Using the new NACB Practice Guidelines to enhance POCT

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The National Academy of Clinical Biochemistry has developed a Laboratory Medicine Practice Guideline for point-of-care testing (POCT). This POCT guideline systematically reviews the scientific literature linking POCT to patient outcome and makes recommendations for the optimal use of POCT in patient care.

This guideline is a resource for those implementing new POCT as well as those reviewing their current practice and interested in evidence to support their practice. This guideline represents the most comprehensive systematic review of the POCT literature to date, and the recommendations from this guideline will be useful in establishing our current POCT knowledge as well as defining needs for future research.

pH testing and occult blood are discussed as examples of how the recommendations can be utilized to enhance POCT programs.

Introduction

Point-of-care testing (POCT) programs often receive requests from clinicians to add new testing. These requests require POCT coordinators and directors of POCT to independently research the scientific literature in order to determine if the test requests are appropriate and will meet patient needs.

With increasing shortages of nursing staff and hospital resources, POCT staff are more frequently questioning not only new test requests but also ongoing clinical practice to ensure that current practice actually improves patient outcome and is supported by scientific evidence. The need for a resource of our POCT knowledge is the basis for developing Laboratory Medicine Practice Guidelines for POCT.

The National Academy of Clinical Biochemistry (NACB) is a professional organization and the academic core of the American Association for Clinical Chemistry (AACC) dedicated to advancing the science of clinical laboratory medicine through research, education, and professional development. The NACB publishes Laboratory Medicine Practice Guidelines (LMPG) for the application of clinical biochemistry to medical diagnosis and therapy.

The NACB has published more than a dozen LMPGs on laboratory testing for nutritional status, thyroid, cardiac markers and risk factors, hepatitic injury, diabetes, maternal/fetal health, therapeutic drug monitoring, emergency toxicology, and most recently POCT. These LMPGs are available on the NACB website at www.nacb.org and are also linked to the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse.

POCT is an increasingly popular means of delivering laboratory testing. POCT has the potential to deliver faster test results and therapeutic intervention. However, when incorrectly performed or inappropriately applied to patient care, POCT results can be misleading and pose increased patient risk and healthcare costs. Clinicians need guidance in the proper utilization of POCT.

This POCT LMPG systematically reviews the scientific literature relating POCT to patient outcome and makes recommendations regarding the optimal use of POCT in patient care. This POCT LMPG is intended to be a resource for POCT directors, coordinators, physicians and clinical staff who are implementing POCT into their testing strategies or are questioning the evidence supporting current clinical practice.

Development of practice guidelines

To develop the POCT LMPG, the field of POCT was divided into 13 test- and disease-specific focus groups including quality management, non-invasive bilirubin, cardiac, coagulation, critical care, diabetes, drugs and ethanol, infectious disease, occult blood, intraoperative parathyroid hormone testing, pH, renal and reproduction.

Input was balanced to reduce bias in the recommendations by ensuring physician, laboratory and manufacturer membership on each of the focus groups.

Experts in POCT were recruited to formulate the pertinent clinical questions and review the scientific literature relating POCT to patient outcome. Scientific; PubMed and OVID Medline and evidence-based databases; Cochrane and National Guideline Clearinghouse, were searched. Citations were limited to peer-reviewed journals in English containing studies on human subjects.

Abstracts were reviewed by each focus group, and those manuscripts pertaining to the clinical questions were reviewed and graded according to the U.S. Preventive Services Task Force levels of evidence [1]:

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Focus groups combined the pertinent manuscripts to develop guidelines based on the strength of evidence in the format recommended by AHRQ [2]:

A. The NACB strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.
B. The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C. The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.
D. The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.

The guidelines were presented at various national and international meetings, including the 2004 AACC Annual Meeting, and the guidelines were published on the NACB website in order to invite public comment. All comments were referred to the appropriate focus group for resolution in finalizing the recommendations. The final POCT LMPG is now available on the NACB website at www.nacb.org [3].

Using the guidelines: pH

Recommendations from the POCT LMPG are useful as a resource for staff questioning current POCT or seeking the evidence to support current or new POCT. At Baystate Health, we have used the recommendations to evaluate our use of pH paper testing in our institution. pH paper is utilized in a variety of clinical settings throughout the hospital.

pH paper is available in the emergency department for evaluation of acid/base exposure and the potential for residual chemical and burns during skin or eye washing. pH paper is also available in our intensive care units for evaluation of gastric fluid and antacid therapy as well as in the general medical units for placement of nasogastric tubes.

The POCT LMPG questioned the evidence linking use of pH testing in these clinical applications and made the following recommendations:

- We note that pH paper may have utility in monitoring the treatment of chemical exposure in the Emergency Department and Urgent Care patient populations, but there is insufficient evidence to make a strong recommendation for or against its routine use. (Strength I, Level III)
- Although the use of pH testing is common on critical care units, there is a lack of evidence that pH monitoring to adjust antacid therapy improves either morbidity or mortality in these patients. (Strength C, Level II and III)
- We recommend the use of pH testing to assist in the placement of nasogastric tubes. (Strength B, Level II and III)

Based on these recommendations, we stopped the intermittent testing of gastric fluid on critical patients in our intensive care units. Current antacid therapies are so effective that the need to repeatedly test patients is unnecessary.

Making this small change in practice saved valuable time for our limited nursing staff without significantly impacting patient outcome. We further revised our nasogastric tube placement protocols to rely more on pH testing to determine placement over x-ray confirmation.

Although x-ray confirmation is still required in difficult tube placements, we were able to eliminate the need for x-rays in the majority of simple placements, reducing both the patient load in radiography and the radiation exposure of patients. Finally, we questioned the need for pH testing in the emergency department.

Although pH testing has been a longstanding practice in chemical exposure, there is no evidence to support that this practice leads to improved patient outcome; decreased burns, length of stay or cost of care.

Despite the lack of evidence, our clinicians felt there was no added risk to patients with testing, while discharging a patient with insufficient skin or eye washing poses a greater risk for continued burns. Our physicians and hospital risk management thus chose to continue the practice as so many other institutions continue to perform pH testing on chemical exposure patients, and there was a desire to meet *"standard of practice"* regardless of the lack of evidence to support this practice.

We were, however, able to convince staff to take measures to ensure quality pH test results. pH paper needs to be checked for reactivity and a quality control program has been implemented to require regular performance and documentation of pH controls in those areas utilizing pH paper.

In addition, we have verified that the appropriate range of pH paper is available based on clinical need. For nasogastric tube placement, we utilize a paper with pH range 1-8, while in the emergency room we utilize a wide range, pH 1-12 paper. The POCT guidelines have therefore allowed us to evaluate our current practice and support our current practice with literature evidence.

This not only helps us justify expenditure of limited hospital resources, but has led to significant improvement in patient care by reducing unnecessary testing in critical care patients and exposure to radiation in our nasogastric tube placements.

Using the guidelines: gastric occult blood

In another area of our hospital, we questioned the use of occult blood testing for gastric fluids. The POCT LMPG reviewed the literature and found only one paper supporting the use of occult blood testing in gastric fluid [4]. This was a small study of 41 intensive care patients receiving antacid prophylaxis and at risk for gastrointestinal bleeding that found 13/14 patients who were positive for gastric fluid occult blood and had a source of bleeding found on follow-up endoscopy.

This suggests that occult blood testing may be useful in these patients; however, none of the negative patients had endoscopy. There was thus no means of determining the false negative rate of the test or how many of the patients had bleeding that was missed by the test. The POCT LMPG made the following recommendation:

- We cannot currently recommend for or against the use of gastroccult to detect gastric bleeding in intensive care unit patients receiving antacid prophylaxis. Only one study to our knowledge has indirectly addressed this issue. No randomized controlled trials have been performed. (Strength I, Level III)

Based on this recommendation, we approached our Gastroenterology Department and with the help of our Healthcare Quality Department took steps to remove the test. A letter was drafted outlining several key points.

First, there is no evidence supporting improved patient outcome from routine occult blood testing of gastric fluid. Second, occult blood testing after nasogastric tube placement is inevitably positive due solely to the trauma of tube placement. Third, overt bleeding is a medical concern, but does not require the test to detect. Finally, pH testing is medically useful in determining tube placement, but pH testing through the use of pH/occult blood combined cards is more expensive than simply using pH paper.

Elimination of the combined pH/occult blood cards reduced the burden of staff training, competency and quality documentation. In addition, removal of the gastric occult cards prevented the possibility of staff confusing the gastric developer with the fecal occult developer, two separate products that needed to be stocked, controlled, and managed.

Removal of the gastric occult blood test has led to a direct savings of USD 26,000 in reagents and developer and indirect savings of USD 36,500 in labor required to perform 12,000 tests annually. This change has led to significant savings in both labor and cost to the institution without impact on patient outcome.

Summary

In summary, the POCT LMPG is a resource for staff considering the implementation of new POCT or questioning current practice. These guidelines represent the most comprehensive systematic review of the POCT literature to date.

The POCT LMPG will be useful in sorting fact from conjecture when utilizing POCT, and provides research

evidence to support optimal use of POCT in clinical practice. Most important, the POCT LMPG provides the extent of our current POCT knowledge base and indicates those areas of our knowledge that are lacking.

The POCT LMPG will also be useful in guiding future research and indicating the types of high-quality studies needed to provide a better link of POCT to patient outcome. Staff is encouraged to question their practice and new test requests and to utilize these guidelines in order to improve their diagnostic testing strategies.

References

1. Harris RP, Helfand M, Woolf SH, *et al*. Current methods of the U.S. Preventive Services Task Force: A review of the process. Am J Prev Med 2001; 20:21-35.

2. Systems to Rate the Strength of Scientific Evidence. Bethesda, MD: AHRQ Publication 02-E016, April 2002:11pp. www.ahrq.gov (Accessed March 2006).

3. Nichols JH, Christenson RH, Clarke W, Gronowski A, Hammett-Stabler CA, Jacobs E, *et al*. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Evidence Based Practice for Point of Care Testing. AACC Press: 2006.

4. Derrida S, Nury B, Slama R, Marois F, Moreau R, Soupison T, *et al*. Occult gastrointestinal bleeding in high-risk intensive care unit patients receiving antacid prophylaxis: frequency and significance. Crit Care Med 1989; 17:122-5.