An involved attitude of the care provider is important here in order to have the patient measure and regulate with motivation. The care provider must evaluate together with the diabetes patient the measured and recorded blood glucose values. The care provider must help the patient to interpret the values correctly and joint decisions should be made on modifications to lifestyle and/or medication programme.

3.6.3 Patients' perspective

For people with diabetes, self-monitoring can give a large measure of independence and autonomy. Education is of great importance in this. Insight into the factors that affect blood glucose values, the measurement of the effect of these said factors and the power to react adequately might give people with diabetes the opportunity to live as normal a life as possible. Particularly the grip on diabetes, the presumed reduction in the likelihood of complications and feeling better with good values are important to the diabetes patient's motivation. Self-monitoring may possibly be experienced by the diabetes patients as a support, for example for checking the operation and presence of insulin in order to prevent hyper- and hypoglycaemic dysregulation. With self-monitoring, the patient can concentrate on the hard-to-regulate times of the day and attempt to make improvements there.

The possibly negative aspects of self-monitoring that patients themselves indicate should not be lost sight of.

The possibly negative aspects of self-monitoring that patients themselves indicate – the mental burden they experience – should not be lost sight of. Reluctant equipment, pain, confrontation, visibility of the condition and powerlessness are negative factors that diabetes patients indicate during self-monitoring.

3.6.4 Costs

As regards the costs, an investment in self-monitoring for this group of diabetes patients will probably lead to reduced costs in due course, given that a good correlation exists between the level of HbA1c and the risk of diabetes-related complications and hospital admissions.

3.7 Recommendations

Despite the absence of robust justification from the literature, the workgroup states that

for people with diabetes with an intensive insulin programme of three or more injections per day or insulin pump therapy, targeted self-monitoring of an average of four to five times a day is to be recommended.

Self-management is vital in this regard.

In incidental cases and/or when more insight is needed, a greater number of measurements per day may be necessary. In the NDF Guideline (2003) it is proposed if necessary: weekly or fortnightly a seven- or eight-point curve (before and after meals and if desired during the night).

Also, there are conceivable situations where less-frequent monitoring would be sufficient. The diabetes care provider and patient can decide this in mutual agreement.

4. Self-monitoring and education

4.1 Introduction

In studies described earlier (in Chapter 2) it was emphasised that self-monitoring should not be seen as an intervention: the provision and use of a blood glucose meter in themselves do not improve glucose regulation. The improvement arises from the actions that are undertaken in response to the values found. Self-management is thus inseparably linked to education, which must lead to self-management by the diabetes patient.

The attention to self-management in diabetes care has increased steeply in recent years. The NDF framework[21] 'Self-management education for diabetes' appeared in 2011. This framework of competencies for healthcare professionals contains the following:

The 'Chronic Care Model' [22] *describes self-management as the individual power of a person with a chronic illness to cope well with symptoms, treatment, physical and social consequences, and lifestyle modifications inherent to living with such an illness. This supposes the presence of insight, motivation and capability in the individual patient. In the case of diabetes it is evident that self-management is a necessary condition to achieve adequate regulation of the blood glucose and cardiovascular risk factors. Self-management is also important to threatened or existing complications of diabetes.*

Not only the professional but especially the diabetes patient him/herself is responsible for the results of his/her care process and treatment (the achieving of the stated health goals). The professional has the important task of supporting the patient in this.

Knowledge and skills are in general acquired through patient education, an essential component of diabetes management.

21 Education Framework from NDF Committee on Education and Instruction (2011).

22 The Chronic Care Model is an aid for the development and improvement of chronic care. The teamwork between the patient and his/her care providers is central.

It is supposed that knowledge of diabetes and the gaining of important skills for self-management play an essential role in the reduction or prevention of complications and the improvement of the quality of life. Knowledge and skills are in general acquired through patient education, an essential component of diabetes management.

Self-management imposes heavy requirements on the diabetes patient. Many decisions must be made every day to keep food intake, physical activity and medication in balance. Diabetes education should thus not only be given in the first months after the diagnosis, but should remain a key component of continuing care.

Self-management demands education. Further in the NDF report:

Self-management comprises (…) more than the provision of information and the instruction of the patient. It is targeted at (helping) the development of intrinsic motivation, insights and skills that enable the patient to manage the diabetes and its resultant physical and psychosocial consequences adequately in the longer term and under changing circumstances.

It is actually unclear in what form this education should be offered. A relevant question here is whether the teaching of self-monitoring, embedded in an education programme, has more effect on things including HbA1c and well-being than simply providing a blood glucose meter without structured education and guidance. The necessity for diabetes education is in itself not under discussion. It is indeed important to know what structured forms of education have the most effect on knowledge, skills and above all physical and mental outcomes.

4.2 Question

The above led in the workgroup to the following question.

Question 4: Which structured forms of patient education lead to the successful learning and implementation of self-management in people with diabetes types 1 or 2?

4.3 Method

In a literature search, systematic reviews, HTA (Health Technology Assessment) reports and RCTs were looked for in Medline and the Cochrane Library (Cochrane Database of Systematic Reviews; Cochrane Central Register of Controlled Trials; Health Technology Assessment Database).

Of the twenty HTA reports and systematic reviews found, five were considered relevant to the initial question stated above. Only one RCT added anything new to the systematic reviews and HTA reports.

The literature search strategy is included in Appendix 4.1.

4.4 Literature discussion

The systematic reviews found were all of good quality, but the methodological quality of the studies included in these was rather variable. In the education programmes, attention was mainly given to nutrition, self-monitoring of blood glucose values, physical activity and body weight. The description in the studies of the interventions to be taught was generally neither detailed nor specific. The duration of the interventions was variable. The interventions concerned both group and individual education. The outcome measures to which most attention was paid were HbA1c, quality of life, knowledge of diabetes and diabetes medication.

A more comprehensive discussion of the literature can be found in Appendix 4.1.

4.5 Conclusion (level 2)

There are few robust studies in which the effect of various forms of education for the purposes of self-management have been investigated and compared. No studies were found that provided adequate information to assess whether some sub-groups gained more benefit from a certain educational intervention. Group education would seem more effective than individual education insofar as the outcomes such as HbA1c in the short term (< one year) are concerned.

Group education would seem more effective than individual education.

Education with the focus on encouraging a positive attitude and greater self-sufficiency (‘behaviour-related tasks’) would seem more effective than knowledge transfer-related education.

Diabetes education sometimes had the consequence that less medication could be sufficient or that the quality of life improved. More often, diabetes knowledge increased after having followed an education course.

It is plausible that self-monitoring supplemented by education is more effective than self-monitoring alone in terms of reducing HbA1c. This fall would seem to be in the order of 5.7 mmol/mol (0.52%) with respect to conventional monitoring, and around 2.2 mmol/mol (0.2%) with respect to self-monitoring alone, albeit that the outcomes featured substantial heterogeneity.

4.6 Other considerations

Particularly if the patient him/herself can use the measurement results for behavioural change, self-monitoring can be called a successful intervention.

When the development of this guideline was started, a sticking point analysis was done among interested parties in Dutch diabetes care. In the reactions, reference was often made to the importance of education targeted at self-management. Only when patients themselves could interpret the values and use them to achieve behavioural change (change in medication dosage, change in food intake and/or activity pattern) could self-monitoring be called a successful intervention. Unfortunately 'education' as an intervention is hardly straightforward to investigate. The many studies in which the effect of education in self-monitoring was looked at differ so much in design, methodology, duration and intensity of the intervention that the outcomes are hard to indicate.

In the preparation of recommendations, use was mainly made of the general recommendations in the NICE guideline of 2008.[23]

23 National Collaborating Centre for Chronic Conditions. Type 2 diabetes: national clinical guideline for management in primary and secondary care (update). London: Royal College of Physicians, 2008.

4.7 Recommendations

1. Structured education is an essential part of diabetes care and must be offered to all people with diabetes, in any event at the time the diagnosis is made.

Structured education ought to be offered to diabetes patients annually and must be evaluated.

2. Conditions with which structured education must comply and which can also be used as evaluation criteria:

   - Education must link up with the individual needs and goals of the diabetes patient and be clear for the patient to understand. It must be available locally and be integrated into the conventional care.

   - Education programmes must be evidence-based with a structured plan of approach, contain clearly formulated goals and learning subjects and be presented by adequately trained educators. Group education is preferred because it appears more effective than individual education. An equivalent alternative must however be available for patients who cannot/do not want to participate in group education.

   - The NDF Standard of Care should serve as basis for the content.

   - The outcomes of the programme must be evaluated both under participants and as a programme itself.

The workgroup moreover posits that web-based education programmes can be a valuable addition. These can be set up and adapted flexibly, and can be offered continuously so that continuity is ensured.

Examples of education programmes running in the Netherlands are DIEP (http://www.diep.info/index.php), PRISMA (http://www.prisma-diabetes.nl) and the educational provisions of the patient association, the DVN (http://www.dvn.nl/).

Structured diabetes education programmes for diabetes patients who do not speak Dutch or have too poor a command of it are unfortunately not available. The workgroup recommends further investigation into the availability of such programmes in other countries and their usability in Dutch healthcare.

5. Implementation of self-monitoring

Diabetes patients rely completely on the values they measure. This makes the reliability of the measurement crucial.

5.1 Introduction

Self-monitoring is a central part of self-regulation and diabetes patients rely wholly on the values they measure. This makes the reliability of the measurements crucial. This reliability is mainly determined by the patient him/herself and by the device. The patient determines how the procedure is conducted and how the device is used and maintained. The care provider has a role in the checking of the correct implementation and of the equipment.

Recently (2011), a guideline 'Procedures for the use and checking of glucose meters by care providers and patients with diabetes mellitus' was developed by the KNMP (Royal Dutch Association for the Advancement of Pharmacy), the NVKC (Netherlands Society for Clinical Chemistry and Laboratory Medicine), and the NVZA (Netherlands Association of Hospital Pharmacists). This guideline was used with the approval of the KNMP-NVKC-NVZA workgroup in answering the initial question posed about the implementation of self-monitoring and the checking of the measuring equipment. By making use of the guideline mentioned, a contribution is also made to its implementation and a watch is kept on the uniformity of concepts and (especially) of advice and recommendations. Another publication has appeared very recently in *Diabetes Care* (Hortensius, Diabetes Care 2011) in which the results of a study conducted in the Netherlands about the implementation of self-monitoring are described. This publication was also used in answering initial question 5.

5.2 Question

The above led in the workgroup to the following question.

Question 5: With what conditions must the implementation of self-monitoring by people with diabetes comply in order to allow the measurement results to be relied on?

5.2.1 Sub-questions

The above question raised a number of sub-questions:

1. With what conditions must the materials comply?
2. Must the first drop be wiped away or can it be used?
3. How should fingers be cleaned: disinfect or not?
4. What is the correct way of applying pressure to obtain more blood?

5.3 Method

The method for the literature search is not described systematically. To answer the question and the associated sub-questions, extensive use (with approval) was made of the Guideline 'Procedures for the use and checking of glucose meters by care providers and patients with diabetes mellitus' by the KNMP-NVKC-NVZA workgroup. In this Guideline, equivalent questions are central, and these were answered with the help of literature research:

- Which glucose meters are reliable enough to recommend for the use of patients with diabetes?
- Which meters (glucose and cholesterol) can be used for (prevention) measurements by pharmacist and GP?
- How often should a meter (belonging to patient, pharmacy, general practice) be calibrated, with what and by whom?
- What are the prior conditions for reliable measurements?
- When should a measurement be done by a clinical chemist (at a clinical chemistry laboratory)?

5.4 Literature discussion

A quantity of (mainly clinical chemistry) literature was used to find answers to the questions, from which four mutually related documents were developed. These documents, which can be found on the websites of the organisations involved, are:

- a recently published article in which an SKML (Foundation for Quality Control in Medical Labs) Quality Mark for blood glucose meters is described
- a recommendation for calibration of patients' blood glucose meters by a clinical chemistry laboratory
- a recommendation for calibration of care providers' blood glucose meters
- a *standard operating procedure* for the conduct of a blood glucose measurement by a care provider.

The processing of the literature, the conclusions that were drawn from this and the formulation of recommendations happened in consensus meetings with the workgroup members.

5.5 Conclusion

Glucose meters should preferably have an SKML Quality Mark and must comply with analytical criteria based on the concept of biological variation, generally accepted in clinical chemistry, and as described in the SKML Quality Mark article.

The patient must be instructed on how to perform the measurement with attention to the pre-analytical (prior to the determination itself), the analytical and also the post-analytical aspects. The conduct of the blood glucose measurement by the patient must be checked once a year; in case of deviation, the blood glucose meter must be calibrated. Thereafter, instruction of the diabetes patient should happen again. Instruction, checking and calibration should happen under supervision of a laboratory accredited by CCKL (Lab Accreditation Foundation).

If it emerges from the blood glucose meter instruction that there are hindrances to the (reliable) conduct of self-monitoring due to patient-specific problems, the care provider must take measures with the patient, if necessary in discussion with others (for example medical specialist, blood glucose meter manufacturer, laboratory specialist). Measures could for example be the provision of a blood glucose meter with a bigger display, a lancet easier for this patient to handle, bigger strips or the organisation of practical support in carrying out the self-monitoring.

5.5.1 Answer to sub-question 1
With what conditions must the materials comply?

- **Reuse of lancets**

The single use of *disposable* material, including lancets for obtaining a blood drop, is the standard in the Netherlands.

- **Check of blood glucose meter, including operating life of the blood glucose meter and correct use of blood glucose strips**

In the NVKC/KNMP/NVZA Glucose Meters Guideline (2011), the principle is employed that the conduct of the blood glucose measurement should be checked annually and the blood glucose meters should be calibrated annually. In place of 'checking' the term 'calibration' is used to demonstrate that this is a comparison of the blood glucose device with a standard to establish its characteristics.

Preferably, the check should be done by a CCKL-accredited laboratory. However, given the high costs associated with this, and the burden on the patient, this could also be done by a care provider, under supervision of a CCKL-accredited laboratory. Supervision could comprise schooling with certification.

If necessary, the meter could once again be presented to the laboratory for checking and be calibrated. If everything complies with the standard in force, the patient should be instructed again in how to conduct the blood glucose measurement.

In the annual refreshment of the instruction, use can be made of the document 'Standard Procedure for Blood Glucose Value Determinations by a Care Provider'. In this, prescriptions are specified for:

- checking the operation of the meter
- the preparation for the measurement by the care provider
- the procedure for the test, conducted by care provider

5.5.2 Answer to sub-question 2
Must the first drop be wiped away or can it be used?

In carrying out the self-monitoring by the patient, the use of the first drop after washing the hands is recommended. If the care provider carries out the test, the recommendation is, after washing the hands, to wipe away the first drop

and use the second. In a recently published article about this, it is confirmed that patients in conducting self-monitoring can use the first drop of blood, provided that the hands have been washed (with soap) and properly dried (Hortensius, Diabetes Care 2011).

5.5.3 Answer to sub-question 3
How should fingers be cleaned: disinfect or not?

On cleaning, only the washing of the hands as standard action with a preference for drying with a disposable towel is mentioned. Hortensius additionally recommends 'washing with soap'.

Moreover, in connection with he feasibility of this recommendation, it is stated that 'if washing the hands with soap is not possible and the hands are not visibly dirty nor have recently been exposed to sugar-containing products, a second drop can be used' (Hortensius, Diabetes Care 2011).

5.5.4 Answer to sub-question 4
What is the correct way of applying pressure to obtain more blood?

The blood should have been obtained straightforwardly, without applying pressure. Hortensius also recommend avoiding application of pressure as 'external pressure can cause a deviation of 10% in glucose concentration in 5-13% of the participants' (Hortensius, Diabetes Care 2011).

5.6 Recommendations

In a follow-on to the NVKC-KNMP-NVZA Guideline with recommendations from recently published documents from Dutch research, the workgroup recommends:

1. giving individual instruction at the start of self-monitoring and repeating it annually.

2. having patients' blood glucose meters checked and recorded annually by a CCKL-accredited laboratory, or a care provider under supervision of such a lab.

3. as standard advice, having patients wash their hands and dry them properly before conducting the test.

4. allowing patients to use the first drop of blood for their measurements providing their hands have been washed.

5. if handwashing is not possible, the first drop may be wiped away and the second may be used, incidentally and under conditions.

6. avoiding applying pressure when obtaining the blood drop.

6. And what now?

At the start of this project, the Self-Monitoring Guideline workgroup formulated a set of initial questions, based on a sticking point analysis, which lie at the foundation of the final guideline. It gradually emerged that no or little (thorough) research has been done into many subjects, and some subjects have remained neglected.

In this chapter, gaps in knowledge in the field of self-monitoring that the workgroup observed are described. Firstly, a summary is presented of a series of questions that are not answered in this guideline and that deserve attention, mainly because these subjects were indeed mentioned in the sticking point analysis. Then recommendations for future scientific research are made.

6.1 Open questions

- What is the effect of self-monitoring in combination with structural education on fasting blood glucose values and medication usage in diabetes patients who only use tablets?
- What effect does self-monitoring have on the prevention of (serious) hypoglycaemic incidents?

During the guideline development, new questions arose:

- To what extent is self-monitoring by diabetes patients with insulin usage experienced as a burden rather than a help?
- Does the frequency of self-monitoring have an effect on the number of hospital admissions as a result of hyperglycaemic dysregulation?
- How can structural self-management education be embedded into conventional diabetes care?
- What are the costs of self-monitoring?
- Are the costs of self-monitoring justified against the benefits in the field of well-being?
- Are the costs of self-monitoring justified for the prevention of diabetes-related complications?
- What is the effectiveness and efficiency of multidisciplinary interventions in self-management education of diabetes patients?
- What is the effect of the permitted deviation of blood glucose meters on the patients' diabetes regulation?

2 Recommendations for scientific research

Research questions or proposals of which the workgroup believes they deserve priority:

6.2.1 Potential target groups and promising interventions

Question: What personally related factors determine the success of self-monitoring of blood glucose values in patients with type 2 diabetes without insulin therapy?

For the identification of subgroups of patients who might benefit from self-monitoring, research into potential target groups and promising interventions to improve glycaemic control is desirable. To this end it is first necessary that more evidence is obtained that demonstrates that the results of self-monitoring can lead to modification of treatment and behaviour. An example of such research is the article by Polonsky[24] discussed in the guideline.

6.2.2 Optimum frequency of self-monitoring

Question: What determinants affect the optimum frequency of self-monitoring of blood glucose values by diabetes patients with a once- or twice-daily insulin therapy?

Just as for diabetes patients without insulin therapy, the possibility is absent to employ insulin flexibly in this group of diabetes patients for high blood glucose values or for changes in their eating or activity patterns. The research findings of studies already carried out could be reanalysed for statements and findings about this frequency. Another option is to set up an RTC in which different groups, each with a specifically described intervention, are mutually compared for the effect of self-monitoring.

24 Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program Study. Diabetes Care 2011;34:262-7

6.2.3 Effect of self-monitoring

Question: What constituents of self-monitoring of blood glucose values are effective in improving diabetes patients' blood glucose regulation?

By constituents of self-monitoring, the associated education is meant primarily. Every diabetes patient in the Netherlands has access to a quarterly checkup at the treating doctor, often deputised by the diabetes nurse/practice assistant, usually forming part of a multidisciplinary treatment team. Conventional control is in broad terms directed at standard measurements such as blood pressure and weight, blood glucose and other laboratory values, and medication usage. It is supposed that education makes a major contribution to the diabetes patient's self-management. A trial with properly specified interventions could provide building blocks for further analysis.

6.2.4 Effect of education

Proposition: There is a need for justification of the effectiveness of education programmes with regard to the teaching of skills for self-monitoring.

The studies to be instigated should pay attention to relevant patient characteristics, particularly socio-economic status and ethnicity/cultural background.

6.3 Implementation

A guideline is only a meaningful document if there is consensus about its content among all relevant parties and it finds its way into everyday practice. In order to achieve this for the present guideline, right from the start, practice was involved as much as possible in its development:

- Prior to the literature study, a sticking point analysis was conducted 'in the field'.
- The workgroup was composed of (diabetes) professionals and one diabetes patient, all representatives of their own professional organisation.
- In the draft phase, the guideline was presented for comment to relevant parties in the field.
- Finally, the guideline was presented for authorisation to the NDF.

In this way, conditions were created to simplify the guideline's implementability. Distribution will take place via all the professional organisations involved. The guideline will be made available widely as a paper document, in a convenient form, including a summary card with key recommendations. The appendices will be largely omitted from the paper version; these can be found in the guideline's digital version, on the websites of the NDF, EADV and other (professional) organisations.

Various initiatives will be taken to bring the guideline to the attention of a wide audience, namely:

- (poster) presentations at congresses and symposia
- publications in various professional journals
- subject of e-learning education programmes
- being offered to educational institutions in healthcare

Besides this, the guideline will be included in the implementation programme of the National Diabetes Action Programme 2012.