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#### **ORIGINAL ARTICLE**

## Quality assurance of laboratory work and clinical use of laboratory tests in general practice in Norway: A survey

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#### **Abstract**

Objective. Virtually all the general practices in Norway participate in the Norwegian Quality Improvement of Laboratory Services in Primary Care, NOKLUS. In order to assess and develop NOKLUS's services, it was decided to carry out an investigation in the largest participating group, general practices. Design. In autumn 2008 a questionnaire was sent to all Norwegian general practices asking for feedback on different aspects of NOKLUS's main services: contact with medical laboratory technologists, sending of control materials, use and maintenance of practice-specific laboratory binders, courses, and testing of laboratory equipment. In addition, attitudes were elicited towards possible new services directed at assessing other technical equipment and clinical use of tests. Results. Responses were received from 1290 of 1552 practices (83%). The great majority thought that the frequency of sending out control material should continue as at present, and they were pleased with the feedback reports and follow-up by the laboratory technologists in the counties. Even after many years of practical experience, there is still a need to update laboratory knowledge through visits to practices, courses, and written information. Practices also wanted quality assurance of blood pressure meters and spirometers, and many doctors wanted feedback on their use of laboratory tests. Conclusion. Services regarding quality assurance of point-of-care tests, guidance, and courses should be continued. Quality assurance of other technical equipment and of the doctor's clinical use of laboratory tests should be established as part of comprehensive quality assurance.

**Key Words:** Family practice, laboratories, quality assurance

Norwegian quality improvement of laboratory services in primary health care, NOKLUS, was established in 1992 and its objective is to ensure that laboratory analyses outside hospital are ordered, carried out, and interpreted in accordance with the patients' need for evaluation, treatment, and follow-up. NOKLUS (http://www.noklus.no) financed by a quality fund, which receives funds pursuant to an agreement between the state and the Norwegian Medical Association. At first, the services were offered to general practitioners and specialists in private practice, of whom virtually all now take part. More recently, NOKLUS has included other participants such as nursing homes, oil installations, military hospitals, and prisons. The organization

has employed medical laboratory technologists (MLTs) and specialists in clinical chemistry/laboratory medicine in all the counties, with headquarters and an office in Bergen for sending out quality control material, as well as for other national functions. NOKLUS is ISO certified pursuant to NS-EN ISO 9001:2008, and had 2172 participants in 2009.

NOKLUS is unique in that it offers in-house guidance and courses in addition to external quality assessment of laboratory analyses, and also since it considers additional technical and clinically focused services for primary care practices. In order to improve NOKLUS's services, a survey including all these aspects was carried out in our largest participating group, general practices.

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After many years of quality assurance of laboratory work in Norway, a review of current and planned activities was undertaken.

- Quality assurance of analytical work was appreciated, but there is still a considerable need for courses and instruction.
- Many general practitioners would like feedback on their use and ordering of laboratory analyses.
- Quality assurance of other technical equipment in doctors' offices is desirable, for example testing of blood pressure meters and spirometers.

#### Material and methods

There is no set procedure for how such surveys should be carried out [1,2], and no other organizations have a corresponding type of follow-up of general practices. Since NOKLUS has extensive field knowledge, we chose to organize the survey ourselves.

In autumn 2008 a questionnaire was sent to all general practices participating in NOKLUS, i.e. 99% of Norwegian general practices. The questionnaire had nine pages and was divided into seven sections reflecting the various activities of NOKLUS, as well as eliciting background information on the practices. The first five sections related to different aspects of NOKLUS's routine activities: visits by and other contact with county MLTs, issues of control material, use and maintenance of the paper-based laboratory binders (with targeted information pertinent to the pointof-care instruments used in the specific practice), courses, and tests of laboratory equipment. Further, a section on overall experiences with present services and a section on practices' views on possible future services, briefly described in the questionnaire, were included. The questionnaire was to be filled in together by at least one of the staff and one general practitioner in the office, apart from a few doctor-specific questions. The questions were either general or related to incidents that many would remember ("have needed acute help with laboratory work"). Crossing off on a five-item Likert scale from "very satisfied" (or equivalent wording) to "very dissatisfied" with a neutral and a "don't know/not relevant" alternative was used for most of the questions.

The questionnaire was sent for consideration by NOKLUS and piloted in six practices. On the whole, only small alterations were made, but the questions on follow-up of deviating results of external quality control were revised as a result of piloting.

For practical reasons questionnaires were labelled with the participant number of the practice in

NOKLUS and thus the survey was not anonymous, but we assured participants of confidential treatment. Two reminders were sent out. Data were analysed using SPSS version 15.0 with simple frequency analyses and cross-tables.

#### Results

We received answers from 1290 of 1552 general practices (83%). In 57% of cases, only staff members filled in the questionnaire, but since there were only minor differences between the answers from these questionnaires and those with doctor involvement, all answers were included with the exception of responses to doctor-specific questions. Nearly all questionnaires were complete.

Contact with the medical laboratory technologist

Most practices wanted routine visits from the MLT (Table I), most of them yearly, while 35% wanted visits every other year or less frequently. About two-thirds had needed "acute" assistance from the MLT "sometimes" (Table I), and virtually everyone was (very) satisfied with the help they had received. Equally good evaluations were made regarding the telephone availability of the MLT and the answers given by the MLT to questions concerning laboratory work in general.

#### Issues of control material

NOKLUS sends out control material for 17 different constituents/analyses once or twice yearly (http://www.noklus.no), and practices were signed up for an average of 8–9 constituents. Nevertheless, 91% considered that the frequency of sending out control material was suitable (see Table I). About the same percentage considered that the instructions for use of the control material and the feedback reports were (very) easy to understand. Almost everyone agreed that NOKLUS's self-imposed deadline for feedback reports of four weeks was "acceptable". In 81% of the practices the feedback reports were gone through at regular intervals (see Table I), although overall doctors were involved in only 49% of practices.

About 90% of practices wished to be contacted by the MLT when the analytical quality for a quantitative analysis (e.g. haemoglobin) was "poor", and 10% wanted to be contacted even when the quality was acceptable. For semi-quantitative analyses (e.g. urine stix) the term "doubtful" replaces "acceptable" because of greater uncertainty regarding the assessment. This wording resulted in a far greater need for help concerning correction, i.e. 42% and 58% wanted

Table I. Responses to selected questions on services pertinent to analytical quality in the office laboratory (percentages).

	Type of practice: 1 vs. 2–3 vs. > 3 doctors <sup>1</sup>	Localized in town or larger village vs. smaller village <sup>2</sup>	Recent practices vs. established practices <sup>3</sup>	All n = 1227
The practice would like routine visits	84–91–96	89–96	95–90	91
The practice has needed acute help with laboratory work	61–72–72	67–73	59–67	69
The frequency of external quality assessment (EQA) surveys should be "as at present"	87–92–94	91–93	90–90	91
Feedback on EQA reports is gone through regularly	78–84–78	79–82	83–81	81
Staff have looked up something in laboratory binders during past month	59-64-67	59–75	70–62	64
Staff have taken part in a NOKLUS course during the past year	37–54–57	47–57	52–51	50
The practice has visited http://www.noklus.no	30-38-48	34-51	39–38	39
Information from both the supplier and NOKLUS when purchasing analysis equipment	34–39–50	39–45	26–43	41
Experienced deficiencies regarding control material, feedback reports, offerings of visits or courses	19–20–16	17–21	20–18	18

Notes:  $^{1}n = 320$  (solo practices) versus 545 versus 344 practices;  $^{2}n = 824$  (town or larger villages – more than 5000 inhabitants) versus 330 (smaller villages);  $^{3}n = 96$  (recent practices – started 2004–2008) versus 869 (established practices).

to be contacted by the MLT when the analytical quality was deemed "doubtful" and "poor", respectively.

Laboratory binders, courses, and testing of point-of-care instruments

NOKLUS has prepared two binders with information on laboratory work, including internal quality control and procedures adjusted to the repertoire of the practice. Practices receive the paper-based binders when they join, but the binders are also accessible on our website. Two-thirds of the practices had used the binders during the past month. Recently started practices and practices in small places had looked up slightly more (see Table I). The information in the binders was regarded as (very) useful by 85% of the practices. NOKLUS issues updates of the files as paper copies twice yearly, and nearly everyone said that they had good filing routines for these updates. A great majority (84%) still preferred paper updates, while 7% wanted to download electronic updates. Only 9% had no need for paper versions of the binders.

In 2009 NOKLUS arranged 59 courses, with about 400 GPs and 2000 staff members participating. In half the practices, one or more of the staff had attended a course during the past year (see Table I), and in almost all the practices (86%) one staff member had attended a NOKLUS course "on some occasion". Equivalent figures for doctors were

15% during the past year and 47% "on some occasion". Seemingly a varied offer of courses from short evening courses to courses lasting for 1-2 days should still be available. About half the practices wanted an offer of courses once a year, the rest wanted courses twice yearly, irrespective of whether themes were covered by other arrangers. Suggestion for themes "during the next year" (2009) covered the entire spectre of NOKLUS's courses, i.e. courses on technical aspects (instruments, handling of samples, analytical procedures) as well as clinically focused courses on interpretation of test results and laboratory investigation of clinical conditions were all suggested by about 50% of practices. A more comprehensive course on laboratory medicine in general was suggested by about 20% of practices, and is more targeted at doctors.

Scandinavian testing of laboratory equipment for the primary health services (SKUP, http://www.skup.nu) is headed by NOKLUS and organizes standardized evaluations of point-of-care instruments used in primary care in Denmark, Norway, and Sweden [3]. Half the practices knew about SKUP, and 15% of practices had visited their website, compared with 40% for NOKLUS's website (see Table I). When purchasing new laboratory equipment, the main sources of information were instrument suppliers as well as MLTs (Table I), but about 20% used either only the instrument supplier or only NOKLUS/SKUP.

Routine activities - and new services

About 18% had experienced deficiencies in NOK-LUS routines (see Table I), i.e. 10% allegedly had not been offered a practice visit, while for other routines the percentage varied from 1% to 6% for deficiencies during a two-year period.

Table II shows that there was still a need for "basic knowledge" such as information on sample taking and control procedures. Doctor-related questions indicated a need for information on analysis repertoire, and also that NOKLUS probably should develop procedures for other equipment such as blood pressure meters and spirometers. Future offers such as case-history-based questionnaires highlighting clinical use of a certain laboratory test, and excerpts from electronic journal systems to improve doctors' rational use of laboratory tests in general, seemed also to be welcomed. NOKLUS has tried out these services, especially case history questionnaires, and prepared feedback reports to GPs detailing the GP's answers or use of laboratory tests compared with peer practitioners (Table II).

#### Discussion

The high response rate and completeness of answers, with few additional comments, are indicative of an acceptable face validity of the questionnaire. Further, practices are not in a customer relationship with NOK-LUS, and NOKLUS does not possess formal sanction rights, thus inviting genuine answers. We chose to design the questionnaire so as to get an overall impression of NOKLUS's activities, but some findings will be in need of more detailed investigation, drawing on experiences from an investigation of feedback reports [4] as well as laboratory customer satisfaction surveys [5].

Most GP practices have been members for more than five years, but surprisingly still wished to be visited yearly by the NOKLUS county MLT and to be offered courses twice a year, which is twice as often as stated in NOKLUS's internal routine guidelines. This mismatch may be perceived as a deficiency in routines (see Table I). Also, courses and guidance in "basic" themes such as taking and handling of samples were still in demand. Taken together, these findings indicate that laboratory work is regarded as important and complicated, with a need for ongoing updating and maintenance of skills and knowledge. For a comprehensive quality assurance organization, the message is that "baseline" activities must be lasting and probably be even more standardized, structured, and focused.

We were pleased to learn that daytime courses and the rather frequent sending of control material for analysis actually were acceptable to the practices. However, we did not fully recognize the implications of using the term "doubtful" as an intermediate category in the assessment of semi-quantitative analyses, although professionally justified. NOKLUS should therefore be more specific with regard to consequences of the wording in feedback reports so that unnecessary measures are not undertaken. Probably doctors should be involved more in going through reports, and it is possible that providing a historical review of the analytical quality could evoke interest, in addition to being a tool for follow-up of consequences of corrective measures undertaken.

Within NOKLUS, there is a continuous exchange of information to ensure competence in handling "emergency" laboratory situations, as well as common day-to-day problems [6–8] that probably explains the high degree of satisfaction with these activities. Regarding choice of laboratory equipment,

Table II. Evaluation of present and possible future offers to the practices (percentages).

	(Very) useful	Neutral	Not very useful or useless	Not assessed or irrelevant
Established offers:	93.5	4.8	1.7	_
Regular information on sample handling, analytical quality, maintenance of laboratory equipment <sup>1</sup>				
Established offers:	84.7	11.6	3.7	_
Advice on office laboratory repertoire				
Not established offers:	75.1	8.4	7.1	7.6
Assessment of blood pressure meters and spirometers				
Not established, but has been carried out for periods:	69.7	12.7	8.8	8.8
Yearly submission of case vignettes to the GP to focus on appropriate use of a certain laboratory test				
Not established offers (tried out in several practices):	55.7	19.0	11.4	14.0
Yearly reports on the GP's use of laboratory tests based on data excerpts from electronic case records				

Notes:  $^{1}$ All the answers are included (n = 1235); for the other questions, only questionnaires in which the doctor also took part are included (n = 509).

the fact that relatively few have visited http://www.skup.nu indicates both that SKUP was less known than is desirable, but also that the MLT conveys this rather complex information. Contact with instrument suppliers probably supplements information from NOKLUS/SKUP, and it seems reasonable to assume that test reports are used in sales promotion. Since this survey, SKUP has distributed a brochure to all practices, and plans to publish simplified summaries of instrument reports.

The laboratory binders are still much used, in line with findings on the use of information sources in doctors' offices [9]. Although almost all the practices had internet access, paper-based binders were still preferred. Tradition and problems with internet connection may be part of the explanation, but there is probably a real need for education and instruction as well. The gain could be considerable, since updating of laboratory binders and communication on analytical quality results should be web-based.

Finally, it is promising that a majority of doctors seemingly were positive both as regards regular quality assurance of other technical equipment, but also concerning offers to improve their use of laboratory results by responding to case histories and receiving feedback on excerpts from electronic journal systems. It seems natural that such services are rated lower than established offers (see Table II). The work on quality assurance of use and ordering of laboratory analyses should be systematized and evaluated since studies have shown large differences between individual doctors [10, unpublished data on file at NOKLUS] as well as a preponderance of only marginally abnormal laboratory results [11], and the feasibility of testing other technical equipment should be examined.

#### Conflict of interests

The study was financed by NOKLUS. The authors report no conflicts of interest.

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