

Point-of-care testing, now and in the near future

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Introduction of point-of-care testing (POCT) in hospitals requires the use of principles of change management. Manufacturers can support this process. E-learning programs adapted to the local situation with regular updates, a centralized accreditation and user-registration system and service level agreements are helpful in embedding POCT in hospitals.

In respect to the development of new products, cooperation between manufacturers, experts in the field and end-users, is of the utmost importance. Installing a POCT-officer in the laboratory and a specially trained end-user in each department where POCT is in use may help to answer questions rapidly and helps to convince end-users (nurses and physicians) of the advantages of POCT.

The Isala Klinieken is located in Zwolle in the Netherlands. Our hospital is one of the largest non-academic hospitals in the Netherlands with 1000 beds. The hospital provides general medical treatments to a population of 450,000 people.

However, for cardiology this may be as many as one million people or more. In addition to cardiology, our hospital has a neonatal department, internal medicine department, pulmonary department, emergency department, sports medicine department, dialysis department, and performs bone-marrow transplantations.

The laboratory we are working in supports the hospital, but also supports general physicians and runs a thrombosis treatment service. The laboratory is known for preparing the gold standard for HbA1c for the rest of the world and is part of the European Reference Laboratory for Glycohemoglobin.

Furthermore, we test all blood glucose meters supplied to the Dutch market, including both patient and hospital meters. The laboratory is a reference site for blood glucose control material.

We started a diabetes excellence center in the hospital three years ago. Besides the diabetic work, the

laboratory performs plasma and bone-marrow feresees on patients. Neonatal screening for the northern region of the Netherlands is done at our site, as is prenatal screening.

Our approach to POCT

POCT is a rapidly booming business. This is partly a market-driven development. Therefore, when we looked at introducing point-of-care glucose meters in our hospital in 2000, we sat down and thought about the consequences.

We discussed the reasons for the introduction of POCT in the hospital with our end users, nurses, diabetologists and other physicians. We formulated starting principles, strategic considerations and analytical considerations.

Later on we assessed whether or not we had to adjust some of these ideas. During the process we were confronted with manufacturers who wanted to sell meters, but whom were unable to provide a complete overview of how to introduce this new approach to laboratory analysis at patient bedsides.

This article deals with most of the aspects that we have been confronted with and thought about.

Our guidelines for when to use POCT

For introductory purposes we formed a multidisciplinary team consisting of clinical chemists, specialized technicians, customer care employees, nurse practitioners, and diabetologists. This team came up with the following guidelines:

POCT will be supported by the laboratory, if:

- It is better for the patient
- A physician or patient requests POCT and a medical question can be solved rapidly

POCT will be allowed if:

- Minimal quality criteria are met (these had to be

redefined in accordance with what was clinically needed)

- The laboratory checks the quality
- The laboratory has the authority to exclude end-users
- As long as the laboratory is able to support POCT in the hospital
- All POCT data are collected in the laboratory information system and in the yet-to-be introduced electronic medical status

Reasons to perform POCT were: fewer erroneous results due to handling, fewer communication steps preventing telephone communication errors between nurses and the laboratory, fewer interpretation and transportation errors. Additionally, nurses and physicians can stay focused on the same patient and possibly save time in making decisions. Lean and keen by short vein-to-brain time!

Our concerns about POCT

As laboratory specialists we felt ourselves just as responsible for all POCT values as we were for the in-laboratory measurements. As specialists in measuring analytes in human fluids we were very reserved to dump POCT meters in the hospital because of:

- A lack of awareness about pre-analytical errors among the new end-users
- A lack of awareness about matrix effects (interfering substances)
- The absence of overall failure and error management
- A reduced focus on technology and feelings associated with this

Therefore, the overall responsibility for the analyses had to stay with the laboratory experts. The final choice of meters had to be made by the laboratory.

The analytical technology to be used had to be robust, easy to use, with clear and short instructions, and preferably supported by an interactive education program (with regular updates).

A centralized system of registration of end-users with mandatory accreditation was required, run by the laboratory POCT officer. An external quality assessment scheme was also mandatory.

Training of medical staff

To be able to control the introductory process we proposed a uniform introduction protocol in our hospital with as little variation in measuring principles as technically possible.

At that point we expected to receive guidance on how to introduce POCT in the hospital from companies promoting POCT in the market. Unfortunately this was a learning process for them as well.

It started with the training of the medical staff. This can be done in three different ways, by:

1. Individual training, providing highly skilled employees, but through a rather time-consuming process.
2. Train-the trainer principles supported by a certification system, also providing highly skilled medical staff members, but through a time consuming process that requires the support of an administrative system.
3. Video/DVD, less time consuming, but without checks that enable the lab to control the skills.

We learned that a mixture of these three forms was the optimal procedure. We started by providing video/DVD-based training, followed by trainer education by the lab, and where necessary individual training sessions.

Convincing the end-users of the advantages to their patients in terms of shorter turn-around-times and more rapid treatment is important to the success of the education process (studies about the advantages of tight glycaemic control were important).

To be able to provide rapid answers to questions from end-users, we placed a POCT officer and a specially trained end-user in each department to answer really urgent questions.

E-learning program

A pitfall for some manufacturers in the beginning was that they failed to sufficiently realize that selling POCT meters is not like selling laboratory analysis machines.

Nowadays we like to sit down and work out a program in which we are able to influence the development of new POCT machines and at the same time provide the manufacturer with a platform to test their products on so that we finally end up with products that fit in our daily routines.

For instance, an e-learning program that can easily be updated by the manufacturer can only be developed with the users and experts in the field. Updating these e-learning programs is important because otherwise they are simply used as a one-time proof of knowledge for the end-user.

We also noticed that e-learning programs had to be adapted to the local situation. A "one size fits all" e-learning program is not very appropriate, because, for example, treatment guidelines are often different from country to country.

Change of management structure and work culture

We have now arrived at a process of change management because we feel that the introduction of POCT requires a lot of changes.

End-users must learn to deal with rapid answers to their questions (in the past they had time to discuss with others or just to think things over), learn to work with analytical machines, think in terms of pre-analytical errors, quality control, patient conditions influencing the final measurement result, and so forth.

It is our job to minimize these items, but until that is fully organized we will have to change the way that nurses and physicians work and think.

When introducing POCT it is important to realize what

the effects will be within the hospital. The placement of some employees may need to be shifted from the laboratory to other hospital departments.

The working areas of the laboratory technician may, for instance, shift to surgery rooms so as to be able to locally service the POCT meters.

On some occasions the technicians will have to work in a team of nurses and/or physicians, which brings them into a different culture that requires a different way of managing them in respect to their competencies.

Moreover, in the end a different management structure may need to be set up to support these developments (more managers for individual jobs). Additionally, the logistics of disposables need to be described and employees need to be involved in this.

A service level agreement (SLA) between the laboratory and a department in the hospital stating what might be expected from the laboratory and from the POCT users can also be helpful.

Conclusions

To make the conversion to POCT easier in hospitals, changes in management and work culture may be required. It also requires a flexible e-learning program, which is regularly updated, a centralized accreditation and registration process as well as SLA's.

Placing a POCT-officer in the laboratory and a specially trained end-user in each department where POCT is used helps to answer questions rapidly and will give the end-users (nurses and physicians) more rapid confidence in POCT.