Effectiveness of practices to reduce blood sample hemolysis in EDs: A laboratory medicine best practices systematic review and meta-analysis

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A B S T R A C T

Objective: To complete a systematic review of emergency department (ED) practices for reducing hemolysis in blood samples sent to the clinical laboratory for testing.

Results: A total of 16 studies met the review inclusion criteria (12 published and 4 unpublished). All 11 studies comparing new straight needle venipuncture with IV starts found a reduction in hemolysis rates, [average risk ratio of 0.16 (95% CI=0.11–0.24)]. Four studies on the effect of venipuncture location showed reduced hemolysis rates for the antecubital site [average risk ratio of 0.45 (95% CI =0.35–0.57)].

Conclusions: Use of new straight needle venipuncture instead of IV starts is effective at reducing hemolysis rates in EDs, and is recommended as an evidence-based best practice. The overall strength of evidence rating is high and the effect size is substantial. Unpublished studies made an important contribution to the body of evidence. When IV starts must be used, observed rates of hemolysis may be substantially reduced by placing the IV at the antecubital site.

Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the CDC.

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Introduction

When blood samples are hemolyzed they can produce unreliable laboratory results. Hemolysis can produce interference and bias in 39 different laboratory tests [1]. Thus, hemolyzed samples are rejected for coagulation testing [2] and in transfusion medicine for ABO typing and antigen screening [3]. Hemolysis may interfere with bilirubin determination, which, in turn, may affect the accuracy of plasma bilirubin measurements in preventing the occurrence of neonatal kernicterus [4]. Potassium results from hemolyzed samples may falsely indicate or disguise a life-threatening abnormality and lead to inappropriate treatment(s) [5,6]. Immunosassays based on non-isotopic detection systems can also be affected by hemolysis [7,8]. When blood samples are hemolyzed, a new clinical sample is often required. It has been recognized that re-collection of hemolyzed blood samples may delay patient care in overcrowded emergency departments (EDs) [9].

Quality gap: hemolyzed blood samples

Despite these problems, hemolyzed blood samples are frequently received in clinical laboratories, comprising as much as 3.3% of all routine samples and accounting for up to 40%–70% of all unsuitable samples identified — nearly five times higher than other causes, such as insufficient, incorrect, and clotted samples [10]. The American Society for Clinical Pathology established a 2% or lower benchmark for hemolysis rates among laboratory blood samples [9]. Hospital EDs have been identified as a major source of hemolyzed samples. Two studies in hospital EDs found hemolysis rates of more than 30% [11,12], while many others observed rates (ranging from 6.8 to 19.8%) that were considerably higher than the established benchmark [13–17]. Several studies [16,12,17] identified ED hemolysis rates that were significantly elevated compared to other hospital departments.
Practice descriptions

There are a wide variety of standard practices for drawing blood samples in the ED. The practices used are largely dependent upon the personal preference of the ED medical staff conducting the blood draw, taking into consideration the particular patient characteristics and the immediate circumstances. The choices may also be influenced by training and/or position of the medical staff person. Laboratory oversight of the training and competency of the ED blood collection staff varies. Literature citations, practitioners and experts in the field, defined a set of practices associated with drawing blood samples in the ED that could potentially impact the rates of hemolysis. These factors include:

Who? — Phlebotomist vs. ED medical staff: Phlebotomists are specifically trained and practiced in drawing blood using straight needle venipuncture, and are generally not trained in starting IVs. Some nurses and other ED medical staff are trained in and use both methods of blood collection.

What? — New straight needle venipuncture vs. IV start: Some ED patients may have IV lines placed. By using these IV starts for collecting blood, many nurses and ED medical staff believe they can both save time and reduce patient discomfort by avoiding a second needle stick [18]. Considerable variety is found in both the IV’s and straight needles used for venipuncture in the ED. This review did not distinguish between the types and brands that were used within each method. For example, no distinction was made between regular and butterfly straight needles in the evidence analyses.

How? — Use syringe vs. vacuum tube: When drawing blood from an IV start, the rate of hemolysis may be impacted by the level of vacuum applied to the needle. Compared to the fixed pressure of a vacuum tube, syringes allow the ED medical staff collecting blood samples to control the amount of vacuum applied. The use of syringes can either reduce or increase the vacuum applied to the needle by the ED medical staff conducting the draw depending on the patient’s situation and difficulty in obtaining blood from the patient [19]. If blood is collected by syringe, blood is transferred to tubes by a wide variety of methods. These methods were not part of the analysis.

Where? — Antecubital site vs. more distal site: The antecubital fossa provides a large vein for drawing blood samples, allowing easier access, the use of larger needles, and a lower likelihood of vessel collapse. At more distal vascular sites, veins are smaller.

What? — Smaller (>21 gauge) vs. larger (≤21-gauge) bore needle: The size of the needle may affect hemolysis by impacting the stress and/or turbulence for the red blood cells as they are collected. While emphasis has been on the fluidic shear experienced by cells passing through very small needles, using too large a needle may increase the flow rate too much, causing turbulence within both the needle and the collection tube as blood is collected.

How? — If using a vacuum tube, use partial vs. full vacuum tube: Partial vacuum tubes reduce the blood transfer rate relative to full vacuum tubes and thus may reduce hemolysis. Vacuum levels in blood collection tubes are rarely reported unless they are the actual focus of a study. However, according to personal communication with a tube manufacturer’s field representative, partial vacuum tubes are being used more commonly. Partial vacuum tubes reduce the blood transfer rate compared to full vacuum tubes. This practice is applicable across all alternative practices, except the practice of using a syringe for blood collection.

When? — Tourniquet time: less than 1 min vs. longer: Tourniquets constrict blood vessels and can, themselves, result in hemolysis. It has been recommended that tourniquets not be applied for more than 1 min when collecting blood [20].

Methods

This evidence review followed the CDC-sponsored Laboratory Medicine Best Practices Initiative’s (LMBP) “A-6 Cycle” systematic review methods for evaluating quality improvement practices [21]. This

Fig. 1. Analytic framework — when drawing blood samples for laboratory testing from patients in the ED, what practices are effective in reducing hemolysis rates among these samples?
approach is derived from previously validated methods, and is designed to produce transparent systematic review of practice effectiveness to support evidence-based best practice recommendations.

A review team conducts the systematic review and includes a review coordinator and staff trained to apply the LMBP methods. The team is guided by a multi-disciplinary expert panel including at least one LMBP Workgroup member and individuals selected for their diverse perspectives and relevant expertise in the topic area, laboratory management, and evidence review methods.

The question addressed by this evidence review is: “When drawing blood samples for laboratory testing in the ED, what practices are effective in reducing hemolysis rates among these samples?” (Fig. 1). The relevant PICO elements are:

- **Population**: Patients receiving treatment in hospital-based EDs.
- **Interventions**: Blood collection practices in the ED hypothesized to be associated with hemolysis rates.
- **Comparison**: Comparison practices are generally ongoing ED practices, which include various combinations of all the practices being studied.
- **Outcome**: Hemolysis rates are the outcomes of interest. There are two widely used methods of measuring hemolysis in centrifuged blood samples: direct spectrophotometric readings by instrument (quantitative and objective), and visual comparison of blood samples with a color chart by laboratory personnel (semi-quantitative and subjective). Hemolysis in a blood sample is a continuum, and the level of hemolysis considered significant can vary among institutions. The level at which hemolysis impacts clinical laboratory results varies by the type of test being conducted.

A comprehensive electronic search for literature was conducted with the guidance of a professional librarian from July through October 2011. It included English-language publications (or availability of an English abstract) since 1990.

Search of databases for published, peer reviewed literature as well as gray literature included the NIH maintained PubMed, two professional electronic databases, CINAHL (Cumulative Index to Nursing and Allied Health Literature) and Embase (focusing on international biomedical literature) and VHINL (Virginia Henderson International Nursing Library). The search terms used are included in Appendix C. In addition, hand searches of references in identified publications were also conducted. Finally, a general request for unpublished data that may have been collected by hospital EDs for their own internal surveys was spread through contacts supplied by the LMBP Hemolysis Expert Panel.

Table 1

<table>
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<tr>
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<tr>
<td>Giavarina et al. (2010)</td>
<td>Good</td>
<td>Substantial</td>
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<tr>
<td>Lowe et al. (2008)</td>
<td>Good</td>
<td>Substantial</td>
</tr>
<tr>
<td>Mary Washington Hosp (unpub)</td>
<td>Good</td>
<td>Substantial</td>
</tr>
<tr>
<td>Raisky et al. (1994)</td>
<td>Good</td>
<td>Substantial</td>
</tr>
<tr>
<td>U of Minnesota Hosp (unpub)</td>
<td>Good</td>
<td>Substantial</td>
</tr>
</tbody>
</table>

1 See Appendix A for the LMBP Hemolysis Expert Panel Members. Each Expert Panel is assembled based on the systematic review topic, and the panel determines best practice definitions, the relevance of outcome measures, and effect size rating categories. The Panel also assesses individual study quality and the overall strength of a practice-specific body of evidence.

2 See Appendix B for the LMBP Workgroup members. The Workgroup consists of 13 invited members, and two ex officio representatives from federal agencies (CMS and FDA); members are clinicians, pathologists, laboratorians, and specialists in systematic evidence reviews. As the recommending body, the Workgroup reviews the Expert Panel’s work and determines whether a recommendation can be made to designate “evidence-based best practices.”
Published studies and unpublished data were screened by at least two independent reviewers to reduce subjectivity and the potential for bias, and all differences were resolved through consensus. Initial screening of titles and abstracts was used to exclude studies from full review if it was clear they did not satisfy the following criteria: 1) address hemolysis; 2) were relevant to the ED; and 3) were related to one of the practices of interest. During full review, studies and data were eliminated if they did not: 1) address hemolysis rates in a hospital ED; 2) evaluate one of the practices of interest for effectiveness; or 3) include sufficient data in an appropriate format to constitute a study. Studies and data that passed full review were abstracted and evaluated for quality and evidence of effectiveness according to LMBP methods [21].

All abstracted results that received a “good” or “fair” study quality rating had their results converted to risk ratios, which were plotted on common graph for each practice reviewed. A grand mean estimate of the result of the practice was calculated using inverse variance weights and mixed-effects models, a valuable tool for estimating precision and assessing the consistency and patterns of results across studies [22]. The key criteria for including studies in the meta-analyses were sufficient data to calculate an effect size and use of an outcome that is judged similar enough to the other studies being summarized.

The grand mean estimate and its confidence interval were considered more accurate representations of the results of a practice than that obtained from individual studies [23]. By convention, all meta-analysis results are presented in tabular forest plots and are generated using Comprehensive Meta-analysis software (v. 2.2.064, Statistical Solutions). For this review, an expert review panel determined that a “substantial” effect is a reduction of hemolysis by 50%, as represented by a risk ratio of 0.5 or less.

Results

A total of 545 non-duplicate bibliographic records were identified, 541 from structured searches and 4 from hand searches. In addition, 22 hospital EDs responded to requests for unpublished data. The source that generated the most submissions of unpublished data for this review was a request disseminated in the newsletter of the Center for Phlebotomy Education, Inc.

The review of all 545 published titles and abstracts (Fig. 2) eliminated 514 references as off-topic. The remaining 31 published studies were subjected to full text review. Of these, a further 17 studies were excluded for not meeting minimum criteria, and 2 were eliminated during abstraction and quality review. The remaining 12 published studies were included in our analyses.

Among the 22 institutions that offered unpublished findings, only 4 had sufficient data on the topics of interest to be included in the analysis. The most common reason for exclusion of unpublished data was the lack of denominator data (total blood draws from which the hemolyzed samples were observed). Thus, a total of 16 studies (12 published and 4 unpublished) contributed data to the review of practices to reduce hemolysis in the ED.

Most of the studies reviewed were conducted in general EDs with no specific age limitations, and a number of studies addressed more than one practice of interest. Below we review the meta-analysis results by practice.

Evidence of use of phlebotomists vs. ED medical staff practice effectiveness

No studies were found directly comparing rates of hemolysis among phlebotomists with ED medical staff all using straight needle venipuncture. Therefore, this practice was dropped from further analysis.
Evidence of straight needle venipuncture vs. IV start practice effectiveness

Eleven studies provided evidence for the effectiveness of straight needle venipuncture over IV starts and all results indicated that straight needle venipuncture is associated with a “substantial” reduction in hemolysis rates relative to drawing blood using IV starts. More than half of the studies were judged to be of “good” quality, with the remainder being judged “fair” (Table 1). Both “fair” and “good” studies showed similar heterogeneous distributions of results, but the random estimates of the effectiveness of straight needle venipuncture for each quality group are almost identical (Q=0.004, p=0.95) (Fig. 3). Although there is significant variation in the results obtained (QOverall = 48.32, p=0.00, I² = 79.3), the overall reduction in hemolysis from using straight needle venipuncture is consistently supported by the evidence, significant, and equal to about 84% (RR = 0.16, 95% CI = 0.11–0.24; see Fig. 3). Applying the LMBP criteria, the overall strength of evidence for use of straight needle venipuncture for reduction of hemolysis rates is “high”.

Evidence of antecubital site vs. distal sites practice effectiveness

Only studies using IV starts were available for this practice comparison. Four studies of blood draws using IV catheters provided evidence on the effectiveness of drawing blood from the antecubital site rather than a more distal site. One of the studies was judged to be of “fair” quality while the remaining studies were rated “good” (Table 2). All four studies were judged by the expert panel to show consistent, “substantial” reductions in hemolysis in the use of antecubital rather than distal sites. Based on these four studies, the overall expected reduction in hemolysis of 55% (RR = 0.45, 95% CI = 0.35–0.57) and the results are homogeneous (QOverall = 2.20, p = 0.00, I² = 0.00) (Fig. 4). Applying the LMBP criteria, the overall strength of evidence for use of the antecubital site for reduction of hemolysis rates is “high”.

Evidence of use of syringe vs. vacuum tubes practice effectiveness

Only studies using IV starts were available for this practice comparison. Three studies were identified testing the reduction in hemolysis achieved by using a syringe rather than a vacuum tube in IV starts to obtain blood samples. Only one of the studies was rated “good” and only one study had a “substantial” effect size rating. The other two studies’ effect size ratings were “minimal/none” (Table 3) with effect size risk ratios of close to 1 (Fig. 5). The meta-analysis results for syringe effectiveness are heterogeneous (QOverall = 19.29, p = 0.00, I² = 89.63), with a reduction in hemolysis from use of a syringe of approximately 3% and not statistically significantly different from no effect versus the comparison practice (RR = 0.97, 95% CI = 0.81–1.17). Applying the LMBP criteria, the effectiveness evidence for the use of syringes to reduce hemolysis in IV starts is “inconsistent”, and the overall strength of evidence is “insufficient.”

Evidence of use of ≤21-gauge (larger) needles practice effectiveness

Most studies of straight needle venipuncture reported a very limited range of needle sizes for analyses (usually either 21 or 22 gauge), therefore only studies using IV starts were available for this practice comparison. Three studies provided evidence about needle size for reducing hemolysis in IV starts. Two studies received “fair” quality ratings because they did not control for needle location. These two studies reported “substantial” reductions in hemolysis when using ≤21 gauge (larger) needles while the single study which was rated “good” reported a “minimal/none” reduction in hemolysis, when the location of venipuncture was controlled (Table 4). Although the meta-analysis mean risk ratio for ≤21 gauge (larger) needles is substantial (RR = 0.37, 95% CI = 0.27–0.52) and equal to approximately 63% reduction in hemolysis, the individual study effect size results for needle size are “inconsistent” and heterogeneous (QOverall = 14.82, p = 0.001, I² = 86.50) (Fig. 6). Applying the LMBP criteria, the
from the two studies were "suggestive."

Evidence for use of low (partial) vacuum tubes practice effectiveness

Only two studies provided evidence on the effectiveness of low (partial) vacuum tube for reducing hemolysis relative to standard (full) vacuum tubes. Both studies' effect sizes were rated "substantial" and one had a quality rating of "fair" while the other was rated "good" (Table 5). The meta-analysis (Fig. 7) mean effect size rating for the two studies is equal to a reduction in hemolysis of approximately 89% (RR = 0.11, 95% CI = 0.02–0.52). Although the effect size results from the two studies were "consistent," they are heterogeneous (Q = 4.66, p = 0.03, I2 = 78.54). Applying the LMBP criteria, the overall strength of evidence for using partial vacuum tubes to reduce hemolysis in IV starts is rated "suggestive."

Evidence of tourniquet time: less than 1 min vs. longer effectiveness

No studies of tourniquet time and hemolysis were found for the ED setting. Therefore, this practice was withdrawn from further analysis until such time as additional relevant studies are available.

Additional considerations

Feasibility of implementation

Straight needle venipuncture is a common practice and requires no additional training of personnel. When compared to using IV starts for collecting blood samples, there is a modest additional cost and time in placing both an IV and collecting blood from straight needle venipuncture, but this cost is likely mitigated when laboratory staff time to evaluate a hemolyzed sample is added to the burden of soliciting, executing, and evaluating a second draw is taken into consideration.

The antecubital fossa provides a large vein for drawing blood samples, typically with easy access, allows the use of larger needles, and is less likely to collapse. IV placement is often a matter of personal preference and training, and when tolerated by the patient's condition, no barriers to implementation are anticipated.

Implementing use of partial vacuum tubes represents a decision by the laboratory department and requires no change in staff behavior. Use of partial vacuum tubes is likely applicable across all other alternative practices except the use of a syringe, where it directly competes as a method of reducing the applied vacuum.

Potential harms

The recommended practice of using a straight needle for blood draws in the ED frequently requires an additional venipuncture. All venipuncture procedures pose a risk to ED staff of needle stick injury and exposure to infectious or other harmful agents [24]. Venipuncture procedures should always be performed using universal precautions [24]. Patients are also at some small risk for needle site injury when multiple attempts are made to obtain blood samples.

Future research needs

The use of partial vacuum tubes provides a potential solution for significantly reducing hemolysis in the ED that requires no behavioral changes on the part of ED medical staff, and does not appear to place an economic burden on the hospital (personal communication with company field representative). Additional studies are needed to provide more evidence of practice effectiveness.

In addition, some ED nurses (personal communication with ED nurses and supervisors) believe that using IV starts for phlebotomy may cause IV lines to clog and report that patients often need new IV lines placed when they get to the wards. This, along with the higher rates of hemolyzed samples, may boost the costs, inconvenience and delay of patient care associated with drawing blood through IV starts. Future studies should include patient follow-up on the ward to evaluate the impact of this ED practice.

Study limitations

A wide variety of practices for drawing blood samples are observed in the ED, largely determined by the personal preference of the ED medical staff person conducting the blood draw. Many of the studies summarized in this review controlled for one or two variations in those practices and allowed the others to vary without evaluation. However, their conclusions attributed all the variation in hemolysis to the practice of interest. To the extent practices are unrelated, differences in concurrent practices may increase error variation in outcome estimates. Error variance increases cross-study heterogeneity and reduces confidence in the grand mean estimated for the practice, but does not fundamentally bias the overall estimate of effectiveness for the practice. However, to the extent these practices

Table 4

| Needle gauge ≤21 (larger) vs. needle gauge >21 (smaller) (IV starts only). |
|---|---|---|
| Study | Quality | Effect size rating |
| Dugan et al. (2005) | Fair | Substantial |
| Kennedy et al. (1996) | Fair | Substantial |
| Dameron Hosp (unpub) | Good | Min/none |

Fig. 5. Results for use of syringe vs. vacuum tube (IV starts only). Mixed effects analysis using forest plot representations.
are related, this error variance creates a bias that can systematically inflate or deflate the practice effectiveness estimate. This was considered in our evaluation of these practices.

In addition, hemolysis may not be solely the result of pre-analytic practices. As Lippi and colleagues have observed [10], improper centrifugation, delayed separation of specimens, and re-spinning of tubes with gel separators may each contribute to specimen hemolysis, albeit at considerably lower rates than pre-analytic collection and transport practices.

While the LMBP systematic review methods are consistent with practice standards for systematic reviews [22], there still remains a measure of subjectivity in evaluating studies. Bias may be subtly introduced even when consensus is used to establish relevant outcome measures and effect size rating categories (e.g., “substantial,” “moderate,” “minimal/none”). Other factors, such as the experience and academic disciplines of the raters, and the criteria for study inclusion/exclusion may also influence findings. The restriction to English language studies (at least for an abstract) to satisfy the requirement of multiple reviewers for each study may also introduce bias. Most of the evidence for this review is from quality improvement studies, thus the primary data are limited to a single institution and site-specific differences may impact study results and conclusions. Despite this variation among institutions, the recommended practices had consistently favorable results.

Conclusions and best practices recommendations

Use of straight needles for venipuncture is effective in reducing hemolysis in the ED and is recommended by LMBP as an “evidence-based best practice.” This recommendation is on the basis of six “good” and five “fair” studies conducted in the ED that examined the effectiveness of using straight needles and consistently found “substantial” reductions in the rates of hemolyzed samples from straight needle venipuncture relative to using IV starts as a source for blood samples.

While the use of IV starts for collecting blood samples in the ED is associated with increased hemolysis and should be avoided, it is assumed that this common practice may continue for some time. Indeed, the “Infusion Nursing Standards of Practice,” published in a supplement to the January/February 2011 issue of the Journal of Infusion Nursing, discusses phlebotomy using vascular access devices including several warnings [25].

Evidence exists for practices that can improve hemolysis results when IV starts are used. Four studies, three rated “good” and one rated “fair” examined the effectiveness of drawing blood from an IV start placed at the antecubital site rather than a more distal site. Each of these studies reported “substantial” reductions in hemolysis when drawn from an antecubital site relative to a more distal site. Thus, when the decision to use an IV start for collecting blood samples in the ED has been made, then the use of antecubital sites is recommended by LMBP as an evidence-based best practice to reduce the rates of hemolyzed samples.

In addition, consistent and “substantial” reduction in hemolysis was observed in the two studies contrasting the effectiveness of low vacuum tubes in reducing hemolysis relative to regular vacuum tubes in the ED. However, with only one “good” and one “fair” study providing evidence for the effectiveness for this practice, the overall strength of evidence for this practice is only “suggestive”. Given tubes of the same size, a partial vacuum tube collects less blood than a full vacuum tube and this has been reported as an advantage when multiple draws are necessary, especially with pediatric patients.

Two practices, use of ≤21 gauge syringes (compared with >21 gauge syringes) and use of a syringe (rather than a vacuum tube) when collecting blood from an IV start, had “insufficient” overall strength of evidence of effectiveness for reducing hemolyzed samples in the ED.

Human subjects protection

No human subjects research was conducted for the purposes of the findings reported here.

Funding source

CDC funding for the Laboratory Medicine Best Practices Initiative to Battelle Centers for Public Health Research and Evaluation under contract W911NF-07-D-0001/DO 0191/TCN 07235.

Definitions

Antecubital fossa: the triangular cavity of the elbow that contains a tendon of the biceps, the median nerve, and the brachial artery. It is the region from which peripheral blood is commonly drawn because superficial veins cross through it.

Table 5

<table>
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Fig. 6. Results for ≤21 gauge (larger) needles vs. >21 gauge smaller needles (IV starts only). Mixed effects analysis using forest plot representations.
Gray literature: literature produced at all levels of government, academics, business and industry in print and electronic formats, but is not controlled by commercial publishers.

Hemolysis: the rupturing of erythrocytes (red blood cells) and the release of their contents (hemoglobin) into surrounding fluid (e.g., blood plasma).

IV start: a successful initiation of a peripheral intravenous line.

Acknowledgments

Melissa Gustafson, Devery Howerton, Elizabeth Leibach, Barbara Zehnbauer, LMBP Hemolysis Expert Panel, LMBP workgroup members, and the submitters of unpublished studies.

Appendix A. Laboratory medicine best practices hemolysis expert panel members

- Karen Bowers, Laboratory Manager, Edward Hospital
- Dennis Ernst, Director, Center for Phlebotomy Education
- Julie A. Gayken, HealthPartners, Bloomington, MN*
- Kathy Inglis, St. Elisabeth Medical Center
- Susan Morris, St. Luke’s Magic Valley Medical Center
- James Nichols, Tufts University School of Medicine and Baystate Health*
- James Reston, Health Technology Assessment Group, ECRI Institute

* LMBP workgroup member

Appendix B. LMBP workgroup members

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Associate Chief Medical Officer
Senior Patient Safety Officer
Rush University Medical Center

Robert H. Christenson, PhD, DABCC, FACB
Professor of Pathology and Medical Research Technology, University of Maryland Medical Center

John Fontanesi, PhD
Director, Center for Management Science in Health; Professor of Pediatrics and Family and Preventive Medicine
University of California, San Diego

Julie Gayken, MT(ASCP)
Senior Director of Laboratory Services
HealthPartners Medical Group and Clinics and Regions Hospital
Bloomington, MN

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Chief Medical Officer, COLA
Trustee, American Medical Association

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Director, Clinical Chemistry
Baystate Health

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Agency for Healthcare Research and Quality

Stephen Raab, MD
Department of Laboratory Medicine
Memorial University of Newfoundland & Clinical Chief of Laboratory Medicine, Eastern Health Authority

Milenko Tanasijevic, MD, MBA
Director, Clinical Laboratories Division and Clinical Program Development, Pathology Department
Brigham and Women’s Hospital

Ann M. Vannier, MD
Regional Chief of Laboratory Medicine & Director, Southern California Kaiser Permanente Regional Reference Laboratories

Sousan S. Altaie, PhD (ex officio)
Scientific Policy Advisor, Office of In Vitro Diagnostic Device (OIVD)
Evaluation and Safety Center for Devices and Radiological Health (CDRH), FDA

Melissa Singer (ex officio)
Centers for Medicare and Medicaid Services
Center for Medicaid & State Operations
Survey and Certification Group
Division of Laboratory Services

Appendix C. Structured search databases and terms

Date of Search: 8/19/2011
PubMed — NIH Database
Catheters:
- ((hemolysis [mesh] AND Blood specimen collection [mesh] AND catheters [mesh]) AND "1990"[Publication Date] : "3000"[Publication Date]) AND "0"[Publication Date] : "3000"[Publication Date]
Appendix D. LMBP reducing hemolysis in the ED systematic review eligible studies

Included studies — published
Included studies — unpublished data
__ (2011) Dameron Hospital Association, Stockton, CA.
Christine Schmotzer. (2011) Case Western Reserve University Hospitals, Cleveland, OH
Kathryn E. Hamilton & Cheryl Orr. (2011) Mary Washington Hospital, Fredericksburg, VA.
Cindy Hudson. (2011) University of Minnesota Medical Center, Fairview, MN.
Excluded studies — published


Appendix E. Evidence summary tables for reducing hemolysis in the ED

Note: Scoring information see: Christenson et al. (2011)
(Unless otherwise noted, numbers in parentheses show points deducted)

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<td>- Description: (0)</td>
<td>- Description: (0)</td>
<td>- Type of findings: (0)</td>
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<td>Agos, MD; Lizarra, R; Gamba, D; Maranon, A; Orozco, C; Diaz, E.</td>
<td>- Facility/location: (0)</td>
<td>- Practices evaluated: 1) IV draws = 3 specific IV catheters (18 or 20 gauge) 2) Straight needle venipuncture (21 gauge) - Duration: (0) 34 days over 3 months - Training: (0) Minimal - Staff/other resources: (0) Minimal - Cost: (0) Not provided</td>
<td>- Hemolysis as determined by laboratory staff — no other description - Recording method: (1) Not described</td>
<td>- Rates of hemolysis - Findings/effect size: (0) 1) Straight needle vs. IV start 7/348 (2%) vs. 222/1583 (14%) Other findings: IV catheter size: Gauge 18: 115/867 (13%) Gauge 20: 107/708 (15%) IV catheter type: Teflon: 39/475 (8%) + 18 Gauge: 19/301 (6.3%) + 20 Gauge: 20/164 (12.2%) Polyurethane: 77/426 (18%) + 18 Gauge: 51/243 (21.0%) + 20 Gauge: 26/183 (14.2%) Vialone: 106/684 (15%) + 18 Gauge: 45/323 (13.9%) + 20 Gauge: 61/361 (16.5%) - Statistical significance/test(s): (0) Authors calculate ORs and 95% CI - Results/conclusion biases: (1) Usefulness of results is restricted by lack of information on staff drawing blood, site, and syringe vs. vacuum tube</td>
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<tr>
<td>Publication: 1933 Adult (≥15) ED patients</td>
<td>- Population/sample: (0)</td>
<td>- Type of findings: (0) Rates of hemolysis</td>
<td>- Findings/effect size: (0) 1) Straight needle vs. IV start 7/348 (2%) vs. 222/1583 (14%) Other findings: IV catheter size: Gauge 18: 115/867 (13%) Gauge 20: 107/708 (15%) IV catheter type: Teflon: 39/475 (8%) + 18 Gauge: 19/301 (6.3%) + 20 Gauge: 20/164 (12.2%) Polyurethane: 77/426 (18%) + 18 Gauge: 51/243 (21.0%) + 20 Gauge: 26/183 (14.2%) Vialone: 106/684 (15%) + 18 Gauge: 45/323 (13.9%) + 20 Gauge: 61/361 (16.5%) - Statistical significance/test(s): (0) Authors calculate ORs and 95% CI - Results/conclusion biases: (1) Usefulness of results is restricted by lack of information on staff drawing blood, site, and syringe vs. vacuum tube</td>
<td></td>
</tr>
<tr>
<td>Analecta del sistema sanitario</td>
<td>- Collection: (0)</td>
<td>- Design: (0) All nurse draws are by IV with 12 mL syringe. All phlebotomist draws are by straight needle venipuncture with vacuum tube or syringe. Two 24-H count to observe ratio of phlebotomist to nurse draws - Duration: (0) Two 1-day reports 1 month (August 2011) case-control. - Training: (0) None - Staff/other resources: (0) Volunteer time of phlebotomy supervisor - Cost: (0) Minimal</td>
<td>- Hemolysis as determined by hospital lab. Use both visual and automated colorimetric analysis using a Beckman DXC. - Recording method: (0) Abstraction from records</td>
<td>- Type of findings: (0) 1) Case-control Odds Ratios (based upon % of a given practice among cases — hemolyzed samples and controls — non-hemolyzed samples) 2) Rates of hemolysis (based upon estimates of number of nurse draws) - Findings/effect size: (0) 1) Antecubital vs. other (ORs) Odds Ratio = 1.87 2) ≤21 vs. &gt;21 gauge Odds Ratio = 1.43 Above findings based upon 177 cases (hemolysis) and 177 controls (see attached calculations). 3) Straight needle vs. IV start Phlebotomist: 10/1292 (0.8%) Nurse: 39/431 = 6.7% Above findings based upon certain estimates from two 24-H observations (see attached calculations). - Statistical significance/test(s): (0) None conducted</td>
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| Quality rating: 7 (fair) | Practice (2 max): 2 Outcome (2 max): 1 Practice (2 max): 2 Outcome (2 max): 1 | Practice (2 max): 2 Outcome (2 max): 1 Practice (2 max): 2 Outcome (2 max): 1 |
|--------------------------|----------------------------------|----------------------------------|----------------------------------|
| Effect rating: Minimal | - Study (3 max): 2 Practice (2 max): 2 Outcome (2 max): 1 | - Study (3 max): 2 Practice (2 max): 2 Outcome (2 max): 1 |
| Relevance: Internal | - As noted, lack of control for potential confounders Practice (2 max): 2 Outcome (2 max): 1 | - As noted, lack of control for potential confounders Practice (2 max): 2 Outcome (2 max): 1 |

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<td>Practice (2 max): 2</td>
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<td>Outcome measures*</td>
<td>Need to estimate denominators for nurse draws to calculate RRs</td>
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<th>Results/findings*</th>
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<tr>
<td><strong>Author(s):</strong></td>
<td>Lisa Dugan, BC; Karen Gabel</td>
<td>Corriher, Speroni; Joy S. D.; Giavarina, M. D. Leech; Lida Leech; BC,</td>
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<td>Giavarina, D.; Pasquale, L.; Mezzena, G.; Soffritti, G.</td>
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<td>As noted, used multiple tubes per patient as independent samples. Also, lack of control for confounding</td>
<td>As noted, lack of information process</td>
<td>Small sample size, potential confounders and non-independence of outcomes when multiple tubes collected.</td>
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### Quality Information

**Bibliographic information**

**Overall rating**

- **Affiliations:**
  - San Bortolo Hospital, Vicenza
  - Funding: Internal

- **Quality rating:** 7 (fair)
- **Effect rating:** Substantial
- **Relevance:** Direct

#### Bibliographic information

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<th>Results/findings*</th>
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#### Practice Information

- **Study (3 max):** None observed — only one sample per patient drawn. However, needle venipunctures came from intensive care and IV starts came from ED. Need size is controlled, but not the same in each practice (this is usual).
- **Outcome measures:** Minimal
  - Cost: (0) Not provided

#### Results/findings

- **Type of findings:**
  - Staff collecting bloods and site.
  - Also, while implied, not clearly stated that vacuum tubes were used over syringes (stated that in general practice vacuum tubes had replace the use of syringe except in particular circumstances).

### Bibliographic Information

**Overall rating**

- **Author(s):**
  - Marian Sue Grant
  - Year: 2003
  - Publication: Journal of Nursing Practice (3 max): 2
  - Population/sample: (0)
  - Time period: (0)

- **Affiliations:**
  - Johns Hopkins Hospital, Baltimore, MD
  - Funding: Internal

#### Bibliographic information

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#### Practice Information

- **Study (2 max):** As noted, potential confounding by comparing different populations
- **Outcome measures:** As noted, lack of information process
  - Cost: (0) Not provided

#### Results/findings

- **Type of findings:**
  - Comparison between ED and ICU.
  - Also, missing information on potential confounders

### Bibliographic Information

**Overall rating**

- **Author(s):**
  - N.J. Heyer et al.

- **Study (3 max):**
  - Design: (0)
  - Cross-sectional
  - Observational

- **Outcome measures:**
  - Cost: (0) Not provided

#### Bibliographic information

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#### Practice Information

- **Study (2 max):**
  - Description: (0)
  - Phlebotomist draw (usually straight needle venipuncture at antecubital site) — located in ED, also had draw room for patients waiting to be triaged.

#### Results/findings

- **Type of findings:**
  - Rates of hemolysis
  - Findings/effect size: (0)

- **Outcome measures:**
  - Rates of hemolysis
  - Any hemolysis
  - Any hemolysis
  - Any hemolysis
  - Any hemolysis
  - Any hemolysis

- **Results/findings:**
  - Type of findings: (0)
  - Rates of hemolysis
  - Findings/effect size: (0)

- **Other findings:**
  - Statistical significance/test(s): (0)
  - Chi-square significance tests using SAS.
### Bibliographic Information

<table>
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<tr>
<th>Year</th>
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<th>Author(s)</th>
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<td>2011</td>
<td>Unpublished</td>
<td>Cindy C. Kennedy</td>
<td>Random assignment experiment</td>
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#### Practice Information

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#### Conclusion

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#### Findings

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<th>Practice(^*) Category (points deducted)</th>
<th>Outcome measures(^*) Category (pts deducted)</th>
<th>Results/findings(^*) Category (points deducted)</th>
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<td>- Year: 1996</td>
<td>ED Patients requiring both an IV and blood draw for complete blood cell counts (CBC) or electrolyte levels. Two randomly assigned groups for blood draw through a) IV (14–24 gauge) with a 12 mL syringe (N = 87) or b) a separate venipuncture with 21-gauge needle and vacuum tube (N = 78 — note, originally 85, but 7 failed to obtain blood — no reason given).</td>
<td>- Description: (0) Detai</td>
<td></td>
<td>- Type of findings: (0) Rates of hemolysis</td>
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<tr>
<td>- Publication: J Emergency Nursing</td>
<td>- Practice (2 max): 2 Cross-over study should be more balanced; not implemented as designed</td>
<td>- Hemolysis defined as any visually detectable level. Level of hemolysis determined by automatic reader. Lab blinded to experimental status.</td>
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<td>- Findings/effect size: (0)</td>
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<tr>
<td>- Affiliations: The Medical Center Columbus, GA</td>
<td>- Results/conclusion biases: (1)</td>
<td>- Recording method: (0) Standardized data collection form completed by nurses — trained in completing form.</td>
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<td>- Statistical significance/test(s): (0)</td>
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<td>- Funding: Internal</td>
<td>- Comparator: (0)</td>
<td>- Duration: (0) April 5 to May 30, 2006</td>
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<td>1) Straight needle (butterfly) vs. IV start: 1/355 (-1%) vs. 28/498 (5.62%) p &lt; 0.001</td>
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<td>- Staff/other resources: (0)</td>
<td>- Minimal</td>
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<td>2) For IV start: antecubital vs. other arm: 4/139 = 2.9% vs. 24/355 = 6.8% Other site specifics: Forearm: 7/147 (4.8%) Hand: 12/111 (10.8%) Wrist: 5/97 (5.2%)</td>
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<td>- Cost: (0) Not given</td>
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<td>- Statistical significance/test(s): (0)</td>
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<tr>
<td>Schellart, M;</td>
<td>Emergency and outpatient depts. Last half of 2008</td>
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<td>Gorissen, C;</td>
<td>Kleinveld, HA.</td>
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<td>– Year:</td>
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<td>– Publication:</td>
<td>4 blood draws each from 100 ED patients (all IV)</td>
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<td>Ned Tijdschr Klin Chem Labgeneesk</td>
<td>50 straight needle draws from outpatients</td>
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<td>Atrium Medical Center, Heerlen, Netherlands</td>
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<tr>
<td>Marcus EH Ong; Yiong</td>
<td>Cross-Sectional with follow-up</td>
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<td>Huak Chan;</td>
<td>Observed regular (unregulated) practices — did not provide data allowing control for potential confounding factors.</td>
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<td>Chin Siah</td>
<td>Limitation of 300 or more.</td>
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<td>Lim.</td>
<td>No description provided of who drew the samples or how subjects were selected.</td>
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<td>Ann Acad Med Singapore</td>
<td>No description, Estimated an average of 200 UE samples collected daily</td>
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<tr>
<td>– Affiliations:</td>
<td>No requirements put upon personnel drawing blood</td>
</tr>
<tr>
<td>Atrium Medical Center, Heerlen, Netherlands</td>
<td>None observed. Although multiple tubes collected — primary results reported for first tube only</td>
</tr>
<tr>
<td>– Comparators:</td>
<td>None in Phase 1 — Education in phase 2.</td>
</tr>
<tr>
<td>Internal</td>
<td>Study bias (1):</td>
</tr>
<tr>
<td>– Author(s):</td>
<td>None observed — only used UE samples.</td>
</tr>
<tr>
<td>Marcus EH</td>
<td>Did control for other parameters (but did state no statistical influence by operator).</td>
</tr>
</tbody>
</table>

Download sample with little description and no data provided to control for other practice parameters.
### Bibliographic information

<table>
<thead>
<tr>
<th>Overall rating</th>
<th>Study* Category (points deducted)</th>
<th>Practice* Category (points deducted)</th>
<th>Outcome measures* Category (points deducted)</th>
<th>Results/findings* Category (points deducted)</th>
</tr>
</thead>
</table>

- **Publication:**
- **Ann J Med**
- **Affiliations:**
- **Singapore General Hospital, Singapore**
- **Funding:**
- **Internal**

**Quality rating:** 6 (fair)

**Effect rating:** Substantial

**Relevance:** Direct

**Study (3 max):** 1

- No description of study time period, hospital, etc. Lack of cross-parameter analyses.

**Practice (2 max):** 1

- Very minimal description of study

**Outcome (2 max):** 2

- Lack of control for other practice parameters and sample size does not support logistic regression

*Numbers in () by category headings reflect the number of points deducted from the maximum points for that column domain.

### Author(s):

- **Blum, D.**
- **Marchal, A**
- **Gauthier C**
- **Raisky, F.**

**Year:** 1994

**Publication:**

- **Clin. Lab.**
- **French**
- **Dole**
- **Cedex**
- **France**

**Funding:**

- **Internal**

**Design:**

- Random Assignment experiment

**Facility/setting:**

- Hospital ED in France — No other description

**Time period:**

- July and August, 1992

**Population/sample:**

- 350 (195 f and 155 m) aged 1–95. Any patient undergoing blood sampling and infusion in the ED.

- Randomized by number sheet in blocks of 11/95 (11.6%) vs. 97/200 (48.5%)

**Comparator:**

- Straight needle vs. IV start:
- Vialon: 55/100 (55%)
- Te: 42/100 (42%)

**Groups comparable in:**

- Site and gender (tests for randomness).
- All data recorded on randomization form.

**Duration:**

- July and August, 1992

**Training:**

- None

**Staff/other resources:**

- None

**Cost:**

- Minimum — used standard collection conditions

**Description:**

- Very detailed with brand names of all parts of systems. Full protocol including order of tubes provided.
- Straight needle: antecubital site in 85.3%, 20 g needle in 74.8% (also 21 & 22 g)
- Catheter: antecubital site in 6%, forearm in 90%

- None observed — usual practice introduced confounding by location, needle size.

**Funding:**

- Internal

**Comparators:**

- 6. Post-exclusion for non-standard sampling (N = 45), missing or insufficient tube (N = 6), pathological interference with measuring hemolysis (N = 4).

**Final N:**

- Needle-95; IV starts: 100+100

**Sampling:**

- 5 mL glass vacuum tubes.
- All samples collected in 5 mL glass vacuum tubes.
- Groups comparable in age and gender (tests for randomness).

**Hemolysis status of patient determined by:**

- Visual and calibrated automatic photometric reader (detection limit of 0.05 g/l of plasma).

**Data collected on randomization form which was sent to lab with sample. Lab blinded to status.**

**Results/conclusion biases:**

- None

**Data analysis:**

- ANOVA by ranks (non-parametric). Note: all comparisons between groups (3-way and pairwise) had significance of p<0.00001

- Results/conclusion biases: None

### Quality rating:

- **9 (good)**

### Effect rating:

- **Substantial**

### Relevance:

- **Direct**

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<td>Category (pts deducted)</td>
<td>Category (points deducted)</td>
</tr>
</tbody>
</table>

### Author(s):

- **Design:** (0)
- **Facility/setting:** (0)
- **Population/sample:** (1)
- **Study bias:** (0)
- **Comparator:** (0)
- **Real world comparator:** (0)

### Affiliations:

- **NY Hospital Medical Center of Queens, Flushing NY**
- **Funding:** Internal

### Quality rating:

- **Time period:** (0)
- **Population:** (0)
- **Sample:** (0)

### Practice (2 max): 2

- **Description:** (0)
- **Use of low vacuum tubes for blood chemistries.**
- **Duration:** (0)
- **Results/conclusion biases:** (0)

### Outcome (2 max): 1

- **No description of how hemolysis was measured or recorded.**

### Results/findings (3 max): 2

- **Real world results based solely on introduction of a new product — low (partial) vacuum tubes.**

### Findings/effect size:

- **Statistical significance:** (0)
- **Effect rate:** (0)

### Findings/effect size:

- **Statistical significance:** (0)
- **Effect rate:** (0)

### Notes:

- **Baseline rate taken from period (B) with 752 observations.**
- **Effect rate take from period (C 1&2) with 660 and 715 observations.**
- **Hemolysis:** (0)

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<tr>
<td>Quality rating: 10 (good)</td>
<td>Study (3 max): 3</td>
<td>Practice (2 max): 2</td>
<td>Outcome (2 max): 2</td>
<td>Results/conclusion biases: (0)</td>
</tr>
<tr>
<td>Direct</td>
<td></td>
<td></td>
<td></td>
<td>No bias observed. Based upon usual practice with isolated change. No major effects observed.</td>
</tr>
</tbody>
</table>

Quality rating: 7 (fair) Effect rating: Substantial Relevance: Direct

- Design: (0)
- Description: (0)
- Hemolysis determined by visual inspection and reported as none, moderate and gross. Critical hemolysed sample was defined as having potassium levels >5.1 mEq/L (outside normal range), which requires re-sampling.
- Study bias: (1)
- Statistical significance/test(s): (0) p<0.0001 (method not specified)
- Results/conclusion biases: (1) Unit of measure is the potassium lab sample (thus one per patient except for redraws). However, no explanation is given for why volume during the test period was double that of the baseline period. No attempt to evaluate percent straight needle v IV start draws during baseline. Short term study could be impacted by observation effect. Study does highlight real life changes.

- Results/conclusion biases: (0)
- Type of findings: (0) Rates of hemolysis
- Findings/effect size: (0)
- N total = 2879.
- Baseline week N = 315
- 4-Week trial N = 2564 (64/week)
- Straight needle vs. IV start Baseline rate:
- Hemolysed = 23% (CI: 16.7—29.1)
- Critical = 6.7%
- Trial rate (100% straight needle):
- Hemolysed = 6.6% (CI: 5.5—7.5)
- Critical = 2.0%
- Results/findings (3 max): 2
- Discordant patient volume between baseline and trial. Training adds confounding

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References


