SKUP

SCANDINAVIAN EVALUATION OF LABORATORY EQUIPMENT FOR PRIMARY HEALTH CARE

Establishment of SKUP and the First Evaluations

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Summary

One important factor in assuring good analytical quality is the use of adequate laboratory equipment. Users can choose the most appropriate equipment only if they have access to objective information concerning quality and user-friendliness. Thus, it is important that the equipment is evaluated in an objective manner, i.e. tested under the actual conditions under which it will be used. This is one of the reasons *Scandinavian Evaluation of Laboratory Equipment for Primary Health Care*, SKUP, began operating in the autumn of 1997.

The goal of SKUP is to produce objective and independent information concerning the quality and user-friendliness of laboratory equipment for physicians' offices outside the hospital. SKUP is a collaboration that includes NOKLUS, EQUALIS and the laboratory medicine and the primary health care in Denmark. A main office has been established in association with NOKLUS in Norway and with coordinators in Denmark and Sweden. SKUP personnel are financed with funds from their respective countries, while the actual testing is funded by the equipment suppliers.

Courses were held for 21 co-workers from the three Scandinavian countries. Some evaluations have been completed, others are in prosess, and more are being planned.

For suppliers this offers an opportunity to have their equipment subjected to standardized testing all over Scandinavia. For consumers it means easy access to objective information on equipment, and health care authorities will be able to gain an overview of the equipment (and its quality) available on the market at any given time.

We believe SKUP will play a significant role when the new directive on in vitro diagnostics is implemented.

Background

A number of different instruments for use outside the hospital are currently on the Scandinavian market. It may be mentioned, for example, that for measuring hemoglobin alone there are more than 60 different types of instruments in Norwegian physicians' offices [1]. There has been no agency in Scandinavia for approving or evaluating laboratory equipment ready for marketing. Laboratory equipment is frequently sent out on the market without having been evaluated under the conditions under which it will be used in reality. Results from various smaller, local evaluations are often difficult to interpret. The buyer of such equipment has little chance to obtain information about the market and in many ways he/she is at the mercy of chance information, often offered by the distributor of the instrument or test. Users of such equipment have had a great desire for a place to turn to for objective information regarding the equipment. It is important to have solid and relevant studies on which to base this information.

In England, some instruments are evaluated by the Medical Device Directorate and the NHS Procurement Directorate, but some are calling for an established arrangement for instrument evaluation [2]. In Scandinavia there was no system of instrument evaluation. In Sweden an "experience bank" was called for to hold information on various instruments [3].

This is why *Norwegian centre for external quality assurance in primary health care,* NOKLUS, *External quality assurance in laboratory medicine in Sweden,* EQUALIS and the laboratory medicine and primary health care of Denmark joined forces to establish *Scandinavian Evaluation of Laboratory Equipment for Primary Health Care*, SKUP.

Scandinavian Evaluation of Laboratory Equipment for Primary Health Care, SKUP

SKUP was established in the autumn of 1997 at the initiative of professionals and health authorities in Norway, Sweden, and Denmark. During 1998 staff was employed, and an information brochure was distributed to physicians' offices, equipment suppliers and health care authorities in the three countries (in Danish, Swedish, and Norwegian versions). The SKUP organization was mentioned in the national profession journals.

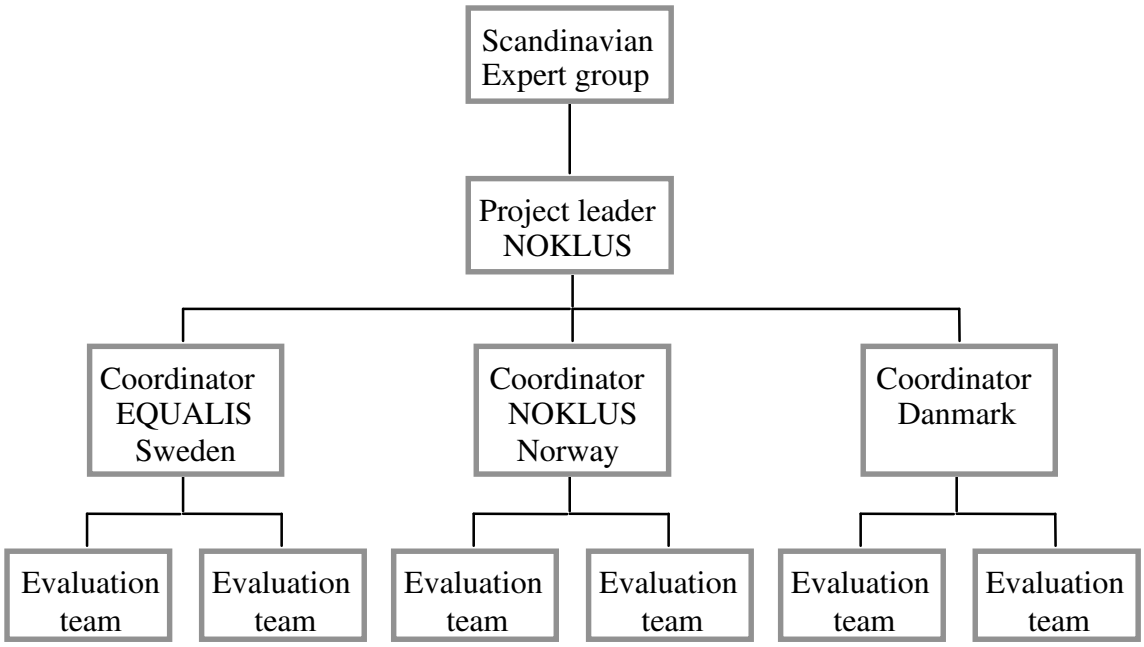
The goal of SKUP

The goal of SKUP is to produce objective and independent information concerning the quality and user-friendliness of laboratory equipment for physicians' offices outside the hospital. An important part of this information will be provided by organizing SKUP's own evaluation program.

SKUP will distribute information about laboratory equipment to physicians' offices, laboratory medical councils, laboratory advisors and healthpolitical authorities. Evaluation results can also be published and distributed over the internet.

Scandinavian Cooperation

SKUP is a cooperative venture by Norway, Sweden, and Denmark, led by a Scandinavian expert group. The main office and project leadership are at NOKLUS in Bergen. Coordinators have been employed at EQUALIS in Sweden and at the Department of Clinical Chemistry, Odense University Hospital in Denmark. The advantage of having a Scandinavian organization is that it will carry more professional weight, and lab equipment suppliers will be more interested in utilizing our services. SKUP is also a project under the Nordic Association for Clinical Chemistry. The organizational model of SKUP is outlined below.



Financing

Each coordinator is paid with funds from his/her respective country. In Norway, money is allocated from Quality Assurance Fund III, which was established by an agreement among the Norwegian Medical Association, the Norwegian Association of Local and Regional Authorities, and the Ministry of Social- and Health Affairs. In Sweden, the organization's work is financed by EQUALIS, and in Denmark quality assurance funding comes from some of the counties. SKUP will arrange evaluations of laboratory equipment. The evaluations are financed by the suppliers of laboratory equipment. Ultimately, the intention is that the system will be self-supporting.

SKUP's tasks can be divided into the following four:

Registering previously existing information about laboratory equipment.

This may be reports (from external quality assurance programs, for example) and published material, as well as information on quality and user-friendliness of equipment that can be used in doctors' practices outside the hospital. Based on this material, the expert group can estimate to which degree Scandinavian evaluations are necessary. Frequently the instruments are not studied in the real-life situations in which they will be used, namely at physicians' offices outside the hospital. Supplementary evaluations could be arranged in such cases.

Organizing the evaluation of laboratory equipment.

The instruments will be evaluated in accordance with an excisting guideline [4]. The guideline includes a pre-analytic part in which the physical and practical aspects of the instrument are assessed, followed by an analytic evaluation in a large laboratory. Among other things, this

part examines precision, trueness, carry over and interference. Finally, there is the important part in which the equipment is examined under the conditions in which it is to be used - namely in primary health care. Precision and trueness are evaluated here as well. In addition valuable information will be acquired on how the equipment will work in a daily use. It frequently happens that the achieved quality of the equipment is different when it is evaluated in primary health care, compared to the results in a hospital environment. The optimum situation would be to have the same kind of evaluation in all three countries, so that three independent data sets can be collected. This would vary somewhat, however, depending on the type of equipment being studied. The evaluation will be coordinated by the main office.

In the autumn of 1998, with support from Nordfond, a two-day course was held for 21 participants from Norway, Sweden, and Denmark. They represented 21 laboratories that have expressed their willingness to evaluate laboratory equipment and test kits. This network of contacts will be expanded in the future. Detailed instructions on how to conduct instrument-evaluation were presented at the course.

Establishing a database.

SKUP will set up a database with information about laboratory equipment. The database will contain references to everything that is written about the instruments, basic characteristics of each instrument, as well as important information from SKUP's evaluations of the instruments' analytical quality and user-friendliness.

Distributing information about laboratory equipment.

One important task will be to convey information to those who are interested. In particular, this will include doctors' offices, laboratory advisers, laboratory medical councils and authorities. As doctors are overloaded with information, it is important that the information supplied to them by SKUP will provide reasonably simple answers to the questions they are asking: Is the quality of the equipment good enough? Is the instrument robust enough? How long does it take to analyze samples? Users can turn to SKUP for this information.

The suppliers of laboratory equipment will recieve copies of the reports on their own instruments. The reports can also be bought from SKUP. The results can be published and disseminated on the internet. Summaries of evaluations can be published in *Klinisk Kemi i Norden* (Clinical Chemistry in the Nordic Countries), as well as in the publications of the medical associations and primary health care journals in Scandinavia.

How will a typical evaluation be carried out?

Instruments that are already on the market.

SKUP receives requests for evaluation of laboratory equipment from both suppliers and instrument users. SKUP can also contact the suppliers to find out if they are interested in getting an instrument evaluated. Inquiries will sometimes be sent to the SKUP coordinators in the various countries. They will contact the project leader and the expert group to assess the

possibility of a joint Scandinavian evaluation. A preliminary cost estimate will then be presented to the supplier.

SKUP will arrange a meeting with the evaluation-team and the equipment supplier. They will agree on a detailed testing protocol, a reference method, price, contract, etc. After an agreement has been signed on how the evaluation is to proceed, the evaluation is made public.

The actual evaluation is then performed by people who have participated in the SKUP-course. In this way the evaluation is standardized, regardless of where it is conducted. The coordinator in the country in question stays in constant contact with the evaluation-team.

An initial evaluation report is written by the evaluation-team and the coordinator. Based on this, a preliminary report is written by the project leader and is examined by the expert group. This report is sent to the equipment supplier, who has a chance to comment on the report. These comments will be discussed by SKUP and the report may possibly be changed following an input from the equipment supplier. A new report is then sent to the supplier. If the supplier still wants to comment on the report, these comments will be appended to the report as a supplement, along with the response from SKUP. The report is now made public, and a summary of the evaluation will be published on the internet and in scientific journals.

Instruments that are not on the market

Quite frequently, a pre-marketing evaluation of an instrument is desired. In this case, the setup differs somewhat from that outlined above. The evaluation is not made public, i.e. SKUP will not announce that an evaluation is under way unless the supplier wants it announced. The report will be written and commented on as above, but it will not be available to the public. This means that the results will not be placed in a database or published in any other way. However, if the supplier decides to market the instrument or test kit, the report will be published.

Accreditation

The Scandinavian accreditation organizations have been contacted. They have expressed their willingness, as part of a SKUP evaluation, to see if it is possible to include the instrument or test kit in question under an accreditation. Such an assessment can be a part of the evaluation agreed upon between SKUP and the equipment supplier.

Relationship between SKUP and the new directive for in vitro diagnostics (IVD); Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998

The new directive sets requirements as to what documentation the suppliers of equipment must submit before the instrument or test kit can be marketed in the EU. Requirements to documentation and approvement vary considerably, depending on which analyses are involved.

SKUP will probably play a significant role when it comes to supporting the manufacturer in producing the documentation required for marketing within the EU. This will involve so-

called pre-marketing evaluations, which will not be published. At a meeting of the Nordic Project Group for IVD Standardization in May 1999, it was stressed that SKUP should be able to carry out this type of work. Larger equipment also need to be evaluated, and SKUP will investigate the possibility of entering that area, as well.

When it comes to “post-marketing surveillance” it is unclear how this will be performed. It is possible that SKUP, along with the organizations involved in external quality control, could play a role here.

Status of evaluations at SKUP

SKUP has been very well received by both equipment users and suppliers. The users are interested in an objective, readily available information on instruments and test kits. The suppliers of laboratory equipment are pleased to have an organization to turn to for organized, standardized evaluations in both hospital labs and in primary health care. The practical work with SKUP-evaluations began in the late autumn of 1998. SKUP has now completed evaluations of several new glucose instruments and a urine test strip, together with instruments for HbA1c and CRP. A number of other evaualtions are in the preparatory stage, including some pre-marketing evaluations.

Where will SKUP be in five years?

It is a positive sign that experts in the Scandinavian countries agreed there was a need for an organization such as SKUP. Thus, it is important to integrate the total laboratory medicine environment into SKUP's activities. If this effort is successful, SKUP will be able to serve instrument users, suppliers and health authorities.

SKUP will gradually build a database with information about all instruments on the market in Scandinavia. This will be the standardized way to distribute information about these instruments.

SKUP will surely play a role in producing the documentation which the suppliers of equipment need for marketing equipment and test kits.

SKUP will probably evaluate equipment that is not intended for the primary health care as well. Even now, point of care (POC) instruments are being evaluated by SKUP, and there will be a gradual movement towards accepting larger evaluation assignments.

In Norway, NOKLUS has evaluated some of the equipment for blood sugar self-testing. Evaluation has been conducted in the laboratory as well as among diabetics. This will probably be an important and major task for SKUP, in cooperation with health authorities in Scandinavia.

However, all this means that SKUP must establish close contact with experts in Scandinavia, so that the evaluations can always be carried out where the experts are currently located.

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