

Liisa Lehto

INTERACTIVE TWO-STEP
TRAINING AND MANAGEMENT
STRATEGY FOR IMPROVEMENT
OF THE QUALITY OF POINT-
OF-CARE TESTING BY NURSES

IMPLEMENTATION OF THE STRATEGY IN BLOOD
GLUCOSE MEASUREMENT

UNIVERSITY OF OULU GRADUATE SCHOOL;
UNIVERSITY OF OULU,
FACULTY OF MEDICINE,
INSTITUTE OF HEALTH SCIENCES,
CLINICAL LABORATORY SCIENCE;
INSTITUTE OF DIAGNOSTICS,
DEPARTMENT OF CLINICAL CHEMISTRY;
OULU UNIVERSITY HOSPITAL;
NORTHERN FINLAND LABORATORY CENTRE NORDLAB



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LIISA LEHTO

**INTERACTIVE TWO-STEP TRAINING
AND MANAGEMENT STRATEGY FOR
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POINT-OF-CARE TESTING BY NURSES**

Implementation of the strategy in blood glucose
measurement

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Abstract

Point-of-care testing (POCT) is defined as laboratory tests performed outside the traditional clinical laboratory close to the patient at the time and place where care is received, such as hospitals and healthcare centers. The main reason for the use of POCT is that they provide rapid results and enable prompt interventions, with hopefully improved patient outcomes. All phases of laboratory procedure are included in POCT offering many opportunities for errors, which can influence on patients' treatment. The measurements are more often performed by nurses than by laboratory professionals. These nurses have different kinds of professional backgrounds, e.g. public health nurses, registered and practical nurses, with minimal or no knowledge of laboratory procedures.

The aim of the study was to develop a two-step training and management strategy for nurses to do POCT in hospital and primary healthcare center. In accordance with the strategy, with reasonable investment of laboratory resources, designated contact nurses were first trained in POCT by laboratory professionals, after which the contact nurses trained other nurses in POCT their respective units.

Blood glucose, the most common point-of-care (POC) test, was chosen as an example to investigate the influence of training on the quality of the test performed by nurses. The quality of blood glucose measurements was studied by analyzing the control results obtained by nurses and biomedical laboratory scientists (BLSs). The study participants included nurses who were either untrained or trained to do POCT by using the developed interactive two-step training strategy.

In conclusion, the nurses trained by using interactive two-step strategy achieved near-similar quality of blood glucose measurements as BLSs. The good quality of glucose measurements, once achieved by training, was also sustained in the long-term.

Keywords: blood glucose, external quality assessment, in-service training, internal quality control, nurses, point-of-care systems, quality improvement

Lehto, Liisa, Kaksiportainen vuorovaikutteinen koulutus- ja hallintomalli hoitajien tekemien vieritutkimusten laadun parantamiseksi. Mallin soveltaminen veren glukoosimääritykseen

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Tiivistelmä

Määritelmän mukaan vieritutkimuksiksi kutsutaan laboratoriotutkimuksia, joita tehdään perinteisen laboratorion ulkopuolella, tarvittaessa lähellä potilasta sairaalassa ja perusterveydenhuollon alueella. Pääasiassa vieritutkimuksia tehdään silloin kun tulos halutaan saada nopeasti ennen hoitopäätöstä tai tulevaa toimenpidettä. Vieritutkimusten tekeminen sisältää kaikki laboratorio työn vaiheet ja jokaisessa vaiheessa on mahdollisuus tehdä virheitä, jotka voivat vaikuttaa potilaiden hoitoon. Laboratorioammattilaisten sijaan määrittäjiä tekevät yhä useammin hoitajat sairaalan eri yksiköissä ja perusterveydenhuollon alueella. Näillä hoitajilla on erilainen ammatillinen peruskoulutus, kuten perushoitajan tai sairaanhoitajan koulutus, ja heillä on vähän tai ei ollenkaan tietoa laboratoriomenetelmistä.

Tämän tutkimuksen tarkoituksena oli kehittää hoitajien vieritutkimustoimintaan koulutus- ja hallintomalli, joka toimisi sekä sairaalassa että terveyskeskuksessa. Strategian perusteena oli käyttää suhteellisen vähän laboratorioresursseja ja päästä silti hyvään laadulliseen lopputulokseen. Strategiaksi valittiin kaksiportainen, vuorovaikutteinen koulutusmalli, jossa laboratorioammattilaiset kouluttivat sairaalan ja perusterveydenhuollon yksiköissä ns. yhdyshenkilöt, jotka puolestaan kouluttivat edelleen oman yksikkönsä muut hoitajat tekemään vieritutkimuksia.

Veren glukoosimääritys, joka on yleisin vieritutkimus, valittiin esimerkkitutkimukseksi tutkittaessa koulutuksen vaikutusta hoitajien tekemien vieritutkimusten laatuun. Veren glukoosimääritysten laatutasoa tutkittiin analysoimalla hoitajien ja laboratoriohoitajien tekemien kontrollinäytteiden tuloksia.

Tutkimukseen osallistui hoitajia, jotka oli koulutettu kehitetyllä vuorovaikutteisella kaksiportaisella koulutusstrategialla vieritutkimusten tekemiseen, sekä hoitajia, jotka eivät olleet saaneet vastaavaa koulutusta. Koulutusmallin avulla hoitajien suorittamien vieritutkimusten laatu parani ja he saavuttivat lähes saman laatutason kuin laboratoriohoitajat. Hyvä, kerran saavutettu glukoosimääritysten laatutaso säilyi myös pitkällä aikajaksolla.

Asiasanat: hoitajat, laadun parantaminen, sisäinen laadun ohjaus, toimipaikkakoulutus, ulkoinen laadunarviointi, verengluukoosi, vieritestit

*First, to Minna, second to all laboratory professionals
who work with POCT*

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Oulu, October 2014

Liisa Lehto

Abbreviations

ADA	American Diabetes Association
BLS	biomedical laboratory scientist
CV%	coefficient of variation
EQA	external quality assessment
EQAS	external quality assessment scheme
ICU	intensive care unit
IQA	internal quality assurance
IQC	internal quality control
OUH	Oulu University Hospital
POC	point-of-care
POCT	point-of-care testing
SKUP	Scandinavian evaluation of laboratory equipment for primary healthcare
SMBG	self-monitoring blood glucose
STAT	short-turn-around-time
TAT	turn-around-time

List of original publications

This thesis is based on the following publications, which are referred throughout the text by their Roman numerals:

- I Lehto L, Liikanen E, Melkko T, Ebeling T & Kouri T (2011) An interactive two-step training and management model of point-of-care glucose testing in northern Finland. *Int J Circumpolar Health* 70(3): 329–338.
- II Liikanen E & Lehto L (2013) Training of nurses in point-of-care testing: a systematic review of the literature. *J Clin Nurs* 22(15–16): 2244–2252.
- III Lehto L, Bloigu A, Liikanen E & Ruokonen A (2014) Interactive two-step strategy for training nurses. A practical tool for achieving better-quality point-of-care glucose testing in hospital and primary health care unit. *Point of Care* 13(2): 41–47.
- IV Lehto L, Bloigu A, Liikanen E & Ruokonen A (2014) Interactive 2-step training strategy for nurses – the long-term quality of glucose point-of-care testing in hospital and primary healthcare unit. Manuscript.

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1 Introduction

Point-of-care testing (POCT) is defined as laboratory measurements performed outside the traditional, clinical laboratory and near respective patient, usually by non-laboratory personnel (Ehrenmeyer 2011). POCT has been carried out from very early times. Around 1500 BC the Egyptians first mentioned a disease that was later named diabetes. An Arab physician Avicenna (980–1037) made the first clear reference with detailed clinical features and complications of the disease. Physicians analyzed urine abnormalities by smelling and tasting urine at the patients' bedside. In the 1960s Ernie Adams and his group developed the first semiquantitative, visually readable blood glucose test strip, Dexotrostix[®], to be used in doctor's offices. In 1970 Anton Clemens developed an instrument to produce quantitative results of Dexotrostix[®] by detecting the reflected light. Since then there has been great progress during the past 40 years in developing glucometers, strips and measurement technology. (Mendosa 2000, Tonyushkina & Nichols 2009, Clarke & Foster 2012).

The use of POCT has continually expanded during the last decades. In fact POCT is the fastest growing laboratory test segment on the market (Kasmierczak 2008, Plebani 2009, O'Kane *et al.* 2011). In 2001 Nichols estimated that the number of POCT implementation was growing at annual rate of 12%, one of four laboratory test was done as POC test and in 2008 it represented a quarter of the entire global diagnostics market (Huckle 2008). At global level, the total value of the POCT market was estimated to reach USD 18.7B by 2013 (Melo *et al.* 2011). The benefits that contribute to the popularity of POC tests are rapid production of results and patients' follow-up. The use of these tests reduces turn-around-time (TAT) and improves patient treatment and outcomes (Meier & Jones 2005, Plebani 2009, Giavarina *et al.* 2010, Ehrenmeyer 2011). One of the most commonly used POC tests is blood glucose measurement; other common tests are urine dipstick, INR, D-Dimer, hemoglobin and lipid profile tests.

POCT entail various risks for preanalytical, analytical and postanalytical errors which may influence the quality of results and, furthermore, patient safety (Kost 2001, Kost 2003, Plebani 2009). The POC measurements are typically performed by a large number of nursing staff with very diverse professional backgrounds (Wood 2007) and little knowledge or experience of laboratory procedures. Studies have shown that the majority of errors arise from inadequate or minimal training of nurses to perform POCT. (Blake & Nathan 2004, Wood 2007, Corl *et al.* 2012).

Nurses are trained to perform POCT using various methods and interventions but according to literature review (Liikanen & Lehto 2013) only a few studies have been published focusing on the influence of training on the analytical quality of measurements. By training the nurses, the analytical quality of glucose results can be assured. To the best of our knowledge, the influence of training on the analytical quality of the blood glucose measurements of nurses' POCT has not been studied systematically before this work. Requirements for analytical quality include the following: 1. understanding the analytical goal, 2. seeking an assay that fulfills those goals, 3. establishing the user's performance with that assay, 4. setting warning and action limits for the assay results and 5. applying quality control tools to every important step (Sikaris 2008). In this study the influence of nurses training on the analytical quality is assessed and followed by quality control samples using accuracy and precision data as criteria of quality.

The POCT quality standard, EN ISO 22870 (2006), support the development of a training and management strategy for organizing POCT. As an accredited laboratory, the laboratory of Oulu University Hospital, later Northern Finland Laboratory Centre NordLab, has defined the development of POCT as one of its main targets. The purpose of this study was to develop with reasonable laboratory resources a comprehensive training and management strategy for nurses to perform POCT and at the same time investigate its influence on the analytical quality of glucose POCT.

2 Review of literature

2.1 Point-of-care testing

Laboratory tests performed where healthcare would be provided close or near the patient are called point-of-care testing (POCT). Other commonly used terms are near-patient testing (NPT), bedside testing, extra-laboratory testing, decentralized laboratory testing or out-of-office testing. In literature various names are found to describe it. POC tests are performed and applied in several areas of medical care such as hospital clinics, physicians' offices, and different healthcare units, and they are also carried out by mobile units providing ambulatory care (EN ISO 22870 2006, CLSI 2006, Wood 2007, Plebani 2009, MHRA 2013). In brief POC test are described as tests which are done outside the clinical laboratory and near the patient (Ehrenmeyer 2011).

One of the main reasons and advantages of using POCT is the need for rapid availability of laboratory results by reducing the TAT (Meier & Jones 2005, Plebani 2009, Giavarina *et al.* 2010, Ehrenmeyer 2011) for diagnosis and delivering follow-up treatment (Kendall *et al.* 1998, Altinier *et al.* 2001). According to Price (2001) these activities have been found to shorten hospital stays and minimize complications, but however it was reported by Parvin *et al.* (1996) and Nichols *et al.* (2000) that the period of hospitalization or the time before starting treatment was not reduced by using POCT.

2.2 Standards and guidelines of POCT

The standards and guidelines are intended to ensure the use of POCT and avoid the risk of malpractice in health care. The international standard for POCT EN ISO 22870 (2006: 1) defines POCT as “*testing that is performed near or at the site of the patient with the result leading to possible change of the patient*” and Guidelines on point-of-care testing by The Royal College of Pathologists (2004: 2) as “*an analytical test undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory*”. The EN ISO 22870 (2006: 1) standard is intended to give specific requirements to POCT “*when POCT is carried out in hospital, a clinic, or healthcare organization providing ambulatory care*”. In addition to EN ISO 22870 (2006) many guidelines have been compiled to support decision-making processes in

POCT. Guidelines are defined as “*systematically developed statements to assist practitioners with decisions about appropriate health care for patients in specific circumstances*” and are usually based on the best available evidence (Farrance 2012: 6). Many countries have created national guidelines or standards for POCT. Some of these are classified as “standards” while others are “guidelines”. These documents commonly consist of development, implementation, management and clinical governance, competency and training, quality assurance and funding for POCT. (Ihalainen *et al.* 2002, The Royal College of Pathologists 2004, Nichols *et al.* 2006, Nichols *et al.* 2007, Collier *et al.* 2007, Bridggs *et al.* 2008, Tirimacco *et al.* 2008, Linko *et al.* 2009, Pascal *et al.* 2009, Ryan *et al.* 2009, Giavarina *et al.* 2010, Soto *et al.* 2009, MHRA 2013).

2.3 Functional and technical requirements for quality of POCT

The management and successful implementation of POCT is dependent on an effective and suitable organizational structure (Price *et al.* 2004, Junker *et al.* 2010, MHRA 2013), particularly because POCT is defined as laboratory test performed outside of the traditional laboratory environment (Altinier *et al.* 2001, Price 2001). Some key elements should be organized together with agreement of the responsibilities when establishing and maintaining POCT.

2.3.1 Establishment of POCT management group

The establishment of a multidisciplinary management group or committee for the delivery and overseeing of POCT from the laboratory to other healthcare units and to follow its later success is essential when the improvement of POCT is planned to start (Ihalainen *et al.* 2002, Wyer & Moriarty 2004, EN ISO 22870 2006, Linko *et al.* 2009, MHRA 2013). The existence of the committee has proved to be a backbone for the improvements as recommended (Wood & Burnett 2004). Managers of the laboratory and clinical governance should be represented in a POCT committee e.g. representatives of laboratory staff, clinicians, nursing staff, specialist nurses, information technology and finance (MHRA 2013). Representation of primary healthcare should also be included (The Royal College of Pathologists 2004) and all members should be aware of their responsibilities (The Royal College of Pathologists 2004, MHRA 2013). A written policy should be created by the committee to guide the POCT (EN ISO 22870 2006) with the responsibility for service development (EN ISO 20870 2006, MHRA 2013) and

its quality by the laboratory (Pearson 2006). The committee must have a director. The director of the clinical laboratory usually holds the ultimate responsibility for the overall operation and administration of POCT (Geyer 2001). The committee should designate a POC coordinator who is substantially responsible for the POCT training in the clinical units (Wood & Burnett 2004, EN ISO 22870 2006, CLSI 2006).

2.3.2 Purchase of POC instruments

POCT instruments including reagents and quality control materials should be procured and purchased by the laboratory professionals (EN ISO 22870 2006). The laboratory director or a designated qualified person, e.g. a clinical biochemist in the laboratory, should be responsible for the evaluation and documentation of the selected devices and other materials (EN ISO 22870 2006, MHRA 2013) in accordance with laboratory protocol (Lehto *et al.* 2011, Lehto *et al.* 2014a, Lehto *et al.* 2014b). A suitable selected system should meet the recommended quality specifications e.g. for blood glucose monitoring devices set in EN ISO 15197 (2013) or The American Diabetes Association (ADA 1987, 1996, 2004).

2.3.3 Standardization of measurements and quality control procedures

The POCT group should ensure that standard operating procedures (SOPs) are drawn up for each measurement with quality control procedures by the laboratory professionals (Geyer 2001, The Royal College of Pathologists 2004, EN ISO 22870 2006) a familiarization program for each measurement has also proved to be useful (Linko *et al.* 2009, Lehto *et al.* 2011, Lehto *et al.* 2014a, Lehto *et al.* 2014b). The SOPs should be written in language that will be understood, avoiding laboratory jargon (Wyer & Moriarty 2004, Lehto *et al.* 2011) with a copy of the manufacturer's instructions for users in place wherever POCT is performed (MHRA 2013).

A designated quality manager e.g. a clinical biochemist in the laboratory is responsible for establishing and arranging the documented quality policy and protocols of POCT. The design and implementation would conform to the quality standard of the central laboratory. (EN ISO 22870 2006, Linko *et al.* 2009, MHRA 2013). According to The Royal College of Pathologists (2004) the usage of internal quality assurance (IQA) ensures that POC results are of an acceptable

standard for use in patient care. Also external quality assessment (EQA) of POC devices, when available, would be mandatory (The Royal College of Pathologists 2004, EN ISO 22870 2006). The schemes are important when evaluating participants' performance and also in the assessment of the method (Libeer *et al.* 1996).

2.3.4 Data collection and recording

Recording of POCT results varies from the traditional paper/pen method or recording the manually onto a computer to downloading the results from the device into an electronic medical record (Bogner 2001). According to the EN ISO 22870 (2006), "*POCT results shall be reported with necessary detail... permanently recorded in the patient's record*" and "*the identity of the person performing test should be recorded*". The guidelines also emphasize the mandatory electronic record-keeping and documentation of both patients' and controls' results. The records should include, date, device type, batch numbers, result, operator identity and patient identity. (The Royal College of Pathologists 2004, Linko *et al.* 2009, MHRA 2013). The POC results shall be distinguished from those of the central laboratory or its satellites (EN ISO 22870 2006) e.g. with brackets (Lehto *et al.* 2011).

2.3.5 Financing POCT

At the beginning of POCT the costs and financing of POCT should be carefully agreed on by the management group (Bogber 2001, Linko *et al.* 2009, MHRA 2013). The costs of POCT could be linked with the storage of patients' results in the laboratory information system or included in the billing of POC reagents including purchasing devices, maintaining quality assurance and continuous supervision of the laboratory (Lehto *et al.* 2011).

2.4 General overview of nurses' education and training in POCT

The guidelines and studies emphasize education and training in order to achieve reliable POCT results (ADA 1987, Goodwin 2008, Thomas 2008, Montagnana *et al.* 2009). However guidelines and most studies do not specify how training of POCT users should be carried out in order to ensure its efficiency. In addition Lee-Lewandrowski & Lewandrowski (2001) found that clinical units may

perhaps not have been able to prepare themselves with the proper training needed in their increased use of POCT. Studies about training and usability of glucose POCT devices operated by patients (Skeie *et al.* 2002, Kristensen *et al.* 2004, SKUP 2004, Solnica & Nasalski 2007, Vesper & Myers 2007, SKUP 2009), by specially trained nurses in inpatient diabetes units (Godine *et al.* 1986) and by biomedical laboratory scientists (BLSs) (Skeie *et al.* 2002, Kristensen *et al.* 2004, SKUP 2004, SKUP 2009) have been published. Based on the literature search very few studies have been published of nurses' training in POCT. Nurses were trained with diverse of methods and interventions in different healthcare settings with the involvement and assistance of laboratory professionals (Liikanen & Lehto 2013). The interventions were reported to be successful in achieving cooperation between trainees and trainers (Hansen 1988, Sanchez-Margalet *et al.* 2005, Shephard *et al.* 2009, Knapp *et al.* 2011, Lehto *et al.* 2011, nurses' satisfaction with the training program (Sanchez-Margalet *et al.* 2005, Shephard *et al.* 2009, Knapp *et al.* 2011, Lehto *et al.* 2011), better use of devices (Shephard *et al.* 2009, Lehto *et al.* 2011) and meeting analytical goals (Hansen 1988, Lehto *et al.* 2011, Sanchez-Margalet *et al.* 2005).

A large quality improvement program, Q-Probes, was launched in 1989 by The College of American Pathologists (Howanitz 1990, Bachner & Howanitz 1991). The program gathered data from a large numbers of laboratories for systematic quality improvements efforts. Jones & Howanitz (1996) identified characteristics associated with the ability to produce accurate results in 544 institutions as a part of the Q-Probes program. Most of the participants reported that there was a specific person or persons responsible for the organization of the overall glucose monitoring program. Nursing personnel was predominantly responsible for the actual POC glucose testing. Nearly all (94%) participants reported that they had both an organized training program and a written procedure manual specially for testing. The content of training included a classroom lecture or demonstration, written instructions, bedside instruction or demonstration and a videotape. In addition 90% of the participants reported that the training was repeated and/or performance reviewed. A higher degree of accuracy was achieved for example when the laboratory personnel was included in training of blood glucose monitoring operators, the training schedules were repeated and/or performance reviewed, videotapes were used in as a part of training and POC results were regularly compared with laboratory results. Howanitz & Bruce (1996) measured changes in practice characteristics, including changes in "organized training program" and accuracy of bedside glucose monitoring

between 1991 and 1994. They compared data collected by a questionnaire for quality variables and data from paired specimens for accuracy. The results showed that although the process of glucose POCT improved, the testing accuracy remained unchanged. The percentage of participants in the organized training program did not show significant changes between the two years. The content of the training programs was not introduced.

POC tests are typically performed outside of laboratories by a large number of nursing staff trained at different levels and with great diversity in terms of professional backgrounds, such as public health nurses, registered and practical nurses (Wood 2007). The wide range of operators without laboratory background can lead to procedural errors in measurements (Blake & Nathan 2004). According to Rock (1991) and Corl *et al.* (2012) the insufficiency of adequate training and familiarity with quality control and has been shown to be directly related to number of operator errors. Lack of instruction or lack of motivation to learn bioscience behind POCT may also cause errors (Lamb *et al.* 1995, McVicar & Clancy 2001, Kyriacos *et al.* 2005). POCT poses a risk for preanalytical, analytical and postanalytical errors which may affect the quality of the results and, furthermore, patient safety (Kost 2001, Kost 2003, Plebani 2009). For example there are opportunities for errors in POC glucose testing because of the different kinds of devices used and the large number of non-laboratory operators performing tests with inadequate training (Nichols 2011), insufficient supervision (Giavarina *et al.* 2010) and limited understanding of the meaning of quality assurance (Ehrenmeyer 2011, Corl *et al.* 2012).

Operators' training is crucial for ensuring correct POCT (Plebani 2009, Lippi *et al.* 2011). To ensure the quality of POCT the training of users should be associated with processes typical in laboratory work, such as preanalytical (e.g. sample collection), analytical (e.g. accuracy of the result) and postanalytical (e.g. documented result) phases (Wood & Burnett 2004). Users should be trained in the operation and analytical principles of devices, interpretation of the results, and understanding the importance of reliable results appropriate to patients in their medical care (The Royal College of Pathologists 2004, CLSI 2006). Baum *et al.* (2006) for example found that analytical errors in patients' glucose measurements resulted from miscoding errors of the glucometers. However O'Kane *et al.* (2011) and O'Kane (2014) reported that two-thirds of errors occurred in the analytical phase of the POCT process as having no or minimal impact on patients' care but, in truth, POCT may be more prone to error than conventional laboratory testing.

The training should be followed by standardized procedures, paying attention to management of POCT, quality assurance, including the use of internal and external quality controls, and the health and safety of patients (The Royal College of Pathologists 2004, EN ISO 22870 2006). The trainer should be satisfied with the competence of the users before they are allowed to perform tests. Once the competence is obtained the training must be registered and signed by both the trainer and trainee. (The Royal College of Pathologists 2004, EN ISO 22870 2006, MHRA 2013, Linko *et al.* 2009, Lehto *et al.* 2011). In-service training or retraining to recertification and updating users' competence is also recommended by the standard and guidelines (The Royal College of Pathologists 2004, EN ISO 22870 2006, Linko *et al.* 2009) for example due to the rapid turnover of nursing staff (Rock 1991). Continued support by the laboratory is also recommended (Liikanen & Lehto 2013).

2.4.1 Interactive training

A close liaison between the users and the local laboratory is recommended on all issues relating to POCT (The Royal College of Pathologists 2004, MHRA 2013). In the 1980s and 1990s (Kohles & Barry 1989, Rock 1991, Handorf 1994) underlined collaborative approaches involving laboratory and nursing administration when organizing a framework for training in POCT. Laboratory professionals should be actively involved in design training programs for non-laboratory professionals (Rock 1991). Nurses' view of POCT is often that it constitutes "add-on" duties with no additional staffing, adding an extra work burden. Geyer (2001) pointed out that, when establishing the training program, effective cooperation and communication is needed between laboratory and clinical administration. To avoid the negative attitudes associated with POCT, especially when starting the program in clinical units, a comprehensive account of the aims of POCT and as well organized training, including quality control procedures and the testing of patient specimens should be planned. Jacobs *et al.* (2009) also emphasized the importance of direct communication system between clinical operators and laboratory personnel in solving the problems.

Interactive training is based on an active learning process that promotes deep understanding (Brown 2004): it is a learner-centered method supported by structured educational material, dialogue and the discussion of goals (Kääriäinen 2007). Similar elements are found in educational literature (Van den Berghe 1995). However, this kind of experimental learning requires active participation by the

members of staff and also by the trainers, and it is convenient for adult learning (Kolb 1984). As onsite training beyond the development of active support procedures, interactive training has been seen to increase staff-client interactions. Active support was designed to help staff organize and deliver practical support for meaningful client participation in everyday activities. (Toogood 2008). Staff views were positive, their assistance and client engagement increased (Toogood 2008) and the use of interactive training method directly affected staff behaviour and was positively perceived by staff (Totsika *et al.* 2008).

2.5 Analytical quality of glucose POCT

Studies published about glucose POCT have mostly focused on the reliability of the technology used and on the analytical quality between results using POCT glucometers and those using laboratory instruments. Glucose devices should be evaluated and tested before use and the selection of the glucometer should be based on technical and clinical performance in the patient population (Tonyushkina & Nichols 2009). A number of studies have been published about the analytical quality and performance of glucose devices (Skeie *et al.* 2002, Kristensen *et al.* 2004, SKUP 2004, Vesper & Myers 2007, Solnica & Nasalski 2007, SKUP 2009, Boren & Clarke 2010).

Skeie *et al.* (2002) and Kristensen *et al.* (2004) compared the performance of self-monitoring blood glucose (SMBG) glucometers by patients and by BLSs. The findings showed in both studies that the analytical quality obtained by patients was poorer than that of BLSs. Skeie *et al.* (2002) suggested that in the future glucometers should be tested with patients who are trained in device use in a routine way, whereas Kristensen *et al.* (2004) underlined that evaluation of new glucometers and strips should be standardized concerning both the part of users as well as the part that deals with analytical quality measurements such as experienced BLSs. The analytical quality of SMBG depends on the performance of the glucometer and especially of the skill of the user. Patients' poor technical skills and uncertainty about the glucometers' performance should be improved under the supervision and assistance of healthcare professionals. (Skeie *et al.* 2002, Solnica & Nasalski 2007).

Kimberly *et al.* (2006) studied the variability of five POC glucometers. One experienced licensed practical nurse collected samples and performed all testing of 93 participants. It was found that the results of different kinds of glucometers varied significantly and agreement between them was poor. The results indicated

that the major source of variation was lot-to-lot variability between strip lots. Baumstark *et al.* (2012) investigated four different strip lots with five different blood glucometers. The measurements were performed by well-trained clinical personnel. The study showed considerable differences in the quality of different strip lots. Kristensen *et al.* (2005) concluded that the between-lot variation of strips might influence external quality assessment (EQA) results of participants and as well as method assessment (assessment of different methods and instruments). They used three different kinds of glucometers and three different lots of strips with each device. Method assessment was analyzed by using capillary blood and three control materials to calculate between-lot differences.

Buhling *et al.* (2003) tested the usefulness of six different types of glucometers in screening pregnant patients with gestational diabetes. The measurements were performed by two well-trained laboratory persons. The results showed that the accuracy of most of the tested devices was acceptable for use in gestational diabetes screening when used by trained users. Lacara *et al.* (2007) examined the results agreement of POC glucometer and laboratory instrument and determined the effects of hematocrit, serum carbon dioxide, and mean arterial pressure on the accuracy of POC results. The samples were obtained from 49 critically ill patients first from a catheter for laboratory testing and then from a catheter and via fingerstick for POCT. The results of POCT from fingerstick sample and laboratory measurements did not differ significantly: in catheter samples hematocrit and serum carbon dioxide levels accounted the difference between POCT and laboratory glucose values, whereas Shearer *et al.* (2009) found that glucose values with a POC device differed significantly from those obtained by laboratory analysis. In their study, the samples of 63 critically ill patients obtained via fingerstick and catheter for POC glucometer and via catheter for laboratory testing were compared. No differences were found between POC glucose values for catheter and fingerstick blood samples. The results between these two studies were opposite, which highlights the question of using POCT to guide insulin titration for tight glucose control. In the study by Lacara *et al.* (2007) only one user performed the POC testing whereas in the study by Shearer *et al.* (2009) testing was done by nine different persons. The user error showed to be lower when a limited number of users performed testing: in practice this is not the actual situation in hospital which is why the importance of user training is emphasized.

One part of the study by Jones & Howanitz (1996) which was mentioned before, involved comparing blood glucose monitoring results with corresponding

clinical laboratory results from 242 institutions, altogether 6.653 paired results using a single type of POC device and one lot of test strips. POCT was performed either by a user who was regularly responsible for blood glucose monitoring or by a user who usually performed the majority of the tests. Approximately 56% of the POCT results were within $\pm 10\%$ and 75% within $\pm 15\%$ of the corresponding laboratory result. In the above study, the analytic goal corresponding to clinical laboratory results was not achieved. In the study by Novis & Jones (1998), also including Q-Probes studies, 217 participants submitted 6.095 paired split-samples simultaneously performed on a POC device and on laboratory glucose analyzers. Approximately 45% of the results varied more than 10%, a quarter varied more than 15% and nearly 14% differed from each other more than 20%.

According to Vesper & Myers (2007), the variability of glucometer results can be related to the monitoring itself, instrument calibration, sample matrix effect, or sample collection. These factors can be minimized by harmonization or standardization of the variability in standard operating procedures, by training, and by designing stable control samples addressed to users. EQA programs by training and by designing stable control samples addressed to users. Also Wood (2007) considered the matrix differences in the control samples to the results from human blood suggesting that it is imperative to control patients' devices independently by means of external quality assessment scheme (EQAS) in hospital and doctor's office, whereas at home the responsibility shifts to the patient requiring continuing training. Kristensen *et al.* (2006) showed that EQAS designed to office laboratories among diabetes patients may improve the analytical quality of SMBG and patients' motivation. Jacobs *et al.* (2009) suggested a 2-step quality assessment procedure for quality improvement of POC glucose testing. The first step of POC glucose quality improvement was to use appropriate control materials to assess glucometer functionality: the results should subsequently be confirmed by the central laboratory to ensure consistency for patients.

Scandinavian evaluation of laboratory equipment for primary healthcare (SKUP) is a co-operative commitment between Norway, Denmark and Sweden established in 1997 *"to improve the quality of near-patient testing in Scandinavia by providing objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP evaluations"* (SKUP 1997). The evaluations of the analytical performance of the glucometers used in the present study, Ascensia Contour and Contour, are presented in SKUP reports (SKUP 2004, SKUP 2009).

3 Aim of the present study

The aim of this study was to develop a comprehensive POCT training and management strategy for nurses in hospital and primary healthcare center. Blood glucose, the most common POC test, was chosen as an example to investigate the influence of the training on the quality of a test performed by nurses. This study consists of four sub-studies (I–IV) and addresses the following research questions:

1. How to develop the training and management strategy for POCT in hospital and implement it a pilot study (I)?
2. How had the nurses been trained in POCT and would this have an effect on our research plan (II)?
3. What is the influence of the two-step training strategy on the analytical quality of blood glucose POCT performed by nurses in hospital and in primary healthcare center (III)?
4. What is the long-term influence of the two-step training strategy on the analytical quality of blood glucose POCT performed by trained nurses in hospital and in primary healthcare center (IV)?

4 Materials and methods

This chapter describes the different parts (Fig 1) of this four-phase study (I–IV). The data collection was carried out in the laboratory of Oulu University Hospital (later Northern Finland Laboratory Centre NordLab), in the departments of Oulu University Hospital and in the primary healthcare units of Oulu City (I, III, IV). The literature search for systematic review of nurses training was made in the CINAHL, The Cochrane Library, Medline (Ovid) and Scopus databases (II).

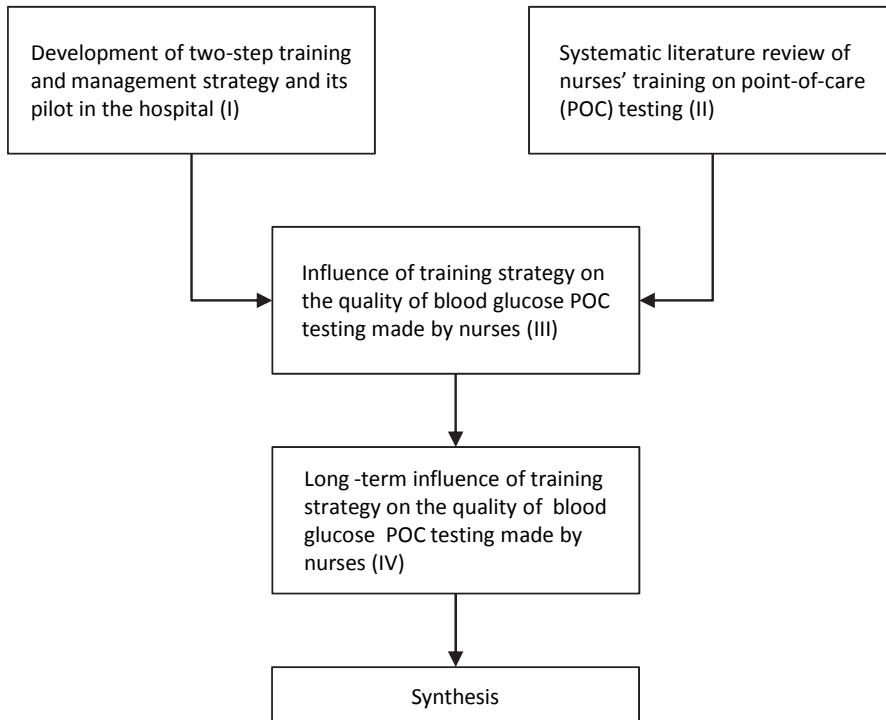


Fig. 1. The flowchart of the present investigation.

4.1 Development of an interactive two-step training and management strategy for the nurses to perform POCT in hospital and in primary healthcare center (I)

POC tests are usually carried out by nurses with a range of different qualifications, such as public health nurses, registered and practical nurses. From now on all are simply referred to simply as nurses. A comprehensive strategy for training and managing of POCT at clinical departments of Oulu University Hospital (OUH) was launched by setting up a multidisciplinary POCT management group. The aim of the group was to design a high-quality strategy with special attention on training nurses to do POC tests. The two-step training and management strategy could be applied for wide areas of responsibility. The model of the strategy was based on the international standard for POCT (EN ISO 22870 2006) and the national Finnish guidelines for POCT (Ihalainen *et al.* 2002, Linko *et al.* 2009). The key elements of the strategy were as follows (Fig 2):

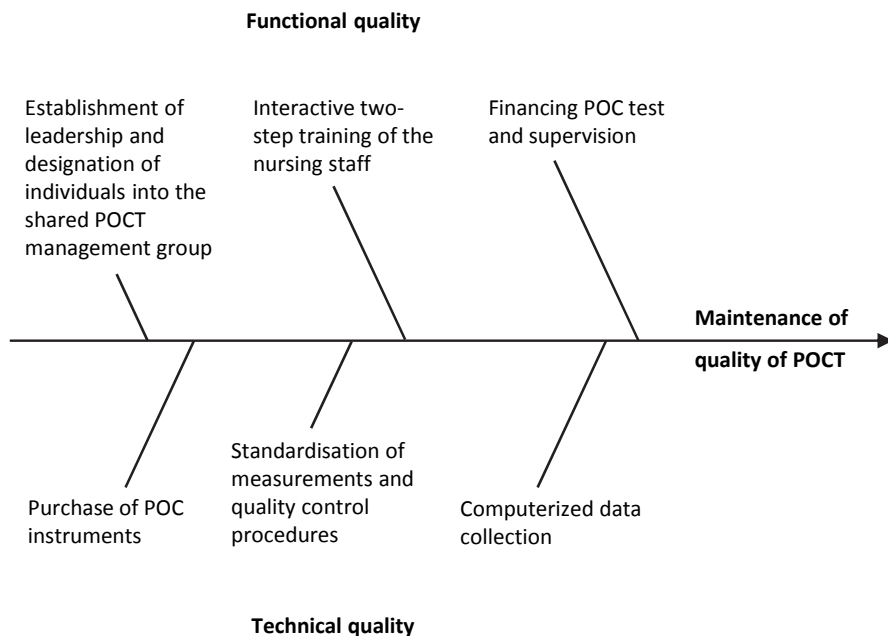


Fig. 2. Functional and technical requirements for good quality of POCT.

4.1.1 Establishment of leadership and designation of individuals into the shared POCT management

In the hospital

The multidisciplinary POCT management group was set up in 2006 with laboratory professionals at OUH: a POC coordinator, a clinical biochemist, a laboratory physician and representatives of the units of the Department of Internal Medicine at OUH, a senior clinical consultant in endocrinology and diabetes care, participants from one hospital ward, and one intensive care unit (ICU). The management was shared by all participants. The two-step training strategy was applied in blood glucose testing. After the pilot study the strategy was extended to the other units in the hospital.

In the primary healthcare center

Once the strategy had been implemented in the hospital, it was introduced to the primary healthcare units in Oulu City. The multidisciplinary POCT group for strategic planning was established in 2008. Two alternative options, strategies A and B were considered for managing the training strategy. The two strategies are presented in Fig. 3 and Fig. 4. OUH laboratory already had eight satellite laboratory units in the area of Oulu City for sample collection among other things. In the first management strategy option (Fig. 3) the idea was that professionals of the POC unit (a clinical biochemist, a POC coordinator and BLS) of the OUH laboratory were in charge of training and supporting one BLS in each laboratory units to be as a POC coordinator in their area. With the support of the POC unit this BLS would then train selected contact nurses, who would train the other nurses in their healthcare unit.

The healthcare sector of Oulu City was divided into three different organizational sectors; healthcare center for citizens to visit and see a doctor, nursing homes for elderly citizens and health services in patients' homes. In the second training model (Fig. 4) the idea of the organizational strategy was based on these sectors. In each sector a person in charge was selected to put the strategy into practice in his/her area of responsibility together with the POC unit. After selection of contact persons in each primary healthcare unit, the POC unit would train these contact persons to be in charge of training their colleagues in their respective units. The persons in charge would organize the training sessions for

selected contact nurses. Strategy B was selected because of an existing organizational structure and it was implemented in the healthcare center of Oulu City.

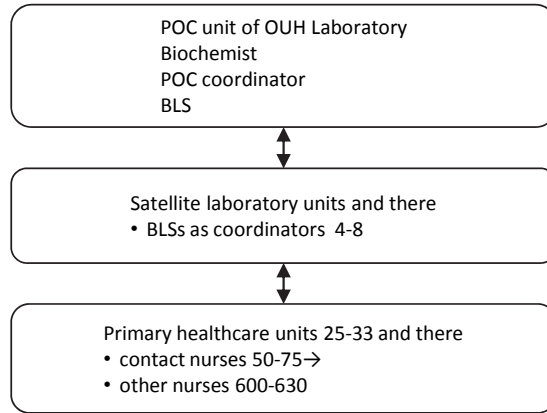


Fig. 3. Training and management strategy A in healthcare units of Oulu City.

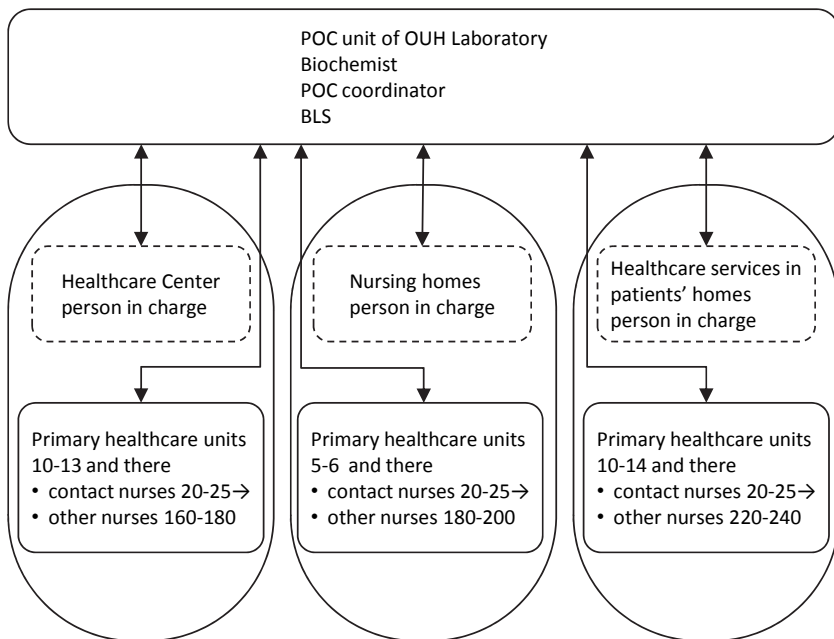


Fig. 4. Training and management strategy B in healthcare units of Oulu City.

4.1.2 Purchase of POC instruments

In the hospital

A single type of glucometer Ascensia Contour (Bayer Healthcare Mishawaka, USA,) with 15 second measuring time was purchased for the laboratory and clinical units of the hospital. The purchasing and the evaluation, including validation and verification, of the device were conducted in accordance with the laboratory protocol based on analytical applicability to various patient populations such as newborns and patients with peritoneal dialysis, and multi-user environment. The batches of Contour reagent strips (Ascensia Microfill strips in a pilot) and Contour “normal level” internal control (Ascensia Microfill internal “normal level” control in a pilot) solutions were distributed to the units by the laboratory to ensure the identity of the batches.

In the primary healthcare center

In the primary healthcare units the nurses were supplied a newer model of the same kind of device, i.e., a Contour glucometer (Bayer Healthcare Mishawaka, USA) with 5 second measuring times. The measurement times are quoted from manufacturer’s specifications. The difference between the devices is that the Contour device incorporates an error correction algorithm to compensate for low and high hematocrit values. The Contour device uses the same kind of Contour strips and Contour “normal level” control solutions. Batches of strips and control solutions were also distributed to the healthcare units by the laboratory.

4.1.3 Standardization of measurements and quality control procedures

The clinical biochemist and POC coordinator of the laboratory drew up standard operating measurements, quality control procedures and a familiarization program for the nurses both in the hospital and in the primary healthcare units. The training included preanalytical, analytical and postanalytical phases of POC glucose testing. The details of instructions were: 1. Use of the device, 2. Sample collection and analysis, 3. Evaluation and reporting of patient results, 4. Quality assurance, 5. Handling of reagents and control material, 6. Trouble shooting, 7. Laboratory information system and 8. Equipment maintenance. Standardized

procedures were implemented after their legibility was tested by a nurse from a clinical department (Wyer & Moriarty 2004). The familiarization program served as an outline for the teaching events.

4.1.4 Interactive two-step training of the nursing staff

An interactive two-step training strategy was developed at first in the hospital and extended to the primary healthcare units. In our strategy designated contact nurses in the hospital were first trained in glucose POCT by laboratory professionals after which they trained other nurses in their respective units. At first, before implementing the strategy in the units of the hospital and healthcare center, the nursing personnel was informed of the new procedures to foster a positive attitude towards the new approaches in POC glucose testing.

Our training strategy was based on an interactive model. The key element of the training was to increase learners' engagement by influencing the amount, quality and momentary effectiveness of tutor-learner interactions that relate to nurses engagement (Toogood 2008). Responsible contact nurses were designated to the task. Both in the hospital units and in the primary healthcare units each of them was trained in groups by the laboratory POC unit in order to provide them with genuine interaction and a possibility to address and train other colleagues on POC glucose testing. The training events lasted 60 – 90 min. Times for training were scheduled in advance, and the place for training was peaceful and well suited for the purpose. The contact nurses were trained according to the familiarization program including all phases of the laboratory process focusing on test results, sources of error, uncertainty of measurements and the consequences of false results. In addition the laboratory professionals organized lessons on sample collection for all nursing staff members. Specific characteristics and nurses' needs in different types of units, such as skin puncture sample collection from patients with poor peripheral circulation or collection of glucose samples from babies' heels in the newborns unit were also taken into account in the interactive training program.

Our training strategy required active participation by laboratory POC coordinator, contact persons and nurses, especially at the beginning of the new procedures of POC glucose testing. The POC unit supported nurses actively by visiting them and by being available by e-mail or phone when necessary. The interactive manner of training encouraged contact persons as well as other nurses to challenge their previous POCT practices in their units.

4.1.5 Computerized data collection

In the hospital

In the hospital both patient and IQC results were stored in databases. IQC results were collected manually with local computer software via local area network in the laboratory. Another computer interface was developed to record patients' POC glucose results manually. They were reviewed together with the patients' other laboratory results within the laboratory information system with the POCT results marked in brackets. The nurses were permitted to add glucose test results into electronic patient records, carefully avoiding transcription errors after familiarization by the contact person.

In the primary healthcare center

In the units of primary healthcare center the POC glucose results of patients were entered manually to computer to be reviewed marked as POC results. The quality control results are first collected on a form and forwarded to the laboratory every month and entered manually to a database.

4.1.6 Financing POC tests and supervision

In the hospital

Billing of the costs of POCT was linked with the storage of patients' POC results into the laboratory information system. A discount price was used as compared with the price of glucose testing supervised by the laboratory. The purpose was to compensate the use of nursing staff in the measurements, including the costs caused by purchasing devices, strips and control solutions, maintaining quality system, data transfer and storage and continuous training.

In the primary healthcare center

In the healthcare center the billing of POCT was included in the costs of the reagent strips and control solutions distributed by the laboratory to the healthcare

units. The costs were caused by purchasing devices, strips and control solutions, overseeing the quality system and continuous training by the laboratory POC unit.

4.1.7 Follow-up of training strategy

The laboratory POC unit consists of a clinical biochemist, POC coordinator and one BLS. From 2006 to 2012 the number of personnel has increased by one BLS. For the maintenance of the training strategy professionals train new contact persons when needed, such as when a contact nurse retires or for the duration of a contact nurse's maternity. The existence of contact nurses is necessary and important for the continuity and stability of the strategy in all healthcare units. They act as links between the laboratory and their units. They are responsible e.g. for ordering POC glucose materials to their unit from the laboratory and for updating colleagues' knowledge of new operation procedures together with the laboratory POC unit.

The nurses measured the glucose IQC samples with a different frequency in different units. The frequency depended on the volume of patients' measurements and the workload of the glucometers (CLSI 2006). For example in ICU, because of the large volume of the patients' glucose measurements and many glucometers the QC sample is measured every day as opposed to only once a week in nursing homes. The measurement frequency is agreed in cooperation with the laboratory emphasizing that the IQC sample is measured regularly by each device in use and in turn by every nurse in charge of patients' measurements. Quality control rules for nurses are designated by the laboratory's POC unit. The main rule is that unexpected or out-of-range results in a control sample should be repeated by reanalyzing the same control sample. If the result is still out-of-range strips and controls must be replaced by new ones. If the problem still persists the glucometer must be taken out of use. IQC results are stored on a database. In the hospital nurses collected them manually with local computer software; in the primary health care units results are collected on a form and forwarded to the laboratory POC unit and entered manually to the database.

The clinical biochemist reviews the control results and together with the POC coordinator and BLS provides targeted feedback about glucose POCT to the units on a regular basis. The feedback consists of a summary of the density of IQC measurements, coefficient variations (CV%) of the results and an evaluation of the nurses' POCT performance. The feedback is compiled avoiding laboratory jargon. Feedback is given quarterly in the hospital and biannually in the primary

healthcare units. In the case of observed problems, e.g. if the compliance of density of IQC measurements is not fulfilled as appointed, the POC coordinator or BLS informs to the units at once. The documented feedback is sent by e-mail and also given in organized feedback sessions to persons in charge of the management groups and to contact persons who forward it to their colleagues in their own units. The feedback sessions have been found to be very valuable situations in motivating and retraining nurses. Annual internal audits have been conducted every year in some primary healthcare units to review the processes together by the clinical biochemist as auditor and the POC coordinator or BLS. The audit reports consist of general evaluation of the process, observed problems and the proposals for action to improve and correct them. The reports are sent both to the persons in charge of primary healthcare center and laboratory and also to the contact persons who forward it to their colleagues. Internal audits are not yet been used in the hospital.

4.1.8 Evaluation of two-step training and management strategy in a pilot study in hospital (I)

Two clinical departments were selected as the pilot units of the training strategy at the hospital: an ICU and an internal ward with diabetic patients. After the contact persons of both pilot units had been privately trained by the laboratory POC coordinator they trained other nurses in their own units with the same manner. Once training was completed a certificate was signed by both the contact person and each trained nurse. Between April and September 2007 a total of 49 nurses in the pilot departments signed the cards as their “driving licenses” for glucose testing.

In addition a total of 35 nurses in pilot units were trained and instructed in small groups by the POC coordinator on skin puncture sample collection and on the importance of measurements of control samples behind successful POCT. The nurses practiced their skills and discussed relevant issues related to POC glucose testing during these sessions. Written standard operating procedures were available in the units at the training sessions and afterwards. At the end of the training the nurses recorded quality control and patient results by themselves under the supervision of tutors

The functional quality of training was investigated with interviews with contact persons and a questionnaire to the trained nurses. Interviews with two contact nurses were conducted by a researcher who had not met them before. The

aim of the interview was to check the POC coordinator's role in the training process; the themes focused on the content and circumstances of training, implementation of strategy and changes in contact nurses' POC action. Objectivity in data collection is very important in qualitative research (Malterud 2001). The two interviews, which lasted 25 and 38 minutes, were recorded and transcribed.

The questionnaire about the satisfaction of nurses POC test training by their contact nurses consisted of four themes: sufficiency and practical arrangements of training, prerequisites of clinical contact persons to provide training and utility of training. The respondents were also asked to express their opinion on the training process as a whole. The validity of the questionnaire was checked by a panel of laboratory professionals. The respondents were asked to rate their perceptions with 25 Likert-scale questions (-2 – +2; strongly disagree – strongly agree) and two open-ended questions. A neutral response (neither agree nor disagree) was scored as 0. In open-ended questions the nurses could answer in their own words, while the Likert scale made it possible to discriminate different points of view. The questionnaires were sent to 49 trained nurses.

The technical quality of the trained nurses was studied by comparing IQC Ascensia Microfill Control, "normal level" results obtained by personnel of OUH Laboratory and nurses at the ICU and clinical ward during two periods in May 2008 and in January 2009. A summary of the materials and methods of this sub-study is presented in Table 2.

4.1.9 Statistics

The interview data of two contact persons were analyzed using qualitative content analysis. The contents of narrative data were brought up prominent themes and patterns among themes (Polit & Beck 2008). A guiding principle of sampling in qualitative studies is data saturation. There the sampling point is the point where no new information is obtained and redundancy is achieved. (Polit & Beck 2008, Pope *et al.* 2000). Two contact persons were interviewed and their responses were assessed. We had to find out redundancy of key elements within the interviews and the questionnaire. Data were broken down into smaller units that were coded and named according to the contents they presented, and the coded material was grouped based on shared concepts.

The questionnaire for trained nurses was analyzed. The frequencies and the means of the respondents' answers were calculated. Four sum variables were

created evaluating the internal consistencies with Cronbach's α coefficient (Polit & Beck 2008). Cronbach's α is used as an index of internal consistency or homogeneity to estimate the extent to which several items are reliable measuring the critical attribute. Normal range of values is between 0.00 – 1.00 (Polit & Beck 2012). In our study consistencies ranged from 0.80 to 0.93.

Technical quality of trained nurses at the pilot departments was investigated by comparing the means and CV%s of IQCs to those obtained by laboratory professionals.

4.2 Literature review of the nurses training in POCT (II)

A systematic literature review was conducted to describe the training of nurses in POCT. The aim was to find and try to identify information gaps to guide the focus of future researches. The study was based on four multidisciplinary databases: CINAHL, The Cochrane Library, Medline (Ovid) and Scopus databases. The research questions were:

1. Which POC tests are used and where is the training delivered?
2. What kind of training is given?
3. What are the results of training?

The framework for the study was population, exposure and outcomes (Khan *et al.* 2003). The reliability and validity of the study was increased by having the work conducted by two researches (Petticrew & Roberts 2006, Bettany-Saltikov 2010a). The searches were performed with agreed search terms by one researcher with the help of an information specialist. The whole of each database was targeted and covering publications from the establishment of the database up to autumn 2011. The search terms are presented in Table 1.

Table 1. Databases, search terms and dates of searches.

Database	Search terms	Date of search
CINAHL	(advis* OR educat* OR supervis* OR counsel* OR train* OR guid* + MH "Education+") AND (MH "Point-of-Care Testing" OR alternat* test* point-of-care test* OR bedside test* OR near patient test* OR poct)	2011/9/14
The Cochrane Library	(educat* OR supervis* OR counsel* OR advis* OR guid* OR train*) AND (point-of-care test* OR bedside test* OR near-patient test*)	2011/11/4
Medline (Ovid)	(point-of-care test* OR bedside test* OR near-patient test) AND (advis* OR educat* OR supervis* OR counsel* OR train* OR guid* Education, nursing, continuing/or education professional, retraining/or exp education, nursing)	2011/11/4
Scopus	(point-of-care test* OR bedside test* OR near-patient test) AND (advis* OR educat* OR supervis* OR counsel* OR train* OR guid*)	2011/9/29

The search focused on peer-reviewed journals in English, and total of 1.539 titles were identified. The inclusion criterion of these titles was that they must deal with training nurses in POCT. Thirty one abstracts were selected to screen for identifying those that reported on nurses' training in POCT. Exclusion criteria were: (a) training other health professionals, e.g. general practitioners, in POCT and (b) other activity in POCT e.g. implementation of POCT. The relevance of selected publications was critically checked and finally six papers were selected for review (Fig 5).

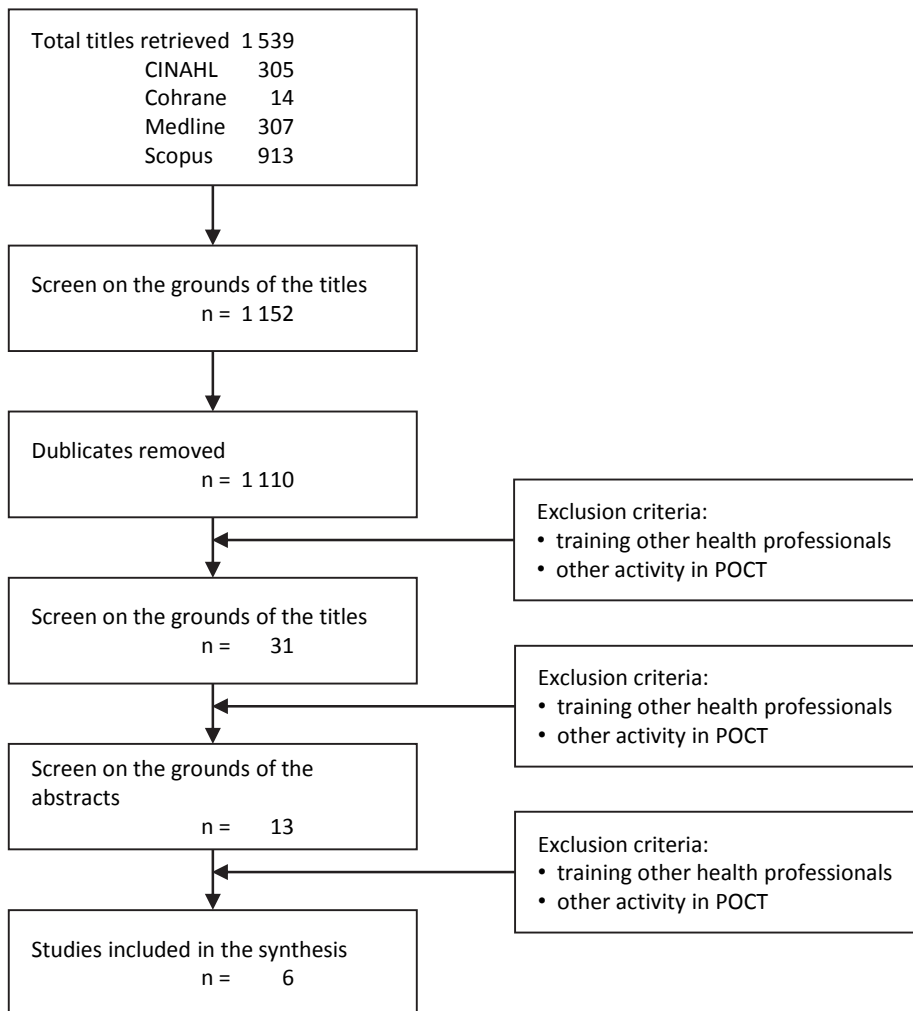


Fig. 5. The process of the literature review on the training of nursing staff in point-of-care testing and selection of papers for review.

The titles were first separately evaluated by both researches, the abstracts were then assessed together by both and finally full papers for review were selected. The results of the review were presented in a narrative form because of the small number of studies and the great heterogeneity in study designs and outcome

measures. A summary of the materials and methods of this sub-study is presented in Table 2.

4.2.1 Statistics

For the agreement between the two researchers a Kappa coefficient value based on the choice of study titles was calculated (Cohen 1960). Kappa coefficient value is used to measure reliability of interrater agreement between researchers. The value of 0.60 is minimally acceptable and values of 0.75 or higher are very good. Statistical analysis was performed with PASW statistical software, version 18 (SPSS Inc, Chicago, Illinois, USA).

4.3 Evaluation of the training and management strategy on the analytical quality of blood glucose POC testing (III)

The effect of the two-step training strategy on the analytical quality of POC glucose measurements was investigated by analyzing EQA results. The EQASs are provided by an company, Labquality Inc., who provides EQA services and control materials for clinical laboratories and POCT. The results of an EQAS obtained by trained and untrained nurses in units of the OUH and Oulu City healthcare center were compared with those of BLSs in the OUH and the other EQAS participants who used Ascensia Contour and Contour glucometers in 2010 and 2011. The total number of control results of glucose POC tests received by Labquality Inc. was 2993 in 2010 and 3144 in 2011 in those schemes. The results obtained with both the Ascensia Contour and Contour glucometers were analyzed from the schemes conducted on 3/2010 (normal level sample) and 3/2011 (high level sample). Excluding the results of OUH and Oulu City, the total number of results analyzed for the Ascensia Contour and Contour glucometers in 2010 were 435 and 1.173, respectively. In 2011 the corresponding figures were 384 and 1.223.

4.3.1 Devices, control materials, reagent strips and participants

The BLSs in the laboratory and nurses in the clinical units at the OUH used Ascensia Contour 15 second glucometers. In the healthcare center of Oulu City nurses used a newer model of the same kind of device, i.e., a Contour glucometer with 5 second measuring time. The control material used was a stabilized human-

based whole blood sample for *in-vitro* use with chemicals and preservatives. EQA samples were distributed by the POC coordinator and one BLS to the different satellite units of the laboratory, to the units of OUH and to the primary healthcare units in Oulu City. The control material was measured once by each glucometer. The Contour strips were distributed to the users by the laboratory. The lot numbers and expiry dates of the strips were 9AC3D04 (2011–01), 9MC3D10 (2011–12), 0HC3D04 (2012–08), DP1BC3D164 (2013–02). No information was available about the strips used by the other EQAS participants, and therefore these strips are referred to as “unknown strips”.

The term “trained nurses” was used to describe nurses who had undergone our two-step training between 2007 and 2011, whereas “untrained nurses” referred to nurses that who had done glucose POC tests in their routine practice, but had not yet undergone our training. The professional background and training of other users of the same glucometers in the EQAS was unknown, and so these participants were labeled as “user and training unknown”.

The results were classified into different groups according to device, users, such as BLSs, trained or untrained nurses, settings and lot numbers of the strips used in the years 2010 and 2011. The main characteristics of the study groups are presented in article III. A summary of the materials and methods of this sub-study is presented in Table 2.

4.3.2 Statistics

Outliers were detected using the method described by Burnett (1975). Outlier frequencies were calculated and any outliers were excluded from the subsequent analysis. Coefficients of variation were calculated as follows: $CV\% = (\text{standard deviation}/\text{mean}) \times 100$. Bias-corrected and accelerated 95% confidence intervals of the standard deviations were computed with 1000 bootstrap resamples. Standard deviations were compared using Levene’s test. Student’s t-test was used to compare mean values between two groups. When two or more groups were compared to the same group, one-way analysis of variance was performed and Dunnett’s post hoc test was used to correct for multiple comparisons. The level of statistical significance was set at $P < 0.05$. Statistical analyses were carried out using PASW 18.0 for Windows (SPSS Inc., Chicago, Illinois, USA).

4.4 Evaluation of the training and management strategy on the analytical quality of blood glucose POC testing in the long-term (IV)

The long-term influence of the two-step training strategy on the quality of POC glucose measurements was evaluated by analyzing IQC results obtained by BLSs and trained nurses in hospital and in primary healthcare units in 2010, 2011 and 2012. The aim was to study whether the good analytical quality of blood glucose testing obtained by the nurses will persist in the long-term. The success of trained nurses in testing was also compared to BLSs and the effect of the glucometers, strips, and controls on the variation of the results studied. The results obtained by both Ascensia Contour and Contour glucometers during September, October and November in 2010, 2011 and 2012 were analyzed. The total number of results analyzed for the Ascensia Contour glucometers was 3665, 4601 and 4939 in 2010, 2011 and 2012, respectively and for the Contour glucometers 999, 911 and 1104 in 2010, 2011 and 2012 respectively. Total number of results was 16.219.

4.4.1 Devices, control materials, reagent strips and participants

The BLSs and nurses in OUH used Ascensia Contour 15 second glucometers whereas nurses in Oulu City used Contour glucometers with 5 second measuring time. The IQC samples (Contour control “normal level” sample) consisting of an aqueous glucose solution for in-vitro diagnostic use were provided by Bayer Healthcare Newbury, UK. The lot numbers and expiry dates of the Contour strips used in this study were 9AC3D04 (2011–01), 9MC3D10 (2011–12), 0HC3D04 (2012–08), DP1BC3D164 (2013–02) and DP1MC3F01A (2013–12). The number of participants, means and CV% of every five study groups are presented in article IV. The same analytical strips and IQC samples were used at the same time for both glucometers and they were distributed to the units by the laboratory. The control material was measured as appointed by each glucometer in the units. The results were collected to the database. All nurses who participated in the study underwent two-step training between 2007 and 2012. The IQC results were grouped according to year, user, glucometer and strip lots used. The results during three months in three consecutive years were combined in each users group and setting. Within all users’ groups results in each setting for 2010 were compared to

the corresponding results in 2011 and 2012. A summary of the materials and methods of this sub-study is presented in Table 2.

4.4.2 Statistics

Outliers were identified using the method described by Burnett (1975) and then excluded from subsequent analyses. The calculated CV%s were compared using Miller's test for the equality of coefficients of variation (Miller 1991). Mean values were compared using a Student's t-test. When the mean values of three groups were compared, one-way analysis of variance (ANOVA) followed by Dunnett's post hoc test was used for multiple comparisons. The level of statistical significance was set at $P < 0.05$. Statistical analyses were carried out using IBM SPSS Statistics version 21.0 (SPSS Inc., Chicago, Illinois, USA).

4.5 Ethical aspects

Ethical considerations are essential in studies of involving training of healthcare professionals (Polit & Beck 2008). In the first study the impact of applied training model was measured functionally. At first the head nurses of the pilot units were privately informed about the research by the POC coordinator. After that all nurses in the pilot units were fully informed about the study's aim and procedures in an information session. Nurses were informed of the confidential and voluntary nature of the study and the anonymity of the data. The functional quality of the applied training model and its effect on the quality of POCT was measured by the interviewing to two designed contact nurses. The interviewer had not met the contact nurses before. The two contact nurses interviewed took part in the interviews voluntarily and they had an opportunity to withdraw and stop the interview at any time without giving any justification. The functional quality of the training model was also measured by a questionnaire completed by the trained nurses. In the nurses satisfaction survey of POC test training by their contact nurses in the clinical units of the university hospital no personal data of nurses appeared in the responses. The questionnaire was sent to the nurses by POC coordinator with a covering letter informing them about the purpose of the questionnaire signed by the chief physician of the laboratory. In the cover letter the respondents were also informed that they could answer voluntarily and anonymously. The technical and analytical quality of the training strategy was studied by analyzing control results of EQASs and IQCs. Collecting quality control results from the laboratory statistics and analyzing them is a part of routine development of laboratory processes.

5 Results

A detailed description of the results is given in the original publications I–IV. In this section, the main results are presented in four parts. The first describes the results of the pilot study in the hospital while second contains a systematic literature review concerning nurses training according to published articles. In the third and fourth parts the analytical quality of glucose POCT is presented, first for untrained and trained nurses, and after training for all nurses in the long-term in comparison to the analytical quality achieved by laboratory professionals.

5.1 Implementation of the two-step training and management strategy in the pilot units (I)

The results of the pilot study were divided into functional and technical qualities. The functional quality was investigated by interviews with the contact nurses and by a questionnaire to the trained nurses in the pilot units. The qualitative content analysis of contact persons' interviews concerning POC coordinator's training brought out four themes in training: basic requirements for training, interpersonal communication, quality interaction and the advantages of change. The statements of the contact nurses interviewed were mainly, positive and they felt that the POC coordinator had succeeded in her task. The only criticism was that the training sessions were too hasty.

The functional quality of the training by the contact nurses was studied by a satisfaction questionnaire to 49 nurses in pilot units. The questionnaire was returned by 28 nurses, the response rate being 57%. The means and consistencies of four sum variables are presented in Table 3. The values of Cronbach's α for sum variables were good (range 0.80–0.93), reflecting high consistency within sum variables. The mean values of all sum variables were positive, higher than 0.50 indicating basic satisfaction towards POC glucose training. The nurses were the most satisfied with their contact nurses' prerequisites for training (mean 1.58, sum variable 3). According to the respondents contact nurses had an adequate knowledge of glucometer and sample collection, and their attitude towards training had been positive. The nurses were the most dissatisfied with the practical arrangements of training (mean 0.51, sum variable 2). During the training sessions nurses were encouraged to ask questions and they felt free to express their opinions concerning glucose testing issues. Nurses were satisfied with the sufficiency of training (mean 0.80, sum variable 1). Trained nurses were

confident with their skills to operate the device and analyze the patient samples. The contact persons showed that they had received essential knowledge from the POC coordinator to master analytical and control procedures (mean 0.75, sum variable 4). However some of them answered that training had not motivated them to do glucose testing. The respondents were satisfied with the training process as a whole (mean 0.84). Open-ended questions revealed wishes for more time and a peaceful place for training.

Table 3. Satisfaction of clinical nurses with POC training given by their contact nurses. Means and consistencies (Cronbach's α coefficient) of the four sum variables.

Variables	Mean	Consistency
1. Sufficiency of training	0.80	0.84
2. Practical arrangements	0.51	0.93
3. Prerequisites of clinical contact persons to provide training	1.58	0.80
4. Utility of training	0.75	0.89
Training process as a whole	0.84	

The technical quality of the training was analyzed comparing the results of IQC measurements by laboratory personnel in two different periods personnel to those of the nurses in two pilot units. The results are presented in Table 4. During both periods imprecision (CV%) was low among laboratory personnel (from 2.6 to 2.9) and nurses in pilot units (from 2.4 to 3.7) showing closely similar quality of POC glucose measurements. The mean values were also very close to each other in both periods using the same kind of glucometers and same lot of strips.

Table 4. Repeatability of POC glucose measurements by the personnel of OUH Laboratory, the Intensive Care Unit and the in-patient ward of Internal Medicine with frequent diabetic patients.

Participants	Period ¹			Period ²		
	May 1 – May 31 2008			January 1 – January 31 2009		
	Mean mmol/L	CV% ³	n ⁴	Mean mmol/L	CV% ³	n ⁴
Laboratory personnel	6.66	2.9	300	6.69	2.6	307
ICU personnel	6.64	2.4	173	6.79	2.4	180
Ward personnel	6.59	3.7	40	6.68	2.8	48

¹ Laboratory: 10 devices, 10 users; ICU: 7 devices, 36 users; Ward: 2 devices, 23 users

² Laboratory: 10 devices, 10 users; ICU: 7 devices, 34 users; Ward: 2 devices, 30 users

³ Coefficient of variation

⁴ Number of all measurements by different users

5.2 Nurses' training in POCT according to literature review (II)

The six studies presented in Table 5 met all the inclusion criteria in the literature search. The Kappa value was 0.836 indicating very good agreement (Krippendorff 1980).

Table 5. Studies on training nursing staff in point-of-care testing.

Author	Country and setting	Design	Participants	Intervention	Main results
Beisey, Morrison, Whitlow, Baer, Nelson & Hardwick 1987	Canada and USA inpatient	Pre-/post-test	2,100 nurses	Self-learning videotape, demonstration review technique, retest, retraining by the diabetes nurse-educator	Managing the quality of bedside glucose testing requires identification of those who are to be professionally and administratively responsible for the reliability of these tests. The program helped improve the reliability of bedside glucose test information
Hansen 1998	USA inpatient	Randomized controlled trial	262 nurses	Demonstration by the educator, who was a member of either the laboratory or nursing staff	Nurses performed urine dipsticks and quality controls significantly better when trained by laboratory educators
Knapp, Chan, Anaya & Goetz 2011	USA outpatient	Post-test only	In-person training: 16 nurses. Online training: 20 nurses	In-person training: activation kits, lectures, webcam with a health science researcher. Online training: activation kits, internet learning, live meeting supported by webcam technology, observing point-of-care laboratory manager	Distance learning is equivalent to in-person training. The method is more cost-effective and efficient than in-person training

Author	Country and setting	Design	Participants	Intervention	Main results
Lehto, Liikanen, Melkko, Ebeling & Kouri 2011	Finland inpatient	Descriptive, post-test	Questionnaire for nurses (n = 28) Interviews (n = 2). Repeatability of POC glucose measurements (laboratory personnel n = 180, nursing personnel n = 355) 5642 control samples measurement by nurses	2-step training, training in small groups, visit, e-mail, telephone conversations, feedback. The point-of-care coordinator of the laboratory trained the contact persons, after which they trained the other nurses in their own units	Training succeeded because of basic resources, interpersonal communication and high-quality interactions. Day-to-day repeatability better than 3% was possible for both nursing and laboratory staff
Sánchez-Margalef, Rodríguez-Oliva, Sánchez-Pozo, Fernández-Gallardo & Goberna 2005	Spain inpatient	Pre-/post-test		Initial information, training in groups of two, telephone, feedback from the laboratory point-of-care manager	The glucose meters achieved the suggested analytical goals with respect to total error (< 7.9%) and optimal error for high glucose concentrations of < 5%
Shephard, Mazzachi, Watkinson, Shephard, Laurence, Gialamas & Bubner 2009	Australia outpatient	Descriptive, post-test	74 practice staff, 6 general practitioners	Resource package, workshops conducted by trainers with strong medical science backgrounds	The posters were useful for explaining how to conduct POC test and practical training in small groups was satisfactory as a training method. The quality and appropriateness of the POC test training resources and the workshop overall was rated as either good or excellent. Rural and remote practices had greater need for training and support compared to their urban counterparts and may require more flexible training options

5.2.1 The quality of reviewed studies, training interventions and the results

The quality of the six studies was evaluated on the basis of 14 questions (JMI 2008). The distribution of the quality assessments is presented in Table 6, Panel A.

Table 6. The quality of studies, contents of the training and the common issues of the reviewed studies.

Panel A		Panel B		Panel C	
Quality assessment of JMI	Total	The contents of the training included	Total	The common issues to several studies	Total
Is purpose of study well defined?	6/6	Introduction	6/6	Better use of devices	3/6
Is study design appropriate to the study objective?	6/6	Use of the device and reagents	3/6	Analytical goals	3/6
Is data collection described?	4/6	Use of the quality control sample	6/6	Cooperation between trainees and trainers	4/6
Does data collection apply to study design?	4/6	Sample collection	5/6	Nurses' satisfaction with the training program	3/6
Participants are adequately represented?	5/6	Evaluation of patient result	4/6		
Is outcome measure adequate?	5/6	Recording patient and control sample results	3/6		
Is setting described?	6/6	Maintenance and waste disposal	4/6		
Are interventions adequately represented?	6/6				
Is intervention adequate?	6/6				
Were outcomes measured in a reliable way?	4/6				
Is data analysis described?	5/6				
Was appropriate analysis used?	4/6				
Is ethical consideration represented?	2/6				
Can results be generalized?	5/6				

The results of quality assessments showed that the purposes, designs, settings and interventions were described in each of the six studies. Participants were represented, data analysis and outcome were described and generalization of the results was evaluated in five studies. Ethical considerations were brought out in only two studies. Table 6, panel B shows the contents of training interventions. An introduction phase and the use of quality control sample were included in all studies whereas recording patient and control sample results and training to use the device and reagents were reported in only three studies.

The evaluation of the intervention results revealed a few issues common to several reviewed studies: these are presented in Table 6, panel C. The main common factor in the reviewed studies was cooperation between the trainees and trainers. Active cooperation was seen to impact on trainees learning. Other common issues, such as better use of devices, analytical goals and nurses' satisfaction with the training program were also found in these studies.

5.3 The influence of training and management strategy on the quality of blood glucose POC testing (III)

5.3.1 Results obtained with Ascensia Contour glucometers in 2010 and 2011

The EQAS results of the Ascensia Contour glucometer obtained by BLSs in laboratory and by nurses in OUH and other participants of EQASs in 2010 and 2011 are presented in Table 7. All nurses using this type of glucometer were trained using the interactive two-step strategy. When BLSs (group A, CV% 4.0) were compared to trained nurses (group B, CV% 3.5) who used the same batch of strips the same analytical quality ($p = 0.722$) was reached in 2010. In 2011 the imprecision obtained by the trained nurses (group F) was worse (CV% 5.1) than that obtained by the BLSs (group E, CV% 3.3). In 2010 when compared to the results obtained by the other participants of EQAS (group C, CV% 5.0) there were no significant differences ($p = 0.447$) compared to those of the BLSs (group A, CV% 4.0); however in the next year the general EQAS results (group G, CV% 6.1) compared to BLSs (group E, CV% 3.3) showed statistically significant difference ($p < 0.01$).

In 2010 imprecisions of trained nurses (group B, CV% 3.5 and D, CV% 4.4) showed no significant differences compared to the other EQAS participants

(group C, CV% 5.0), who used unknown lots of strips. In 2011 CV%s of trained nurses varied more (from 5.1% to 6.7%) than in 2010, and group H (CV% 6.7) showed worse imprecision than the other EQAS participants (CV% 6.1). However combined CV% of the two nurse groups (group I) showed the imprecision to be similar to that of the other EQAS participants.

The mean values for control samples often differed statistically in both years but were very close to each other (maximum difference, 2.8% in 2011) considering that several lots of strips were in use.

Table 7. Results obtained with Ascensia Contour glucometers by BLSs and nurses in OUH and other EQAS participants in 2010 and 2011.

Groups	2010				2011				
	n	SD	Mean mmol/L	CV% P for SD ¹ P for Mean ²	Groups	n	SD	Mean mmol/L	CV% P for SD ¹ P for Mean ²
A ^a (BLSs)	40	0.10	2.57	4.0	E ^e (BLSs)	37	0.49	15.10	3.3
B ^b (Nurses, trained)	69	0.09	2.56	3.5	F ^f (Nurses, trained)	79	0.75	14.68	5.1
A ^a (BLSs)	40	0.10	2.57	4.0	E ^e (BLSs)	37	0.49	15.10	3.3
C ^c (EQAS, training unknown)	421	0.13	2.63	5.0	G ^g (EQAS training unknown)	374	0.92	15.11	6.1
B ^b (Nurses, trained)	69	0.09	2.56	3.5	F ^f (Nurses, trained)	79	0.75	14.68	5.1
C ^c (EQAS, training unknown)	421	0.13	2.63	5.0	G ^g (EQAS training unknown)	374	0.92	15.11	6.1
D ^d (Nurses, trained)	84	0.11	2.55	4.4	H ^h (Nurses, trained)	57	1.02	15.15	6.7
C ^c (EQAS, training unknown)	421	0.13	2.63	5.0	G ^g (EQAS training unknown)	374	0.92	15.11	6.1
					I ⁱ (Nurses, trained)	136	0.90	14.88	6.1
					G ^g (EQAS training unknown)	374	0.92	15.11	6.1

^a Results by biomedical laboratory scientists (BLSs) in the OUH; strip lot, 9MC3D10

^b Results by nurses in the OUH; strip lot, 9MC3D10; trained

^c Results by other participants of the EQAS, users not known; strip lot, unknown; training unknown

^d Results by nurses in the OUH; strip lots, 9MC3D10 and 9AC3D04; trained

^e Results by biomedical laboratory scientists (BLSs) in the OUH; strip lot DP1BC3D164

^f Results by nurses in the OUH; strip lot, DP1BC3D164; trained

^g Results by other participants of the EQAS, users not known; strip lot, unknown; training unknown

^h Results by nurses in the OUH; strip lot, 0HC3D04; trained

ⁱ Results by nurses in the OUH; strip lots, DP1BC3D164 and 0HC3D04; trained

¹ Levene test for equality of variances

² T-test if not otherwise specified

³ Dunnett test

5.3.2 Results obtained with Contour glucometers in 2010 and 2011

All nurses who used the Contour glucometers have participated in the training program in primary healthcare units. In 2010 Contour glucometers were also used by untrained nurses in some clinical units at the hospital. BLSs in the laboratory did not use this glucometer at all. The results obtained by the participants who used Contour glucometers in 2010 and 2011 are presented in Table 8. In 2010 trained nurses (groups J and M, CV% 4.5 and CV% 3.5, respectively) achieved better imprecision than untrained nurses (groups K, L and N, CV% 6.0, 7.4 and 6.3, respectively). In groups L and N the difference was greater when untrained nurses used several different lots of strips. Trained nurses (groups J and M) also showed better imprecision (CV% 4.5 and 3.5, respectively) than the other EQAS participants (group O; CV% 7.9; $p < 0.001$ and $p < 0.01$, respectively). This demonstrates the importance of training when this glucometer is used for glucose POCT. In 2011 trained nurses (groups P and R) achieved better imprecision (CV% 5.3 and 5.9, respectively) than the other EQAS participants (group Q; CV% 8.6; $p < 0.01$), showing a significant difference in both comparisons even though three different lots of strips were used in group R. The mean values were close each other: the greatest difference was seen for the oldest strip lot 9AC3D04. In that case trained nurses (group M) obtained on average 0.3 mmol/L (10%) higher results at the 3.1 mmol/L level than the other EQAS participants (group O) and untrained nurses (group L).

Groups	2010				2011			
	n	SD	Mean mmol/L	CV% P for Mean ²	n	SD	Mean mmol/L	CV% P for Mean ²
M ^m (Nurses, trained)	36	0.12	3.41	3.5	125	1.29	21.94	5.9
O ^o (EQAS training unknown)	1163	0.25	3.11	7.9 < 0.01	1215	1.85	21.51	8.6 < 0.01
L ^l (Nurses, untrained)	75	0.23	3.05	7.4				
O ^o (EQAS training unknown)	1163	0.25	3.11	7.9 0.495 < 0.05				

^j Results by nurses in Oulu healthcare center; strip lot, 9MC3D10; trained
^k Results by nurses in the OUH; strip lot, 9MC3D10; untrained
^l Results by nurses in the OUH; strip lot, 9MC3D10 and unknown; untrained
^m Results by nurses in Oulu healthcare center; strip lots, 9AC3D04; trained
ⁿ Results by nurses in the OUH; strip lot, unknown; untrained
^o Results by other participants in the EQAS, users not known; strip lot, unknown; training unknown
^p Results by nurses in Oulu healthcare center; strip lot, 0HC3D04; trained
^q Results by other participants in the EQAS, users not known; strip lot, unknown; training unknown
^r Results by nurses in Oulu healthcare center; strip lots, 9MC3D10, 0HC3D04 and DP1BC3D164; trained
¹ Levene test for equality of variances
² T-test

5.4 The long-term influence of training and management strategy on the quality of blood glucose POC testing (IV)

The results of IQC measurements obtained by BLSs and nurses with Ascensia Contour glucometers in hospital and nurses with Contour glucometers in primary healthcare units in 2010 were compared to the corresponding results in 2011 and 2012 and are presented in Table 9. The most important result was that the performance of trained nurses was unchanged and that the good analytical quality once achieved persisted from 2010 to 2012. We also found that each year the results obtained by BLSs were only occasionally better than those obtained by OUH nurses using the same Ascensia Contour glucometers. CV%s ranged from 2.8 to 3.3 for BLSs, and from 3.2 to 3.7 for OUH nurses ($p = 0.238, 0.038,$ and 0.522 in 2010, 2011, and 2012 respectively, not shown in Table 9). In addition participants who used Ascensia Contour devices, with 15 second measuring time always had better CV%s than Contour users with 5 second measuring time (from $p < 0.01$ to $p < 0.001$, not shown in Table 9).

The mean values between the BLSs and OUH nurses were practically identical during each year, with the greatest difference (0.07 mmol/L) seen in 2011 (Table 9). The mean concentrations were highest in 2011 and lowest in 2012 in all the groups. This reflects small changes in the various lots of control samples and strips that were used simultaneously during the study periods.

The mean values obtained by Oulu nurses using Contour devices, were higher than those obtained by the BLSs and OUH nurses using Ascensia Contour glucometers ($p < 0.001$, not shown in Table 9). The matrix effects of the artificial control samples are probably the reason for this because the measurements were done using two glucometers having different method technology.

The results of the five study groups are presented in article IV. The main result was that the lot-to-lot CV%s were similar across all groups of nurses, and were usually best for the BLSs, followed by the OUH nurses and the Oulu nurses. In fact, the strip lot DP1BC3D16A which was relatively old, having only four months until its expiry date (2012–8) at the time of its use in 2012, had higher CV%s for all groups of users in 2012 than in 2011 (CV%s $4.0 - 4.8$ and $2.8 - 3.5$, respectively).

Table 9. Internal quality control results obtained by BLSs and OUH nurses with the Ascensia Contour, and by Oulu City nurses with the Contour glucometers in 2010, 2011 and 2012. Results from 2011 and 2012 were compared to the results from 2010.

Groups	n	SD	Mean mmol/L	CV%	P for CV ¹	P for Mean ²
2010 OUH BLSs ^a	2626	0.18	6.54	2.8		
2011 OUH BLSs ^a	2662	0.20	6.66	3.0	0.324	< 0.001
2012 OUH BLSs ^a	2718	0.21	6.19	3.3	0.043	< 0.001
2010 OUH nurses ^b	1039	0.21	6.56	3.2		
2011 OUH nurses ^b	1939	0.25	6.73	3.7	0.252	< 0.001
2012 OUH nurses ^b	2221	0.22	6.24	3.5	0.402	< 0.001
2010 Oulu nurses ^c	999	0.33	7.27	4.5		
2011 Oulu nurses ^c	911	0.31	7.30	4.2	0.779	< 0.05
2012 Oulu nurses ^c	1104	0.32	7.01	4.5	0.960	< 0.001

^a Results from biomedical laboratory scientists at the Oulu University Hospital (OUH BLSs); combined strip lots in 2010, 2011 and 2012.

^b Results from trained nurses at Oulu University Hospital (OUH nurses); combined strip lots in 2010, 2011 and 2012.

^c Results from trained nurses at Oulu Healthcare Center (Oulu nurses); combined strip lots in 2010, 2011 and 2012.

¹ Miller's test for the equality of coefficients of variation compared to 2010.

² Dunnett's test compared to 2010.

6 Discussion

6.1 Nurses' training in POCT (II)

POCT measurements obtained by nurses have been used in patients care for many years. It has been shown in studies that nurses have inadequate or minimal competence to do POCT which may lead to errors in patients' care. The need for in-service training for nurses to improve their abilities to perform POCT was obvious. (Kost 2001, Kost 2003, Plebani 2009). In the present study we did not investigate all the details of the training strategy developed by us. Most importantly, the analytical quality of the outcome was studied.

Only few studies concerning nurses' training in POCT were found in the literature search: most commonly interventions in glucose testing were undertaken. The interventions usually involved many training methods. In only one study (Knapp *et al.* 2011) distance learning included the use of participant activation kits (including quality control procedure, a pocket card detailing the test operational protocol, a sample information brochure, laboratory certification paperwork, and in-service satisfaction survey). In the study in question the training improved POCT and the online in-service training was shown to be as cost-effective as face-to-face training. Appropriate information prior to training can increase nurses' motivation for POCT (Geyer 2001). Motivation on a part of nurses to do POCT is an important part of the training process (e.g. Kyriacos *et al.* 2005) and requires continuous support from the laboratory (Lehto *et al.* 2011). According to Wood & Burnett (2004) and Kyriacos *et al.* (2005), no training is effective in the long-term if it takes place only once in a single training session. Regular feedback between the laboratory staff and nurses is also essential in order to keep the system running effectively (Sánchez-Margalet *et al.* 2005). All in all, cooperation between the laboratory staff and nurses is a key element for enhancing POCT quality (Jacobs *et al.* 2009, Lehto *et al.* 2011).

The quality assessment of the studies included a review by us on basis of 14 questions. In general all six studies can be considered of sufficient quality. Ethics were not considered in four of the studies although they involved individuals (Polit & Beck 2008). Success of training simply on the basis of satisfaction on the part of the trainees is not sufficient (Shephard *et al.* 2009), and more rigorous analyses are necessary, e.g. as described by Sánchez-Margalet *et al.* (2005) and Lehto *et al.* (2011).

As for the contents of the training interventions, it is likely that at least the use of the relevant device and reagents, as well as recording patient and control samples should be included. However, the use of a quality control sample was mentioned in all studies. This was rather significant because nurses do not necessarily consider quality control to be important (Baer *et al.* 1993): however, quality control procedures are included in EN ISO 22870 standard (2006). The training was organized and delivered in somewhat different ways in the studies reviewed, making it difficult to assess and compare their contents.

The studies reviewed had a few issues common like as focus on better use of the device and analytical goals. The training program created should be suitable for nurses with respect to clinical issues (e.g. reliable sample collection and the significance of control samples) while achieving better quality of measurements. Cooperation between trainees and trainers and nurses' satisfaction with the training program were also features that had in common. Nurses' training in POCT should be planned in multiprofessional groups including representatives of nurse managers, laboratory managers, nurses and laboratory professionals. This makes it possible to plan the training based on the nurses' needs. In the studies examined, the training interventions were organized and run, or at least planned, with laboratory professionals. The use experienced primary trainers with strong medical science backgrounds and expertise in tailoring training methods to different healthcare professionals contributes significantly to the success of training programs (Shephard *et al.* 2009).

The training must be planned to contain all aspects of POCT with using multiple methods. One method to achieve effective learning in POCT is to use interactive training with various teaching techniques, for instance face-to-face training and workshops. Either nurses or laboratory professionals can be competent trainers but they should have experience in training and the ability to motivate nurses to perform POCT. Ongoing learning and training with updates for nurses should be planned in cooperation with the laboratory professionals, for example by e-learning. A detailed analysis of the literature review is presented in the study II.

6.2 The two-step training and management strategy and its evaluation in the pilot units (I)

An interactive two-step strategy for training and managing POCT for non-laboratory personnel was developed in this study. The model comprises

preanalytical, analytical and postanalytical phases of the laboratory process and considers both functional and technical aspects of POCT. Training is a key prerequisite to reduce errors in all phases of the laboratory process (CLSI 2006). It is also important to consider both functional and technical dimensions when planning a training strategy for nurses to perform tests. The idea of the strategy was to establish standardized procedures for everyday practice by using interactive training. The strategy followed the main recommendations of international standards and Finnish national guidelines of good quality of POCT (EN ISO 22870 2006, Ihalainen *et al.* 2002, Linko *et al.* 2009). The main elements of our model were as follows: 1. establishment of a multidisciplinary POCT management group with representatives of both laboratory and nursing staff, 2. standardization of devices and measurements, 3. reagents and quality control procedures, 4. an interactive two-step training strategy with a familiarization program, 5. computerized data collection for both patients and control results, and 6. financial issues. The training program was applied for the most commonly used POC test in health care, blood glucose measurement. Our strategy was based on active interaction between nurses and laboratory personnel. In accordance with our strategy, designated contact nurses were first trained by laboratory professionals, after which, contact nurses trained other nurses in glucose POCT in their respective units.

In the pilot study the establishment of the training strategy was found to be successful. All procedures improved the quality of POC glucose measurements and the model was well suited for training nursing staff for POCT. The contact nurses emphasized the importance of the basic requirements for training (such as written procedures and familiarization program), interpersonal communication and high-quality interaction: in addition they felt that changes in operation resulted in many advantages in their ward. The knowledge and practical skills of the nurses improved through the interactive training strategy used. Qualitative interaction enabled multifaceted means of communication between POC coordinator and contact nurses, and further, between contact nurses and the other nurses in their respective units, which pleased all the participants in the study. Basic support and training resource should be focused on interaction: in addition the personality of the teacher should promote successful training (Van den Berghe 1995). Interactive training based on learners' needs enables learners to set their own goals for training (Jonassen 2003). Our strategy included educational material and discussion of goals as elements described in educational literature (Van den Berghe 1995, Kääriäinen 2007). For the laboratory, the deeper meaning

of these discussions was to find out good practices for nurses' training and for the nurses to facilitate the understanding of quality in POCT. The nurses had thus an opportunity to influence the goals and contents of training and the familiarization program in the future. The impact of the applied training was measured both functionally and technically.

Nurses and also contact persons were satisfied with their trainers' competences to provide training in glucose POCT. The nurses felt that their knowledge on POC glucose measurement had increased and that the operation of the device and patient sample analysis had improved. They had also understood the meaning of the control procedures and measuring the control samples. The respondents were generally satisfied with the training process as a whole. Motivating the nurses to do glucose testing, defining the purpose and objective of the training and giving positive feedback to the nurses were included in the training model. In laboratory-clinical communication it is important to create an encouraging atmosphere where the nurses feel free to express their opinion with genuine dialogue and attentive participation. Regular update sessions with mandatory attendance by nursing staff were recommended in order to maintain the quality of POCT (Wood & Burnett 2004) and also in this study continuous POCT training was expected by the contact persons as well as by the nurses.

Our two-step training strategy also included the technical requirements of quality of POCT. In this pilot study the laboratory professionals were used as a control group to show that trained nurses can reach the same level of technical quality as laboratory professionals. According to Handorf (1994) laboratory professionals often orient themselves on "hard data", i.e., technical quality, and overlook the functional quality of POCT management. Our pilot study showed that if functional quality is not considered, technical quality of measurement procedures may also remain beyond control, due to human factors.

6.3 The influence of training on the quality of blood glucose POC testing (III)

The effect of training on the quality of glucose POC test results was studied by analyzing EQA results. The EQA samples of POC blood glucose were delivered by the laboratory to the participating units and the results were collected and classified into peer groups of the two types of devices, users, settings and lots of strips, focusing on users' training. Generally our study showed that the imprecision of Ascensia Contour glucometers was better than that of the Contour

glucometer users both in 2010 and 2011. The imprecision of the trained nurses using Ascensia Contour glucometers was similar to that obtained by BLSs and other participants in the EQAS in 2010. This result supports the finding of our pilot study (I), where day-to-day repeatability after training was found to be the same for both nursing and laboratory personnel who used this type of glucometer. After training, the imprecision of the Contour glucometer users improved significantly and reached the level of BLSs. In 2010 trained nurses using Contour glucometers in the healthcare center achieved significantly better analytical quality than untrained nurses using the same type of glucometer in the hospital as well as better results than the other participants in the EQAS in 2010 and 2011 who used the same devices.

The study revealed a positive influence of training on the performance of nurses in the primary healthcare units with Contour glucometers users. The results of EQAS suggest that the use of the Ascensia Contour glucometer is less dependent on the operators' competence than the Contour glucometer, even though we did not have imprecision data for nurses using the Ascensia Contour glucometer before training. However, the repeatability of the nurses trained with the two-step training strategy was better than that of the other participants of EQAS. From the point of this study, the results and repeatability of nurses trained using the two-step strategy was better than the results of the other participants of EQAS. It could thus be concluded that the training strategy had a positive influence on imprecision of the results.

One probable explanation for the differences in CVs between these two glucometers is the difference in their method technology. It is likely that in the hands of untrained nurses the short 5 second measuring time of the Contour glucometer causes poorer repeatability of results. We do not believe that contact nurses in the primary healthcare units were more motivated towards training given by the laboratory and further more motivated to train their own colleagues than nurses in the hospital.

According to Vesper & Myers (2007) studies should be carefully designed in order to recognize the reasons for variability in control results. Difficulties in creating a suitable EQA samples have also been discussed (Lieber *et al.* 1996, Kristensen *et al.* 2006, Wood 2007). The EQA solution was a stabilized human-based whole blood sample for *in-vitro* use, and which did not have the same properties as blood. The matrix effect of the control sample may be an explanation for the large differences in the mean values between these two types of devices. The increased variation of participants' EQA results has been found to

be due to variability between different strip lots, and it has also been seen to be affected by the age of the strips (Libeer *et al.* 1996, Kimberly *et al.* 2006). Kristensen *et al.* (2005) reported about between-lot variations as high as 1.3 mmol/L for a glucose level ~ 7 mmol/L. In our study mean values of the participant groups using the same type of glucometer often differed statistically but were usually close to each other. The greatest deviation from the mean was 10%, which was obtained with the oldest strip lot.

According to our literature review nurses, had been trained using a variety of methods to do POCT (II) and the nurses who participated in this study also had diverse professional backgrounds. Several guidelines and publications have indicated that training as well as in-service training of nurses is highly essential to ensure accurate results with low variability (e.g. ADA 1996, ADA 2004, Ehrenmeyer & Laessig 2008, Nichols 2011, O’Kane *et al.* 2011). We have found that it is not practical or even possible for laboratory professionals to train every nurse in POCT. According to our model the POC unit of our laboratory was only responsible for training of certain contact persons, who in turn trained their colleagues. According to the EN ISO 15197 (2003) standard 95% of individual glucose results should fall within ± 0.83 mmol/L (results < 4.2 mmol/L) and within $\pm 20\%$ (results ≥ 4.2 mmol/L). In the new standard EN ISO 15197 (2013) 95% of individual glucose results may fall within ± 0.83 mmol/L (results < 5.55 mmol/L) and within $\pm 15\%$ (results ≥ 5.5 mmol/L). ADA (1987, 1996, 2004) has recommend stricter quality specifications for devices designed for self-monitoring and POCT of glucose; such as a total error (including analytical and user) should not exceed 10% in the range 1.67–22.2 mmol/L. In this study, imprecision obtained by trained nurses give a good basis to reach the above analytical goals.

EN ISO 22870 (2006) suggests in-service training as well as internal audits to recertify nurses’ competence to do POCT. It is important to offer update training as a part of nurses’ ongoing training, not only at the beginning of their work in POCT. In the future nurses’ recertification should be developed and managed locally through in-service training conducted in cooperation with hospital laboratories to ensure good quality in POCT. Training methods such as face-to-face and distance learning courses using web-based e-learning are recommended. The same training strategy has already been applied to other POC measurements conducted in our district, such as the international normalized ratio (INR), C-reactive protein (CRP) and troponin.

6.4 The long-term quality of blood glucose POC testing achieved by training (IV)

The long-term effect of training on the quality of glucose POC testing was studied by analyzing IQC results. We analyzed POC blood glucose IQC results obtained by the BLSs and the trained nurses in the hospital and healthcare center during three specific months for three consecutive years. We grouped the results according to type of device, user, setting, and strip lots. In our previous studies we showed that our strategy is a practical tool demanding only reasonable laboratory resources (I, III).

The main finding of this investigation was that the good analytical quality of POC glucose measurements once achieved by training was sustained in the long-term. The other important finding confirmed the results of our previous study (III) that trained nurses and BLSs can achieve near-similar analytical imprecision when performing glucose testing. The results by laboratory professionals had only occasionally better imprecision than those performed by OUH nurses using the same type of glucometer. CV%s ranged from 2.8 to 3.3 for BLSs, and from 3.2 to 3.7 for OUH nurses ($p=0.238$, 0.038 , and 0.522 in 2010, 2011, and 2012 respectively).

When designing studies potential sources of variability must be carefully assessed (Vesper & Myers 2007). The difference between matrix and human blood often causes difficulties to generate suitable control samples for POCT (Libeer *et al.* 1996, Kristensen *et al.* 2006, Wood 2007, Jacobs *et al.* 2009). The IQC solution used in this study was synthetic, aqueous glucose sample for *in-vitro* diagnostic use, which differed from natural blood. The differences in mean values obtained with these two types of glucometers may be explained by this matrix effect. As also observed in this study, deviation in participants' IQC results has been seen to be caused by factors such as variability between different strip lots as well as the age of the strips used (Libeer *et al.* 1996, Kimberly *et al.* 2006, Lehto *et al.* 2014a). In this study, trained nurses had an opportunity to reach the quality specification of the new standard's recommendation as well (EN ISO 15197 2013).

As mentioned before POC tests are often used to reduce TAT, and are even said to be quicker than short-turn-around-time test (Meier & Jones 2005, Giavarina *et al.* 2010). For this reason the training is highly recommended to preventing and evaluate errors in the preanalytical, analytical and postanalytical phases of POCT (ADA 1996, Kost 2001, Kost 2003, ADA 2004, CLSI 2006,

Plebani 2009, Giavarina *et al.* 2010) not just during the analytical phase (Ehrenmeyer & Laessig 2007, Carraro & Plebani 2009). All phases were included in our interactive training strategy and familiarization program. Our study showed that once achieved, good analytical quality obtained by training can be maintained by encouraging continuous feedback. The nurses, especially contact nurses, felt that they were continually cared for. Today, ongoing training at regular intervals or systematic retraining for nurses is not included in our strategy. Contact nurses and other nurses are retrained by the laboratory POC unit whenever necessary, for example, for IQC sample measurements or sample collection via fingerstick.

EN ISO 22870 (2006) suggests regular internal audits and in-service training to recertify nurses' abilities to perform POCT. Today we have internal audits in place in the primary healthcare units and will extend them to include the hospital units. The audits on POCT are conducted to review the local processes for identifying weak points in the system where errors could occur. The findings will be utilized to create self-evaluation checklists for reviewing and identifying weak points of the procedures. Also, in-service training for nurse recertification and distance courses using web-based e-learning methods are being developed. However, face-to-face training is still of the utmost importance for contact nurses. Ongoing training for nurses emphasizing the pre- and postanalytical phases is also important for reducing errors when performing POCT.

6.5 Limitations of the study

The two-step training and management strategy developed included all three phases, as the preanalytical, analytical and postanalytical phases of the laboratory process. In addition both functional and technical requirements were taken into consideration when planning the strategy. As mentioned, errors may occur in all phases of the laboratory procedure. In the present studies we were able to investigate only technical and analytical performance of the nurses. In the study of EQASs (III) all the nurses who used Ascensia Contour glucometers were trained in glucose POCT prior to the onset of the study. Therefore, we did not have quality control data for this glucometer before training.

The control materials (EQA and IQC) used in studies I, III and IV were synthetic, and therefore may not give the same results as natural blood samples. The matrix effect of control samples may have influenced the results. Furthermore in study III the EQA control material was probably not suitable for

both types of devices. In addition, many lots of strips were used in that study (III), meaning that the number of control results for each peer group was small.

The literature search included only publications in English. This could have had an effect on the number of publications and as well as causing language bias (Bettany-Saltikov 2010b). According to Bruce *et al.* (2008) positive results tend to be published more frequently in journals than negative ones. In addition, authors are more likely to publish randomized controlled trials in an English-language journal if the results are statistically significant (Egger *et al.* 1997).

6.6 Suggestions for future research

We studied the quality of glucose POC test by analyzing the control results obtained by nurses. It would be worthwhile to study the nurses' competence to perform tests from patients' blood samples via fingerstick. The participants of the study could be both untrained nurses and nurses trained with two-step training method. The results obtained by nurses would be compared to those obtained by BLSs.

Functional requirements were included in the two-step training and management strategy developed. It would be interesting to know these qualitative aspects for maintaining quality in developing the strategy. In fact a questionnaire has already been completed after training by contact nurses in hospital and in primary healthcare units, but the results have not yet been analyzed.

In study IV altogether 16.219 IQC results were collected. In order to see how the trained nurses succeeded in their duties these POC glucose control results could be compared to the control results from laboratory analyzer. A more sophisticated quality control rules for POCT could be developed.

When planning the training and management strategies it would be valuable to investigate further what kinds of training methods are the most effective and in which settings. Randomized controlled trials where the training interventions are described in detail would give more information about training.

7 Conclusions

From these studies the following is concluded:

1. Nurses have been trained using a variety of methods in different health care settings. Competence can be achieved through in-service training, which can be delivered effectively via various methods. Very few studies have documented in detail the training of nurses in POCT. The findings of the literature review did not influence our research plan. They confirmed our suspicions that the influence of training on the performance of nurses in POCT had not been studied statistically in the manner we intended.
2. The interactive two-step training and management strategy offers a practical tool to improve the analytical quality of POCT performed by nurses. It was found to be well suited for training of nursing staff with continuous support on the part the laboratory
3. The nurses who participated in the training had variable experience in conducting glucose POC tests before the training, but the study showed that the training improved their competence further.
4. The participants who used Contour glucometers had higher CV% in EQA than those who used Ascensia Contour glucometers, but the quality of the results obtained with this glucometer was significantly improved by the influence of training. Training did not statistically improve the quality obtained with Ascensia Contour glucometers: the originally good analytical quality remained unchanged.
5. Use of the same reagent strip lots and quality control samples at the same time in all healthcare units is important and helps to assess the real analytical performance of the nurses. The use of old reagent strips should be avoided.
6. The interactive two-step training strategy for nurses proved to be an effective tool for organizing training for nurses in hospital and in primary healthcare center. Trained nurses achieved near-similar imprecision as laboratory professionals, and long-term institutionally-recommended quality was also achieved. The developed strategy is also suitable for application with other POC tests.

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