



**Near-Patient Testing (NPT)
of coagulation time in health care institutions**

Study into the effectiveness, safety and a well-considered introduction of
Near-Patient Testing

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Preface

Many people contributed to the realization of the study and are curious about the results. I am therefore pleased to announce that the report is now available.

At the start of the study, in February 2008, it was assumed that sufficient organisations (anticoagulation clinics and health care institutions) would participate at the end of the same year to stop the inclusion of new organisations. However, as time passed it appeared that there was a long period between the moment that the interest of an anticoagulation clinic was aroused and the actual agreement with a health care institution to introduce Near-Patient Testing. This resulted in several extensions of the inclusion period, until the final date in July 2009. As the collection of the data took seven months, the last process data were collected in December 2009.

The original idea at the start of Near-Patient Testing was that if the treatment results would be disappointing, Near-Patient Testing as a treatment method would have to be discontinued. Nevertheless, 13 anticoagulation clinics and about 60 health care institutions presently use Near-Patient Testing. Some of these – 10 anticoagulation clinics and 21 health care institutions, see Appendix 1 – provided input for this scientific study by completing questionnaires and participating in telephone surveys. The response rate is a rate that many investigators can only dream of (nearly 100%). We therefore wish to warmly thank all participating organisations for their excellent co-operation during the study!

The study could not have been carried out without the support of the companies Roche and Portavita. Roche Diagnostics Nederland B.V. financed the scientific study, and Portavita B.V. made an important contribution to the data collection, the organisation of the study and the final editing of the report – by seconding Marja Kaag, Marcel Bodewitz and Pieter Terpstra. Jan Koetsenruijter carried out the statistical data processing. We express our sincere thanks for the contributions made by all involved.

The findings of the study suggest that Near-Patient Testing deserves further implementation in the treatment of anticoagulated patients. I am sure you will enjoy reading the rest of this document!

Ron van 't Land, Managing Director of Orquaz

Summary

Objective: Description of the effectiveness, safety, and conditions for the introduction of a new method (Near-Patient Testing) of monitoring patients in a health care institution with an indication for anticoagulation treatment.

Method: A non-randomised, comparative study between patients in health care institutions who underwent Near-Patient Testing (intervention group), compared with patients in health care institutions who were monitored using the traditional method (control group).

Results: In comparison with the control group, the INR values in the patients in the intervention group fell significantly more often within the therapeutic range.

Significantly fewer complications occurred in Near-Patient Testing, and vitamin K administration was significantly less often considered necessary.

A subgroup analysis was carried out into the series of INRs of patients who had previously been prescribed doses by a nursing home physician and were transferred to the anticoagulation clinic for Near-Patient Testing. The results indicate a statistically significant trend towards an improved determination of dose requirements. It is unclear whether, and, if so, to which degree, the experience of the prescribing physician plays a role herein.

The process evaluation revealed that patients, anticoagulation clinics and health care staff are very satisfied with Near-Patient Testing. The method is suitable to be implemented in the current organisation of health care institutions and anticoagulation clinics.

Conclusion: As long as adequate support is present, Near-Patient Testing in health care institutions results in at least a similar and probably an even better treatment result than the standard method. Near-Patient Testing can therefore be an effective, safe and reliable new method of monitoring residents in health care institutions with an indication for anticoagulant treatment with vitamin K antagonists, on the condition that the provided support is comparable with the well-known patient self-management support programmes.

1. Reason

Residents of health care institutions who are registered with the anticoagulation clinic, usually receive support in a traditional fashion: anticoagulation clinic staff take blood samples from the residents, the blood is examined in the laboratory, the dose of the patients is determined by the (physician of the) anticoagulation clinic and the adjusted dose is sent to the health care institution by way of a 'dosage letter'.

However, disadvantages are attached to this traditional method. Dosage letters can get lost, the patients are not always easy to locate and the communication between the health care institution and the anticoagulation clinic is not always perfect. Therefore, the Anticoagulation Clinic of Zeeland introduced 'self-measurement' in health care institutions in its region in 2006: instead of the anticoagulation clinic, staff of the health care institution measure the coagulation time themselves. The results of the measurements, the particulars, and the proposed dosage are exchanged between both organisations via a secure Internet application.

This method has important advantages: the INR (International Normalised Ratio = prothrombin time measurement) is determined in the presence of the patient (Near-Patient Testing) to enable a more rapid response in the case of a deviating result. The dosage letters are no longer mislaid, the organisation determines the time of blood sampling, finger-prick blood samples instead of venous samples are collected, and last but not least, the communication between the health care staff and the anticoagulation clinic improves considerably. Everything therefore seemed to indicate that this method improved the treatment quality.

Following adjustments of the software of the web application in order to provide even better support of the process, the question arose: would this method also be a good alternative for the current method in other regions? It soon became apparent that other anticoagulation clinics and health care institutions were also sufficiently interested in this method. Everyone acknowledged that Near-Patient Testing would enable improved chain organisation, which would probably have a favourable effect on the treatment (see Appendices 1 and 2 for the standard method and Near-Patient Testing flow charts).

In order to ensure that, apart from the logistic advantages, at least equally good treatment results are achieved with Near-Patient Testing as with the standard procedure, a scientific study was started. The study was outsourced to Orquaz, an independent consultancy firm for organisation and quality in the health care sector. The company Roche was willing to finance the study, while Portavita supported the study process by collecting data, and by organisational and editorial assistance. The aim of the study was twofold: on the one hand, demonstrate that the treatment results of Near-Patient Testing are at least as good as the standard method, and on the other hand, carry out a qualitative review of the process and the satisfaction of all those involved.

2. Method

Firstly, the most ideal study design was explored, i.e. randomisation ('drawing lots') at the level of the included health care institutions. As large numbers are necessary for this design, randomisation was no option¹. We therefore chose in favour of a design in which all health care institutions embarking on Near-Patient Testing (in the case of a positive response) were included in the study. In order to measure the effect of Near-Patient Testing on the effectiveness and safety of the treatment, we compared the treatment results with those from a control group of health care institutions which used the standard treatment method.

All new anticoagulation clinics and health care institutions that introduced Near-Patient Testing after the start of the study were requested to participate in the scientific study. Initially, all health care institutions were approached. In order to increase nationwide coverage, a maximum of two health care institutions per anticoagulation clinic were included, from the second anticoagulation clinic onward.

This yielded a total intervention group of 10 anticoagulation clinics and 21 health care institutions. This included both home care organisations and nursing homes and a combination of these. In one case the health care institution was an organisation for the support of people with a mental and/or physical impairment. In this report we refer to these different organisations as 'health care institutions'.

The data collection was carried out in two ways: by collecting the quantitative data in the database of the participating anticoagulation clinics and by means of a qualitative study (questionnaires and telephone interviews for the anticoagulation clinics and health care institutions and an oral patient survey).

2.1 Objectives

The objectives of the study are:

1. Is there a difference in outcome between Near-Patient Testing and the 'regular' procedure with regard to effectiveness and safety, measured by the following parameters:
 - a. Dosage of the patient (INR within the therapeutic range);
 - b. Number of complications;
 - c. Number of interventions with vitamin K;
 - d. Punctuality of the measurement.
2. How are the working procedures, which form the basis for Near-Patient Testing, evaluated based on the following parameters:

¹ This type of design means that multi-level analyses must be used to correct for conclusions at the individual patient level. Assuming an α of 0.05 and a β of 0.8, power analyses show that both groups in that case need about 1250 patients to be able to provide reliable conclusions. Furthermore, the multi-level character means that corrections must be made for intra-class correlation. This would require an even larger patient population.

- a. Staff training;
- b. Organisation in health care institutions:
 - 1. Number of staff members to be trained;
 - 2. Desired educational level;
 - 3. Communication with the anticoagulation clinic;
 - 4. Integration in daily routine;
 - 5. Agreements regarding powers and responsibilities;
- c. Knowledge level of the staff of the health care institutions with regard to anticoagulation;
- d. Staff satisfaction;
- e. Patient satisfaction.

During the course of the study the following objective was added:

- 3. Is there any noticeable effect in the dosing of the patient when the treatment is transferred from the nursing home physician to the anticoagulation clinic?

2.2 Study design and study population

2.2.1 Participating organisations

The anticoagulation clinics that were approached to participate in the study, work with Portavita Anticoagulation on behalf of the self-measurement patients. All anticoagulation clinics that started Near-Patient Testing were willing to participate in the study.

For each anticoagulation clinic, five health care institutions were recruited in one case, and in all other cases, one or two health care institutions were recruited. The recruitment was determined by the sequence in which agreements regarding the start of Near-Patient Testing could be made between the anticoagulation clinic and the health care institution. The inclusion period ran from May 2008 through July 2009. All health care institutions that introduced Near-Patient Testing were willing to participate in the study. A total number of 21 health care institutions were included in the study. These health care institutions constituted the intervention group.

The control group consisted of health care institutions that did not participate in Near-Patient Testing and where the patients were therefore treated by the anticoagulation clinic in the usual manner. The anticoagulation clinics that already had experience with Near-Patient Testing were the first ones to be approached for the recruitment of health care institutions for the control group. However, it was necessary for the data collection in the database of Portavita that the anticoagulation clinics concerned worked with Portavita Anticoagulation for the regular patients. This applied to five of the ten anticoagulation clinics that had already started Near-Patient Testing. Therefore, another five anticoagulation clinics were approached that had not yet started Near-Patient Testing, but did work with Portavita Anticoagulation for the regular patients. Four of these promised to participate. These nine anticoagulation clinics were requested to have data collected for the control group in two of the health care institutions (homes care organisations and/or nursing homes) in their area. This

yielded a total number of 18 health care institutions for the control group (see Appendix 3 for all organisations participating in the study).

2.2.2 Data collection

Patient data and treatment data

In order to answer the main question about the effectiveness and safety of the NPT method, use was made of the database of the Portavita record. In addition to several data regarding patients and their treatment, we analysed all INR values, their levels in the therapeutic range (above, within, or below), the number of complications and the use of vitamin K (see Appendix 4 for an overview of the collected data). The data were collected from one month after the start of Near-Patient Testing up to and including seven months after the start.

The same data of patients and their treatment were also collected for the control group. The data collection of the control group was carried out in the period of April 2009 up to and including September 2009.

Evaluation of the training, working procedures and satisfaction

In order to determine the secondary endpoints, we carried out a qualitative study by means of questionnaires and interviews. The first questionnaires were sent to the instructors of the anticoagulation clinic and the trained health care staff one month after the start. The most important subject was the content of the training. Half a year after the start, the working procedures and outcomes (including satisfaction) were evaluated by using a telephone interview. A staff member of the anticoagulation clinic and a manager of the health care institution were approached to this end. The satisfaction of the patients was measured at four organisations by a health care worker who interviewed some patients using a questionnaire (see Appendices 5 - 9 for data collection of the qualitative study).

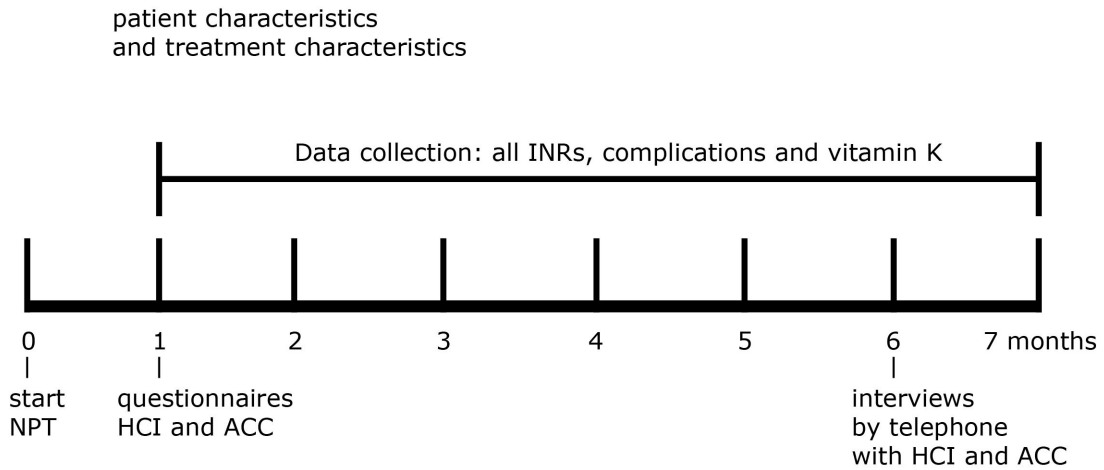
Treatment transfer from nursing home physician to anticoagulation clinic

Due to the introduction of Near-Patient Testing, the treatment was transferred from the nursing home physician to the anticoagulation clinic in several cases. In order to obtain insight into a possible effect of this transfer on the treatment outcome, all INRs of the patients concerned were collected from the moment of the start of Near-Patient Testing. As the initial INR is still a result of the dose prescribed by the nursing home physician, a treatment effect, if any, may possibly become visible in the course of the INR measurements.

2.2.3 Time schedule of data collection

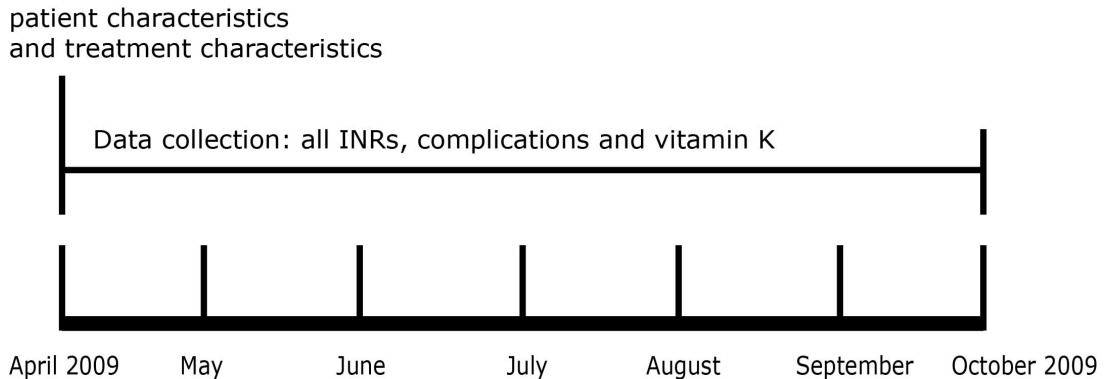
An overview of the data collection for both groups is presented in Figures 1 and 2.

Figure 1: Time schedule for data collection of intervention group (NPT)



NPT = Near Patient Testing
HCI = Health Care Institution
ACC = Anticoagulation Clinic

Figure 2: Time schedule for data collection of control group



2.3 Intervention

On behalf of the intervention, the regular method was changed to Near-Patient Testing.

Regular method

A staff member of the anticoagulation clinic visits the health care institution and takes a venous blood sample. The blood samples are taken to the lab and analysed. On the basis of the INR and additional comments (haemorrhages, etc.), dosing recommendations are drawn up. This 'dosage schedule' is sent by mail at the end of the day by an external printing company and delivered to the health care institution on the following day (see Appendix 1 for the flow chart).

Near Patient-Testing

The health care worker takes a finger-prick blood sample and measures the INR in the presence of the patient. Both the INR and comments, if any, are entered into the patient record of Portavita Anticoagulation. The anticoagulation clinic also has access to this programme and processes the INR and the comments in the patient record, after which the dosage schedule is determined. At the end of the day, the staff member of the health care institution logs in again and prints the dosage schedules (see Appendix 2 for the flow chart).

In order to apply the method correctly, staff members of the health care institutions were trained by the anticoagulation clinic in three areas: 1. knowledge of coagulation and anticoagulation treatment; 2. use of the CoaguChek and 3. Digital Logbook (patient access) of the Portavita application.

As Near-Patient Testing actually involves a delegation of tasks and expertise from the anticoagulation clinic to the health care institution, agreements were made prior to Near-Patient Testing with regard to working procedures, the distribution of powers and responsibilities and also with regard to financial compensation for the health care institution for the activities to be carried out.

2.4 Endpoints

The endpoints are reported on two levels:

1. Primary endpoints: effectiveness and safety

For the *effect*, we focused on the dosage of the patient, in particular on the INR (within or outside the therapeutic range).

On behalf of study question 3 (the effect on the treatment of the transfer of the dose determination to the anticoagulation clinic) all successive INRs were collected after the start of Near-Patient Testing, from the nursing homes where the dose was previously determined by the nursing home physician.

In order to assess the safety, we studied the number of complications and the number of times vitamin K had to be prescribed.

Furthermore, we also examined the punctuality of the measurement in this context. A 'timely' measurement is a measurement that is performed before or on the date that is the outcome of 'blood sampling date + tolerance period'.

2. Secondary endpoints: process, implementation and satisfaction

What are the experiences both of the anticoagulation clinic and the health care institution with regard to the following parameters:

- a. Training of the staff members;
- b. Educational level;
- c. Continuity;
- d. Number of staff members to be trained;
- e. Communication with the anticoagulation clinic;
- f. Integration in daily routine;
- g. Agreements regarding powers and responsibilities;
- h. Satisfaction of the staff members;
- i. Anticoagulation knowledge level of the staff members of the health care institutions;
- j. Satisfaction of the patient.

2.4.1 Statistical processing

Analyses were carried out with SPSS 16.0. The tests used are an ANOVA for the differences in means and a χ^2 test for differences in the number of patients between the control group and the intervention group, as in the INR percentages within the therapeutic range, the presence of complications and the use of vitamin K. The course of the INRs of patients whose dose had previously been determined by the nursing home physician, were analysed using a logistic regression model. The endpoints associated with the secondary endpoints are of a descriptive nature.

3. Results

3.1 Study population

In order to be able to provide reliable conclusions it is important that the control group can be adequately compared with the intervention group. We therefore examined several personal characteristics and treatment characteristics of both groups, see Table 1.

Table 1: Comparison of the control group and the intervention group

Variable	Type	Control Group (%)	Intervention Group (%)
Age		85,3	83
Gender	Woman	299 (68,9)	267 (70,6)
Indication	Atrial fibrillation	273 (62,9)	229 (60,6)
	Leg/pelvic deep venous thrombosis	16 (3,7)	17 (4,5)
	Pulmonary embolism of unknown origin.	15 (3,5)	6 (1,6)
	Paroxysmal atrial fibrillation	14 (3,2)	5 (1,3)
	Recurrent Dvt	13 (3,0)	5 (1,3)
	Prosthetic valve	12 (2,8)	22 (5,8)
	Myocardial infarction	11 (2,5)	10 (2,6)
	Cerebrovascular insufficiency	6 (1,4)	11 (2,9)
	Other (<10)	74 (17,1)	73 (19,3)
Anticoagulant	Acenocoumarol	402 (92,6)	340 (89,9)
	Fenprocoumon	31 (7,1)	38 (10,1)
	Other	1 (0,2)	0 (0,0)
Intensity	1 st intensity group	357 (82,3)	292 (77,2)
	2 nd intensity group	77 (17,7)	86 (22,8)
Total		434 (100)	378 (100)

Table 1 shows that the intervention group and the control group can be compared with regard to several important personal and treatment characteristics. The age of the patients in the control group is slightly higher. The indications for the anticoagulation treatment contain a few minor differences in the indications that occur less often. No statistically significant differences were found with regard to the intensity group and medication.

3.2 Effectiveness

3.2.1 INR within the therapeutic range

Effectiveness of the treatment means that the major number of INRs fall within the therapeutic range. All collected INRs, both from the control group and from the intervention group, were therefore compared with the therapeutic range of the individual patient. A distinction was made between intensity group 1 and intensity group 2 during this process. The findings are shown in Table 2.

Table 2: Comparison of the INR dosage in control group and intervention group for high and low intensity

Below, within or above therapeutic range	Number of INR measurements	Percentage	Number of INR measurements	Percentage
Low intensity	Control group		Intervention group	
Below	543	16,9	390	12,0
Within	1952	60,7*	2210	67,7*
Above	723	22,5	662	20,3
<i>Total</i>	<i>3218</i>	<i>100</i>	<i>3262</i>	<i>100</i>
High intensity	Control group		Intervention group	
Below	223	28,1	258	23,8
Within	402	50,6*	647	59,7*
Above	169	21,3	179	16,5
<i>Total</i>	<i>794</i>	<i>100</i>	<i>1084</i>	<i>100</i>

* $p < 0.05$ (χ^2 -test for the mean within the therapeutic range)

Table 2 shows that the outcomes for the intervention group are better than for the control group, both in the low and in the high intensity group: in the low intensity group 7% more INRs can be found within the therapeutic range, while 9.1% more INRs can be found in the high intensity group. The differences are statistically significant for both groups.

These differences are presented in Figures 3 and 4.

Figure 3: Distribution of the INRs between control group and intervention group for the low intensity

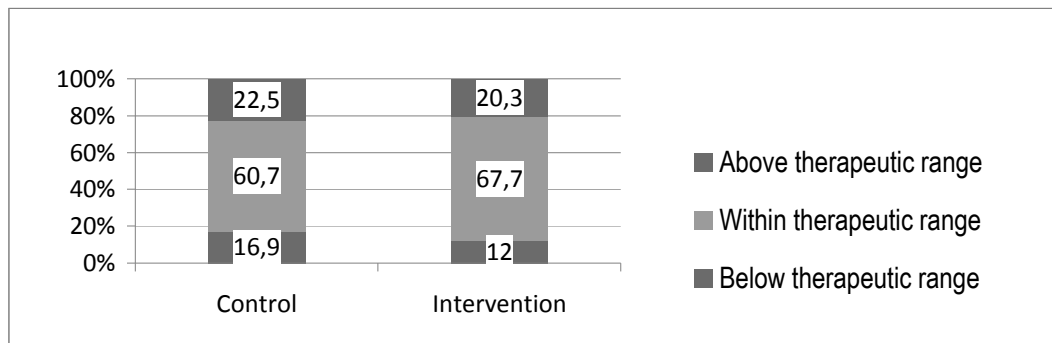
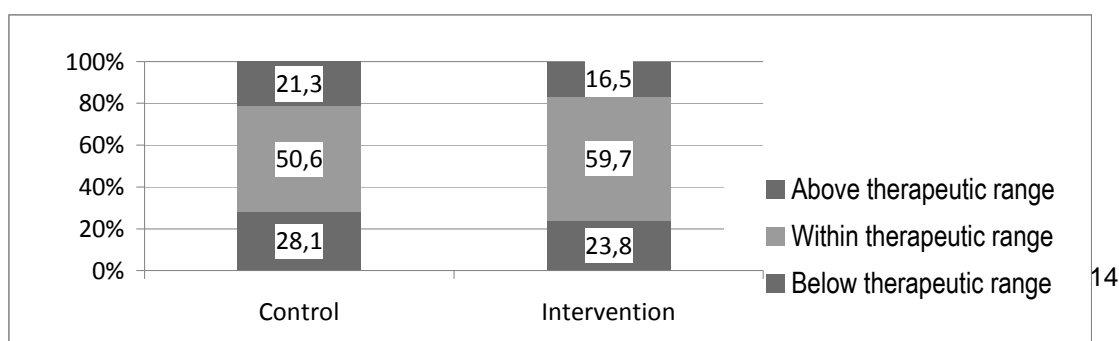


Figure 4: Distribution of the INRs between control group and intervention group for the high intensity



In comparison with the mean FNT² scores (first intensity group approximately 80%, second intensity group approximately 75%) these values would seem low. This can be explained as follows:

1. A different calculation has been applied: for the FNT scores, all last measured INRs are included at one point in time, in this study a series of INRs has been measured for each patient during a period of half a year. It is unclear which effect this has on the outcome;
2. This concerns a special group of patients, i.e. a group of elderly patients in health care institutions for whom it is in general more difficult to determine a dose.

Because of the latter fact it was decided to not compare the data with the FNT statistics, but with a - comparable - control group.

3.2.2 Effect of transfer of treatment to the anticoagulation clinic

In some nursing homes, anticoagulated patients are treated by the nursing home physician. When a health care institution switches to Near-Patient Testing, the treatment and dose determination is in most cases taken over by the staff of the anticoagulation clinic. As we were curious whether this would cause an effect on the treatment results, we collected all successive INRs per patient after the transfer of the treatment to the anticoagulation clinic and studied the course of this procedure. No distinction was made between the 1st and 2nd intensity group.

This study concerned 15 health care institutions; as some health care institutions had only recently switched to Near-Patient Testing, the number of INR measurements per patient decreases with time. Therefore we limited our study to the initial 10 INRs. The outcomes are presented in Table 3.

Table 3: INR after transfer of the treatment to the anticoagulation clinic, for both intensity groups

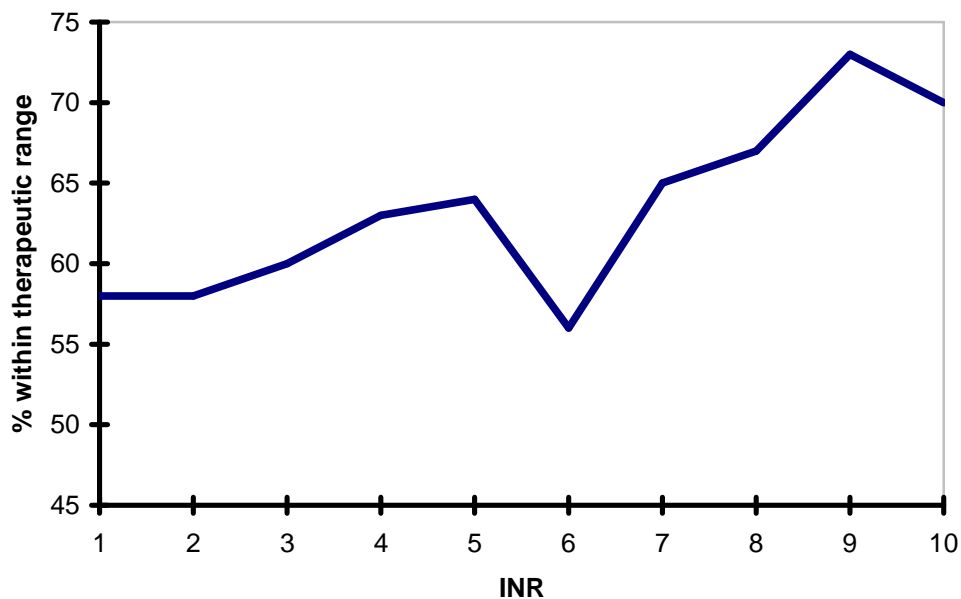
	Below therapeutic range		Within therapeutic range		Above therapeutic range		Total number of INR measurements
	Number of INR measurements	%	Number of INR measurements	%	Number of INR measurements	%	
INR 1	43	20	122	58	47	22	212
INR 2	35	17	119	58	50	25	204
INR 3	34	18	113	60	41	22	188
INR 4	24	15	102	63	36	22	162
INR 5	16	12	86	64	33	24	135
INR 6	19	17	62	56	30	27	111
INR 7	13	13	66	65	22	22	101
INR 8	14	15	64	67	17	18	95
INR 9	11	12	66	73	14	15	91
INR 10	9	10	62	70	18	20	89

² Federation of Dutch Anticoagulation Clinics

The first INR is the result of the prescribed dosage by the nursing home physician. As soon as the anticoagulation clinic takes over the dose determination at the start of Near-Patient Testing, a steady trend can be observed towards a better treatment result (more INRs within the therapeutic range).

In order to illustrate this more clearly, we have plotted all percentages 'within the therapeutic range' in a graph, see Graph 1.

Graph 1: INR within therapeutic range, after transfer of the treatment to the anticoagulation clinic, percentage of the total



The results were tested using a logistic regression model. The p-value is 0.002. A p-value of 0.05 means a 5% chance that the outcome is accidental. The chance that this upward tendency for found p-values is based on chance, is negligible. The results therefore indicate that there is a significant trend towards a better dose determination if the dose determination of patients whose dose was previously determined by the nursing home physician is taken over by the anticoagulation clinic.

Conclusions with regard to the quality of dose determination by the nursing home physician cannot be made without due consideration, because the entire treatment process was changed at the same time. A further study is required, all the more so because the improved dose determination after the take-over of the dose determination by the anticoagulation clinic is more significant than the difference found between intervention group and control group. It is unclear how both improvements relate to each other.

3.3 Safety

3.3.1 Prevention of complications

An important criterion for the safety of the treatment is the prevention of complications. In this study we included the following complications: all types of haemorrhages, cerebrovascular accidents (cause unknown) and thrombosis/embolism. Table 4 compares the control group with the intervention group in this respect.

Table 4: Comparison of complications between control group and intervention group

Complications	Control group	Intervention group
Number of complications	83*	36*
Number of patients with complications	47*	22*
% Patients with complications as compared with all patients	12,21*	6,11*

* $p < 0.05$ (χ^2 -toets)

The statistics significantly show that fewer complications are encountered in the intervention group. The distribution of the types of complications was similar in both groups. One severe complication occurred in the intervention group (a severe nose bleed) and two severe complications occurred in the control group (an intestinal haemorrhage and a cerebrovascular accident). Other less severe complications, such as small haematoma, microscopic haematuria or mild nose bleeds are distributed equally across the control group and the intervention group.

3.3.2 Use of vitamin K

Vitamin K is generally used to control excessive anticoagulation treatment and/or bleeding. Not all anticoagulation clinics have the same policy with regard to vitamin K. As the control group consists, for a large part, of health care institutions that are run by a different anticoagulation clinic than the ones in the intervention group, the data are not completely comparable.

Table 5: Comparison of vitamin K use between control group and intervention group

Use of vitamin K	Control group	Intervention group
Number of times of vitamin K use	35*	15*
Number of patients using vitamin K	29*	12*
% of patients using vitamin K compared with all patients	7,53*	3,33*

* $p < 0.05$ (χ^2 -test)

Table 5 shows that vitamin K was statistically significantly less often prescribed in the intervention group.

3.3.3 Punctuality of the measurement

Timely measurement of the INR does not differ in both methods. In the intervention group timely blood samples were taken from 99.9% of the patients; in the control group timely blood samples were taken from 99.8%.

3.4 Process and satisfaction

As described in paragraph 2.2.3, qualitative data were collected on two different dates, both at the anticoagulation clinic and at the health care institution. The first questionnaire was sent one month after the start of Near-Patient Testing to all health care workers or nurses who had been trained by the anticoagulation clinic. Half a year later a telephone interview was conducted with (a representative of) the management of the health care institution.

The instructors of the anticoagulation clinic also received a questionnaire one month after the start of Near-Patient Testing, and participated in a telephone interview half a year after the start.

3.4.1 Results of health care institution

The management of the health care institution decided how many staff members (health care workers or nurses) had to be trained. This required an optimal balance between the continuity of care and the maintenance of the skills of health care staff by taking sufficient blood samples. On average, health care institutions train between three and seven staff members.

The questionnaire that was sent one month after the start was addressed to all health care workers or nurses who had received the training. The content of the questionnaire concerned the training in particular, and the presence of the correct conditions for the working procedure (see Appendix 5). A total of 93 trained staff members received the questionnaire.

Our questionnaire revealed to what degree the trained staff members were motivated. The response was 94%. On the whole, all trained staff members were enthusiastic about the course. Communication with the anticoagulation clinic improved as a result of the new method. Table 6 shows the results of the analysis.

Table 6: Results of surveys of trained staff members (n=87)

Question	Answer category	Percentage
Sufficient knowledge	(fully) agree	92%
Good training	(fully) agree	95%
Expert instructors	(fully) agree	97%
Good instruction Portavita	(fully) agree	97%
Own skills	(fully) agree	97%
Good preparation	(fully) agree	95%
User-friendly software	(fully) agree	93%
Easy access to computer	(fully) agree	90%
CoaguChek no problem	(fully) agree	90%
Sufficient time	(fully) agree	79%
Good communication with anticoagulation clinic	(fully) agree	91%
Increased quality	(fully) agree	82%
Satisfaction	(fully) agree	87%
Suitability of other health care institutions	(fully) agree	75%

Agreements had been made with all institutions regarding the distribution of the powers and responsibilities between the anticoagulation clinic and the health care institutions. Nearly all health care institutions worked in this context with the certification of staff members. This assessment took place periodically. In practice this occurs at least once a year.

Half a year later an interview by telephone was carried out with 21 contact persons of the management of the health care institutions. During this interview all contact persons indicated that they were still extremely satisfied. The method was patient-friendly, well suited for integration in the daily routine, and the communication with the anticoagulation clinic had improved on a permanent basis. On average, taking a blood sample took about 10 to 15 minutes per patient per blood sample. This investment of time includes the report in the Portavita record and the actions, if any, following dose determination. The health care workers indicated that the patients were also satisfied with the new method: it allowed more flexibility during blood sampling and in-patients were pleased to have their blood samples taken by a familiar person.

Some health care institutions reported problems with personnel, because actually too few people had been trained which led to problems with regard to staffing, especially during the holiday periods. The health care workers indicated

that they thought this method, if properly introduced, would be appropriate for all health care institutions in the Netherlands.

3.4.2. Results of anticoagulation clinic

The instructors of the anticoagulation clinic also received a questionnaire one month after the start of Near-Patient Testing. This questionnaire also focused on the training and the acquired skills (see Appendix 6).

We sent questionnaires to the twelve instructors of the anticoagulation clinic, eleven of them returned the completed questionnaire (92% response rate). This group was also enthusiastic and satisfied with Near-Patient Testing. They indicated that the health care workers were motivated and able to become familiar with the new working method. The course took two to a maximum of four daily periods. The mandatory course components (theory of anticoagulation treatment, instruction regarding the use of the CoaguChek and the Portavita software) were carried out everywhere. On one occasion, some uncertainty regarding the motivation of the health care workers was observed. The question whether this method is applicable throughout the Netherlands was answered by the instructors in a neutral to positive manner. They were of the opinion that the availability of sufficient patients was an important condition in order to maintain sufficient levels of skill.

During the interview by telephone with the anticoagulation clinic, half a year after the introduction of the new method, all contact persons showed a positive response with regard to Near-Patient Testing. The communication with health care institutions had improved on a permanent basis and involvement had increased. All contact persons who completed a questionnaire indicated that the method was suitable for introduction in all health care institutions.

3.4.3 Patient survey

In four health care institutions health care workers conducted our patient questionnaire in an arbitrary group of 21 patients in total. The vast majority of these patients indicated that they found the new method agreeable. Everybody appreciated the fact that blood samples were taken by a familiar person and they were of the opinion that the health care workers performed their task for the anticoagulation clinic well. They were, however, not always pleased with the more frequent blood samples³.

4. Conclusion and discussion

In this study we examined the results of Near-Patient Testing: a new method of monitoring patients with an anticoagulation treatment, in health care institutions. We assessed the effectiveness, the safety, and the process characteristics of this method. We observed the effects of this implementation during a half-year period.

³ This has to do with the fact that patients take blood samples with a self-measuring device. The FNT directives require that in that case the INR must be determined more often than with venous sampling.

The results of the study reveal a significant difference between the intervention group and the control group, in favour of Near-Patient Testing, with regard to the dose determination of the patient (INR value within the therapeutic range), both for the low and the high intensity groups. During the half-year study period significantly fewer complications were observed in the intervention group and vitamin K was prescribed significantly less in the Near-Patient Testing group. In both groups, only few severe complications occurred, which indicates that the quality of the anticoagulation clinics is good, generally speaking, and that this quality is in no way compromised during use of Near-Patient Testing. Timely checks in the context of Near-Patient Testing are also effectively achieved, although blood samples are taken slightly more frequently. Fortunately, our intervention group and control group appear to be excellently comparable, which makes the conclusions reliable.

The general conclusion is that the introduction of Near-Patient Testing in health care institutions results in a similar and probably even better treatment result than the standard method, provided that it is properly supervised. Near-Patient Testing therefore has the potential to become an effective, safe, and reliable new method of monitoring patients of a health care institution with an indication for anticoagulation treatment with vitamin K antagonists, on the condition that support is provided which is comparable with the patient self-management support programmes.

There were no indications during the study that costs for the health care institutions or anticoagulation clinics constituted a problem. However, a specific structure for cost management should be developed, along with a resulting fee. This fee should be based on a treatment protocol which still has to be determined. Determination of the minimum level of education that a staff member has to achieve to be able to be properly trained for this task should be part of this treatment protocol. The health care staff members who have been trained in the context of this study had different levels of education and appeared to be able to perform their tasks properly.

It is clear that additional time has to be invested in this new method, especially in the beginning. In this study we compared Near-Patient Testing with standard care. This means that we are unable to provide an opinion which aspect of Near-Patient Testing provides the main contribution to the favourable result: is it mainly the organisational change, the training of the health care workers, the software or the improved communication between the health care institution and the anticoagulation clinic? Further studies may provide an answer to this question.

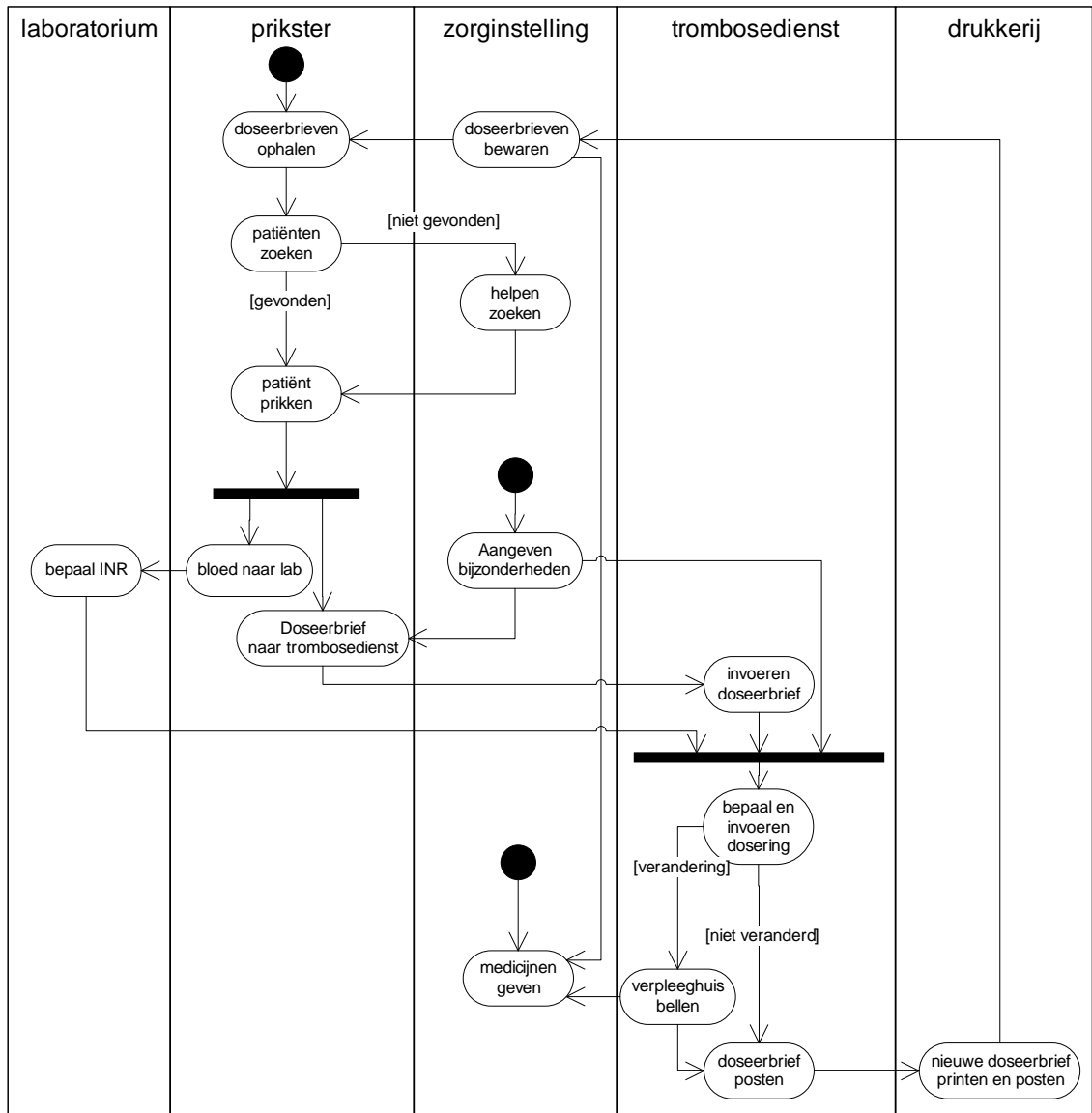
Furthermore, the findings of the sub-study into the course of the INR, if dose determination for Near-Patient Testing is taken over by the anticoagulation clinic from the nursing home physician, are important. Statistical analysis reveals a significant improvement of the treatment results, where the dose determination of the patient is concerned. However, this study concerns a relatively small group and the differences may be interpreted in other ways. The dose determination experience of the physician is only one of these. However, the nature of the findings justifies a larger-scale follow-up study.

Finally, it is important to conclude that Near-Patient Testing has been well received and appreciated by all parties. This study has shown that anticoagulation clinics are capable of organising Near-Patient Testing in cooperation with health care institutions.

All three parties (patients, health care institutions and anticoagulation clinics) are genuinely enthusiastic about Near-Patient Testing, even after the intervention period. This information, in combination with the quantitative findings, justifies the confidence that Near-Patient Testing can be introduced on a nationwide scale.

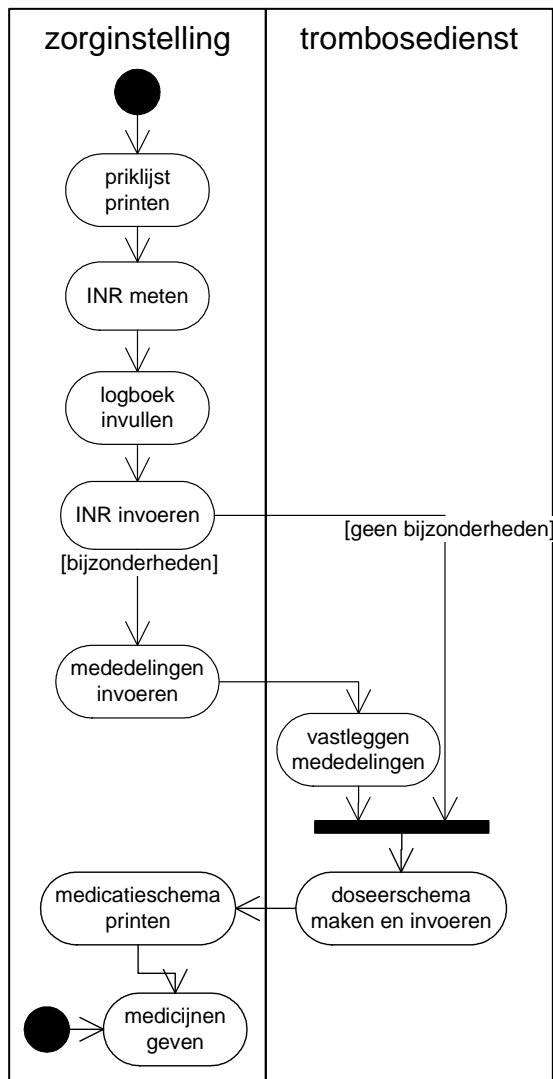
Appendix 1 Current method flow chart

(This flow chart cannot be translated)



Appendix 2 Flow chart Near-Patient Testing

(This flow cart cannot be translated)



Appendix 3 Participating organisations

A. INTERVENTION GROUP

Anticoagulation clinics (name, place-name)

1. Stichting Artsenlaboratorium en Trombosedienst voor de Kop van Noord-Holland en Texel (Den Helder)
2. Stichting Regionale Trombosedienst 's-Gravenhage e.o. (Rijswijk)
3. Stichting Rode Kruis Trombosedienst Neder-Veluwe (Ede)
4. Stichting Trombosedienst voor 't Gooi (Hilversum)
5. Stichting Trombosedienst Schiedam e.o. (Schiedam)
6. Stichting Trombosedienst ZGT Hengelo (Hengelo)
7. Trombosedienst Zeeland (Middelburg)
8. Trombosedienst Ziekenhuis Nij Smellinghe (Drachten)
9. Trombosedienst Ziekenhuis Rivierenland (Tiel)
10. Trombosedienst Zeeuws-Vlaanderen (Terneuzen)

Health Care Institutions (name of location, name of umbrella organisation, place-name of location, type of institution)

1. Berchhiem, De Friese Wouden, Burgum (nursing and home care organisation)
2. Bertilla, ZuidOostZorg, Drachten (nursing and reactivation centre)
3. Bosch en Duin, Respect Zorggroep Scheveningen, Den Haag (assisted-living facility for intensive care)
4. Breukelderhof, Opella, Bennekom (psychogeriatric nursing home)
5. De Blaauwe Hoeve, Stichting Curamus, Hulst (assisted-living facility)
6. De Golfstroom, Stichting Vrijwaard, Den Helder (assisted-living facility)
7. De Lichtboei, Stichting Zorggroep Tellus, Den Helder (health care centre)
8. DrieMaasHave, Stichting Argos Zorggroep, Maassluis (nursing and reactivation centre)
9. DrieMaasStede, Stichting Argos Zorggroep, Schiedam (nursing and reactivation centre)
10. Eben-Haëzer, Stichting Zorgverlening van de Gereformeerde Gemeenten, Middelburg (health care centre)
11. Elisabeth-hof, Stichting Thuiszorg en Maatschappelijk Werk Rivierenland (STMR), Culemborg (health care centre)
12. Goede Ree, Stichting Vrijwaard, Den Helder (assisted-living facility)
13. Halderhof, Opella, Bennekom (somatic nursing home)
14. Huis ter Duin, Stichting Zorggroep Tellus, Den Helder (health care centre)
15. Nieuw-Sandenburg, Zorgstroom, Veere (home care/nursing home)
16. Parkzicht, Stichting Vrijwaard, Den Helder (assisted-living complex)
17. Prinses Margriet, Stichting Vrijwaard, Den Helder (home care institution)
18. Sherpa - ondersteunt mensen met een beperking, Baarn (health care centre for people with a physical and/or mental impairment)
19. Sint Barbara, Dreumel (health care institution)
20. St. Elisabeth, Carint, Delden (assisted-living facility)
21. Ten Anker, Stichting Vrijwaard, Den Helder (assisted-living facility)

B. CONTROL GROUP

Anticoagulation clinics (name, place-name)

1. Stichting Artsenlaboratorium en Trombosedienst voor de Kop van Noord-Holland en Texel (Den Helder)
2. Stichting Rode Kruis Trombosedienst Neder-Veluwe (Ede)
3. Stichting Trombosedienst Schiedam e.o. (Schiedam)
4. Trombosedienst Gelre Ziekenhuizen (Apeldoorn, Zutphen)
5. Trombosedienst Noord-West Veluwe (Harderwijk)
6. Trombosedienst Zeeland (Middelburg)
7. Trombosedienst Zeist (Zeist)
8. Trombosedienst ZGT Hengelo (Hengelo)
9. Trombosedienst Ziekenhuis Nij Smellinghe (Drachten)

Health Care Institutions (name of location, name of umbrella, place-name of location, type of institution)

1. Beatrix, Rijnheugel, Doorn (assisted-living facility)
2. Buitenrust, Zorgstroom, Middelburg (nursing centre)
3. Casa Bonita, Zorggroep Apeldoorn en omstreken, Apeldoorn (nursing home)
4. De Bunterhoek, Woonzorg Unie Veluwe, Nunspeet (health care centre)
5. De Meerpaal, Argos Zorggroep, Vlaardingen (nursing home)
6. De Schauw, Stichting Zorggroep Noordwest-Veluwe, Putten (home care/nursing home)
7. De Stoevelaar, Carint, Goor (assisted-living facility)
8. De Veenkamp, De Goede Zorg, Apeldoorn (assisted-living facility)
9. De Warrenhove, Drachten (assisted-living facility)
10. François Haverschmidt, Argos Zorggroep, Schiedam (health care centre)
11. Het Maanderzand, Ede (nursing home)
12. Het Woolde, Carint, Hengelo (assisted-living facility)
13. Kapellehoef, Woonzorggroep Samen, Den Oever (health care centre)
14. Nassau Odijckhof, Driebergen-Rijsenberg (nursing home)
15. Noorderlicht, Woonzorggroep Samen, Hippolytushoef (health care centre)
16. Oranje Nassau's Oord, Zinzia Zorggroep, Renkum (nursing home)
17. Rispinge, ZuidOostZorg, Drachten (assisted-living facility)
18. Rustenburg, Zorgstroom, Middelburg (nursing home)

Appendix 5 Questionnaire for trained health care staff

This questionnaire was sent one month after the start of NPT and particularly concerns the training and the facilities at the institution.

Please indicate on the 5 point scale below (fully disagree, disagree, agree, fully agree, don't know) to what extent you agree with the following statements in italics.

At the end, you will find space to insert some comments.

The course

1. *My knowledge about anticoagulation has increased due to the training.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

2. *I find the training applicable in actual practice.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

3. *The instructor(s) of the anticoagulation clinic were competent.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

4. *The instructions with regard to the software (Portavita) were clear.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

5. *After the course I felt capable of applying the INR assessment in practice.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

6. *The course has sufficiently prepared me for my work.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

The electronic patient record (Portavita software)

7. *The Portavita software is user-friendly*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

8. *I have easy access to the computer at our health institution.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

(Questionnaire trained health care workers: continued)

In practice

9. *The use of the CoaguChek is not difficult for me.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

10. *The time to take blood samples of my patients is adequate.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

11. *The communication with the anticoagulation clinic is perfect.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

12. *The quality of our service with regard to the anticoagulation treatment has definitely improved.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

13. *I am satisfied with this new working method.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

14. *This new working procedure is suitable for all health care institutions.*

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

Space for additional comments:

1.....

2.....

3.....

Appendix 6 Questionnaire for instructors of the anticoagulation clinic

This questionnaire was sent one month after the start of NPT and especially concerns the training.

1. How many daily periods did the course cover?
.....daily periods.

2. At which location(s) did the training take place?
.....
.....

3. How many people participated in the group?
..... participants.

4. What was the educational level of the participants?
.....
.....

5. Did you discuss any other subjects apart from the three 'mandatory' components (anticoagulation treatment, CoaguChek, and Portavita EPD)?
 - a. yes, i.e.
 - b. no

6. How often should the health care workers return for a training session to maintain their skills?
.....times a year

7. In order to start Near-Patient Testing, health care institutions should at least meet the following conditions:
 - a.
 - b.
 - c.

(questionnaire for instructors of the anticoagulation clinic: continued)

Please indicate on the 5 point scale below (fully disagree, disagree, agree, fully agree, do not know) to what extent you agree with the following statements in italics. Please answer by ticking off the relevant box.

1. The health care workers were as a rule motivated to follow the training.

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

2. After the training the staff members are capable of measuring the INR and detecting particulars (bleedings, etc.).

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

3. Some staff members have such a small part-time job that they do not take enough blood samples to be able to maintain their skill.

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

4. It is difficult for an anticoagulation clinic to keep an eye on the skills of such a large number of trained health care workers.

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

5. After the course the health care workers are sufficiently prepared for their task (INR measurements, detecting particulars).

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

6. All health care institutions are suitable for this concept (Near-Patient Testing).

Fully disagree	Disagree	Agree	Fully agree	Don't know
----------------	----------	-------	-------------	------------

Space for additional comments:

- 1.
- 2.
- 3.

Appendix 7 Telephone interview of manager of health care institution

This interview by telephone was carried out half a year after the start of NPT.

Name health care institution:

Name interviewed person:

Date:

1. Global impression to date. Are there any notable matters worth mentioning?

Bottlenecks and amusing things?

2. How do you manage to fit in this new task in your daily routine?

- can you manage to guarantee the continuity, i.e. to make sure there is always someone who can take blood samples if such is necessary or planned?
- how much time does a health care worker on average spend per patient per INR? Including entering data in Portavita?
- is it easy to take blood samples: carefully and properly?
- does the new working method have an impact on the communication with the anticoagulation clinic? And if so, has communication improved or deteriorated?
- how does working with the Portavita system pass off?

3. How do the patients react?

- a. have they been informed beforehand?
- b. are they happy with the new treatment?
- c. are there any patients who do not participate because of the deductible of their health insurance

5. General satisfaction: yes, no; why yes/no?

Appendix 8 Telephone interview of anticoagulation clinic staff

This interview by telephone was conducted half a year after the start of NPT.

Name of anticoagulation clinic:.....

Name of interviewed person:.....

Date:.....

1. Global impression to date. Are there any notable things to report?
Bottlenecks and amusing things?
2. Does agreement exist between the anticoagulation clinic and the health care institution regarding the distribution of powers and responsibilities?
3. Does the new working procedure have an impact on the communication with the health care institution? And if so, has communication improved or deteriorated?
4. Do you have the impression that the health care staff takes blood samples carefully and properly?
5. Are there any problems with the distribution of the strips and reagents? Is the provisioning well organised?
6. Global satisfaction: yes, no; why yes/no?

Appendix 9 Patient questionnaire

An interview takes approximately five to ten minutes per patient. The health care worker is the best person to judge which patients are or are not eligible. Emphatically a sample is carried out.

It is an open/semi-structured interview.

The health care worker/contact person discusses with 3 to 4 in-patients:

- the new situation regarding the INR measurement
- the positive and less positive experiences

We are especially interested in the comments of residents.

During this interview the health care worker receives answers to the following questions and fills these in after the interview.

<p>1. I find the new working method pleasant/less pleasant/don't care</p> <p>2. How does the health care worker perform her/his task for the anticoagulation clinic? satisfactory/less satisfactory/no comment</p> <p>Important comments from the resident:</p> <p>1.....</p> <p>2.....</p> <p>3.....</p>

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