

# External quality assessment of point-of-care International Normalized Ratio (INR) testing in Europe

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## Introduction

Point-of-care testing (POCT) of prothrombin time, expressed as International Normalized Ratio (INR), is widely used to monitor patients in oral anticoagulation treatment with vitamin K antagonists (e.g., warfarin, acenocoumarol, phenprocoumon). There are several POCT INR devices in use today, and it is important that the devices give reliable and valid results. Good measurement quality is essential for safe and efficacious treatment (1), and efforts have been made to improve harmonization of INR results (2). POCT is performed in several locations, such as hospital clinics, thrombosis clinics, general practitioners offices, nursing homes and in pharmacies (3).

Several guidelines recommend that POCT users should participate in an external quality assessment scheme (EQAS) (1, 4–6). The Clinical and Laboratory Standards Institute (CLSI) (5) which has a focus on the hospital-based POCT programs in general, states that EQAS plays an important role in the POCT quality management in reducing errors. In another CLSI document (6), which deals with POCT and anticoagulation therapy, it is recommended that POCT INR users in professional settings should enrol and regularly participate in an EQAS whenever available. A recent review on POCT in hemostasis (1) states that participation in an EQAS is essential in the overall POCT quality assurance program, and that there are still relatively few providers of these schemes.

External quality assessment (EQA) organizations provide EQAS for many different components, and the focus has mainly been on hospital laboratories. In recent years, however, an increasing number of EQA organizers have established EQAS for different POCT devices, e.g., for blood glucose, hemoglobin, cholesterol, coagulation and urine strips analyses. The purpose of these EQASs is to evaluate and improve POCT quality in order to ensure safe patient treatment. Depending on the type of scheme different aspects can be addressed; the quality of one instrument brand compared to others, the quality of the users instrument and reagent lot compared to others, as well as the competence of the users. Education of the users is considered to be an essential part of the EQAS (7).

Several studies have shown that participation in an EQAS for POCT analyses is useful to improve analytical quality; e.g., for mononucleosis tests and urine dip-slide tests in Norway (8, 9), for group A streptococcus tests in Finland

## Abstract

**Background:** Point-of-care testing (POCT) of prothrombin time, expressed as International Normalized Ratio (INR), is widely used to monitor patients in oral anticoagulation treatment. Guidelines recommend that POCT users should participate in an external quality assessment (EQA) scheme whenever available. The aim of this study was to investigate which European countries provide EQA for POCT INR and to compare how these schemes are organized.

**Methods:** Thirty European countries were invited to participate in this study. Those who reported that they provide EQA for POCT INR filled in a questionnaire dealing with different aspects of their schemes.

**Results:** Nineteen countries reported that they do not provide EQA for POCT INR, while 12 organizations from nine countries reported that they provide this service. Most of these countries circulate lyophilized samples with for the participants unknown target values. Samples with certified INR values and procedures using split samples with fresh patient samples are also used. The acceptability limits vary from 15% to 30%, and the total number of samples circulated per year varies from 1 to 12. Most of the countries organize educational activities together with their schemes.

**Conclusions:** This study demonstrates that there is a wide variation in the way EQA for POCT INR is performed in Europe and that there are many European countries that do not provide this service. Even though our findings indicate that EQA for POCT INR draws some challenges, especially in providing suitable control materials, participation in such schemes is considered useful.

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(10) and in Switzerland (11), for hemoglobin tests in Belgium (12) and for blood glucose tests in Germany (13). The United Kingdom National External Quality Assessment Service (UKNEQAS) has reported their experience with EQAS for POCT INR over a 6-year period, and stated that this kind of control is both possible and necessary for health care professionals to obtain good analytical quality (14).

Publications show that an EQAS for POCT INR is available in the Czech Republic (15), the Netherlands (16), Norway (17) and the UK (14). To our knowledge, however, no studies have investigated the coverage of POCT INR schemes in Europe. The aim of this study is, therefore, to establish which of the European countries provide an EQAS for POCT INR, and to compare how these schemes are organized.

## Materials and methods

This study was carried out in cooperation with the European Organization for External Quality Assurance in Laboratory Medicine (EQALM) (18). In February 2010, an invitation to participate in this study was sent all EQALM members as well as non-members in order to invite as many European countries as possible. A total of 30 of the 44 European countries classified by the United Nations (19) were contacted. The invited countries were asked if they have a national organizer that provides an EQAS for POCT INR. Those EQA organizers that reported that they do provide this service were asked to fill in a questionnaire of 23 questions dealing with different aspects of their schemes. The questionnaires were completed in the period from April to August 2010.

We were not able to contact the following European countries: Albania, Andorra, Belarus, Bosnia and Herzegovina, Greece, Liechtenstein, Macedonia, Malta, Moldova, Monaco, Montenegro, San Marino, Serbia and Ukraine. We have, however, no reason to believe that these countries host any EQA organizers of significance for this study.

## Results

### Providers of EQAS for POCT INR in Europe

Twenty-eight of 30 countries responded to the invitation. Twelve EQA organizers from nine European countries reported that they provide EQAS for POCT INR (Table 1), and all completed the questionnaire. Nineteen European countries (Belgium, Bulgaria, Croatia, France, Germany, Iceland, Ireland, Italy, Latvia, Luxemburg, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden and Turkey) reported that they did not provide this service.

### Different EQAS approaches

Most of the countries offer the traditional EQAS where the participants receive samples with, for the participants, unknown target values (Table 1). In the Czech Republic, they also include a post-analytical phase where the participants are asked to interpret their INR results, based on a short case history. In Denmark and one of the Swiss organizations, they offer a split sample procedure where the POCT users analyze

a fresh patient sample on their device, and send a venous sample to a "certified" hospital laboratory for comparison (Table 1). In Austria and the Czech Republic, no control samples are distributed to the INRatio participants since there are currently no materials available for these instruments. The participants receive test strips from one batch and are simply asked to analyze one arbitrary capillary patient sample and report the two QC values given by the strip (seconds). In the Netherlands, a set of five lyophilized plasmas with certified, but for the participant unknown, INR values are distributed to the participants on request (Table 1).

### Number of samples, participants and POCT devices

The total number of samples distributed per year varies between the EQA organizers from one to 12 with a median of four (two samples two times a year) (Table 1). The number of participants varies from 75 to 2665 (Table 2). Denmark and Hungary have at present no participants. Almost all countries distribute control samples to the general practitioners and to hospital clinics that perform POCT INR. Some nursing homes participate in Norway and in the Quality Control Center Switzerland (CSCQ), and some pharmacies participate in the UK and CSCQ. Only the ECAT organization provides control samples to patients. All countries offer an EQAS for the CoaguChek series users, the most commonly used POCT INR devices (Table 2).

### Types of control material

The control materials used for the different POCT INR devices are shown in Table 3. The majority of EQA organizers reported that they use lyophilized samples, i.e., reconstituted lyophilized plasma or lyophilized whole blood. In addition, a calcium chloride solution is distributed to the CoaguChek users for activation of the coagulation cascade. The Wales External Quality Assessment Schemes (WEQAS) use an artificial liquid material, which is based on bovine plasma with added stabilizers and dyes to make it look like whole blood. Calcium chloride activation is not required and the material is sent frozen. The material exploits the fact that the CoaguChek XS system measures the thrombin produced in the sample. The Federation of Netherlands Thrombosis services (FNT) use fresh frozen pooled patient samples, i.e., plasma to the CoaguChek users and whole blood to the ProTime users. The pooled plasma is stored frozen, thawed on the day of sample distribution and sent to the participants together with a calcium chloride solution. Artificial whole blood samples are prepared by mixing compatible fresh red blood cells with the pooled patient plasma.

### Target value and acceptability limits

In the "non-traditional" EQAS in the Netherlands, a reference method is used to establish the target value, while results from a standard laboratory method is used as target in the split sample procedure in Denmark and one of the Swiss schemes. The other schemes use consensus values from the participants, i.e., mean or median of method group

Table 1 Providers of EQAS for POCT INR in Europe. Type of EQAS, number of samples and special features is shown for each EQAS.

| Country        | EQA organizer | Traditional EQAS  | Number of samples per survey | Number of surveys per year | Total number of samples per year | Special features   |
|----------------|---------------|---|------------------------------|----------------------------|----------------------------------|--|
| Austria        | ÖQUASTA       | Austrian Society of Quality Assurance and Standardization                       | 1                            | 4                          | 4                                | INRatio users receive no control samples, but reports values (seconds, not INR) from the on-board QC system  |
| Czech Republic | SEKK          | External quality assessment system for clinical laboratories                    | 2                            | 2 <sup>a</sup>             | 4                                | Post-analytical phases are included (interpretation of the INR control results based on a short case history)<br>INRatio users receive no control samples, but reports values (seconds, not INR) from the on-board QC system |
| Denmark        | DEKS          | Danish Institute for External Quality Assurance for Laboratories in Health Care | 1                            | 1                          | 1                                | Split sample procedure; comparison with a standard laboratory method   |
| Finland        | Labquality    | Labquality  | 1                            | 2                          | 2                                |  |
| Hungary        | QualiCont     | In Vitro Diagnostic Quality Control Nonprofit Public Utility Ltd.               | 2                            | 6                          | 12                               |  |
| Netherlands    | ECAT          | External quality Control of diagnostic Assays and Tests                         | 5                            | On request                 | NA                               | QC sets of five lyophilized plasmas with certified INR target values are distributed to the participants on request  |
| Netherlands    | FNT           | Federation of Netherlands Thrombosis services                                   | 2                            | 5                          | 10                               | Home-made control material (fresh frozen pooled patient samples)   |
| Norway         | NOKLUS        | The Norwegian Quality Improvement of Primary Care Laboratories                  | 2                            | 2                          | 4                                |  |
| Switzerland    | CSCQ          | The Quality Control Center Switzerland  | 1                            | 4 or 6                     | 4 or 6                           |  |
| Switzerland    | MQ            | Association of Medical Quality Control  | 1                            | 4                          | 4                                | Split sample procedure for INRatio users; comparison with a standard laboratory method   |
| UK             | UKNEQAS       | United Kingdom National External Quality Assessment Scheme                      | 2                            | 4 and 6                    | 8 and 12                         |  |
| UK             | WEQAS         | Welsh External Quality Assessment Schemes                                       | 1                            | 6                          | 6                                | Home-made control material (artificial frozen liquid samples)  |

<sup>a</sup>In 2011, this was increased to four surveys per year.

Table 2 The total number of participants and type of POCT INR devices in the different EQAS.

| Country        | EQA organizer | CC*, CC-S | CC-XS, CC-XS + | Hemochron | ProTime | INRatio | i-STAT | Thrombotrack | Simple Simon | Tilt-tube | Total |
|----------------|---------------|-----------|----------------|-----------|---------|---------|--------|--------------|--------------|-----------|-------|
| UK             | UKNEQAS       | 430       | 2111           | 37        |         |         |        | 87           |              |           | 2665  |
| Switzerland    | MQ            | 1055      | 1152           | 37        |         | 20      |        |              |              |           | 2264  |
| Switzerland    | CSCQ          | 1105      | 1037           | 70        | 8       |         | 12     |              |              |           | 2232  |
| Norway         | NOKLUS        | 137       | 554            |           |         |         |        | 581          | 238          | 14        | 1524  |
| Austria        | ÖQUASTA       | 464       | 339            |           |         | 3       |        |              |              |           | 806   |
| Czech Republic | SEKK          | 20        | 240            |           |         | 10      |        |              |              |           | 270   |
| Finland        | Labquality    | 3         | 150            |           |         |         | 2      |              |              |           | 155   |
| UK             | WEQAS         |           | 126            |           |         |         |        |              |              |           | 126   |
| Netherlands    | FNT           | 43        | 64             |           | 4       |         |        |              |              |           | 111   |
| Netherlands    | ECAT          | 20        | 55             |           |         |         |        |              |              |           | 75    |
| Denmark        | DEKS          |           |                |           |         |         |        |              |              |           | 0     |
| Hungary        | QualiCont     |           |                |           |         |         |        |              |              |           | 0     |

\*CC, CoaguChek.

results as target values. If a certain reagent lot is significantly different to the mean or median, the results from these lots are excluded before calculating the target value in the Norwegian and the UKNEQAS scheme. The acceptability limits used in the different EQAS vary from 15% to 30% (Table 4). In Norway and Switzerland (CSCQ), the uncertainty of the target value is taken into account, meaning that the percentage acceptability limits will vary with the INR levels (see example in Table 4).

### Mandatory or voluntary participation

To receive reimbursement it is mandatory to participate in the scheme in three of the nine countries (Table 4). In these three countries, unacceptable results have consequences for the participants. In Austria and Hungary, the participants will not be awarded certification, but there are no financial or legal consequences. In Switzerland, the laboratories are obliged to participate in at least eight surveys in two years and achieve 75% of the results within the acceptability limits, or else reimbursement will be withheld for one year. In the UK, where participation is voluntary, participants with persistently unacceptable results are referred to the National Quality Assurance Advisory Panel. If their performance does not improve, it may be suggested that the center should stop their service.

### Supervision and education

In all countries, except in the Czech Republic and Finland, participants are contacted, and guided, according to certain criteria. In general, if a participant obtains an unacceptable result, it will be contacted by the national EQA organizer, mainly by letter, telephone or e-mail. The number of annual participant meetings is none in the Czech Republic, the Netherlands and Switzerland, one in Austria, Denmark, Finland, Hungary and WEQAS, and at least one in Norway and UKNEQAS.

### Discussion

This study shows that nine countries in Europe offer an EQAS for POCT INR, and that these schemes are organized in various ways. Although we do not know the extent of the use of POCT INR instruments in Europe, it is probable that a lot of these users do not partake in an EQAS. However, we cannot exclude the possibility that the POCT INR users participate in other quality control systems that are not linked to an EQA organizer.

An optimal EQAS should examine the trueness of the instruments, and is characterized by the use of commutable, stable and homogeneous control materials with the same matrix as patient samples (20, 21). The target value should be established by a reference method and the control samples should be handled similar to patient samples. These optimal conditions are, however, difficult to achieve in the EQAS for POCT INR. A disadvantage with most of the present EQAS is the use of lyophilized control material, which, due to

Table 3 Control material used in the European EQAS for the different type of POCT INR devices.

| POCT INR device   | Manufacturer  | Chemistry                        | Patient samples  | Control material used in the European EQAS   | European EQAS  | Origin of the control material                                    |
|---|---|----------------------------------|--|--|--|---|
| CoaguChek <sup>®</sup> ,<br>CoaguChek S <sup>®</sup> ,<br>CoaguChek XS <sup>®</sup> ,<br>CoaguChek XS Plus <sup>®</sup> | Roche<br>Diagnostics,<br>Mannheim,<br>Germany                     | Dry<br>chemistry<br>(strips)     | Capillary whole<br>blood   | Lyophilized plasma. Water and<br>calcium chloride to be added<br>by the participants<br><br>Fresh frozen pooled patient<br>plasma. Calcium chloride to be<br>added by the participants   | ÓQUASTA, SEKK, Labquality,<br>QualiCont, ECAT, NOKLUS,<br>CSCQ, MQ, UKNEQAS<br><br>FNT | Commercial<br>(manufacturer or<br>EQA organizer)<br><br>Home made |
| Hemochron Jr.<br>Signature <sup>®</sup> , ProTime <sup>®</sup><br>Microcoagulation System                               | International<br>Technidyne<br>Corporation,<br>Edison, NJ,<br>USA | Dry<br>chemistry<br>(cuvettes)   | Capillary whole<br>blood<br><br>Venous whole<br>blood                      | Frozen artificial liquid material<br><br>Lyophilized whole blood.<br>Water to be added by the<br>participants<br><br>Fresh frozen pooled patient<br>plasma added red blood cells.<br>Calcium chloride to be added<br>by the participants | WEQAS<br><br>CSCQ, MQ, UKNEQAS<br><br>FNT  | Home-made<br><br>Commercial<br>(manufacturer)<br><br>Home-made    |
| INRatio <sup>®</sup>  | Hemosense,<br>Milpitas, CA,<br>USA                                | Dry<br>chemistry<br>(strips)     | Capillary whole<br>blood   | Capillary whole blood and<br>venous plasma (split sample)<br><br>Capillary whole blood<br>(on-board QC)  | MQ<br><br>ÓQUASTA, SEKK  | Fresh patient samples<br><br>Fresh patient samples                |
| i-STAT <sup>®</sup>   | Abbott Point of<br>Care, Princeton,<br>NJ, USA                    | Dry<br>chemistry<br>(cartridges) | Capillary whole<br>blood   | Lyophilized plasma. Water and<br>calcium chloride to be added<br>by the participants   | Labquality, CSCQ   | Commercial<br>(manufacturer)                                      |
| Thrombotrack <sup>®</sup> , manual<br>tilt tube technique<br>(Thrombotest <sup>®</sup> reagent)                         | Axis-Shield<br>POC AS,<br>Oslo, Norway                            | Wet<br>chemistry                 | Capillary whole<br>blood<br><br>Venous whole<br>blood<br><br>Venous plasma | Lyophilized plasma. Water to<br>be added by the participants   | NOKLUS, UKNEQAS  | Commercial<br>(manufacturer)                                      |
| Simple Simon <sup>®</sup> PT  | Zafena AB,<br>Borensberg,<br>Sweden                               | Wet<br>chemistry                 | Capillary whole<br>blood<br><br>Venous whole<br>blood<br><br>Venous plasma | Lyophilized plasma. Water to<br>be added by the participants   | NOKLUS   | Commercial<br>(manufacturer)                                      |

**Table 4** Participation and acceptability limits in the different EQAS for POCT INR.

| Country     | EQAS                     | Participation | Acceptability limits                                       |
|-------------|--------------------------|---------------|--|
| Austria     | ÖQUASTA                  | Mandatory     | 30% <sup>a</sup>   |
| Hungary     | QualiCont                | Mandatory     | 20%  |
| Switzerland | CSCQ <sup>c</sup> and MQ | Mandatory     | 15%  |
| Czech Rep.  | SEKK                     | Voluntary     | 20%  |
| Denmark     | DEKS                     | Voluntary     | 26% <sup>b</sup>   |
| Finland     | Labquality               | Voluntary     | 15%  |
| Netherlands | ECAT and FNT             | Voluntary     | 15%  |
| UK          | UKNEQAS                  | Voluntary     | 15%  |
|             | WEQAS                    | Voluntary     | Excellent: ≤8%<br>Good: > 8 and ≤16%<br>Unacceptable: >16% |
| Norway      | NOKLUS <sup>d</sup>      | Voluntary     | Good: ≤5%<br>Acceptable: >6 and ≤11%<br>Poor: >12%         |

<sup>a</sup>Information for 2011 is 20%. <sup>b</sup>Split sample procedure, deviation from a hospital method. <sup>c</sup>Includes the uncertainty of the target value, this means that the acceptability limit will differ in different INR levels. Example, NOKLUS: Calculation shown for level 2.5 INR: Target value = 2.50 INR, target interval = 2.45–2.55 INR, poor performance is <2.16 (2.45 × 0.88) or >2.86 (2.55 × 1.12) INR. The lower and upper acceptable limits represent 14% of the target value ((2.50–2.16)/2.50 = 0.14 and (2.86–2.50)/2.50 = 0.14).

matrix effects (22), makes comparisons between different brands of instruments difficult, and method specific target values have to be used. In addition, since the procedure for the control material is different from how native samples are handled, artificial errors can be introduced. This is inconvenient since the users of these instruments are often without laboratory education. In spite of this, we consider participation in such schemes useful as they give valuable information of the participant's analytical quality compared to the other users of the same method. Some EQA organizers have, however, chosen not to offer this kind of scheme, as is the case in Germany where they also have decided not to offer EQAS for patient home testing due to these control material matrix issues and the large number of patients (23).

Two EQA organizers employ a different control material than the lyophilized samples (Table 3). WEQAS distributes artificial liquid control samples where reconstitution and calcium chloride activation is not required. This is an advantage, but matrix effects are however still present. The most native-like material is used by the FNT in the Netherlands. A disadvantage using this native material is the short stability (24), and all participants are therefore asked to analyze the samples on the same day. Theoretically, this material could be commutable and have common target values across methods groups, making it possible to compare different instrument brands. Until now, however, method specific target values have been used.

When no commercial control materials are available or found acceptable for a POCT INR instrument, other types of EQASs are conducted; in some countries, a split sample procedure using fresh patient samples is offered. This type of quality control has been evaluated and found useful as an alternative to the traditional EQAS (17), although it has been opposed by others (25, 26). A different approach is developed in Austria and the Czech Republic where the INRatio users are asked to report results from the on-board QC system. Evaluation of the user's reagent strips is not possible,

since one lot is distributed to all participants. This approach makes it, however, possible to evaluate the interlaboratory variation of one reagent lot, as well as the user's competence.

The European concerted action on anticoagulation has developed a set of five lyophilized control plasmas with certified INR target values for the CoaguChek instruments (27), in order to examine the trueness of these instruments. These controls are used by ECAT in the Netherlands (16). Since the participant results are compared only with certified INR values, it is not possible to compare one participant's analytical quality with the other CoaguChek users. This approach is, therefore, not an EQAS, but is more similar to control systems where instruments are controlled with certified reference materials.

The frequency of the different EQAS varies from one to six per year (Table 1). Guidelines recommend that a minimum of four surveys should be conducted when the participation is mandatory (28). The guideline is however based on consensus and not on published evidence. A working group in EQALM is currently dealing with optimum survey frequency, investigating whether there is a relationship between measurement quality and survey frequency. In theory, similar to internal quality control, the control frequency should be high when the prevalence of error is high in order to increase the probability of early error detection (29, 30).

The acceptability limits used in the different EQAS varies between countries (Table 4). In general, limits are narrower in EQAS used for educational purposes compared to EQAS where participation is mandatory (Table 4). Discrepancy in acceptability limits means that a participant result can be characterized as satisfactory in one country and unsatisfactory in another. Ideally, the quality specifications should be based on safe patient treatment or clinical outcome, the first step in the quality goal hierarchy (31). The quality goals established by EQA organizations are, however, mainly based on a compromise between state of the art and biological variation (32).

An important purpose of most European EQAS is to educate the participants. This is done by most of the organizers through contact with the users and by including pre-analytical and post-analytical schemes. This activity should be extended and be an integrated part of all EQAS activity (7). Post-analytical schemes have been conducted on a project basis across European countries for different POCT analysis (33–35). For anticoagulation treatment a post-analytical scheme is established in the Czech Republic (15), and recently a post-analytical survey for INR has been carried out in fourteen European countries (personal communication).

The present study has investigated the availability and organization of EQAS for POCT INR in Europe, but it has not examined which EQA approach leads to best quality improvement. An evidence-based conclusion recommending one of these EQA approaches is therefore difficult to give. Studies that examine the relationship between the type of EQAS provided and the quality of the POCT INR instruments in the hands of the users are needed.

In conclusion, this study demonstrates that there is a wide variation in the way EQAS for POCT INR are performed in Europe and that most European countries do not provide this service. The disadvantages in most of the EQAS is the use of lyophilized material that makes method specific target values necessary and the probability that additional measurement errors can be introduced by the pre-analytical handling of the material. To obtain a material that can be handled like patient samples and used across instrument platforms is a major challenge. Even though EQAS for POCT INR faces problems, they do provide important information and links this with educational parts for the users. Participation in such schemes is therefore considered useful, and users of POCT INR instruments should be encouraged to participate in an EQAS.

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