



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

Point-of-care  
testing in

Point-of-care testing in primary care in the Netherlands

primary care

*Management of patient safety related aspects*

in the Nether



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

## **Point-of-care testing in primary care in the Netherlands**

Management of patient safety related aspects

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## Colophon

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## Abstract

### **Point-of-care testing in primary care in the Netherlands**

#### Management of patient safety related aspects

Point-of-care (POC) tests are devices or test strips that can be used near or at the site of patients for a relatively fast diagnosis. Examples are blood glucose meters for diabetes or nitrite test strips to detect a urinary tract infection. Although a majority of general practitioners in the Netherlands is using POC tests in their practice, little is known on how they manage the corresponding patient safety aspects. To maintain good and safe use of POC tests it is important that POC tests are used correctly. Results of the explorative study performed by the RIVM show that some quality aspects receive insufficient attention in GP practices.

#### **Results**

There is not always sufficient attention for quality control measures such as checking the storage conditions, calibration, and maintenance. Furthermore, only half of the respondents take universal hygienic measures, such as washing hands before taking a blood sample. Refresher courses on the use of POC tests are hardly organized. Only a few of the general practitioners contact the manufacturer of the device when a device failure occurs. Without informing the manufacturer of device problems, the manufacturer does not have the opportunity to improve the device or instructions for use, whatever is applicable, so that the problem does not recur. Well-controlled aspects include patient identification, and actions taken when ambiguous test results are obtained.

#### **Recommendation**

To maintain a good quality of care and to prevent the risks of errors with POC tests in GP practices, it is recommended to expand existing general guidelines for GPs with regard to the use of point-of-care tests.

Keywords: point-of-care testing, primary care, general practitioners, patient safety, blood glucose test, nitrite test, haemoglobin test



## Rapport in het kort

### **Point-of-care-testen in de eerstelijnszorg in Nederland**

#### Beheer van patiëntveiligheidsaspecten

*Point-of-care (POC-)*testen zijn apparaten of teststrips die aan het bed van patiënten of in de huisartspraktijk kunnen worden gebruikt om snel een diagnose te stellen. Voorbeelden zijn bloedglucosemeters voor diabetes of nitrietteststrips voor urineweginfecties. POC-testen worden steeds meer gebruikt in huisartspraktijken. Er is echter weinig bekend over de manier waarop de gebruikers van de testen de bijbehorende patiëntveiligheidsaspecten beheren. Voor een goede en veilige uitvoering hiervan is het van belang dat de testen op een juiste manier worden gebruikt. Uit het exploratieve onderzoek van het RIVM naar het gebruik van POC-testen in de huisartspraktijk blijkt dat er voor sommige kwaliteitseisen onvoldoende aandacht is.

#### **Bevindingen**

Er is niet altijd voldoende aandacht voor kwaliteitsbeheersing van de testen, bijvoorbeeld bij opslag, kalibratie en onderhoud. Verder voert slechts de helft van de respondenten universele hygiënische maatregelen uit, zoals handen wassen voordat een bloedmonster wordt genomen. Ook worden opfriscursussen voor het gebruik van POC-testen nauwelijks georganiseerd. En als de testen niet goed functioneren, melden slechts enkele huisartsen dat bij de fabrikant. Hierdoor kan de fabrikant geen maatregelen treffen om zijn product of de instructie voor gebruik te verbeteren. Huisartsen zorgen er wel goed voor dat de monsters aan de juiste patiënten worden gekoppeld (patiëntidentificatie). Ook wordt de benodigde actie ondernomen als de testresultaten onduidelijk zijn.

#### **Aanbevelingen**

Om een goede kwaliteit van zorg te handhaven en risico's op fouten met POC-testen in huisartspraktijken te voorkomen, is het aan te bevelen bestaande richtlijnen voor huisartsen uit te breiden met betrekking tot het gebruik van POC-testen.

Trefwoorden: point-of-care-testen, eerstelijnszorg, huisartsen, patiëntveiligheid, bloedglucosetest, nitriettest, haemoglobinetest.



## Contents

	Summary—9
	Abbreviations—11
<b>1</b>	<b>Introduction—13</b>
<b>2</b>	<b>Method—15</b>
2.1	Questionnaire—15
2.2	Study population, data collection and data analyses—15
<b>3</b>	<b>Results—17</b>
3.1	Characteristics of the respondents—17
3.2	Use of POCT in GP practices—18
3.3	User experience with POC tests—18
3.4	Training of the users—19
3.5	Pre-analytical phase—20
3.5.1	General control measures for the three tests—20
3.5.2	Control measures for blood tests (blood glucose and haemoglobin)—21
3.5.3	Types of urine samples accepted for nitrite tests—22
3.6	Analytical phase—23
3.6.1	Patient identification—23
3.6.2	Hygienic procedures when using blood tests—23
3.6.3	Sample handling when using blood tests—24
3.7	Post-analytical phase—25
3.7.1	Recording test results—25
3.7.2	Interpretation of test results—26
<b>4</b>	<b>Discussion and conclusions—33</b>
4.1	Training—34
4.2	Pre-analytical phase—35
4.3	Analytical phase—36
4.4	Post-analytical phase—37
<b>5</b>	<b>Recommendations—41</b>
<b>6</b>	<b>References—45</b>
	<b>Appendix 1. Questionnaire (translation of the Dutch version)—47</b>
	<b>Appendix 2. Letter sent to the GP practices (Dutch-language)—55</b>





## Summary

The main advantage of using point-of-care (POC) diagnostic tests is that results can be obtained very rapidly at or near the patient site. For general practitioners (GPs) this means that they are able to make a clinical decision during the patient visit. The use of POC diagnostic tests may even result in reducing the need for a second patient visit. This is convenient for patients and may enhance practice efficiency.

Although the majority of GPs in the Netherlands are using POC tests in their practice, little is known on how they manage the corresponding patient safety aspects. In literature, several key elements have been described for managing patient safety aspects related to POCT, such as training, quality control measures, and alternative actions when tests result conflict with symptoms or device failure occurs.

As part of the supervision of medical product safety, the Health Care Inspectorate (IGZ) of the Netherlands has specific attention for the safe introduction, management and use of health care technology. Because POC diagnostic tests are increasingly used in primary care in the Netherlands, IGZ has commissioned the National Institute for Public Health and the Environment (RIVM) to study the use of these products. The aim of this explorative study is to investigate how patient safety aspects related to the use of POCT by GPs are managed in the Netherlands.

This study was executed in close collaboration with the department 'Health Technology and Services Research' of the University of Twente (UT) and the Netherlands Institute for Health Services Research (NIVEL).

A web-based questionnaire on the use of glucose tests, nitrite tests and haemoglobin tests, the most frequently used POC tests by GPs, was developed, and the link to the questionnaire was sent to a random sample of 750 GP practices. This sample was drawn from the registry of the NIVEL, which includes all Dutch GPs (n= 4090). Of this random sample 111 GP practices responded by returning the questionnaires. With 111 responses, 2.7% of the Dutch GP practices are represented.

Results showed that some aspects were well managed, but other issues received insufficient attention. Although training on the use of POC tests was given in almost all practices, important follow-up activities, such as refresher courses and writing a test protocol were hardly ever organized. Patient identification was managed well. Quality aspects relating to accepting and handling urine samples

were adopted correctly by the GP practices. Universal hygienic measures, i.e. washing hands to prevent the transfer of infectious materials and to prevent that contaminants on the hands (e.g. food residues) interfere with the test results, were taken by approximately half of the respondents. All GP practices registered test results. In addition, the vast majority of the respondents registered test results manually in practice's electronic health record (EHR) system. Taking action when ambiguous test results were obtained was an aspect that was well managed, whereas contacting the manufacturer when a device failure occurs was done by only a few of the general practitioners. Notably, for all three types of tests, attention to checking storage conditions and packaging and to calibration and maintenance was insufficient.

To maintain a good quality of care and to prevent the risks of errors with POC tests in GP practices, it is recommended to expand existing general guidelines for GPs with regard to the use of point-of-care tests.

## Abbreviations

EHR	electronic health record
GP	general practitioner
IGZ	the Health Care Inspectorate of the Netherlands
NHG	the Dutch College of General Practitioners
NIVEL	the Netherlands Institute for Health Services Research
POC	point-of-care
POCT	point-of-care testing
RIVM	National Institute for Public health and the Environment
UT	University of Twente



## 1 Introduction

Point-of-care (POC) diagnostic tests are increasingly used by health care professionals for therapeutic decision-making. The main advantage of using POC diagnostic tests is that results can be obtained very rapidly at or near the patient site. For general practitioners (GPs) this means that they are able to make a clinical decision during the patient visit [1]. Thus, they can start treatment immediately when necessary, and they can avoid unnecessary treatment. Appropriate use of POC diagnostic tests may prevent referrals to secondary care. This is convenient for patients and may enhance practice efficiency [2].

Though POC testing (POCT) has advantages, its use holds some risks too. POC tests are used in a variety of settings by various non-laboratory health care professionals, who do not always have the essential training, skills and experience to sample and analyse human body materials. The risks of failure of the testing process and the possibility of false negative or false positive results has to be dealt with. The fact that a therapeutic decision, though only partly based on the test result, may be made immediately on receipt of a POCT result increases the risk to the patient if the result is erroneous [3]. Results of a study among practice nurses in the UK, showed a poor understanding of quality control issues related to near-patient testing, e.g. maintenance of equipment and management of the results [4]. To mitigate the risks of POCT and to ensure patient safety, a health care professional has to adopt a systematic approach when using POC tests for diagnostic purposes.

Although the majority of GPs in the Netherlands are using POC tests in their practice, little is known on how they manage patient safety aspects relating to POCT [5]. Several key elements have been described for managing POCT-related patient safety aspects [6-9]:

- Users must be trained in using the POC diagnostic test.
- Users must have experience with the test.
- Quality control measures are necessary: when receiving the test, before using the test, when the test is performed, and periodical maintenance and calibration.
- The results must be listed in a registration system.
- When a test result conflicts with the observed clinical symptoms, or when the professional does not trust the test result, alternative actions

have to be considered, e.g. repeating the test, or sending a sample to a laboratory for testing.

As part of the supervision of medical product safety, the Health Care Inspectorate (IGZ) of the Netherlands pays specific attention to safe introduction, management and use of health care technology. Because POC diagnostic tests are increasingly used in primary care in the Netherlands, IGZ has commissioned the National Institute for Public Health and the Environment (RIVM) to study the use of these products. The aim of this explorative study is to investigate how patient safety aspects relating to the use of POC tests by GPs are managed in the Netherlands.

This study was executed in close collaboration with the department 'Health Technology and Services Research' of the University of Twente (UT) and the Netherlands Institute for Health Services Research (NIVEL).

## 2 Method

### 2.1 Questionnaire

To obtain information on the management of patient safety aspects, a questionnaire was developed based on a literature study and input from experts in clinical chemistry and GPs. Literature searches were performed using Scopus™ (Elsevier BV) and Medline/PubMed (US National Library of Medicine). Search strings which were used were 'patient safety', 'primary care', 'general practitioner', 'point-of-care testing', 'point-of-care tests', 'blood glucose test', 'nitrite test' and 'haemoglobin test'. Important aspects included in the questionnaire were training of users, intake and storage of test materials, calibration and maintenance of the equipment, hygiene procedures before collecting samples, test performance, registration of results and actions following test results.

Results of an earlier survey among GPs on POCT in 2010 showed that tests for nitrite, blood glucose and haemoglobin are used most frequently by GPs in the Netherlands [5]. Therefore, these three tests were subjects of this study. The nitrite test is used to measure nitrite formed by microorganisms in the urine, to detect a urinary tract infection. The blood glucose test is used to monitor the blood sugar levels in diabetes patients. The haemoglobin (Hb) test is used to measure the Hb level in the blood to diagnose or exclude anaemia.

The questionnaire was divided into four categories, i.e. general information, and the use of blood glucose tests, nitrite tests and haemoglobin tests. All questions were close-ended, with in some cases the opportunity to add comments. In several cases, multiple answers could be given. The complete questionnaire is presented in appendix 1.

### 2.2 Study population, data collection and data analyses

In 2011, 4090 GP practices were registered in the Netherlands[10]. A random sample of 750 GP practices (18%) was drawn from the national registry of practices that is maintained by NIVEL. This register contains nearly all self-employed GPs and GPs employed by other GPs in the Netherlands.

On October 4<sup>th</sup> 2011, a letter was sent to these GP practices, with information on the aim of the study, the contents of the study, and a link to the web-based questionnaire (SurveyMonkey™). In the letter, it was clearly stated that the questionnaire should be filled out by one of the professionals who actually performed the POC tests (see appendix 2). To maximize the response, a reminder was sent to non-respondents three weeks after the first mailing.



Returned questionnaires with a valid identity – that is, the response number correlated with the response number on the letter – were included for further analysis. In the first phase of the study, descriptive statistics were used to analyse the questionnaires on demographic characteristics and on the actual use of POC tests. Secondly, the questionnaires were examined for completeness, i.e., are all questions for general information answered and are all questions related to one or more of the POC tests answered. Incomplete questionnaires were excluded from the study.

To identify the representativeness of the GP practices, the differences between the distribution of practice types across the random sample and within the group of GP practices that returned the questionnaire were analysed, using the chi-square test. The difference was considered to be statistically significant if  $p < 0.05$ . The analyses were performed using the Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics 19).

## 3 Results

### 3.1 Characteristics of the respondents

The random sample of 750 GP practices consisted of 47% solo practices and 53% duo or group practices, which correlated very well with the total population of GP practices from which the sample was drawn (46% solo practices, 54% duo or group practices (NIVEL registry)). Out of 750 GP practices, 8 were excluded from the study for the following reasons: 3 GPs indicated that they were no longer working as a GP, 3 letters were returned to sender, 1 GP could not fill out the questionnaire because of long-term sickness and 1 GP was retired. Two GPs indicated that they did not want to participate in the study. Of the remaining 740 GP practices, 111 (15%) responded by returning the questionnaires. With 111 responses, 2.7% of the Dutch GP practices are represented. No significant difference ( $p=0.548$ ) in distribution of practice types was observed between the random sample of GP practices and the GP practices that returned the questionnaire (50% solo and 50% duo or group practices).

Of the questionnaires, 60% were filled out by GPs, 35% by practice assistants, 1.8% by practice nurses and 2.7% by others (e.g. pharmaceutical assistants). Two thirds of the respondents had more than ten years of working experience. Characteristics of the respondents are summarized in table 1.

*Table 1 Characteristics of respondents (n=111)*

Demographic variables		n	(%)
Function	general practitioner	67	60
	practice assistant	39	35
	practice nurse	2	2
	Other*	3	3
Work experience	0-5 years	22	20
	6-10 years	21	19
	11-15 years	25	23
	16 years or more	43	39
Type of practice	Solo	45	41
	Solo, NHG <sup>+</sup> accredited	11	10
	Duo or group	36	32
	Duo or group, NHG <sup>+</sup> accredited	19	17

\* Pharmaceutical assistant, practice assistant as well as practice nurse; or pharmaceutical quality manager as well as practice assistant.

<sup>+</sup> The Dutch College of General Practitioners (NHG)

Although 111 GP practices filled out the questionnaire, not all questionnaires could be used for further analysis due to incomplete answers.

### 3.2 Use of POCT in GP practices

Of the 109 respondents who indicated that they used blood glucose tests, only 86 completed all questions relating to these tests. For nitrite tests, this was 97 out of 105 respondents, and for haemoglobin tests, this was 45 out of 50 respondents (Table 2). The percentages of GP practices using blood glucose tests, nitrite tests and haemoglobin tests in this study were compatible with the results of the exploratory study by Hofland [5] among 115 Dutch GPs (see the italicized percentages in Table 2).

Table 2 Use of POCT in GP practices (n=111) and completed questionnaires

POCT	Use of POCT		Completed questionnaires	
	n	%*	n	%
Blood glucose test	109	98 (91)	<b>86</b>	78
Nitrite test	105	95 (96)	<b>97</b>	87
Haemoglobin test	50	45 (55)	<b>45</b>	46
All three POCT (blood glucose+nitrite+haemoglobin)	50	45	<b>43</b>	39

\* Percentages (in *italic*) from Hofland, 2010 [5]

### 3.3 User experience with POC tests

A large part of the respondents in this study were experienced users of POC tests. More than 60% of the respondents indicated that they had experience with one or more of these POC tests for more than ten years.

The frequency of use of POC tests was high (Table 3). Nitrite tests were used on a daily basis by 95% of the respondents, 51% indicated that they used blood glucose tests daily, and 18% indicated that they use haemoglobin tests daily. Of the respondents, 69% said they used haemoglobin tests on a weekly basis.

*Table 3 Frequency of use of POC tests*

	Blood glucose test		Nitrite test		Haemoglobin test	
	N=86		N=97		N=45	
	n	(%)	n	(%)	n	(%)
Daily	44	51	92	95	8	18
Weekly	36	42	4	4,1	31	69
Monthly	6	7,0	1	1,0	6	13

### 3.4 Training of the users

Users of POC tests need training to use POC tests, in order to limit the risk of errors. In 2008, the Netherlands Society for Clinical Chemistry and Laboratory Medicine made three recommendations concerning training of users of POC diagnostic devices [7, 11]. They recommended that users must have a protocol available as part of the quality system, that they must be trained and receive a certificate when they pass their exam, and that periodical refresher courses should be introduced.

Although these recommendations were made for employees working at a hospital, they are considered relevant to all users of POC tests. The need for an exam and a certificate could be debated; however, they do provide one way to document and monitor personnel qualification, an important aspects of the quality management system.

More than half of the respondents of the study had test procedures for the blood glucose and nitrite tests that had been written specifically for their practice. For haemoglobin tests, this was 42%. In nearly all GP practices (more than 90% of the respondents), employees were instructed on how to execute POC tests before they were allowed to perform them. Instructions were given by the GP or by other professionals, for instance the practice nurse, practice assistant working at the practice (internal professionals). Of the blood glucose test users, 26% indicated that only the GPs gave instructions, for nitrite tests this was 21% and for haemoglobin tests 36%. Professionals working outside the practice (external professionals), such as the manufacturer, employees at a laboratory or a healthcare centre also gave instructions (Figure 1).

A small group of respondents (<6%) indicated that no instructions were given for the use of POC tests in the practice. Some of them stated that all practice employees using these tests were experienced, or that all employees joining the practice had to be experienced.

The percentage of respondents who indicated that the instructions were completed with an exam was low (less than 6% for each of the three tests). In general, refresher courses were hardly ever organized (for each of the three tests less than 3%). Refresher courses were organized, to a small extent, when the tests or instructions for use were changed (blood glucose tests 28%, nitrite tests 25% and haemoglobin tests 16%).

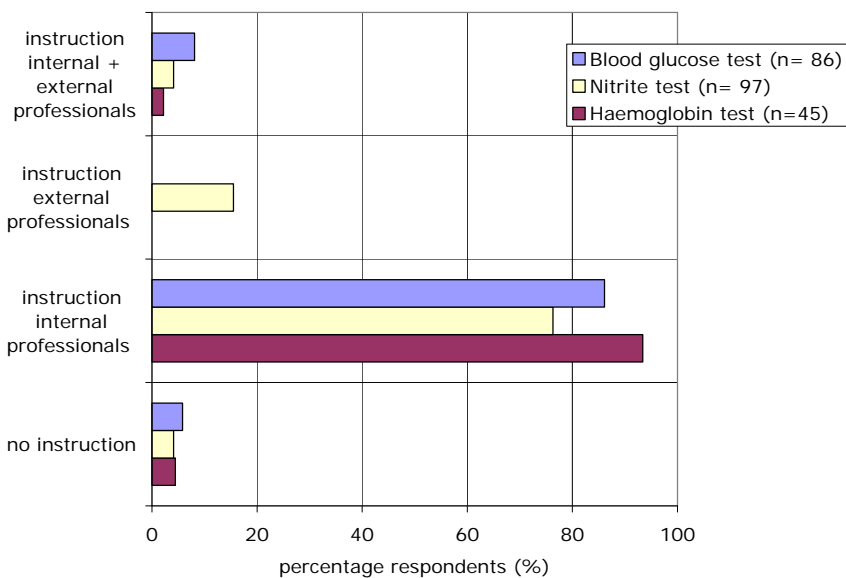


Figure 1. Employees who give instructions for the use of POC tests. Internal professionals are employees working at the practice, e.g. GP, practice assistant; external professionals are the manufacturer of the POC test, and employees at a laboratory or a healthcare centre.

### 3.5 Pre-analytical phase

The pre-analytical phase starts at the moment POC tests are being delivered to the GP practices. Upon receiving a POC test and when making preparations before using the test, several control measures are applicable, for instance, checking the expiry date of test strips and storing the test strips under the correct conditions.

Results for the control measures undertaken by GP practices are summarized in Figure 2. Control measures that are only applicable for the blood glucose tests and haemoglobin tests, are not included in Figure 2, but are described in the text.

#### 3.5.1 General control measures for the three tests

The expiry date of the test strips, was checked by almost all the respondents (>90%) upon receiving the tests. This aspect was checked to a lesser extent

before actual use of the test (<75%). The majority (>75%) of the respondents instructs the patient (e.g. on diet, on how to collect a urine sample) before they use the tests.

Less attention was paid to the control measures: checking the storage conditions of the test strips, checking whether the test strips were clean and undamaged and checking whether the packaging of the test strips was undamaged.

Very few respondents (<10%) did read the instructions for use or the test procedure written for the POC test before using it (Figure 2).

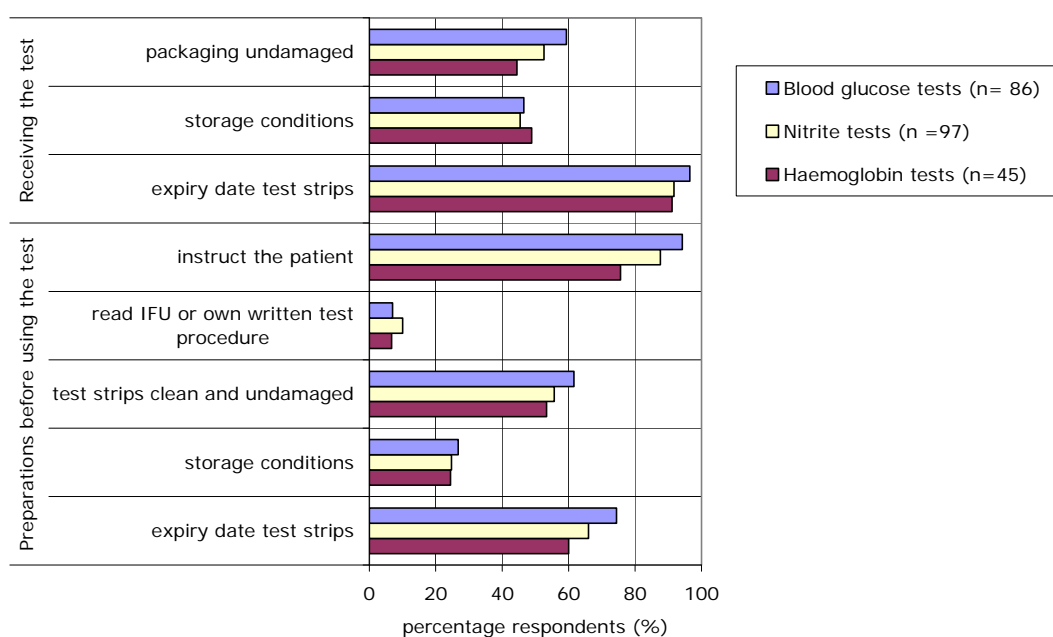


Figure 2. Pre-analytical phase: control measures for all three POC tests carried out by GP practices. Respondents could choose more than one answer.

As further control measures differ for blood and urine tests, these are described separately below.

### 3.5.2 Control measures for blood tests (blood glucose and haemoglobin)

For the blood glucose tests and haemoglobin tests, control measures regarding completeness of the equipment, checking whether the code of the test strips and meter correspond, and calibration and maintenance of the equipment are applicable:

- Around 50% of the respondents using blood glucose tests and haemoglobin tests checked completeness of the equipment.
- An important control measure is checking whether the code of the test strip and meter correspond. Several cases are known in which incorrect

blood glucose levels were obtained with test strips which did not correspond with the blood glucose meters [12]. Of the respondents using blood glucose meters 51% and of the respondents using haemoglobin meters 44% paid attention to this aspect. Some of the respondents answered that checking the code of the test strips and meter was not necessary because of new types of meters.

- Calibration and maintenance of the meters must be carried out periodically to gain reliable test results. Only 20% of the blood glucose test users and 22% of the haemoglobin test users paid attention to calibration. And only 26% of the blood glucose test users and 24% of the haemoglobin test users paid attention to maintenance.

One of the respondents stated that calibration and maintenance was performed on a yearly basis and not every time before they executed a test. Another one added the remark that they performed periodical checks.

### 3.5.3 *Types of urine samples accepted for nitrite tests*

For GPs using nitrite tests, an extra question regarding the acceptance of urine samples was included in the questionnaire, because the outcome of a nitrite test strongly depends on the quality of the urine sample, which is usually collected by the patient at home. The Dutch NHG-standard on urinary tract infection describes which type of urine samples are acceptable [8]. No special precautions are necessary when collecting a urine sample. However first morning samples are preferred as it is most concentrated, i.e. has stayed long enough in the bladder for nitrite to be formed by microorganisms. An unreliable result will be obtained if urine samples are tested which are preserved at room temperature for more than 2 hours or more than 24 hours in a refrigerator, due to propagation of bacteria.

Of the 97 respondents, 87% (n=84) indicated that they only accepted first morning samples and 13% (n=13) indicated they accepted all types of urine samples. Of the respondents who accepted only first morning samples, 58% specifically indicated that they accepted first morning samples that were collected at a maximum of two hours before actual testing.

Some of the respondents added the following remarks:

- Three of the respondents said that they accepted all types of urine samples if a patient had serious complaints.
- One respondent answered that they accepted all types of urine samples, however if the sample was positive and older than two hours, a new sample was requested.

- All urine samples were accepted if they were produced in a sterile container (n=1).
- One respondent accepted urine samples stored for at least four hours in the bladder.
- And two respondents accepted urine samples which were directly produced at the practice (n=2).

### 3.6 Analytical phase

Important key elements for the analytical phase are patient identification, hygienic procedures and blood sample handling.

#### 3.6.1 *Patient identification*

Patient misidentification is a major patient safety issue in health care [13].

A large number, more than 75%, of the respondents paid attention to patient identification (blood glucose tests 77%, nitrite tests 85% and for haemoglobin tests 78%).

#### 3.6.2 *Hygienic procedures when using blood tests*

Universal hygienic precautions to protect the patient and the professional to infectious materials when collecting a blood sample are washing hands before and after testing a patient and putting on gloves before collecting blood samples, but also washing or disinfecting the patients' finger before collecting a blood sample [14, 15]. These hygienic precautions are also important in order to prevent contaminants on the hands (e.g. food residues) interfering with the test results (chemical hygiene)[16]. A relatively large number of respondents in this study did not pay attention to these hygienic procedures (Figure 3). Only 50% of the respondents who used blood glucose tests and 38% of the haemoglobin test users washed their own hands before taking a blood sample. Less than 20% of the respondents indicated that they wear gloves<sup>1</sup>. Disinfectant was used by less than 20% of the respondent. In addition, only a small number of the respondents washed and/or disinfected the patients' fingers. One respondent mentioned that they specifically did not disinfect the patients' fingers.

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<sup>1</sup> Twelve percent of the blood glucose test users and nine percent of the haemoglobin test users answered that they wash their hands and wear gloves before taking a blood sample.



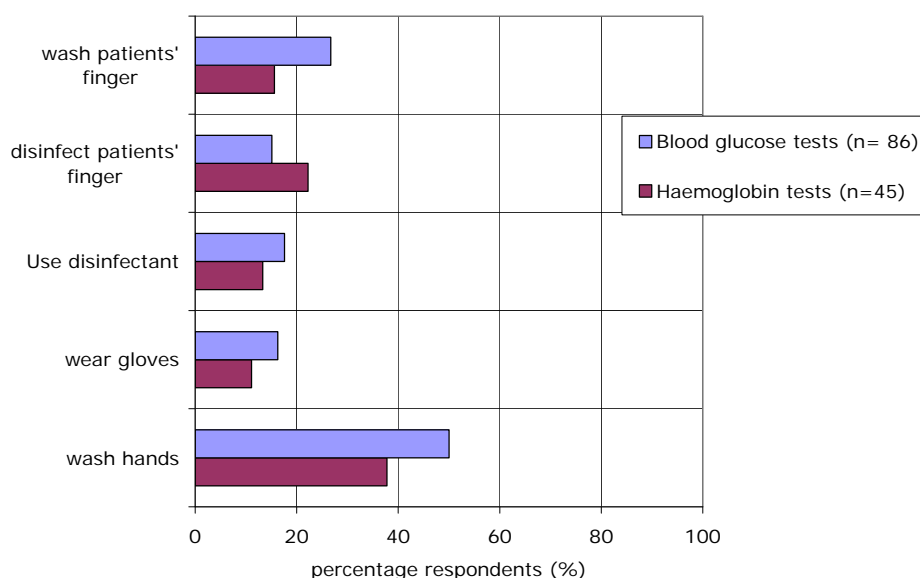


Figure 3. Analytical phase: hygienic measures. See also footnote 1, page 23. Respondents could choose more than one answer.

### 3.6.3 Sample handling when using blood tests

When collecting a blood sample from the finger, the first drop of blood should be wiped away, as this first drop tends to contain some tissue fluid. The same applies to drops obtained by firmly squeezing the blood out of the finger. Tissue fluid in the blood sample will alter the test results [17].

More than half of the respondents indicated that they both removed the first drop of blood and took care to prevent pushing the blood out of the finger when collecting a blood sample (blood glucose tests 55% and haemoglobin tests 56%). Of the blood glucose test users 39% and of the haemoglobin test users 36% answered that they removed the first drop of blood before they filled the test area or that they took care to prevent pushing the blood from the finger near the puncture site<sup>2</sup>. Of the blood glucose meter users 6% and of the haemoglobin test users 9% did not pay attention to either of these aspects (Figure 4).

<sup>2</sup> Of the 39% of the blood glucose users, only 29% remove the 1<sup>st</sup> drop of blood and only 10% took care to prevent pushing the blood from the finger near the puncture site, for the 36% haemoglobin users this was 29% and 7%.

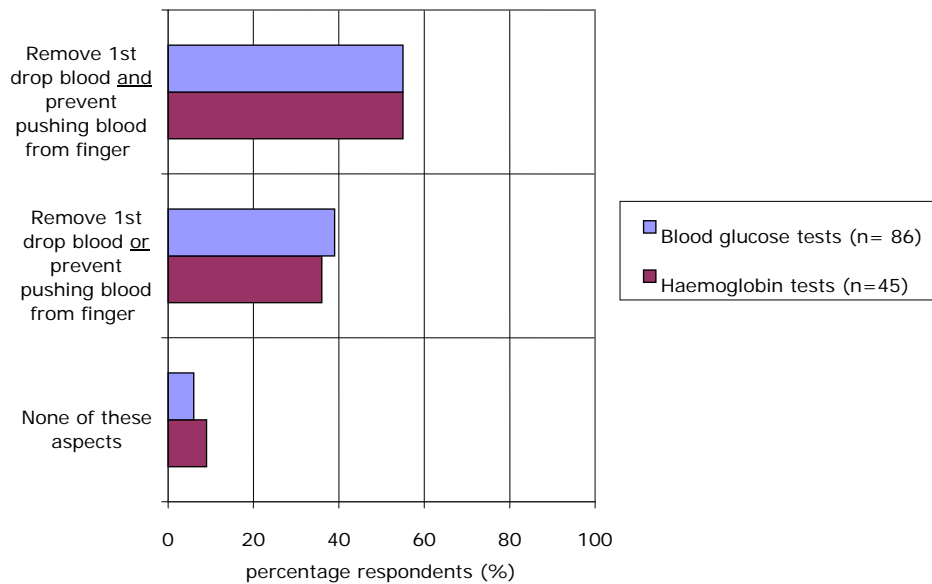


Figure 4. Analytical phase: collecting a blood sample. See also footnote 2, page 24. Respondents could choose more than one answer.

To obtain reliable test results, the test area of the test strips for blood glucose and haemoglobin must be completely filled. Many users, 88% for blood glucose and 82% for haemoglobin, indicated that they did pay attention to this aspect.

### 3.7 Post-analytical phase

The post-analytical phase contains three key elements: recording of test results, control measures and actions in case of a device failure, and control measures and actions regarding interpretation and evaluation of the test results. Test results should be recorded on paper or in electronic format in the practice's electronic health record (EHR) system. This way, a GP remains informed on the status of the patient.

#### 3.7.1 Recording test results

All respondents recorded POC test results:

- A vast majority of the respondents entered the test results manually in their EHR system (blood glucose tests 92%, nitrite test 89% and haemoglobin test 87%).
- Some respondents used a registration system in which tests result were recorded via an electronic link between the device and their EHR system (blood glucose tests 12%, nitrite test 11% and haemoglobin test 13%).
- A small number (<6%) of blood glucose test users and nitrite test users recorded the test results manually in the paper dossier of the patient or on a specific paper form for test results.

### 3.7.2 *Interpretation of test results*

A GP has to interpret the test results, so that he can make a decision on further treatment. Problems arise when a device failure occurs or when test results conflict with the symptoms. Device failure can lead to false test results or yield no results at all. In addition, if a test result conflicts with the observed symptoms, a GP must keep in mind that it is possible that the test result is false. Therefore, control measures and actions to minimize the risk of obtaining false test results are important. Actions to take, when the above-mentioned problems arise, are described in the literature [7-9, 18]. Some examples are:

- Repeat test with new sample.
- Repeat test with another test
- Contact manufacturer.
- Refer a patient to a laboratory for further tests.

#### Control measures and actions in case of device failure (for all three tests)

As shown in Figure 5, more than 75% of the blood glucose test users and haemoglobin test users indicated that they repeated the test with a new sample if device failure occurred. Of the nitrite test users, 32% repeated the test with a new urine sample, whereas 52% indicated they repeat the test with the same urine sample.

Respondents paid less attention to the following control measures and actions in case of a device failure (Figure 5):

- Only a few respondents, 7% for blood glucose test and 9% for nitrite test refer the patient to a laboratory. For the haemoglobin test users this was 44%.
- The manufacturer of the test strips was contacted by a very low number of the respondents: 2% for blood glucose tests, 1% for nitrite tests and 9% for haemoglobin tests.
- Repeating the test with another POC test was done by 40% of the respondents using blood glucose tests, and by less than 5% of the respondents who used nitrite and/or haemoglobin tests.
- The expiry date of the test strips were checked by 40% of blood glucose test users, 32% of nitrite test users and 44% of the respondents who used haemoglobin tests.
- Some respondents indicated that they never experienced a device failure: for blood glucose tests 17% and haemoglobin tests 13%; for nitrite test users this was 36%.

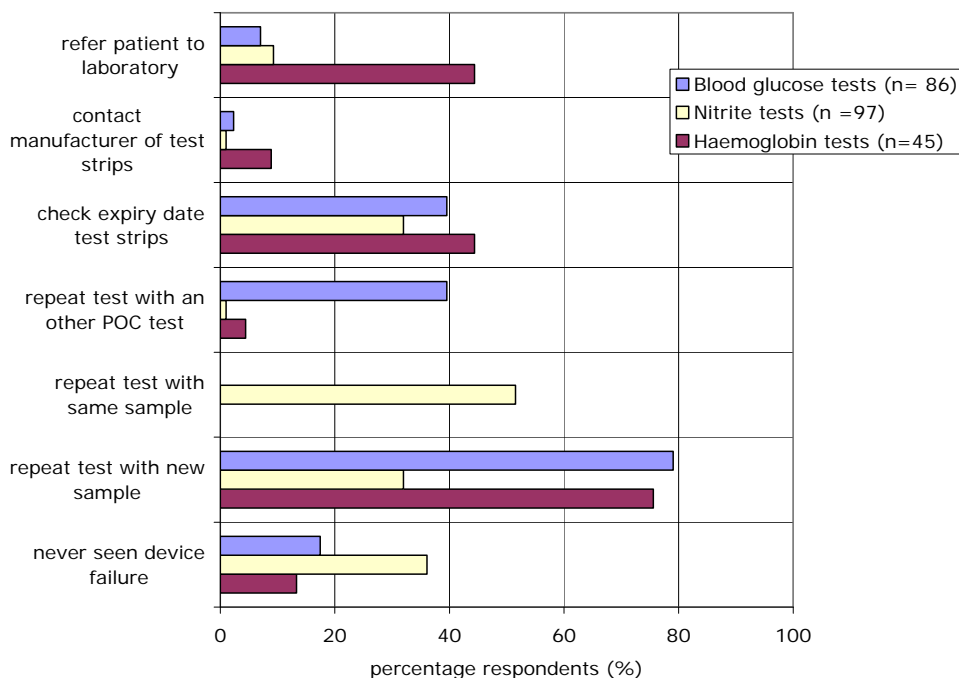


Figure 5 Post-analytical phase: control measures and actions in case of device failure. Respondents could choose more than one answer.

#### Extra control measures and actions in case of device failure (for blood tests)

In case of a device failure for the blood tests, a relatively small number of the respondents paid attention to:

- Checking the meter (56% blood glucose test, 38% haemoglobin test).
- Checking whether the test strip was inserted correctly (49% blood glucose test, 47% haemoglobin test).
- Checking whether the test area of the test strips was completely filled (55% blood glucose test, 58% haemoglobin test).
- Collecting a blood sample by venipuncture and sending it to a laboratory (blood glucose tests 4% and haemoglobin tests 18%).
- Reading the instructions for use to identify the error and find solutions for the problem (less than 3% of the blood test users).

#### Extra control measures and actions in case of device failure (for nitrite tests)

In case of a device failure for the nitrite tests, a relatively small number of the respondents paid attention to:

- Sending the urine samples to a laboratory (16%).
- Examining the sediment of the urine sample (8%).

- Taking a dipslide<sup>3</sup> sample [19] to determine if there was a bacterial infection.

One nitrite test user (1%) answered that he/she did not take any action following device failure.

#### Control measures and actions in case test results conflict with symptoms

When test results conflict with the symptoms, one or more checks and actions may be appropriate, such as checking the test equipment, checking the storage conditions and the expiry date of the test strips, repeating the test or using another POC test, or sending a blood sample to a laboratory for analysis [7]. Results are presented below per type of POC test.

#### Blood glucose tests

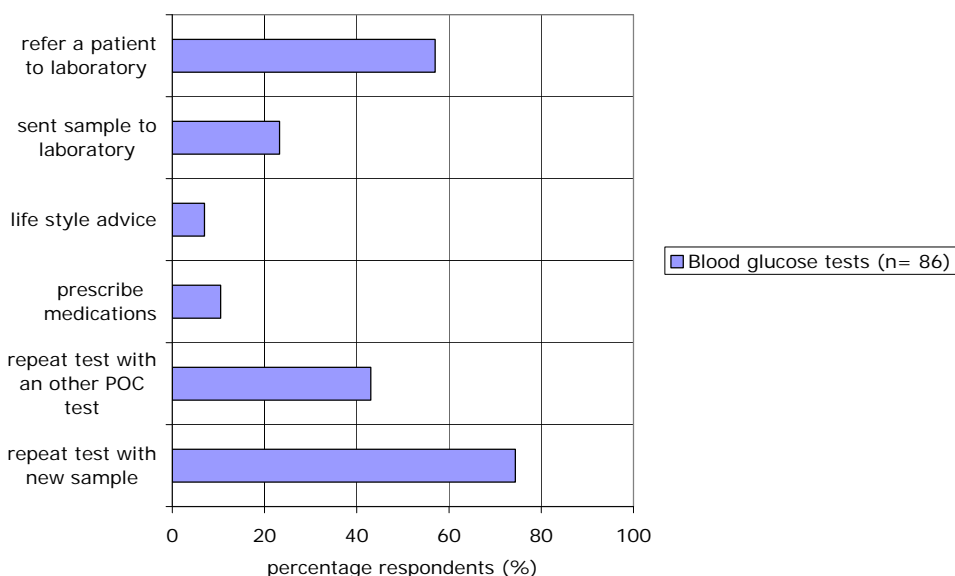
The respondents using blood glucose tests were asked which combinations of test results and clinical symptoms lead to action:

- Ninety-eight per cent of the respondents indicated that they always take action when the measured blood glucose levels were high, even when no symptoms were observed.
- Forty-three per cent would take action if clinical symptoms were observed while the measured blood glucose levels were normal.
- And eighty-four per cent of the respondents would take actions when the measured blood glucose levels were low and symptoms were observed. Without symptoms, this amounted to fifty-eight per cent.

Furthermore, respondents were asked which control measures and actions they undertook following discrepancies between test results and symptoms. Forty-seven per cent of the respondents repeated the test in case test results conflicted with symptoms. Forty-three per cent indicated that they repeated the test using another POC test. More than half of the respondents (57%) referred a patient to the laboratory and 23% collected a blood sample by venipuncture and did send this sample to the laboratory. The test strips and/or the meter were checked by 45% of the respondents. Of the respondents 11% said that they prescribed medication and 7% gave life style advice. Results are summarized in Figure 6.

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<sup>3</sup> A dipslide device is a plastic paddle coated on both sides with agar media. Dipslides are inoculated by dipping the agar-coated slides in the urine sample, where they are incubated at 37°C for 18-24 hours. After incubation the amount of bacterial colonies is determined and compared to a model chart provided by the manufacturer of the dipslide device [19].



*Figure 6 Post-analytical phase: Control measures and actions in case blood glucose test results conflict with symptoms. Respondents could choose more than one answer.*

Some respondents stated other control measures or actions. One per cent checked the test area, expiry date and storage conditions. And two per cent indicated that they consult the GP in case test results conflict with symptoms. One of the respondents indicated that he/she did not know which control measures and actions to take in case test results conflict with symptoms.

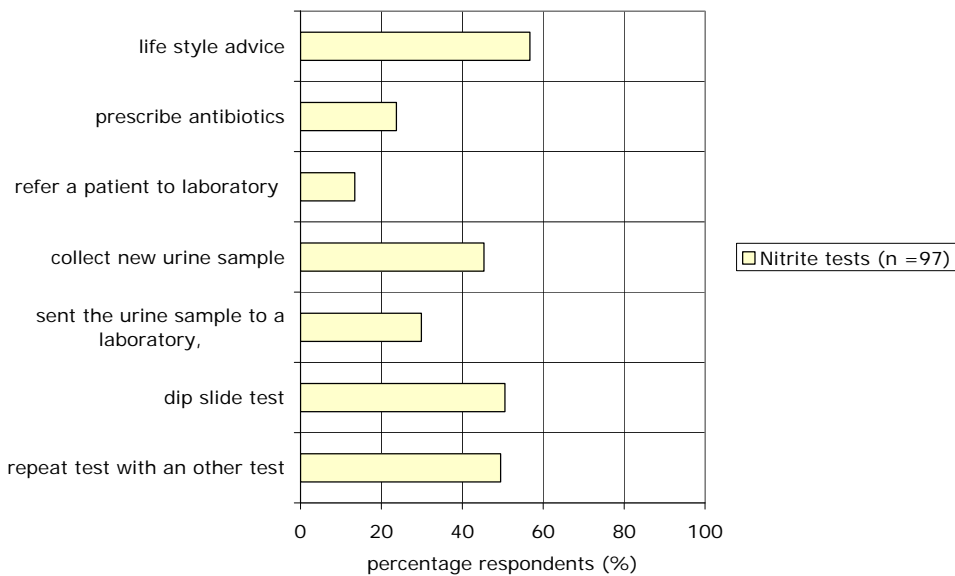
#### Nitrite tests

When a urinary tract infection is suspected by the GP, a nitrite test will be performed. If the result of the nitrite test is negative, whereas the clinical signs point towards an infection, a dipslide test is recommended [8]. Of the respondents who used nitrite tests, 51% indicated that they performed a dipslide test (Figure 7).

Other actions that responders mentioned were:

- Repeating the test with another POC test (50%).
- Sending the sample to a laboratory (30%).
- Collecting a new urine sample (45%).
- Referring a patient to the laboratory (13%).
- Almost a quarter of the respondents (24%) indicated that they prescribed antibiotics in combination with one or more of the above-mentioned actions.
- And 57% of the respondents answered that they gave life style advice to the patients.

- One of the respondents answered that he/she prescribed antibiotics and gave life style advice if a patient did have the symptoms of a urinary tract infection and the nitrite test results were negative.
- Two per cent of the respondents indicated that no actions were taken when test results did not correspond with clinical symptoms. Results are presented in Figure 7.



*Figure 7 Post-analytical phase: Control measures and actions in case nitrite test results conflict with symptoms. Respondents could choose more than one answer.*

Respondents using nitrite test were also asked what kind of action they took when nitrite test results were positive:

- Prescribing antibiotics (95%)
- Giving life style advice (55%)
- Sending a sample to a laboratory (22%)
- Repeating the test with another POC test (21%)
- Performing a dipslide tests (16%)
- Referring a patient to a laboratory (9%)
- Collecting a new urine sample (8%)

Four per cent of the respondents indicated that further actions depended on the type of patient. For instance if the urine sample is from a male, the urine will be sent to a laboratory for further analysis, because urinary tract infections in males are less common than in females. Other aspects mentioned by respondents were: performing a dipslide test if relapse occurred (2%), sending the urine sample to a laboratory to determine antimicrobial resistance if

antibiotics did not work (1%), checking the urine sediment in view of complaints made by the patient (1%), consulting GP (1%), and checking the sediment and then consulting the GP regarding prescribing antibiotics (1%).

#### Haemoglobin tests

The main purpose of haemoglobin tests is to determine whether a patient has anaemia. Possible causes of anaemia are countless and they may be either serious or innocent (e.g. due to an unbalanced diet). Therefore, a GP always has to perform an accurate anamnesis to determine the possible causes of the anemia [20]. Respondents indicated various potential follow-up actions if the haemoglobin levels deviate from standard levels, depending on the clinical condition of the patient:

- referring the patient to a specialist (60%); and/or
- prescribing or adjust medication (51%); and/or
- repeating the test (44%); and/or
- checking the meter (27%); and/or
- inquiring about the patient's diet (20%); and/or
- consulting the GP (9%); and/or
- referring a patient to a laboratory (7%); and/or
- using another meter (7%).





## 4 Discussion and conclusions

The objective of this explorative study was to investigate how patient safety aspects relating to the use of POC tests are managed by GP practices in the Netherlands. To obtain information on this subject, a survey was performed among 750 GP practices of which 15% (n=111) participated in the study. Two thirds of the respondents were professionals with over ten years' work experience, and more than 60% of the respondents had experience with POC tests for more than ten years. The frequency of using POC tests was high, for instance nitrite tests were used on a daily basis by 95% of the respondents. These findings indicate that a majority of the respondents of this study were experienced professionals who used POC tests on a regular basis.

The percentages of GP practices using blood glucose tests, nitrite tests and haemoglobin tests in this study were comparable with the results of the exploratory study of Hofland [5] among 115 Dutch GPs. This confirms that these three POC tests are used by the vast majority of the Dutch GP practices.

In the letter sent to the GP practices, it was clearly stated that the questionnaire had to be completed by personnel who actually performed the POC tests. As it is commonly known that POC tests are mainly performed by GP assistants or practice nurses, it is noteworthy that 60% of the questionnaires were completed by GPs. Therefore, it is quite possible that the questionnaire may not always have been completed by the target population of this study. It is expected that this is of minor influence on the results of this study, because GPs are ultimately responsible for managing patient safety related aspects and therefore should be well informed on how POC tests are used in their practice.

Some caution must be taken when extrapolating the results of the study to the total population of Dutch GP practices. Although the distribution of practice types of the study sample was similar to the population of GP practices from which the sample was drawn, the response rate of GP practices in this study was low. With 111 responses, just 2.7% of the Dutch GP practices of the Netherlands are represented. The low response could be caused by the high work pressure of GPs and/or because the questionnaire was too extensive. In addition, a factor contributing to a lower response might be that at the time the letter for the survey was sent to the GP practices, the GPs went on strike over cuts in the primary care budget. Furthermore, the results may be biased by socially desirable responses, differences in interpretation of the questions and differences between respondents versus non-respondents. For instance, it is possible that responders who filled in the questionnaire used POC tests

frequently, whereas the non-respondents did so less. The low response together with the possible bias in the results may lead to an overestimation or underestimation of the results when extrapolating. Nevertheless, the results of this study give us a good indication on how Dutch GP practices, included in this study, manage patient safety aspects related to POCT.

**Main conclusion:**

Results of the study indicate there is room for improvement in the management of patient safety aspects relating to the use of point-of-care tests by Dutch GPs. Although some key requirements were found to be largely adopted by the GP practices, shortcomings were observed in important aspects, such as hygienic measures to prevent erroneous results, training, quality control measures and actions following test results.

#### **4.1 Training**

Although training on using POC tests was given in almost all GP practices, refresher courses were hardly ever organized, even when the test or the instructions for use were changed.

Approximately half of the GP practices had a test procedure written specifically for their practice. Presumably, the other respondents used the instructions for use supplied by the manufacturer. This can pose certain risks as the instructions for use of POC tests are not always complete, e.g. not addressing instructions in the event of damage of the protective package [21]. In addition, only a very low number of the respondents indicated that they read the test procedure written specifically for their practice or the instructions for use of a POC test before they executed a POC test. Considering the number of respondents who used POC tests on a regular basis, this is understandable. However, the lack of refresher courses and the fact that part of the respondents did not have a test procedure written specifically for their practice is a cause for concern. Errors in using the test may be introduced gradually and go unnoticed, and experiences and problems are not periodically discussed and evaluated [22]. This indicates that part of the respondents do not have a systematic approach to prevent errors and that patient safety aspects are not always guaranteed.

**Conclusion:**

Training on using POC tests is given in almost all GP practices; however, important follow-up activities, such as refresher courses and using a regularly updated test procedure, written for that particular practice, are hardly ever organized.

## 4.2 Pre-analytical phase

More than 90% of the respondents checked the expiry date of the test strips (for all three tests) as soon as these materials are delivered to the GP's office.

However, less attention was paid to other important aspects, such as storage conditions and possible damage to the packaging. Environmental influences, for instance direct sunlight and humidity do have an effect on the stability of the chemicals on test strips [23]. So checking storage conditions and the packaging on damage are important control measures.

A small number of respondents (20%-26%), using blood glucose and/or haemoglobin meters did check whether the meter was calibrated or generally maintained. Neglecting calibration and maintenance of equipment can cause erroneous outcomes of the measurement [24]. Because POC tests in general are often carried out by individuals not previously accustomed to POCT, the need for performing instrument maintenance and calibration may often be viewed by these users as being the responsibility of someone else [1]. However, it is noteworthy that in this study a large number of the respondents were not inexperienced individuals, but individuals who had used POC tests on a regular basis for a considerable amount of time. Furthermore, as calibration and maintenance are important aspects to obtain reliable test results, both aspects, if applicable, should be incorporated in the practice routine.

The outcome of a nitrite test strongly depends on the quality of the urine sample. Urine samples must be collected in a clean sterile container to prevent the risk of contamination resulting in false positive or negative results. Also, the use of vitamin C or antibiotics may result in false negative results [8, 25, 26]. Therefore, it is important to instruct the patients on how to collect the urine sample and to request information on the patient's diet and medication. Furthermore, first morning samples are preferred, as these are most concentrated and have stayed long enough in the bladder for nitrite to be formed by microorganisms. False negative results may occur when the urine has not remained in the bladder for 4 to 6 hours [25]. When the nitrite test is not performed immediately, the urine sample must be stored in a refrigerator, but no longer than 24 hours. Storing the urine samples at room temperature or in a refrigerator for over 24 hours may yield misleading results due to multiplication of the bacteria.

Most respondents instructed the patients with respect to the collection of the urine sample. In general, most respondents indicated that only first morning samples were accepted. Some respondents accepted all types of urine samples when a patient had serious complaints, which pointed towards a urinary tract

infection. In these cases it can be assumed that serious clinical symptoms outweighed the quality of the urine sample and that the nitrite levels are high regardless of the type of urine sample. In addition, these respondents also specified that if the results of the nitrite tests were negative, additional tests were performed, such as testing the urine sample with another POC test and/or testing the urine sample with the urine dipslide test.

**Conclusion:**

Results of this study show that the quality aspects related to urine samples for nitrite tests are correctly adopted by the respondents of this study. However, insufficient attention is paid to control measures, such as checking storage conditions, packaging, calibration and maintenance in the pre-analytical phase with regard to the use of blood glucose tests, haemoglobin tests and nitrite tests.

### **4.3 Analytical phase**

The majority of the respondents of the study paid attention to patient identification. Attention was less frequently observed for other safety aspects relating to the analytical phase. Only a small number of the respondents indicated they wash/disinfect hands and wear gloves, in order to protect the patient and the professional against transfer of infectious materials and to exclude interfering substances when taking a blood sample. About half of the respondents using blood glucose tests and less than 40% of the haemoglobin test users only washed their own hands before taking a blood sample. In addition, less than 20% of the respondents answered they only wear gloves when taking a blood sample for glucose or haemoglobin testing, and also less than 20% of the respondents only disinfect their own hands before taking a blood sample.

Washing and/or disinfecting the patient's finger before blood sampling by finger-prick was done by less than half of the respondents. One of the respondents stated that the patient's finger was never disinfected. Probably this respondent wants to prevent contamination of the blood sample with disinfectant. In recent years, several reports on the lack of chemical hygiene leading to erroneous test results have been described [16, 24]. Contamination with sugar, orange juice, et cetera, gives erroneous results and may subsequently lead to wrong decisions on e.g. insulin dosing. It is therefore recommended that professionals who take the blood sample, wash their hands as well as the patient's finger to prevent chemical interference. To prevent the transfer of infectious materials, the professional should also wash hands or use disinfectants and wear gloves [15, 27]. After rinsing with clean water to remove soap residues or using

disinfectants, the professional's and the patient's hands must be dried, to prevent diluting and contaminating the blood sample.

When collecting a blood sample from the finger, the first drop of blood should be wiped away, as this first drop tends to contain some tissue fluid. The same applies to drops obtained by firmly squeezing the blood out of the finger. Tissue fluid in the blood sample will alter the test results [17]. More than half of the respondents using blood glucose or haemoglobin tests paid attention to removing the first blood drop and not squeezing the finger to obtain a blood sample.

**Conclusion:**

Almost all respondents in this study pay attention to patient identification. Also more than half of the respondents pay attention to the sample handling procedures: removing the first drop of blood after a finger prick and not squeezing the finger to obtain a blood sample.

Respondents paid less attention to (chemical) hygienic precautions, such as washing their own hands, wearing gloves, and washing or disinfecting the finger of the patient.

#### **4.4 Post-analytical phase**

The test results have to be recorded and interpreted, so that the GP can make a clinical decision on further treatment. A problem arises when test results are not recorded, when device failure occurs or when test results conflict with the symptoms. For instance, a device failure can lead to false test results, or yield no results at all. Therefore, appropriate control measures and actions are to be taken. [7-9, 18].

Test results should be recorded on paper or in electronic format in the practice's electronic health record (EHR) system. This way, a GP keeps informed on the status of the patient. All respondents indicated they recorded test results. A vast majority of the respondents entered the test results manually in their EHR system. A small number of respondents recorded the test results manually in the paper dossier of the patient or on a specific paper form for test results. Some respondents used a registration system in which test results were recorded via an electronic link between the device and their EHR system. Although using an electronic link reduces the risk of human errors, for instance typing errors or using inappropriate units, data transfer through an electronic link can also go wrong. Whichever recording method is used, it should be noted

that recorded test results should always be checked for inconsistencies in information transfer [13, 18].

Several respondents indicated that they repeated the test if device failure occurred. Other options, such as contacting the manufacturer or referring a patient to a laboratory, were chosen less often. If the manufacturer is not informed of device problems, he does not have the opportunity to improve the device or instructions for use, whatever is applicable, to ensure the problem does not recur.

If test results conflict with the observed symptoms, a GP must consider the possibility that the test results are false.

A large number of the respondents using blood glucose tests indicated that high blood glucose levels always lead to action, even when no symptoms were observed. In addition, more than half of them would take action if the blood glucose levels were too low and no symptoms were observed. It appeared that many respondents trust the test result blindly. On the other hand, only a very small percentage of the respondents using blood glucose test said that they prescribed medication or give life style advice if test results conflicted with the symptoms. And a large number of them repeated the test with a new sample or referred the patient to a laboratory when test results and symptoms conflicted. This shows that a large part of the GP practices already take the appropriate steps to manage patient safety aspects relating to the interpretation of test results obtained with blood glucose POC tests.

For the nitrite test, the GP practices were less precise when test results conflict with symptoms. Although most respondents took extra measures, such as taking a dipslide test or repeating the test, almost a quarter of the respondents immediately prescribed antibiotics even though nitrite test results were negative. It must be noted that these respondents also indicated they simultaneously took other actions, for instance performing a dipslide test. The high percentage of respondents who prescribe antibiotics when nitrite test results were negative and symptoms were positive may partly be explained by the NHG standard for urinary tract infections [8]. This standard provides the option to prescribe antibiotics for a defined patient population if symptoms point toward a urinary tract infection, even without performing a test. However, as antibiotic resistance is a worldwide problem [28], GPs always have to carefully weigh the risks and benefits of prescribing antibiotics.

The national guideline on anaemia states that in general, anaemia is not often caused by poor nutrition in the Netherlands, because there is no shortage of food. If a GP suspects that the anaemia is caused by an unbalanced diet, the GP has to give the patient an advice on the diet to follow [20]. To do so, the GP has to inquire about the patient's diet especially where elderly people and vegetarians are concerned. Just a small number of the GP practices indicated they make inquiries about the patient's diet if haemoglobin levels deviated from standard levels. On the other hand, more than half of the GP practices immediately prescribed or adjusted the patient's medication. It appears that these GP practices blindly trust the test results from the haemoglobin tests. However, as described by Van den Bosch [29], haemoglobin meters are not always accurate. Therefore, when haemoglobin levels deviate from the standard levels it is recommended to refer a patient to specialist [20, 29]. Fortunately, 60% of the GP practices did refer patients if haemoglobin test results deviated.

**Conclusion:**

Many GP practices take appropriate actions, for instance repeating a test or referring a patient to a laboratory or a specialist if there is doubt about test results.

However, when a device failure occurs, the actions taken are limited to repeating the test. In such cases, hardly any of the respondents contact the manufacturer.

Furthermore, it is remarkable that, regardless of the worldwide problem of antibiotic resistance, almost a quarter of the respondents prescribed antibiotics when test results were negative whereas symptoms pointed toward a urinary tract infection.





## 5 Recommendations

To maintain a good quality of care and to prevent the risks of errors with POC tests, the following recommendations for general practitioners are made:

- It is recommended to expand existing general guidelines for GPs with regard to the use of point-of-care tests.
- Regular refresher courses should be considered, especially when a test or an instruction for use is changed.
- GPs should register who are qualified to perform the tests and when refresher courses were organized.
- Every practice should have a test procedure, written for that particular practice or the instructions for use of the manufacturer of the POC device as part of a quality management system, with a yearly checkup of the procedure.
- More attention is needed for control measures in the pre-analytical phase, i.e. storage conditions, checking packaging, calibration and maintenance.
- For calibration and maintenance, it is important to keep up a registration system in which is recorded who performed the calibration and/or maintenance, and when these activities were performed. Moreover, this registration must be checked every time the POC test is used.
- Users must take hygienic precautions, such as washing their hands, wearing gloves, changing gloves between patient visits, but also cleaning the patient's hand before they take a blood sample.
- To prevent the risk of errors caused by tissue fluid when obtaining a blood sample from the finger, the first drop of blood must be removed and the finger must not be squeezed to obtain a blood drop.
- Manufacturers should be informed when device failure occurs, so that they have the opportunity to improve the device or the instructions for use, as the case may be.
- In view of the antibiotic resistance problem, GPs should only prescribe antibiotics when the necessity is sufficiently substantiated.

Based on the results of this investigation, further research is recommended. It would be a useful follow-up to measure the scale of the effects of the shortcomings on patient safety. Thus, how often do erroneous diagnoses occur as a result of the observed shortcomings, or how often have shortcomings led to adverse events. Results of such research could subsequently be the basis for the development of indicators to determine which GP practices present a risk level to

patients that would definitely warrant action by the GPs and/or health inspectors.

Furthermore, since the development and introduction of POC tests for other parameters is progressing, specific patient safety aspects related to the use of such tests could be evaluated.

Moreover, POC tests are also increasingly used in institutions such as nursing homes and homes for the elderly. It is recommended to investigate management of patient safety aspects in such organizations as well.

Finally, another valuable research line would be to determine how often the use of POC tests in GP practices reduces the use of expensive clinical laboratory testing, prescription of medication or referrals of patients to hospitals.



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## Appendix 1. Questionnaire (translation of the Dutch version)

1. What is your position?

- General practitioner
- Practice assistant
- Practice nurse
- Other: .....

2. How many years have you been in your current position?

- 0 – 5 years
- 6 – 10 years
- 11 – 15 years
- 16 years or more

3. In what kind of practice do you work?

- Solo practice
- Solo practice, accredited by the Dutch College of General Practitioners (NHG)
- Duo or group practice
- Duo or group practice, accredited by the NHG

### Questions related to the use of blood glucose POC tests

4. Do you use blood glucose tests in your practice?

- Yes
- No, go to question 18.

5. Since when are blood glucose tests used in your practice?

Since |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_| (ddmmyyyy)

6. How often do you use a blood glucose test in your practice?

- Daily
- Weekly
- Monthly
- Yearly

7. Is there a test procedure for the blood glucose tests, which has been written specifically for your practice?

- Yes
- No

8. Who gives instruction to the employees on how to use the blood glucose tests?

- General practitioner
- Manufacturer
- Practice assistant
- Practice nurse
- No instructions are given (go to question 10)
- Other: .....



9. Is the instruction completed with an exam?

- Yes, we register who have passed the exam
- Yes, however we do not register who have passed the exam
- No

10. Do you organize refresher courses for the use of the blood glucose test?

- Yes, ..... times a year
- Yes, only if the tests or instructions for use were changed
- No
- Other: .....

11. Which control measures do you take when receiving new blood glucose test materials? (Multiple answers are possible)

- Check the expiry data of test strips
- Check storage conditions of test strips (e.g. temperature of storage space)
- Completeness of the test equipment
- Check if the codes of the meter and test strips correspond
- Check if the sealing of the test strips is undamaged
- None of the above, I may assume that the POC test materials are of good quality
- Other: .....

12. Which preparations do you take before performing a blood glucose test? (Multiple answers are possible)

- Give instruction to the patient (e.g. dietary advice)
- Check expiry date of test strips
- Check storage conditions of test strips (e.g. temperature of storage location)
- Check latest moment of calibration
- Check latest moment of maintenance
- Check if test strips are clean and undamaged
- Completeness of the test equipment
- Read the instructions for use
- Read the test procedure, written specifically for our practice
- Other: .....

13. Which aspect(s) do you consider when taking a blood sample from a finger prick and performing the test? (Multiple answers are possible)

- Patient identification
- Washing your hands
- Wearing gloves
- Use of disinfectant
- Washing the finger of the patient
- Disinfecting the finger of the patient
- Removing first drop of blood
- Preventing pushing blood from the finger
- Filling the test area of the test strip completely
- Other: .....

14. How do you record the test results? (Multiple answers are possible)

- Manually, in the paper dossier of the patient
- Manually, on a specific paper form for test results
- Manually, in an electronic health record (EHR) system
- Manually, as free text on the E and/or P rules of the S,O, E or P rules\* of the EHR system
- Automatically, via an electronic link between device and registry system
- Test results are not recorded
- I do not know

\* S- subjective: reason for contact, O-objective: physical exam, E- evaluation: diagnose, P- treatment plan

15. Which action(s) do you take when the blood glucose meter shows an error? (Multiple answers are possible)

- I never get errors
- Repeat the test
- Check whether the test area of the test strip is completely filled with blood
- Check whether the test strip is inserted correctly into the meter
- Check the meter (e.g. battery)
- Check expiry date of the test strips
- Contact the manufacturer of the test
- Use another meter
- Refer the patient to a laboratory
- Collect a blood sample via venipuncture and send the sample to a laboratory
- I do not take actions
- Other:.....

16. Which action(s) do you take when test results conflict with the symptoms? (Multiple answers are possible)

- Check the meter (e.g. battery)
- Repeat the test
- Use another meter
- Collect a blood sample via venipuncture and send the sample to a laboratory
- Refer the patient to a laboratory
- Refer the patient to a specialist
- Life style advice (e.g. diet)
- Prescribe or adjust medication
- I do not take actions
- Other:.....

17. Which test results and symptoms lead to action? (Multiple answers are possible)

- Glucose levels high, no symptoms
- Glucose levels high, symptoms
- Glucose levels normal, no symptoms
- Glucose levels normal, symptoms
- Glucose levels low, no symptoms
- Glucose levels low, symptoms
- I do not know

**Questions related to the use of Nitrite POC tests**

18. Do you use nitrite tests in your practice?

- Yes
- No, go to question 33

19. Since when are nitrite tests used in your practice?

Since |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_| (ddmmyyyy)

20. How often do you use a nitrite test in your practice?

- Daily
- Weekly
- Monthly
- Yearly

21. Is there a test procedure for the nitrite tests written specifically for your practice?

- Yes
- No

22. Who gives instruction to the employees on how to use the nitrite tests?

- General practitioner
- Manufacturer
- Practice assistant
- Practice nurse
- No instruction is given (go to question 24)
- Other: .....

23. Is the instruction completed with an exam?

- Yes, we register who have passed the exam
- Yes, however we do not register who have passed the exam
- No

24. Do you organize refresher courses for the use of the nitrite test?

- Yes, ..... times a year
- Yes, only if the tests or instructions for use are changed
- No
- Other:

25. Which control measures do you take when receiving the new nitrite test materials? (Multiple answers are possible)

- Check the expiry data of test strips
- Check storage conditions of test strips (e.g. temperature of storage location)
- Check if the sealing of the test strips is undamaged
- None of the above, I may assume that the POC test materials are of good quality
- Other: .....

26. Which preparations do you take before performing a nitrite test?

(Multiple answers are possible)

- Give instruction to the patient (e.g. on how to collect a urine sample)
- Check expiry date of test strips
- Check storage conditions of test strips
- Check if test strips are clean and undamaged
- Read the instructions for use
- Read test procedure written specifically for our practice
- Other,.....

27. What kinds of urine samples do you accept when a patient brings his/her urine sample from home? (Multiple answers are possible)

- First morning urine samples
- First morning samples that are collected at a maximum of two hours before actual testing.
- All types of urine samples
- I do not know
- Other,.....

28. Which aspect(s) do you consider when performing a Nitrite test? (Multiple answers are possible)

- Patient identification
- Other,.....

29. How do you record the test results? (Multiple answers are possible)

- Manually, in the paper dossier of the patient
- Manually, on a specific paper form for test results
- Manually, in the Netherlands information Network of General Practice (LINH) database
- Manually, as free text on the E and/or P rules of the S,O, E or P rules\* of the LINH database
- Automatically, via an electronic link between device and registry system
- Test results are not recorded
- I do not know

\* S- subjective: reason for contact, O-objective: physical exam, E- evaluation: diagnose, P- treatment plan

30. Which action(s) do you take when the nitrite test strip is unreadable (device failure)? (Multiple answers are possible)

- Test strips are always readable
- Repeat the test with the same urine sample
- Check the storage condition of the test strips
- Check expiry date of the test strips
- Collect new urine sample
- Use another batch of test strips
- Contact the manufacturer of the test
- Refer a patient to a specialist
- Refer a patient to a laboratory
- Send the sample to a laboratory
- I do not take actions
- Other:.....

31. Which action(s) do you take when test results conflict with the symptoms?  
(Multiple answers are possible)

- Check urine sample with other point-of-care test
- Test urine sample with dip slide test
- Send the urine sample to a laboratory
- Collect new urine sample
- Refer the patient to a laboratory
- Life style advice
- Prescribe antibiotics
- Other:.....

32. Which action(s) do you take when test results point toward a urinary tract infection? (Multiple answers are possible)

- Test the urine sample with another point-of-care test
- Test the urine sample with a dip slide test
- Send the urine sample to a laboratory
- Collect new urine sample
- Refer the patient to a laboratory
- Life style advice
- Prescribe antibiotics
- Other:.....

**Questions related to the use of haemoglobin POC tests**

33. Do you use haemoglobin tests in your practice?

- Yes
- No.

34. Since when are haemoglobin tests being used in your practice?

Since |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_| (ddmmyyyy)

35. How often do you use a haemoglobin tests in your practice?

- Daily
- Weekly
- Monthly
- Yearly

36. Is there a test procedure for the haemoglobin tests written specifically for your practice?

- Yes
- No

37. Who gives instruction to the employees on how to use the haemoglobin tests?

- General practitioner
- Manufacturer
- Practice assistant
- Practice nurse
- No instructions are given (go to question 10)
- Other: .....

38. Is the instruction completed with an exam?

- Yes, we register who have passed the exam
- Yes, however we do not register who have passed the exam
- No

39. Do you organize refresher courses for the use of the haemoglobin test?

- Yes, ..... times a year
- Yes, only if the tests or instructions for use were changed
- No
- Other: .....

40. Which control measures do you take when receiving new haemoglobin test materials? (Multiple answers are possible)

- Check the expiry date of test strips
- Check storage conditions of test strips (e.g. temperature of storage location)
- Completeness of the test equipment
- Check if the codes of the meter and test strips correspond
- Check if the sealing of the test strips is undamaged
- None of the above, I may assume that the POC test materials are of good quality
- Other: .....

41. Which preparations do you take before performing a haemoglobin test? (Multiple answers are possible)

- Give instruction to the patient (e.g. dietary advice)
- Check expiry date of test strips
- Check storage conditions of test strips (e.g. temperature of storage location)
- Check latest moment of calibration
- Check latest moment of maintenance
- Check if test strips are clean and undamaged
- Check completeness of the test equipment
- Read the instruction for use
- Read test procedure, written specifically for our practice
- Other: .....

42. Which aspect(s) do you consider when taking a blood sample from a finger prick and performing the test? (Multiple answers are possible)

- Patient identification
- Washing your hands
- Wearing gloves
- Use of disinfectant
- Washing the finger of the patient
- Disinfecting the finger of the patient
- Removing first drop of blood
- Preventing pushing blood from the finger
- Filling the test area of the test strip completely
- Other: .....

43. How do you record the test results? (Multiple answers are possible)

- Manually, in the paper dossier of the patient
- Manually, on a specific paper form for test results
- Manually, in the Netherlands information Network of General Practice (LINH) database
- Manually, as free text on the E and/or P rules of the S,O, E or P rules\* of the LINH database
- Automatically, via an electronic link between device and registry system
- Test results are not recorded
- I do not know

\* S- subjective: reason for contact, O-objective: physical exam, E- evaluation: diagnose, P- treatment plan

44. Which action do you take when the haemoglobin meter shows an error? (Multiple answers are possible)

- I never get errors
- Repeat the test
- Check whether the test area of the test strip is completely filled with blood
- Check whether the test strip is inserted correctly into the meter
- Check the meter (e.g. battery)
- Check expiry date of the test strips
- Contact the manufacturer of the test
- Use another meter
- Refer the patient to a laboratory
- Collect a blood sample via venipuncture and send the sample to a laboratory
- I do not take actions
- Other:.....

45. Which action do you take when test results show abnormal results? (Multiple answers are possible)

- Check the meter
- Repeat the test
- Use another meter
- Collect a blood sample via venipuncture and send the sample to a laboratory
- Refer the patient to a laboratory
- Refer the patient to a specialist
- Collect a new urine sample
- Inquire about the patient's diet
- Prescribe or adjust medication
- I do not take actions
- Other:.....

End of the questionnaire!

## Appendix 2. Letter sent to the GP practices (Dutch-language)

**Aan: <geadresseerde>**

Onderwerp: Diagnostische testen in huisartsenpraktijken in Nederland

Geachte Dr. ....,

Er is op dit moment weinig bekendheid over de wijze waarop diagnostische testen, zoals een bloedglucosetest (bloedsuikertest) of nitrietsticktest, binnen Nederlandse huisartspraktijken worden gebruikt.

Het RIVM onderzoekt dit in opdracht van de Inspectie voor de Gezondheidszorg (IGZ) en in samenwerking met het NIVEL en de Universiteit Twente (Health Technology and Services Research).

Graag zouden wij u willen vragen een digitale enquête in te vullen. Dit kost slechts 15 minuten van uw tijd. Hierbij is het van belang dat degene die de testen in de praktijk uitvoert, de vragenlijst invult.

Uw gegevens zullen geheel gecodeerd anoniem worden verwerkt. Voor het invullen van de enquête verwijs ik u naar het volgende webadres:  
[www.surveymonkey.nl/s/labtest](http://www.surveymonkey.nl/s/labtest)

Deze weblink zal u direct doorverwijzen naar de startpagina van de enquête. Hierbij is belangrijk dat u de enquête niet onderbreekt.

Wij willen u vragen de enquête in te vullen vóór **<dag maand jaartal>**.  
Voor eventuele vragen kunt u terecht bij **<naam onderzoeker>**.

Bij voorbaat hartelijk dank.

Hoogachtend,



.....

**C.G.J.C.A. de Vries et al.**

.....

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Cover photo: blood sample to measure haemoglobin level  
by Trudie van der Steeg, Jeroen Bosch Ziekenhuis.

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