POCT net in a hospital

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Hospital POCT

Any laboratory testing done close to the patient within the hospital environment by clinical staff with laboratory POCT team support and supervision

Diagnostic testing in a hospital – the early days

Chemical analysis have been carried out close to the patient, i.e., at the bedside, or more commonly, in specially designated ward side-rooms

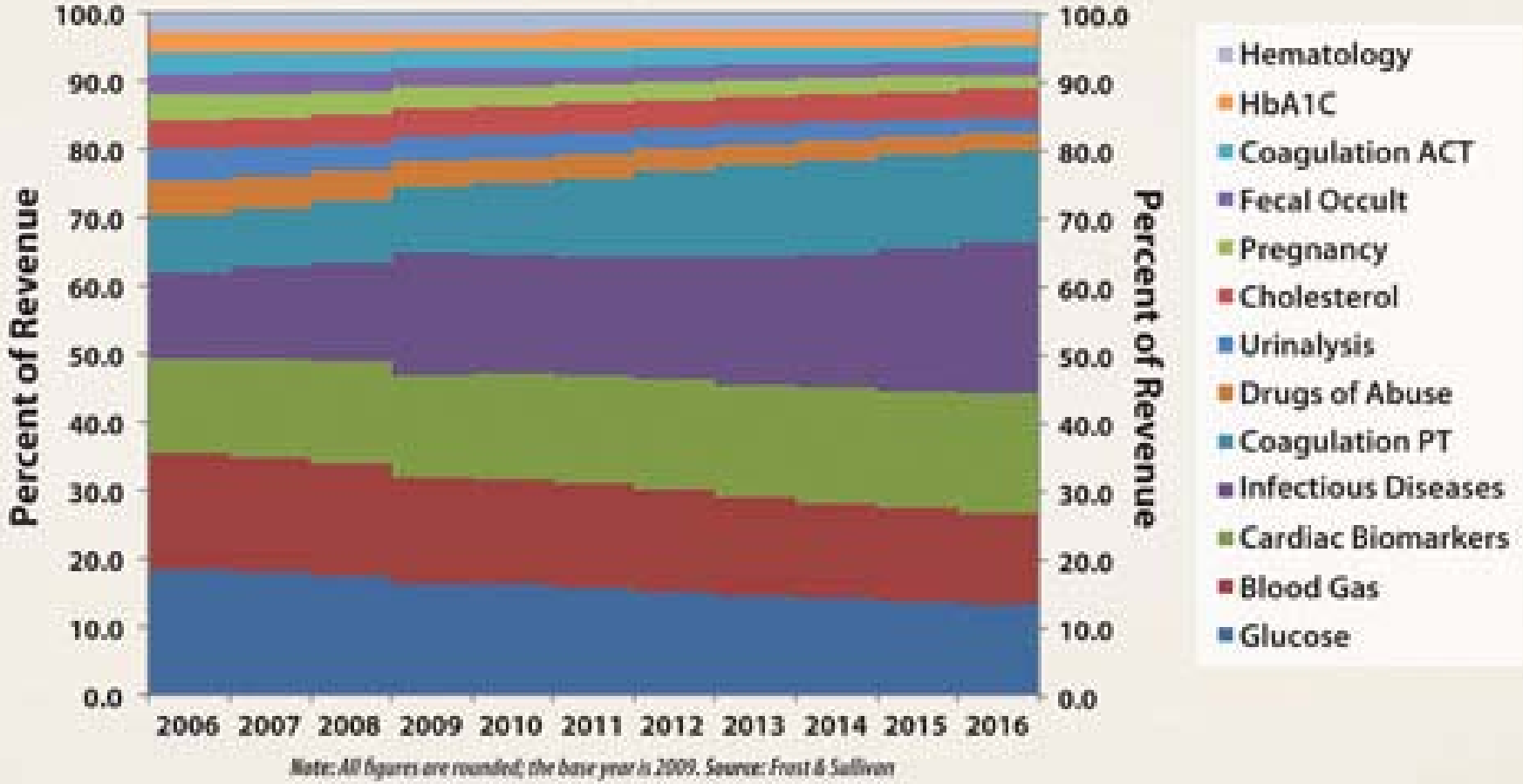
Lancet 956, 1883

During the ensuing 200 years....

- Laboratories have moved further and further away from the patient, then consolidated and centralised, becoming invisible
- They have largely become efficient number factories

- Technology kept developing new devices and started offering new solutions

Total Point-of-Care Testing Market
Revenues by Segment (U.S.)



Note: All figures are rounded; the base year is 2009. Source: Frost & Sullivan

POCT is the most rapidly growing IVD market segment

At 11% annualy, it grows at twice the rate of central laboratory testing

Bowman et al

Arch Path Lab Med, 136;472-73, 2012

How did this happen?

From available evidence, it is not clear whether the (POCT) technology has been developed in response to clinical need or whether marketing strategies have led to the perception that this technology is needed.

Pecoraro et al, CCLM 2013

POCT and patient's outcome – a systematic review

DE GRUYTER DOI 10.1515/cclm-2013-0386 — Clin Chem Lab Med 2013; aop

Review

Valentina Pecoraro*, Luca Germagnoli and Giuseppe Banfi

Point-of-care testing: where is the evidence? A systematic survey

Abstract: Point-of-care testing (POCT) has had rapid technological development and their use is widespread in clinical laboratories to assure reduction of turn-around-time and rapid patient management in some clinical settings where it is important to make quick decisions. Until now the papers published about the POCT have focused on the reliability of the technology used and their analytical accuracy. We aim to perform a systematic survey of the

Background

Point-of-care testing (POCT) is referred to a near patient, bedside, or extra laboratory testing. It is likely to be carried out by unspecialized staff. By providing results quickly this technology could improve some aspects of laboratory organizations in areas such as emergency rooms, opera-

Table 2 Number of studies reporting data about important patients' outcome.

	n	TAT	LOS	Mortality	Several bacterial infection	Number of re-intervention	Recurrence of hyperparathyroidism	Major complication
Bilirubin	19	1	0	0	-	-	-	-
PCT	4	0	0	0	2	-	-	0
PTH	6	1	1	0	-	1	1	1
Tn	25	7	8	4	-	-	-	0
BGa	30	1	0	0	-	-	-	0
TOT	84	10	9	4	2	1	1	1

BGa, blood gas analyzer; LOS, lost to follow-up; PCT, procalcitonin; PTH, parathyroid hormone; TAT, turn-around-time; TN, troponin.
n, number of studies included in each group of POC.

Most of hospital POCT is no longer acute

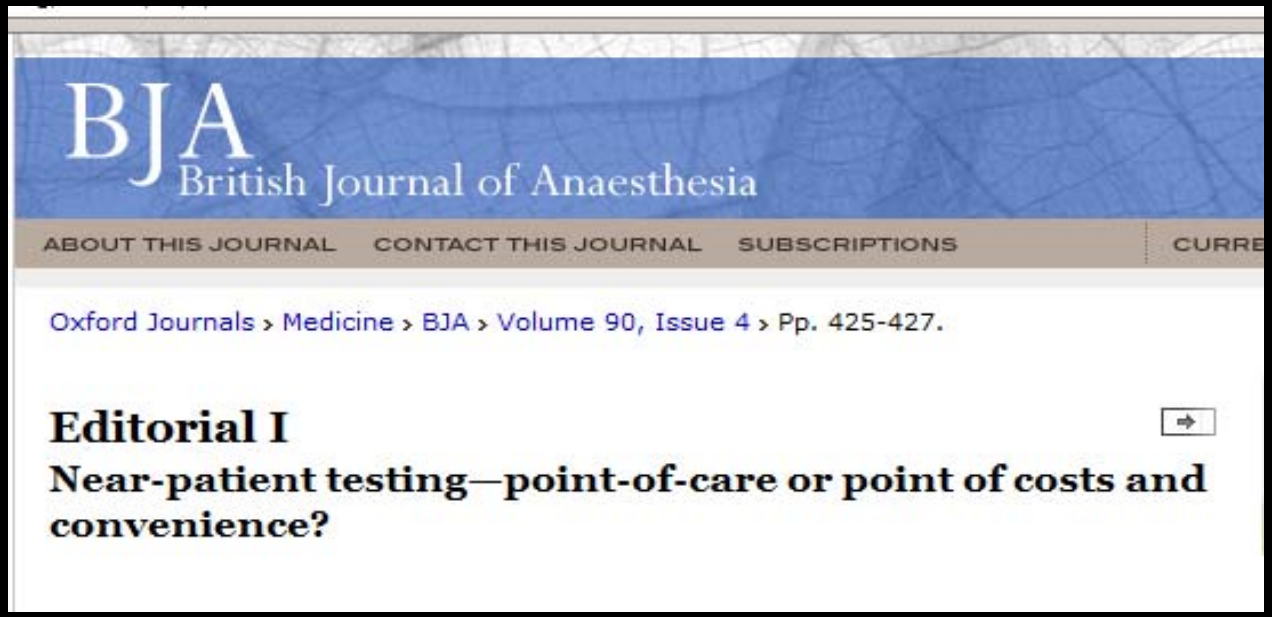
Mainly the requests (perceived needs) stem from the desire to improve the operational efficiency of clinical service, rather than from an absolute medical neccessity

Lewandrowski et al, Assuring quality of POCT, ACP 2011

Faster is better – it is rarely that simple!

MG Scott

Clin Chem 2000;46:441-442



Uncritical and unjustified expansion of near□patient testing technology provides more data and more costs rather than reliable information and benefit.

University Hospital Zagreb

- Blood gases
- CBC
- Glucose
- Coagulation, TEG, aggregometry

The demand.....

- Blood gas – why do they have it and we don’t?
- Coagulation – stroke units
- Glucometers – never enough
- Interventional cardiology – ACT
- Transplantation team – all of the above

What can we do?

Direct vending prevention (single door strategy)

Laboratory should be perceived as capable and trustworthy both by the clinicians and hospital administration

Be bold and recommend or advice against the instruments and/or point out their strenghts and weaknesses

- Choice of the instruments according to the the particular needs:

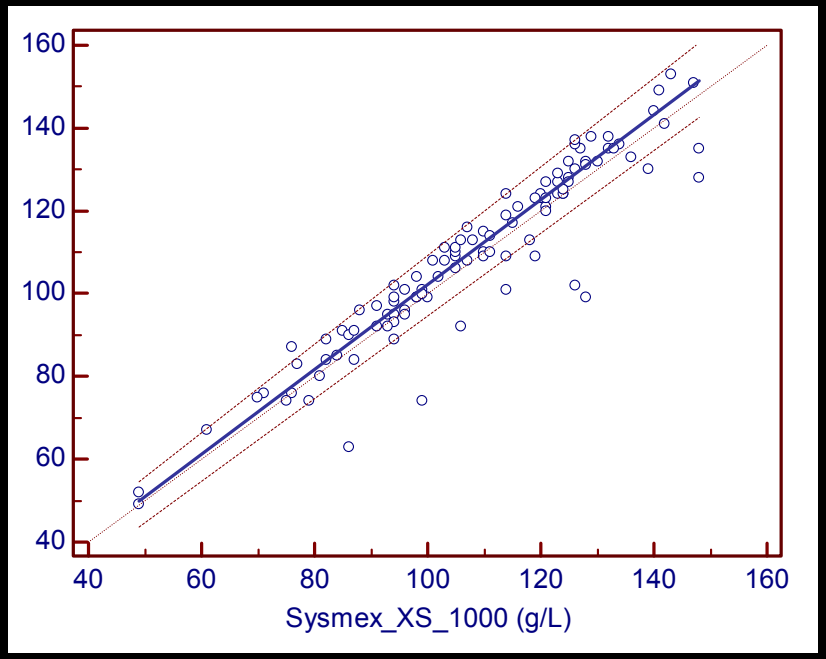
Number of tests/month

Methodology

Interferences

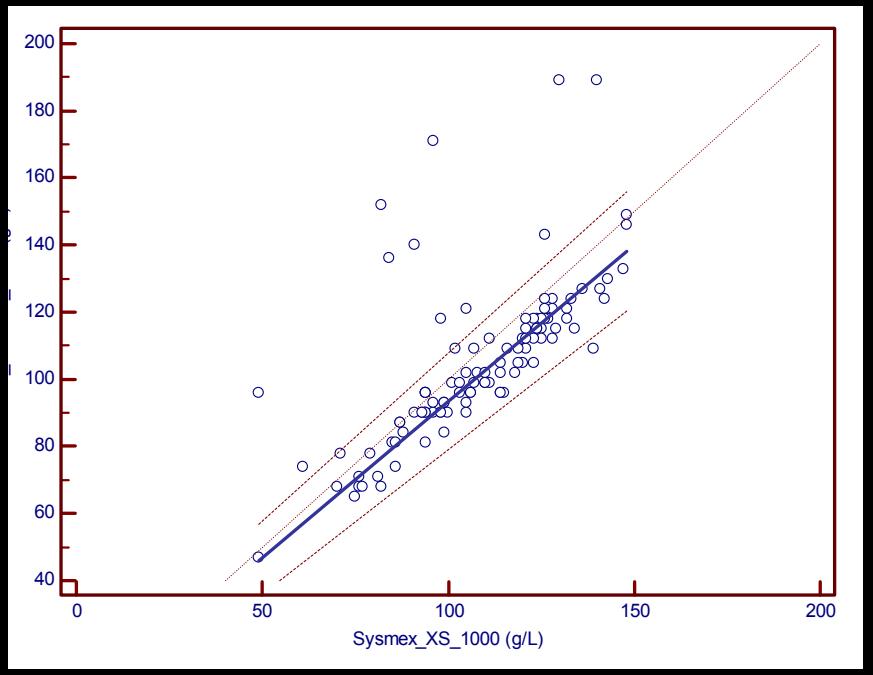
Compatibility with central laboratory

Haemoglobin



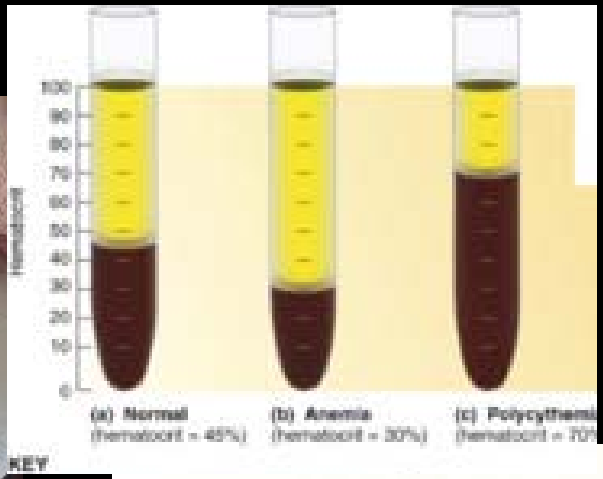
CO-oximetry

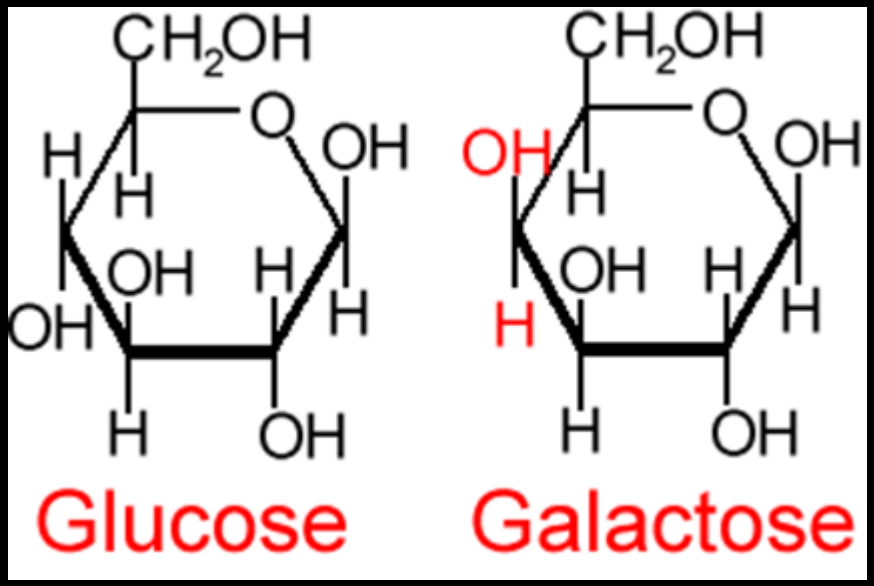
r=0,9451



conductivity

r=0,6728


Hematocrit
100
90
80
70
60
50
40
30
20
10
0
(a) Normal
(hematocrit = 45%)
(b) Anemia
(hematocrit = 30%)
(c) Polycythemia
KEY


CH2OH
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Glucose
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Galactose

What's New
Allergenics
Blood
Cellular & Gene Therapy
Devices
Tissues
Vaccines
Xenotransplantation
Compliance & Surveillance
Consumer & Healthcare Information
eFOIA Reading Room
Industry
Meetings
Product Information
Research

Fatal Iatrogenic Hypoglycemia:

Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product

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INTRODUCTION

In July 2005, the Food and Drug Administration (FDA) received a case report of an elderly male diabetic patient who received a 10% maltose-containing intravenous immune globulin product (Octagam,[1] Octapharma Pharmazeutika Produktionsges m.b.H., Vienna, Austria) and experienced hypoglycemic coma and irreversible neurological damage secondary to excessive insulin administration. His insulin dosing was guided by falsely elevated blood glucose measurements that were obtained from a point-of-care glucose meter (Accu-Chek Inform meter,[2] Accu-Chek Comfort Curve test strips,[2,3] Roche Diagnostics, Indianapolis, IN, U.S.). The glucose meter test strips used glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) methodology,[4] which may overestimate measurements[3,4] when blood maltose levels exceed 0.9 mmol/L.[3]

Adverse events have been reported for immune globulin products that contain maltose,[5-10] which functions as a protein stabilizer[11-13] and an osmotic agent.[14,15] Similar adverse events have been reported for Extraneal (Baxter International, Deerfield, IL), a peritoneal dialysis solution that contains icodextrin,[5,6,8,16-19] which functions as an osmotic agent[17-19] and is metabolized to maltose and other oligosaccharides.[5-8,17-19] Other maltose-containing immune globulin products, parenteral galactose-containing, oral d-xylose-containing, and other intravenous maltose-containing products (e.g., parenteral nutrition products[20]) could theoretically yield overestimated GDH-PQQ glucose readings.[1,3,4,14,21-23] However, we are unaware of similar adverse events involving other FDA-licensed maltose-containing

Compatibility with central laboratory

Troponin

PT/INR

Daily POCT interactions

1. Clinicians – the usualy silent partners


FOR GOD SAKES
JUST GIVE ME THE DAMN NUMBER!

2. Nurses

The main partners in POCT on a daily basis

Pre-POCT times....

- Nurses: laboratory is a murky place somewhere in the hospital where we send specimen to. What they do there, we have no idea.
- Laboratory staff: nurses are sloppy phlebotomists and unappreciating customers, usualy not very pleasant do deal with.

POCT times....

- Nurses: What is QC? Why are they bothering us all the time with administration? The machine broke down again, where shall I find that result the doctor sent me for?
- Laboratory staff: Why are they calling us all the time, can't they think for themselves? Couldn't they realize that the battery has run out?

From nurses, POC testing gems

August 2000
Cover Story

Karen Titus

Your worst point-of-care testing nightmare is about to come true.

It's POC payback time: We're going to tell you what nurses and other nonlaboratory personnel really think of POC-and of you, the laboratory.

Oh, relax. The news is (mostly) good. As nurses and other nonlaboratory professionals have taken on bedside testing, far more than their workload (though we'll get to that later) has increased. They've gained a greater appreciation of the high standards you bring to medical care. They can see, a little more clearly, the impact CLIA and other regulations have on your work lives. And they know you care about patients.

But much as they appreciate the work you do and the support you provide, your POC colleagues have a few bones to pick with you. And, since they arguably are the omphalos of bedside testing-they're the ones drawing the specimens, running the tests, helping to choose the devices, tackling checklists and inspections, and talking to patients about laboratory results-you may want to heed their words of wisdom.

So listen up. Here's what they have to say.

Quality control means very little to them.

(You suspected this all along, didn't you?)

It's not that they don't understand the requirements. They just wish they didn't have to deal with them.

Or, as Tommy Waggoner, RNC, puts it, "We waste a lot of time on QC documentation and procedures."

Case in point: As a labor and delivery nurse with 22 years' experience, Waggoner "can't remember a time when I didn't do urine dipsticks. Nurses have been doing them forever. We're taught how to do them in nursing school."

She and her colleagues still do them, but it's no longer a simple matter now that the nursing staff maintains the POC testing manuals and tracks competencies. "Essentially what happened is the lab people came up and trained us to do something we'd been doing for 20 years," says Waggoner, nurse manager of obstetrical services at Hendrick Health

You don't understand how busy they are.

Despite years of positive interactions between the laboratory and nursing, the latter remains a mystery to the former-or so nurses say.

"I still don't think the lab understands the full scope of what nurses do. I don't think they will ever understand that," Case-Cromer says.

"There is so much going on in any one patient's care. And while point-of-care testing is a helpful portion of that, it's only a very small portion," adds Poe.

Recent POC discussions at Johns Hopkins have focused on downloading data from the bedside blood glucose meters. The most efficient way to accomplish this task, suggested the laboratory, would be to have one nurse from each of the approximately 70 nursing units download the data once a day. "That seemed to them an easy thing to do," recalls Case-Cromer.

And from nursing's perspective? "We thought it was an outrageous request," she says. "To have a nurse-who's doing patient administration, monitoring vital signs, dealing with IV lines, teaching patients, sending them off to procedures, giving whatever other treatments are needed, dealing with questions from patients and family and doctors-to ask them to remember to download lab data so the lab could generate reports seemed like an excessive, unrealistic demand."

Having a laboratory staff person download the data would have required two days' worth of work, she acknowledges, which would appear to bolster the lab's argument that nursing was a more efficient route. After all, the task would take a mere two minutes of a nurse's time.

But time is relative, as nurses are quick to point out. While the actual download might take two minutes, that doesn't account for the time it would take for nurses to track down the multiple glucose meters, wait for their colleagues to finish using the devices, and find an available computer to download the results. "The lab's two minutes are actually 20 to 30 minutes," Case-Cromer calculates.

You still don't get it, do you?
Nurses are busy people.

Poe says she's well aware of one frequent laboratory complaint-that nurses don't take the time to perform simple troubleshooting on POC devices. "We send down a meter that doesn't work, and it turns out to be something like missing batteries or whatever. Then the lab gets mad because they think we should take the time to figure that out.

"Well, we don't have that time," she says. "And if we did, we don't want to use our nursing expertise to figure out what's wrong with the glucometer-we'd rather be with our patients."

Not convinced yet?

Hospital administration

If the simple cost/test were the basis for POCT approval, none of the POCT would ever get through.

who pays?

1. Costs of instruments and tests

2. Costs of laboratory support:
   training and maintenance

"Anything given free is not valued"

an English proverb

Education and training

- System of certification and recertification

  testing the operator and their technique, under their field conditions

In other words “...no user should be allowed to perform tests that will alter clinical management without the trainer being satisfied with the competence of the user”

The Royal College of Pathologists
Guidelines on POCT, 2004

Maintaining the system

- Monitoring adherence to SOP
- Internal Quality Assurance – automated whenever possible and connected with the central laboratory
- EQA schemes

Being visible and available

Assuring Quality in Point-of-Care Testing

Evolution of Technologies, Informatics, and Program Management

Kent Lewandrowski, MD; Kimberly Gregory, MT(ASCP), NCA, CLS; Donna Macmillan, MBA, MT(ASCP)

• ***Context.***—Managing the quality of point-of-care testing (POCT) is a continuing challenge. Advances in testing technologies and the development of specialized informatics for POCT have greatly improved the ability of hospitals to manage their POCT program.

Objectives.—To present the evolving role of technology improvement, informatics, and program management as the key developments to ensure the quality of POCT.

Data Sources.—This presentation is based on a review of the literature and on our experiences with POCT at the Massachusetts General Hospital (Boston).

Conclusions.—Federal and state regulations, along with accreditation standards developed by the College of American Pathologists and The Joint Commission, have established guidelines for the performance of POCT and have provided a strong incentive to improve the quality of testing. Many instruments for POCT have incorporated advanced design features to prevent analytic and operator errors. This, along with the development of connectivity standards and specialized data management software, has enabled remote review of test data and electronic flow of information to hospital information systems. However, documentation of manually performed, visually read tests remains problematic and some POCT devices do not have adequate safeguards to prevent significant errors. In the past 2 decades the structure of a successful POCT management program has been defined, emphasizing the role of POCT managers working in conjunction with a pathology-based medical director. The critical skill set of POCT managers has also been identified. The POCT manager is now recognized as a true specialist in laboratory medicine.

(*Arch Pathol Lab Med.* 2011;135:1405–1414; doi: 10.5858/arpa.2011-0157-RA)

The development of technologies to perform laboratory testing at the point of care (POC) has created unique opportunities to increase the operational efficiency of clinical services and in some cases, to improve patient outcomes.[1] However, ensuring the quality of point-of-care testing (POCT) and achieving compliance with regulatory guidelines has proved challenging in many institutions.[2] For a review of current regulatory guidelines in the United

debacles during routine inspections to renew their accreditation. During the past 2 decades, hospitals have acquired considerable experience in managing test quality and regulatory compliance for POCT. Over the same time, manufacturers of POC tests have made major strides in the design and engineering of devices to improve quality and prevent analytic and operator-related errors. Combining these developments has made it possible to

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Point-of-care testing (POCT) -- Requirements for quality and competence

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Abstract


HELP
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