Mini Review

Anne Stavelin* and Sverre Sandberg

Harmonization activities of Noklus – a quality improvement organization for point-of-care laboratory examinations

<https://doi.org/10.1515/cclm-2018-0061>

Received January 16, 2018; accepted April 13, 2018; previously published online May 16, 2018

Abstract: Noklus is a non-profit quality improvement organization that focuses to improve all elements in the total testing process. The aim is to ensure that all medical laboratory examinations are ordered, performed and interpreted correctly and in accordance with the patients' needs for investigation, treatment and follow-up. For 25 years, Noklus has focused on point-of-care (POC) testing in primary healthcare laboratories and has more than 3100 voluntary participants. The Noklus quality system uses different tools to obtain harmonization and improvement: (1) external quality assessment for the pre-examination, examination and postexamination phase to monitor the harmonization process and to identify areas that need improvement and harmonization, (2) manufacturer-independent evaluations of the analytical quality and user-friendliness of POC instruments and (3) close interactions and follow-up of the participants through site visits, courses, training and guidance. Noklus also recommends which tests that should be performed in the different facilities like general practitioner offices, nursing homes, home care, etc. About 400 courses with more than 6000 delegates are organized annually. In 2017, more than 21,000 e-learning programs were completed.

Keywords: external quality assurance; harmonization; point-of-care testing; quality improvement; total testing process.

***Corresponding author: Anne Stavelin**, The Norwegian Quality Improvement of Laboratory Examinations (Noklus), Haralds plass Deaconess Hospital, Box 6165, N-5892 Bergen, Norway, Phone: +4755979503, Fax: +4755979510, E-mail: anne.stavelin@noklus.no

Sverre Sandberg: The Norwegian Quality Improvement of Laboratory Examinations (Noklus), Haralds plass Deaconess Hospital, Bergen, Norway; and Department of Public Health and Primary Health Care, Faculty of Medicine and Dentistry, University of Bergen, Bergen, Norway

Introduction

The Norwegian Quality Improvement of Primary Care Laboratories (Noklus) was established in 1992 because it had been shown that point-of-care (POC) laboratory examinations were performed with poor analytical quality [1, 2]. The aim of the organization was to ensure that all POC medical laboratory examinations are ordered, performed and interpreted correctly and in accordance with the patients' needs for investigation, treatment and follow-up.

After 25 years with focus on the primary healthcare laboratories, Noklus merged in 2017 with the “Norwegian Clinical Chemistry EQA program” (NKK) – the organization responsible for providing external quality assessment (EQA) schemes to hospital laboratories, and the new organization is now aiming at both primary and secondary healthcare. As a consequence, the organization changed its name to the Norwegian Quality Improvement of Laboratory Examination but kept the acronym Noklus.

The present paper will deal with harmonization activities of Noklus towards laboratories in primary healthcare and will be divided into three parts: (1) an overview of the Noklus organization, (2) the “tools” that Noklus use to promote harmonization and (3) the activities that Noklus use to achieve harmonization.

The Noklus organization – an overview

Noklus is a non-profit organization established by the Norwegian Government and the Norwegian Medical Association. The Board of Noklus consists of representatives from these organizations in addition to the Norwegian Society of Medical Biochemistry. The money allocated to the activity towards the general practitioners (GP) offices is obtained from negotiations between the Government and the Norwegian Medical Association. All GP offices participate for free, whereas other participants like

nursing homes, home care and hospital laboratories pay a participant fee.

An essential aspect when establishing Noklus – and a prerequisite from the specialists in laboratory medicine – was that Noklus should be not only an EQA organization, but also a quality organization that should be able to initiate actions to improve the quality of the whole examination process, from requesting tests to the interpretation of test results. Therefore, Noklus was designed as a quality improvement system by offering the participants advice and follow-up on

- which constituents that should be analyzed at the different sites, e.g. at GPs offices, nursing homes, home care, emergencies centers etc.;
- how to secure that the laboratory test results are correct;
- how to choose the POC device that should be used in different settings;
- how to secure correct interpretations and use of the laboratory results.

For all these areas, it is important first to find the best evidence for what is optimal and achievable practice and thereafter try to harmonize the activity in primary care laboratories to this practice.

Noklus is divided into different sections (Figure 1), each section is characterized by the activity they are performing, e.g. the *EQA section* is characterized by offering different schemes to the participants, both preexamination, examination and postexamination EQA schemes; the *section for education and guidance* is characterized by closer contacts with the participants by offering visits at the participants' facility, by organizing courses and

educational materials, and guiding the participants; the section for *clinical use of the laboratory* is characterized by giving advice on test repertoire and test requesting, and how to interpret the test results; and the *Scandinavian evaluation of laboratory equipment for primary health-care (SKUP)* section is characterized by manufacture-independent evaluations of the analytical quality and user-friendliness of POC instruments. The work of all these sections together make up a quality system for the total examination process and cover most of the elements in the ISO standard for POC testing [3]. Other sections in Noklus (but not dealt with in this paper) are the Norwegian Diabetes Register for Adults, patient self-monitoring of anticoagulation treatment with warfarin, EQA and guidance of hospitals and large private laboratories, and research activities.

Noklus has about 100 employees, whom mainly are biomedical laboratory scientists, but also medical doctors, specialists in laboratory medicine, IT programmers, researchers and statisticians. The headquarter is in Bergen, Norway, where about 35 persons are situated, whereas the rest of the employees are located at 22 different hospitals throughout the country. At these hospitals, the Noklus' employees are entitled "laboratory advisors" (biomedical laboratory scientists), and they are located at the Department for Medical Biochemistry (clinical chemistry). Together with medical doctors (specialists in laboratory medicine), they have the responsibility for supervising and guiding the primary care laboratories in their local geographical area. The Noklus laboratory advisors do not take part in the daily work at the hospital laboratory, but they have their focus on laboratory activities in primary health care.

Each laboratory advisor has the responsibility to maintain an up-to-date register of POCT users in their geographical area. This is practicable because the advisors work and live here, meaning that they know this area well. Each advisor registers their participants (about 50–100 per advisor) in the Noklus national register, meaning that the headquarter has the national overview.

Participation in Noklus is not mandatory; nevertheless, 99% of all GP offices and 96% of all nursing homes in Norway participate voluntarily. In addition, other laboratories like hospital laboratories, large private laboratories, emergencies centers, oil platforms, prisons and home care participate in Noklus – all together more than 3100 laboratories. Home care is provided by a visiting healthcare professional, mainly nurses, and is a new priority of Noklus. The government has given a special grant so that Noklus can extend its quality system into this area. The reason for the high voluntary participation rate in Noklus is that the participants think it is useful to

Figure 1: Organizational chart of Noklus. Only sections with * are dealt with in this paper.

participate, they appreciate the close personal contact, the face-to-face guidance and that they always know who to contact. They see Noklus as a collaborating partner, someone to discuss with and not as a strict control institution. Noklus has a high standing in the primary healthcare in Norway, the Norwegian Medical Association strongly encourage participation and it is considered obvious to participate. In addition, the fact that the course fees are rather low and the variety of different offers may also drive the voluntary participation.

Noklus' tools for harmonization and improvement

Noklus has different “tools” that can be used in the harmonization process (Table 1). These tools are used not only to harmonize but also to improve quality. To be able to use the tools in a sensible way, it is important to understand that the tools itself will not necessarily result in harmonization

Table 1: The Noklus tools for harmonization and improvement of laboratories in primary healthcare.

Site visits
Courses
e-Learning programs
Lab procedures
Educational materials
EQA schemes
POCT instrument evaluation (SKUP)

or improvement. For example, EQA does not in itself improve quality. However, EQA is an excellent system to monitor quality and to identify areas that need closer attention, i.e. areas that needs to be improved and harmonized. It is underlined in a recent paper [4] that although there can be different institutions and stakeholders responsible for initiating a harmonization process, monitoring of harmonization is best done by a national EQA system. Our experience is that EQA indeed is very useful for identifying topics/issues that should be harmonized. An overview of the different EQA schemes provided by Noklus to the primary healthcare is shown in Figure 2.

Once a “problem” has been identified, for example through the use of EQA, a goal must be established for what we want to achieve. Then comes the intervention period where different actions and activities are carried out to solve the problem. At last, the effects of the intervention have to be evaluated and monitored to see if the goal has been achieved and whether it is sustainable. The Noklus' intervention tools are feedback from EQA reports, educational courses, site visits, e-learning programs, laboratory procedures and educational materials, which are used in the education and guidance of the participants and targeted to specific problems. The leadership of Noklus decides what actions that should be initiated to be able to improve and harmonize the situation.

Education and guidance

Noklus uses in principle two different approaches to guide and educate the participants depending on the problem

Figure 2: Number of participants in the different Noklus EQA schemes for POCT. Pre- and postexamination schemes are not shown.

that shall be solved: (1) If a specific problem is discovered for one particular participant, actions like emails, telephone calls or site visits are used to address the specific problem and try to solve it. In this way, Noklus aims to improve and harmonize the activity of the participant. This approach has the advantage of being more relevant and specific for the participants, but the disadvantage is that it is time consuming. (2) If a general problem is discovered, a strategy must be made on how to address it. General advises and guidance to all participants, guidance to participants in a certain area or for a certain group of participants, e.g. nursing homes or GP offices, must be developed. This is done by organizing courses, offering specific e-learning programs, specific EQA programs like, e.g. circulation of case histories, and provide other educational materials. In some situations, with, e.g. reagent lot-to-lot variation or systematic deviations of a measurement procedure from the target value, Noklus will address the manufacturers and in cooperation try to solve the problem.

Noklus offers approximately 400 courses annually, addressing about 6000 healthcare personnel in primary care. The number of completed e-learning programs offered by Noklus was more than 21,000 in 2017 (Table 2). These numbers illustrate the large training activity of Noklus, which are important tools in the harmonization and improvement process.

Noklus has internal guidelines for when the laboratory advisors should intervene with a participant. In general, the aim is to priorities participants that really

need it. The key indicators are as follows: poor performance in EQA, no or insufficient quality control routines, passive participants (e.g. repeatedly not responding to EQA, not participating on courses and no contact with the Noklus advisor), new participants and participants asking for help. The intervention usually starts with a phone or email contact, followed by a visit or a small course at the participants' site. After each site visit/course, a report is written and sent to the participant. In addition, every participant is followed up on an annual basis by the laboratory advisors. As an example, every participant shall be offered to participate on at least one course outside their facility.

Noklus has many different offers regarding training and guidance. Small local courses, face-to-face guidance and site visits are the most successful modalities, but also e-learning programs, circulation of case histories and participation in larger conferences are important factors. By offering such a variety of option, we believe that there is something useful for everyone.

Noklus has made different checklists that can be used by the participants when they (1) receive poor EQA results, (2) when internal quality control (IQC) is out of range and (3) when they get surprising patient results. If they need further assistance to locate the problem, a more comprehensive interactive flowchart has been developed and can be used by the laboratory advisors to help the participants in the trouble shooting process. However, the most important tool in identifying problems is probably to visit the participant at their facility and observe whether the correct procedures are followed.

Table 2: Some key numbers of the main Noklus activities from 2017.

	Number
Participants	3092
GP offices	1693
Nursing homes	880
Home care	133
Others	378
Site visits	1890
GP offices	993
Nursing homes	559
Home care	134
Others	204
Courses	458
Course delegates	6400
Completed e-learning programs	21,400
Different e-learning programs	9
EQA surveys to POCT	32
Preexamination phase	1
Examination phase	30
Postexamination phase	1

SKUP

One of the most important factors to obtain satisfactory results in primary care is the use of high-quality measurement methods. Noklus therefore initiated a collaboration with the Scandinavian countries to evaluate POC instruments. This cooperation is called the *Scandinavian evaluation of laboratory equipment for primary health care* (SKUP) and is a cooperative commitment between Noklus, the Danish Institute for External Quality Assurance for Laboratories in Health Care (DEKS) and the EQA in laboratory medicine in Sweden (Equalis). SKUP was established in 1997 and is a non-profit organization. SKUP is led by a Scandinavian steering committee, and the secretariat is located at Noklus in Bergen, Norway.

The purpose of SKUP is to improve the quality of POC testing in Scandinavia by providing objective and supplier-independent information about analytical quality and

user-friendliness of laboratory equipment [5]. This information is generated by organizing “SKUP evaluations”. SKUP offers manufacturers and suppliers evaluations of equipment for primary healthcare and also of devices for self-monitoring. If the equipment is not yet launched onto the Scandinavian market, it is possible to have a confidential premarketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation. All SKUP evaluations follow established general guidelines, and a specific SKUP protocol is worked out in cooperation with the manufacturer or their representatives for each evaluation. The analytical quality is assessed according to predefined performance specifications. It is extremely important that the end users are heavily involved in the evaluations. Each evaluation is presented in a SKUP report to which a unique report code is assigned [6]. Short summaries are also written in Norwegian, Danish and Swedish and sent to primary care POC users in the different countries.

Noklus’ activities for harmonization

Education and guidance are the main activities to achieve improvement and harmonization. In order to give good advices, the laboratory advisors use all the Noklus tools available, and the focus is on the total examination

process. Noklus has different harmonization activities in the preexamination, examination and the postexamination phase. For details of the essential aspects concerning EQA for POC, see ref. [7].

Preexamination phase

An important aspect of the harmonization of laboratory examinations in primary healthcare is to recommend which tests should be performed at the different facilities. The test repertoire is decided as a consensus among specialists in laboratory medicine and the users of the tests, e.g. GPs [8, 9] after a discussion about what is needed in the different clinical settings. The recommended test repertoire for POC analyses at GP offices, nursing homes, home care and in the emergency room is published at the Noklus homepage [10]. Most of the POC tests performed at the GP offices are reimbursed by the Norwegian Government. Noklus gives advice to the negotiation parties, i.e. the Government and the Norwegian Medical Association, concerning which tests should be reimbursed and which test should not. The reimbursement system is only valid for GPs, meaning that other facilities must cover these costs themselves. Examples of tests that are recommended at GP offices, nursing homes and home care are given in Table 3. Information about test repertoires

Table 3: Recommended test repertoire at GP offices, nursing homes and home care.

	GP offices	Nursing homes	Home care
Basis repertoire	CRP	CRP	CRP
	Glucose	Glucose	Glucose
	Hemoglobin	Hemoglobin	Hemoglobin
	Urine strips (nitrite, leukocytes, protein, glucose, blood)	Urine strips (nitrite, leukocytes, protein, glucose, blood)	Urine strips (nitrite, leukocytes, protein, glucose, blood)
	Fecal occult blood	Fecal occult blood	Fecal occult blood
	INR	INR	INR
	Erythrocyte sedimentation rate		
	Urine hCG		
	Mononucleosis		
	Streptococcus A		
	HbA _{1c}		
	Urine ACR		
Extended repertoire	Hematology (blood count)	Clinical chemistry (sodium, potassium, calcium, ALAT)	
	Helicobacter pylori	Leukocytes, thrombocytes	
	Clinical Chemistry (ALAT, GT, cholesterol, creatinine, potassium)	proBNP	
	Urine microscopy	D-dimer	
	Urine dip slide (including <i>Escherichia coli</i>)	Troponin	
		Blood gas	

ACR, albumin/creatinine ratio; ALAT, alanine transaminase; BNP, brain natriuretic peptide; CRP, C-reactive protein; GT, glutamyl transferase; HbA_{1c}, glycated hemoglobin A_{1c}; hCG, human chorionic gonadotrophin; INR, international normalized ratio.

is presented on courses and at visits at the participants' facilities.

Noklus offers three different EQA programs for the preexamination phase. The first program is aimed at primary care laboratories and has been offered once a year since 2013. This preexamination EQA is a type 1 scheme according to Kristensen et al. [11], meaning that preanalytical routines are registered. Each year the scheme has different focus areas, e.g. venous and capillary blood sampling, patient identification and sample labeling. Some of these topics are repeated to monitor the improvement and harmonization efforts. In general, the participants are asked to fill in a questionnaire with different questions regarding their routines. Based on the results from these EQA schemes, actions have been taken by Noklus to increase the knowledge and awareness about preexamination topics among the participants (e.g. monthly posters with a preexamination topic at the Noklus web page [12], focus on preexamination issues on courses and site visits). For example, it was noticed that the patient identification procedures were poor for some participants, but after an intensive education period, the patient identification was improved [13]. It is interesting to observe that educational efforts more than the preexamination EQA in itself influenced the actions of the users and resulted in an increase in the percentages of participants that followed the guidelines for patient identification [13].

The second EQA program for the preexamination phase is a type 3 scheme [11] in which the hospital laboratories register preexamination errors in samples sent from the primary healthcare laboratories [14]. This program does not directly affect the POC testing process, but it monitors the preanalytical errors made in primary healthcare. Over a period of 3 years, medical laboratories in different fields (e.g. clinical chemistry, microbiology and pathology) registered four different preexamination errors on the request forms received from primary healthcare: (1) missing or wrong patient identification, (2) missing information about the requester, (3) missing information about the time of blood sampling and (4) wrong or insufficient sample material. The median error rate was less than 1.0% for all four preexamination errors, and the error rate was less in laboratories using electronic request forms. However, considering the large number of samples received from primary healthcare, the total amount of errors is considerable [14].

The third preexamination EQA program is aimed at hospital laboratories only and deals with registration of quality indicators. This EQA will not be dealt with in this paper.

Examination phase

There is a long tradition to use EQA to examine the analytical quality of measurement procedures, to compare results from laboratories and to compare results against a reference measurement procedure. It is, however, important for the EQA organizers to define how the results from the EQA schemes should be used, what information that can be obtained and how the results should be communicated to the participants. EQA programs with poor and non-commutable control materials can generate "fake" problems and confuse both the participant and the organizers [15]. In EQA schemes for POC users, the providers are communicating directly with the users of the tests, e.g. medical doctors and nurses etc., and not with specialists in laboratory medicine or medical laboratory scientists. Therefore, the feedback reports and communication with the users must be customized for this. It is also important that the users themselves can see and understand the immediate usefulness of participating in these programs.

The Noklus EQA schemes for primary care (Figure 2) are circulated from one to four times a year, commutable control materials are used in most of the schemes and the feedback reports are developed through user evaluations and are easy to understand. Target values from reference measurement procedures or certified reference materials are only possible for EQA schemes using commutable materials. If non-commutable materials are used, peer group target values must be used, and it is not possible to evaluate systematic differences between measurement procedures. However, these schemes are still valuable for the participants because they can get an evaluation of the participant performance. For international normalized ratio (INR), Noklus runs a combination scheme with (1) commutable patient split samples to evaluate the method performance and (2) EQA with non-commutable control material to evaluate the participant performance [16].

Participants with poor performance are encouraged to contact their laboratory advisors for help. The laboratory advisors have access to the EQA results of the participants in their local region. In each EQA survey, the participants are asked to report which measurement procedure and reagent lot number they have used, the profession of the person performing the analyses, the number of analyses performed per week and the frequency of performing IQC. These parameters are used to identify factors that are associated with good participant performance [17].

Noklus monitors the between-participant variation and the reagent lot-to-lot variation for all POC instruments in use in the EQA schemes, and in cases where a reference

measurement procedure is used, the systematic deviation is also monitored. As an example, this monitoring identified an increase in the between-participant variation for Afinion urine albumin/creatinine ratio (ACR) in three consecutive surveys, which could be explained by an increased reagent lot-to-lot variation [15]. The results were communicated to the manufacturer who investigated the problem, and after the problem was solved, both the reagent lot variation and the between-participant variation decreased.

It has been shown that the type of POC instrument used is one of the most important factors to obtain good performance [17]. Therefore, Noklus has a working group that is dedicated to give advice about which POC instrument to use. These advice are based on a combination of (1) results from the EQA schemes, (2) SKUP evaluations, (3) published studies and (4) personal experience. Noklus gives both general advice, such as a list of recommended and not recommended POC instruments describing the pros and cons for each instrument, but also individual advice to each participant depending on, e.g. the facility, how frequent the instrument is in use and the population of patients. The individual advice are very important because each participant can have very different needs regarding the use of these instruments (e.g. large emergency centers will have different needs than home care testing). Each participant can contact their laboratory advisor to get advice and guidance about which POC instrument to use.

A list with pros and cons for different types of POC instruments for troponin I, pro-BNP, D-dimer, C-reactive protein (CRP) and INR is presently available for internal use in the organization, and more recommendations are under development. As an example, Noklus recommend not to use CRP instruments that do not correct for hematocrit. Noklus also directly advise not to use poor POC methods, meaning that the analytical quality and/or the user-friendliness does not meet the performance specifications. As an example, in 2008 Noklus advised the participants not to use certain POC INR instruments [18], and after some time, none of the Norwegian laboratories used these instruments.

Another Noklus activity related to the examination phase is the guidance about how to perform IQC for POC methods. Even if the IQC of POC testing is very different from central laboratory testing, there is a tendency to copy the principles and routines. However, there is no evidence that the practice for central laboratories is useful for POC testing. Many of the POC methods differ from the large hospital methods in the way that the chemical reaction takes place in the test strips/cartridge, and in many cases the instrument is only a reader. In addition, many of the

POC methods have several built-in control systems, both in the instrument and in the reagent strip/cartridge, and the unanswered question is whether this could be sufficient or if there is a need to perform additional liquid control samples. Noklus is currently creating guidelines on how to perform IQC for POC testing for different types of instruments. It is important to know which part of the system is controlled, and it may not be appropriate to use the same control design to all types of POC instruments and analytes. One size does not always fit all.

It has been shown that participating in the Noklus quality system over time can improve the participant performance [17, 19]. Continuous participation in Noklus improved the performance of quantitative urine albumin measurements at GP offices [19]. The percentage of good performances increased whereas the poor performances decreased with the number of times performing EQA in Noklus for CRP, hemoglobin and glucose [17]. As an example, the poor performance rate decreased from 12% to 3% after performing CRP EQA 1 and 19 times, respectively, over a period of 9 years. Independent factors associated with good performance were found to be type of instrument, performing EQA over time, performing IQC weekly, performing 10 or more tests weekly and having laboratory-qualified personnel performing the tests [17]. However, we think that an important variable not included in these studies [17, 19] is the effects of e-learning programs, the efforts by the laboratory advisors giving courses and education to the users as well as the follow up on their facilities.

Postexamination phase

Noklus circulates case histories as part of the EQA, primarily to GPs, but lately also to nurses and other health-care workers in nursing homes and home care. These case histories focus mainly on how the test results are interpreted, but they often also contain preexamination aspects such as test requesting and sample transportation. This approach is especially useful in primary care because decisions in many instances are less complex and based on relatively few data. When creating a case history, four important elements should be considered: (1) the case history should involve a specific and typical clinical situation in which a specific analyte is important for monitoring or diagnosis, (2) the clinical situation should be frequently encountered, (3) the case history should be short and include only essential information and (4) the writing should be partly “conversational” to make the clinical situation recognizable [20]. In Noklus, the case histories are piloted by GPs to ensure face validity, and in

some cases also reviewed by academic staff and consultants in relevant specialities. An overview of the different Noklus case histories can be found in the study of Thue and Sandberg [20]. A general finding is that there is a substantial variation among the respondents irrespective of the analyte studied. In a recent study on two different case histories on the use of INR and anticoagulation treatment, it was found that only 61% (case A) and 9% (case B) followed published guidelines concerning correct interpretation and warfarin dosing based on INR results [21]. In every Noklus' feedback reports to the participants, recommendations are given concerning which tests should be requested in a specific clinical situation as well as how these test results should be interpreted in the clinical context and what actions the results should generate.

Conclusions

The Noklus harmonization efforts are embedded in a total quality system for laboratory examinations that covers laboratory activity from home care to specialist laboratories. The fundamental for this quality system is that it uses different tools to obtain harmonization, like (1) EQA to monitor the harmonization process and to identify areas that need improvement and harmonization, (2) manufacturer-independent evaluations of POC instruments and (3) education and guidance of the POC users. It has been shown that participating in this quality system over time can improve the POC testing performance.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

Research funding: None declared.

Employment or leadership: None declared.

Honorarium: None declared.

Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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