Clinical Biochemistry 45 (2012) 1012–1032

Contents lists available at SciVerse ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

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

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ARTICLE INFO

Article history:
Received 5 June 2012
Received in revised form 1 August 2012
Accepted 2 August 2012
Available online 9 August 2012

Keywords:
Hemolysis
ED
Phlebotomy/methods
Catheters/indwelling
Clinical laboratory quality improvement
Hospital laboratory organization and administration
Medical laboratory personnel organization and administration

ABSTRACT

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Results: A total of 16 studies met the review inclusion criteria (12 published and 4 unpublished).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 Unpublished studies made an important contribution to the body of evidence.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.

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]. Immunoassays 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.

Abbreviations: CDC, U.S. Centers for Disease Control and Prevention; CI, Confidence Interval; ED, Emergency Department; ICU, Intensive Care Unit; IOM, Institute of Medicine; IV, Intravenous; LMBP, Laboratory Medicine Best Practices Initiative; PICO, Population, Intervention/Practice, Comparator, Outcome; QI, Quality improvement; RR, Risk Ratio.

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0009-9120/$ – see front matter
http://dx.doi.org/10.1016/j.clinbiochem.2012.08.002

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

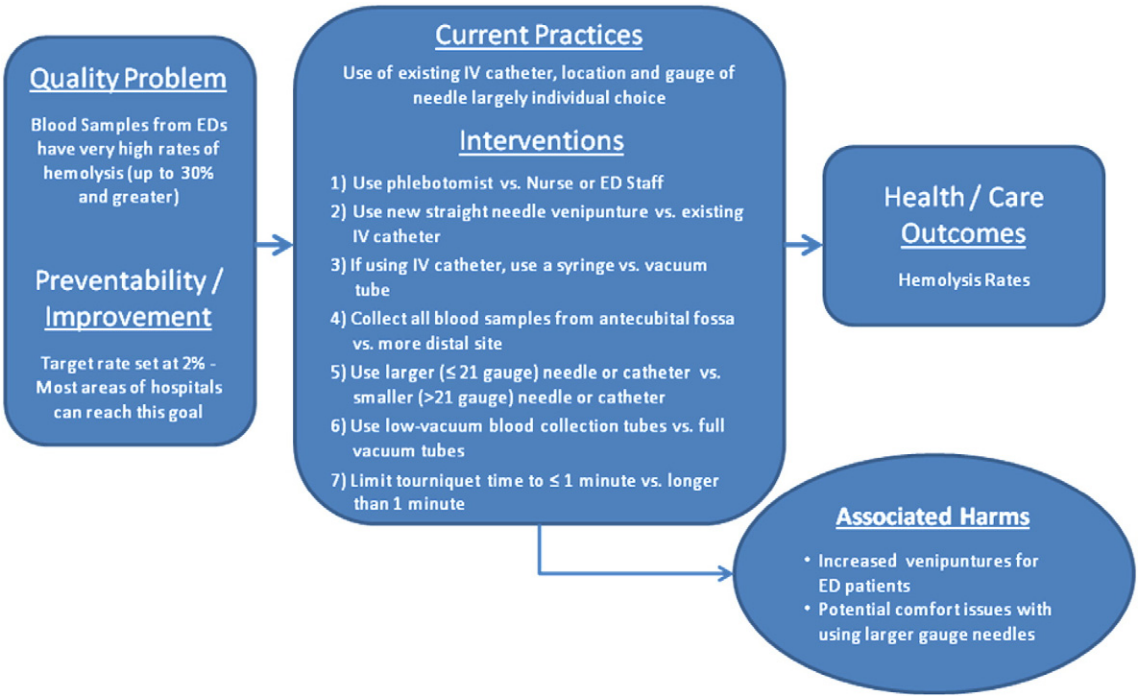

Fig. 1. Analytic framework — when drawing blood samples for laboratory testing from patients in the ED, what practices are effective in reducing hemolysis rates among these samples?

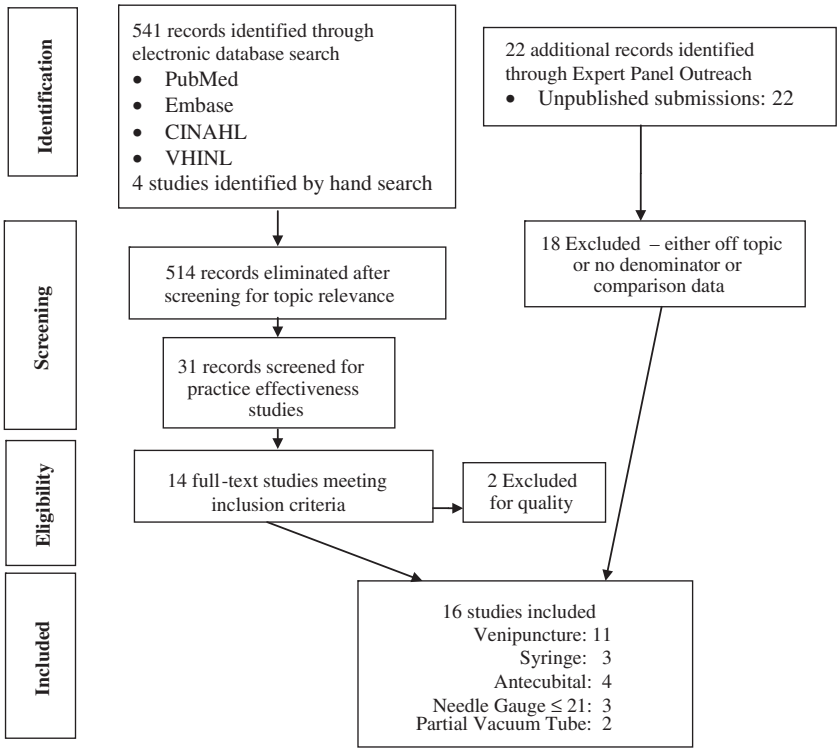

Fig. 2. Systematic review flow diagram. Flow diagram showing appraisal of published studies found in electronic databases and unpublished studies identified through outreach, resulting in the final 16 studies fully reviewed in this analysis.

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[1] including at least one LMBP Workgroup[2] 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 from patients in the ED, what practices are effective in reducing hemolysis rates among these samples?" (Fig. 1). The relevant PICO elements are:

- ***P***opulation: Patients receiving treatment in hospital-based EDs.
- ***I***nterventions: Blood collection practices in the ED hypothesized to be associated with hemolysis rates.
- ***C***omparison: Comparison practices are generally ongoing ED practices, which include various combinations of all the practices being studied.
- ***O***utcome: 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
Straight needle venipuncture vs. IV starts.

Study	Study quality rating	Effect size rating
Agos et al. (2008)	Fair	Substantial
Grant (2003)	Fair	Substantial
Kennedy et al. (1996)	Fair	Substantial
Ong et al. (2008)	Fair	Substantial
Staszewski et al. (2011)	Fair	Substantial
Dameron Hosp (unpub)	Good	Substantial
Giavarina et al. (2010)	Good	Substantial
Lowe et al. (2008)	Good	Substantial
Mary Washington Hosp (unpub)	Good	Substantial
Raisky et al. (1994)	Good	Substantial
U of Minnesota Hosp (unpub)	Good	Substantial

[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."

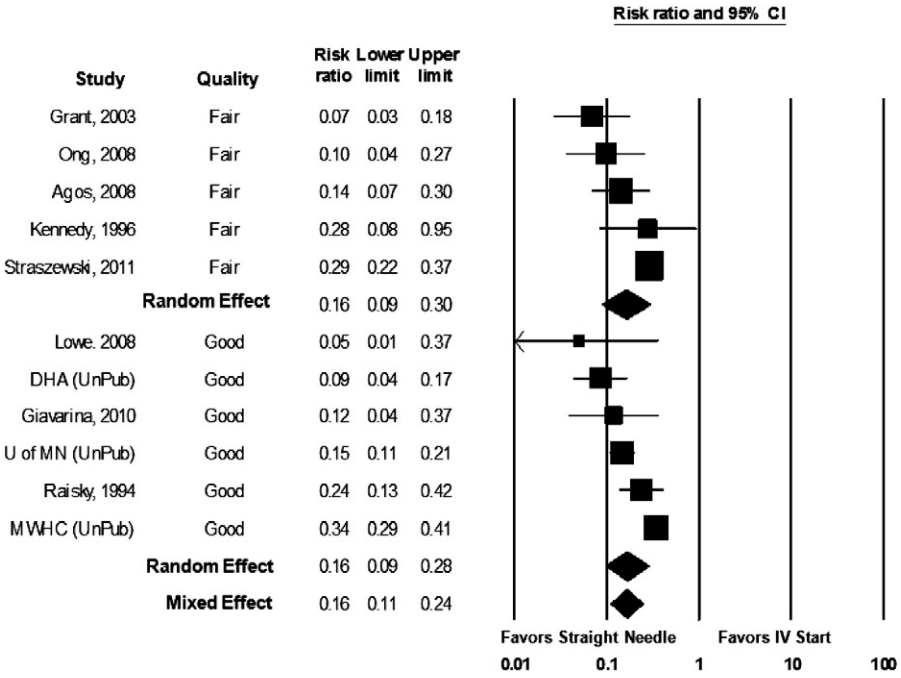

Fig. 3. Meta-analysis results for straight needle venipuncture vs. IV starts. Mixed effects analysis using forest plot representations. In each forest plot the center line labeled '1' equals no difference between practices, and each vertical line represents a 10-fold increase or decrease in hemolysis rates. Estimates to the left of the line favor the tested practice while estimates to the right favor the comparator (or usual practice).

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,[3] 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.[4] 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.[5]

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.

[3] Mixed effects analysis — a random effects model is used to combine studies within each subgroup. A fixed effect model is used to combine subgroups and yield the overall effect. The study-to-study variance (tau-squared) is NOT assumed to be the same for all subgroups — this value is computed within subgroups and NOT pooled across subgroups.

[4] See Appendix D for the list of included and excluded studies.

[5] See Appendix E for the Evidence Summary Tables containing quality ratings for each study.

Table 2
Antecubital site vs. more distal site (IV starts only).

Study	Study quality rating	Effect size rating
Dugan et al. (2005)	Fair	Substantial
Dameron Hosp (unpub)	Good	Substantial
Lowe et al. (2010)	Good	Substantial
Munnix et al. (2010)	Good	Substantial

Table 3
Syringe vs. vacuum tube (IV starts only).

Study	Study quality rating	Effect size rating
Grant (2003)	Fair	Substantial
Dugan et al. (2005)	Fair	Min/none
Case Western Reserve (unpub)	Good	Min/none

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 ($Q_{Overall} = 48.32$, $p = 0.00$, $I^2 = 79.3$), 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 through 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 ($Q_{Overall} = 2.20$, $p = 0.533$, $I^2 = 0.00$) (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 ($Q_{Overall} = 19.29$, $p = 0.00$, $I^2 = 89.63$), 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 a 63% reduction in hemolysis, the individual study effect size results for needle size are "inconsistent" and heterogeneous ($Q_{Overall} = 14.82$, $p = 0.001$, $I^2 = 86.50$) (Fig. 6). Applying the LMBP criteria, the

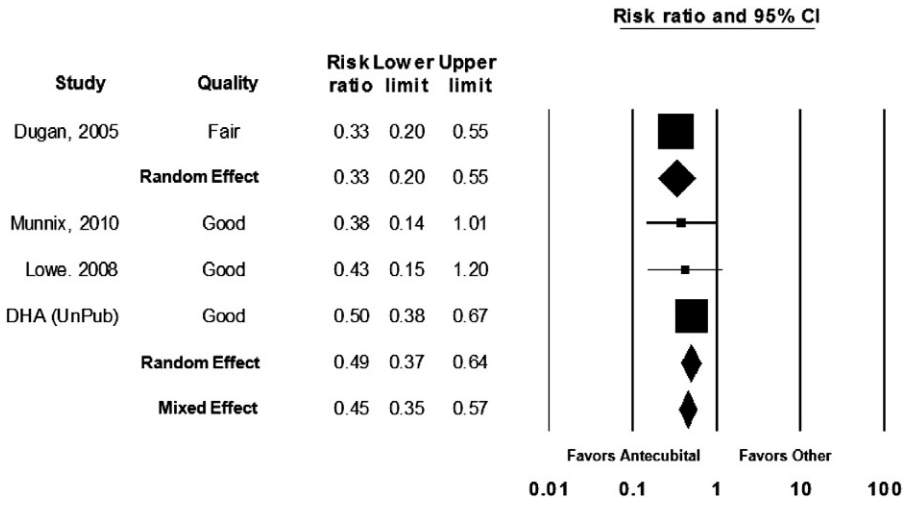

Fig. 4. Results for antecubital site vs. more distal site (IV starts only). Mixed effects analysis using forest plot representations.

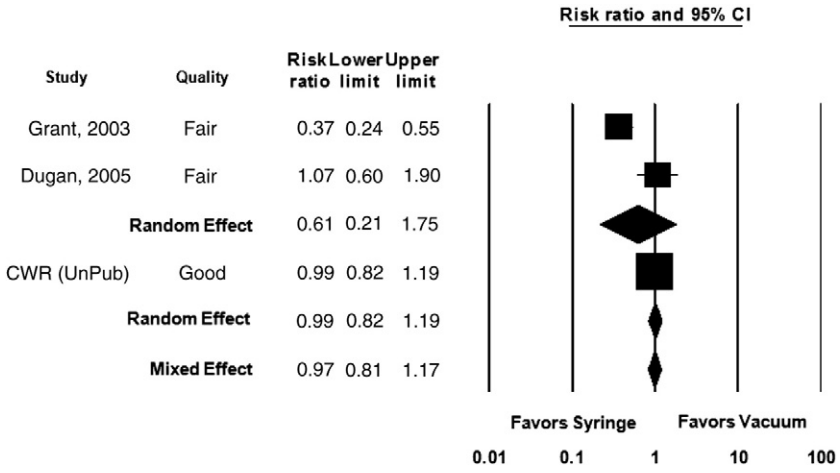

Fig. 5. Results for use of syringe vs. vacuum tube (IV starts only). Mixed effects analysis using forest plot representations.

overall strength of evidence for using larger needles to reduce hemolysis rates in ED IV starts is "insufficient."

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.

Table 4
Needle gauge ≤21 (larger) vs. needle gauge >21 (smaller) (IV starts only).

Study	Study quality rating	Effect size rating
Dugan et al. (2005)	Fair	Substantial
Kennedy et al. (1996)	Fair	Substantial
Dameron Hosp (unpub)	Good	Min/none

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

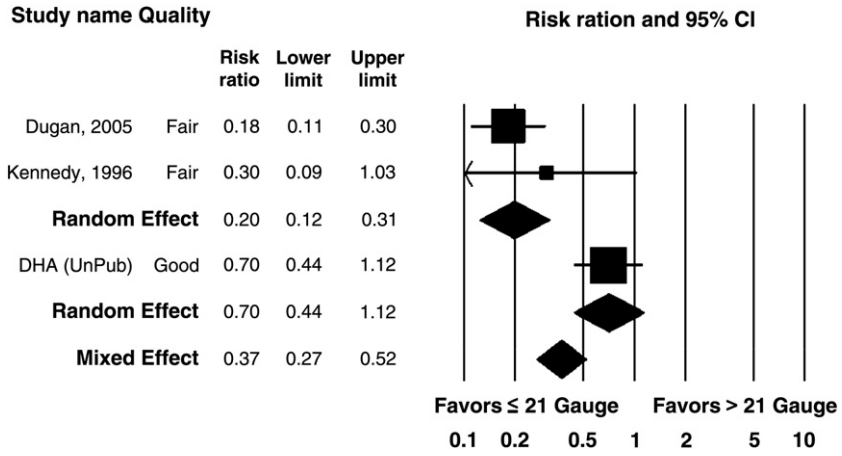

Fig. 6. Results for ≤21 gauge (larger) needles vs. >21 gauge smaller needles (IV starts only). Mixed effects analysis using forest plot representations.

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.

Table 5
Low (partial) vacuum tube vs. regular (full) vacuum tube (IV starts only).

Study	Study quality rating	Effect size rating
Sixsmith et al. (2000)	Fair	Substantial
Cox et al. (2004)	Good	Substantial

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.

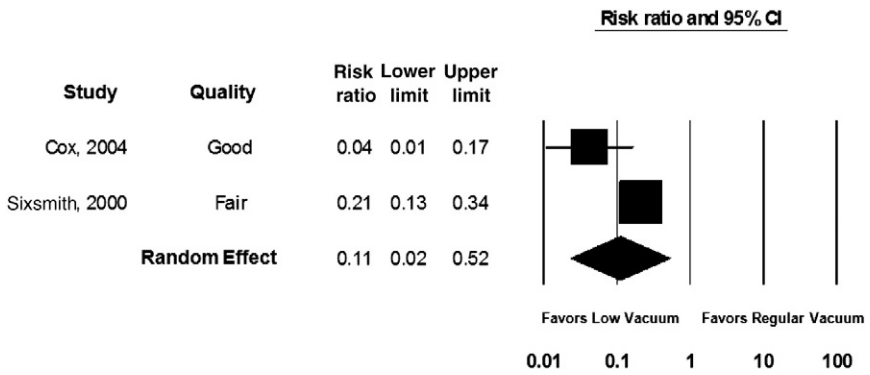

Fig. 7. Results for low vs. regular vacuum tube (IV starts only). Mixed effects analysis using forest plot representations.

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
- Suzanne H. Butch, Blood Bank Admin. Manager, U. Michigan Dept. Path
- 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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Sousan S. Altaie, PhD (*ex officio*)
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Evaluation and Safety Center for Devices and Radiological Health (CDRH), FDA
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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]

Syringes:

((("hemolysis"[MeSH Terms] AND "blood specimen collection"[MeSH Terms] AND "syringes"[mesh]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]) AND "humans"[MeSH Terms]

Phlebotomy:

(("hemolysis"[MeSH Terms] AND "blood specimen collection"[MeSH Terms] AND "phlebotomy"[mesh]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]

Antecubital fossa:

(("hemolysis"[MeSH Terms] OR "blood specimen collection"[MeSH Terms] AND "antecubital fossa" [all text]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]

Needles:

(("hemolysis"[MeSH Terms] AND "blood specimen collection"[MeSH Terms] AND "needles"[mesh]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]

Low vacuum serum collection tubes:

(("hemolysis"[MeSH Terms] OR "blood specimen collection" [MeSH Terms] AND "Point-of-Care Systems"[mesh] AND "INSTRUMENTATION"[SUBHEADING]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT] NOT GLUCOSE[TITLE/ABSTRACT] NOT ("diabetes mellitus"[MeSH Terms] OR ("diabetes"[All Fields] AND "mellitus"[All Fields]) OR "diabetes mellitus"[All Fields] OR "diabetes"[All Fields] OR "diabetes insipidus"[MeSH Terms] OR ("diabetes"[All Fields] AND "insipidus"[All Fields]) OR "diabetes insipidus"[All Fields])

Tourniquets:

(("hemolysis"[MeSH Terms] OR "blood specimen collection"[MeSH Terms] AND "tourniquets"[mesh]) AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]

Duration:

("hemolysis"[MeSH Terms] AND "blood specimen collection"[MeSH Terms] AND "DURATION"[all] AND "1990"[PDAT] : "3000"[PDAT]) AND "0"[PDAT] : "3000"[PDAT]

CINAHL — Cumulative Index to Nursing and Allied Health Literature

search 1

(MM "hemolysis" OR TX "erythrocytolysis" OR TX "erythrolysis") AND (MH "catheters" OR TI "catheters" OR AB "catheters" OR MH "Tourniquet" OR TI "Tourniquet" OR AB "Tourniquet" OR TI "needle" OR AB "needle" OR TI "syringe" OR AB "syringe") AND (MH "emergency medicine" OR TI "ER" OR AB "ER" OR TI "ED" OR AB "ED" OR TI "emergency room" OR AB "Emergency room" OR TI "ED" OR AB "ED" OR MH "Intesive Care Units, Neonatal" OR TI "NICU" OR AB "NICU")

search 2

(MM "hemolysis" OR TX "erythrocytolysis" OR TX "erythrolysis" OR TI "sample hemolysis" OR AB "sample hemolysis") AND (MH "phlebotomy" OR MH "blood specimen collection" OR MH"catheterization") AND (MH "emergency medicine" OR TI "ER" OR AB "ER" OR TI "ED" OR AB "ED" OR TI "emergency room" OR AB "Emergency room" OR TI "ED" OR AB "ED" OR MH "Intesive Care Units, Neonatal" OR TI "NICU" OR AB "NICU")

Embase — International Biomedical Literature

search 1

erythrocytolysis':ab,ti OR 'erythrolysis':ab,ti OR 'hemolysis':de AND ('blood sampling':de,ab,ti OR 'point of care testing':de,ab,ti) AND ('emergency ward':de OR 'newborn intensive care':de) AND [humans]/lim AND [english]/lim AND [1990–2012]/py

search 2

'erythrocytolysis':ab,ti OR 'erythrolysis':ab,ti OR 'hemolysis':de OR 'sample hemolysis':ab AND 'blood sampling':de,ab,ti AND ('catheter':de,ab,ti OR 'tourniquet':de,ab,ti OR 'needle':de,ab,ti OR 'venipuncture':de,ab,ti OR 'syringe':de,ab,ti) AND ('emergency ward':de OR 'newborn intensive care':de) AND [1990–2012]/py

search 3

'erythrocytolysis':ab,ti OR 'erythrolysis':ab,ti OR 'hemolysis':de OR 'sample hemolysis':ab OR 'blood sampling':de,ab,ti AND ('catheter':de,ab,ti OR 'tourniquet':de,ab,ti OR 'needle':de,ab,ti OR 'venipuncture':de,ab,ti OR 'syringe':de,ab,ti) AND ('emergency ward':de OR 'newborn intensive care':de) NOT 'blood stream infections':de,ab,ti AND [1990–2012]/py

search 4: 12 results

'hemolysis'/mj AND ('catheter':de,ab,ti OR 'tourniquet':de,ab,ti OR 'needle':de,ab,ti OR 'venipuncture':de,ab,ti OR 'syringe':de,ab,ti) AND ('emergency ward':de OR 'er':ab,ti OR 'ed':ab,ti OR 'newborn intensive care':de OR 'nicu':ab,ti) AND [humans]/lim AND [english]/lim AND [1990–2012]/py

Appendix D. LMBP reducing hemolysis in the ED systematic review eligible studies

Included studies — *published*

Agos, M. D., R. Lizarraga, et al. (2008). "[Factors related to haemolysis in the extraction of blood samples]." An Sist Sanit Navar **31**(2): 153–158.

Cox, S. R., J. H. Dages, et al. (2004). "Blood samples drawn from IV catheters have less hemolysis when 5-mL (vs 10-mL) collection tubes are used." J Emerg Nurs **30**(6): 529–533.

Dugan, L., L. Leech, et al. (2005). "Factors affecting hemolysis rates in blood samples drawn from newly placed IV sites in the ED." J Emerg Nurs **31**(4): 338–345.

Giavarina, D., L. Pasqualeb, et al. (2010). "Hemolysis by peripheral intravenous catheters: Materials comparison." Rivista Italiana della Medicina di Laboratorio **6**(3): 216–221.

Grant, M. S. (2003). "The effect of blood drawing techniques and equipment on the hemolysis of ED laboratory blood samples." J Emerg Nurs **29**(2): 116–121.

Kennedy, C., S. Angermuller, et al. (1996). "A comparison of hemolysis rates using intravenous catheters versus venipuncture tubes for obtaining blood samples." J Emerg Nurs **22**(6): 566–569.

Lowe, G., R. Stike, et al. (2008). "Nursing blood specimen collection techniques and hemolysis rates in an ED: analysis of venipuncture versus intravenous catheter collection techniques." J Emerg Nurs **34**(1): 26–32.

Munnix, I. C., M. Schellart, et al. (2010). "Factors reducing hemolysis rates in blood samples from the ED." Clin Chem Lab Med **49**(1): 157–158.

Ong, M. E., Y. H. Chan, et al. (2008). "Observational study to determine factors associated with blood sample haemolysis in the ED." Ann Acad Med Singapore **37**(9): 745–748.

Raisky, F., C. Gauthier, et al. (1994). "Haemolyzed samples: responsibility of short catheters." Ann Biol Clin (Paris) **52**(7–8): 523–527.

Sixsmith, D. M., F. Weinbaum, et al. (2000). "Reduction of hemolysis of blood specimens drawn from ED patients for routine chemistry tests by use of low vacuum collection tubes. In: 2000 SAEM ANNUAL MEETING ABSTRACTS." Academic Emergency Medicine **7**(5): 524–525.

Straszewski, S., L. Sanchez, et al. (2011). "Use of separate venipunctures for IV access and laboratory studies decreases hemolysis rates." Internal and Emergency Medicine **6**(4): 357–359.

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*

Burns, E. R. and N. Yoshikawa (2002). "Hemolysis in serum samples drawn by ED personnel versus laboratory phlebotomists." Laboratory Medicine **33**(5): 378–380.

Danks, R. R. (2003). "Commending "The effect of blood drawing techniques and equipment on the hemolysis of ED laboratory blood samples."." J Emerg Nurs **29**(5): 401.

Dietrich, H. (2008). "Blood draws, venipuncture versus intravenous catheter, an alternate conclusion." J Emerg Nurs **34**(3): 196; author reply 196–197.

Dwyer, D. G., M. Fry, et al. (2006). "Randomized, single blinded control trial comparing haemolysis rate between two cannula aspiration techniques." Emerg Med Australas **18**(5–6): 484–488.

Ellis, G. (2009). "An episode of increased hemolysis due to a defective pneumatic air tube delivery system." Clin Biochem **42**(12): 1265–1269.

Fang, L., S. H. Fang, et al. (2008). "Collecting factors related to the haemolysis of blood specimens." J Clin Nurs **17**(17): 2343–2351.

Fernandes, C. M., R. Walker, et al. (1997). "Root cause analysis of laboratory delays to an ED." J Emerg Med **15**(5): 735–739.

Fernandes, C. M., A. Worster, et al. (2006). "Pneumatic tube delivery system for blood samples reduces turnaround times without affecting sample quality." J Emerg Nurs **32**(2): 139–143.

Gayler, M. (1999). "Haemolysis of blood samples: what it is and how to avoid it." Nurs Times **95**(21): 54–55.

Halm, M. A. and M. Gleaves (2009). "Obtaining blood samples from peripheral intravenous catheters: best practice?" Am J Crit Care **18**(5): 474–478.

Hardin, G., G. Quick, et al. (1990). "Emergency transport of AS-1 red cell units by pneumatic tube system." J Trauma **30**(3): 346–348.

Nathan-Ulloa, P. J. (2003). "Thoughts on "The effect of blood drawing techniques and equipment on the hemolysis of ED laboratory blood samples"." J Emerg Nurs **29**(5): 401–402; author reply 402–403; discussion 403–404.

Ong, M. E., Y. H. Chan, et al. (2009). "Reducing blood sample hemolysis at a tertiary hospital ED." Am J Med **122**(11): 1054 e1051–1056.

Pretlow, L., T. Gandy, et al. (2008). "A quality improvement cycle: hemolyzed specimens in the ED." Clin Lab Sci **21**(4): 219–224.

Soderberg, J., P. A. Jonsson, et al. (2009). "Haemolysis index—an estimate of preanalytical quality in primary health care." Clin Chem Lab Med **47**(8): 940–944.

Sodi, R., S. M. Darn, et al. (2004). "Pneumatic tube system induced haemolysis: assessing sample type susceptibility to haemolysis." Ann Clin Biochem **41**(Pt 3): 237–240.

Stair, T. O., J. M. Howell, et al. (1995). "Hemolysis of blood specimens transported from ED to laboratory by pneumatic tube." Am J Emerg Med **13**(4): 484.

Tanabe, P. (2004). "The effect of blood-drawing techniques and equipment on the hemolysis of ED laboratory blood samples." J Emerg Nurs **30**(2): 106–108.

Tanabe, P., D. N. Kyriacou, et al. (2003). "Factors affecting the risk of blood bank specimen hemolysis." Acad Emerg Med **10**(8): 897–900.

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

Note: Scoring information see: Christenson et al. (2011)
(In the tables — numbers in parentheses show points deducted)

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Agos, MD; Lizarraga, R; Gambra, D; Maranon, A; Orozco, C; Diaz, E. **– Year**: 2008 **– Publication**: Anales del sistema sanitario de Navarra **– Affiliations**: Hospital Virgen del Camino Pamplona, Spain – **Funding**: Internal	– **Design**: (0) Cross-sectional Observational – **Facility/setting**: (0) Accident & Emergency Dept. in a tertiary hospital serving >200,000 – **Time period**: (0) 34 days (Sept–Nov 2006) — three uneven time periods assigned to 3 types of IV catheters – **Population/sample**: (0) 1933 Adult (≥15) ED patients A) 3 catheter groups: 1) 'Protectiv' (Teflon) N=475 (10 days) 2) 'Protectiv plus' (polyurethane) N=426 (9 days) 3) 'BD-Nexiva' (Vialone) N=684 (15 days) B) Straight needle venipunctures — N=384 (entire 34 day period) — **Comparator**: (0) 1) Straight needle vs. IV start **— Study bias**: (1) No systematic bias noted, but did not provide data to control potential confounding by training, site of venipuncture, use of syringe or vacuum tubes	**-Description**: (0) 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 — not described – **Cost**: (0) Not provided	**– Description**: (0) Hemolysis as determined by laboratory staff — no other description – **Recording method**: (1) Not described	**– Type of findings**: (0) Rates of hemolysis – **Findings/effect size**: (0) 1) *Straight needle vs. IV start* 7/348 (2%) vs. 222/1585 (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 (16.9%) – **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
Quality rating: **7 (fair)** **Effect rating**: **Substantial** **Relevance**: **Direct**	**Study (3 max)**: **2** As noted, lack of control for potential confounders	**Practice (2 max)**: **2**	**Outcome (2 max)**: **1** As noted, lack of information process	**Results/findings (3 max)**: **2** As noted, suffered from lack of sufficient information

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Anonymous **– Year**: 2011 **– Publication**: Unpublished **– Affiliations**: Dameron Hospital Assoc Stockton, CA. **– Funding**: Internal	**– Design**: (0) Full review for 24-h period plus Semi-random case–control record review for nurse draws (case= hemolyzed, pulled next non-hemolyzed nurse draw to compare methods) **– Facility/setting**: (0) **– Time period**: (0) **– Population/sample**: (1) 1) all ED patients over two 24-h 2) all hemolyzed nurse draws and semi-randomly selected non-hemolyzed nurse draws / also phlebotomist draws **– Comparator**: (0) **1) Antecubital vs. other** **2) ≤21 vs. >21 gauge** **Also** **3) Straight needle vs. IV start** **– Study bias**: (0) None observed.	**-Description**: (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 One-month review of hemolysis cases with semi-random case–control evaluation of practice parameters for 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	**– Description**: (0) Hemolysis as determined by hospital lab. Use both visual and automated colorimetric analysis using a Beckman DXC. **– Recording method**: (0) Abstraction from records	**– Type of findings**: (0) **1) Case–control Odds Ratios** (based upon %'s 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. >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

(*continued*)

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
				– Results/conclusion biases: (1) No evident bias. Elevated OR for non-antecubital sites PLUS suggestion of elevated OR for smaller needle size (larger gauge)
Quality rating: **8 (good)** **Effect rating**: **Substantial, minimal/ none, substantial** **Relevance**: **Direct**	**Study (3 max)**: **2** Need to estimate denominators for nurse draws to calculate RRs	**Practice (2 max)**: **2**	**Outcome (2 max)**: **2**	**Results/findings (3 max)**: **2** Have to estimate denominator for nurses — part of the case–control design

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Sandra R. Cox; Jeanne H. Dages; Dave Jarjoura; and Susan Hazelett **– Year**: 2004 **– Publication**: J Emergency Nursing **– Affiliations**: Summa Health Systems, Akron, OH Northeastern Ohio University, Rootstown, OH – **Funding**: Internal	– **Design**: (0) 4 group/cross-over (patient acts as own control with order of tubes varied) Experiment — each patient randomly assigned to one of 4 groups to have 2 tubes of blood drawn. Two groups used one each full or partial vacuum tubes with opposite orders of draw, while two groups had both tubes either full or partial vacuum. Note: usual practice is to draw 2 tubes – **Facility/setting**: (0) Emergency Dept. in a 579 bed teaching hospital. Approx 72,300 ED patients/year; 300 blood samples collected and 75 IVs started each day; 60% ED patients have both IV and blood samples. – **Time period**: (0) 2 months **– Population/sample**: (0) 300 ED patients with IV starts excluding those with trauma. Divided into four groups of 75 – **Comparator**: (0) 1) Partial vs. full vacuum tubes. **– Study bias**: (1) Used 12 trained nurses and only larger bore catheters (<22 gauge). 32 (11%) excluded from analysis due to insufficient blood (15) or missing tubes (17). These are large error numbers and were not discussed — could bias results	**– Description**: (0) Practices evaluated: 1)-IV draws using high vs. low vacuum tubes (10 mL tube with 75 mm Hg vacuum vs. 5 mL tube with 53 mm Hg vacuum. Needle size restricted to 18 or 20 gauge – **Duration**: (0) 12 ED nurses representing all shifts over 2 months — 300 patients – **Training**: (0) 12 trained nurses — level of training unknown – **Staff/other resources**: (0) Minimal – **Cost**: (0) Unknown	**– Description**: (0) Hemolysis determined by automated spectrographic reader + visual inspection — both recorded. **– Recording method**: (0) Standardized data collection form completed by nurses or lab staff on daily basis.	**– Type of findings**: (0) Rates of hemolysis – **Findings/effect size**: (0) 1) *Partial vs. full vacuum tubes*. Based on visual inspection (0 = none, 1 = slight, 2 = slight/mod; 3 = moderate; 4 = mod/ gross and 5 = gross). Defining hemolysis as both tubes ≥4 (only same tube samples): 24/75 (32%) vs. 1/75 (1.3%) – **Statistical significance/test(s)**: (0) Using mean visual hemolysis rating (1.8 vs. 0.5), regular vacuum had 1.3 + − 0.13 higher rating ($p<.0001$) Using spectrographic analysis (larger number = more hemolysis): 10 mL vs. 5 mL tubes: 77 (+ − 11) points higher ($p<.0001$). Effect size = 0.6 SD No other parameters were significant: Order: − 0.9 + − 12 points ($p=0.94$); Differential carryover (5 to 10 mL) was − 3.5 + − 16 points ($p=0.83$). Interaction tube type by order not sig ($p=0.41$). **– Results/conclusion biases**: (0) Well controlled experiment focused only on tube vacuum level for IV draws — shows lower hemolysis with lower vacuum. Problem with spoiled or missing samples (11% of total) — too high to go unexplained. Fortunately, the low % hemolysis among partial vacuum tube pairs (1.3% of 75) can only be explained if no more than one of these tube pairs was correct if no more than one tube pair were excluded (i.e.1/73 is 1.4%).
Quality rating: **9 (good)** **Effect rating**: **Substantial** **Relevance**: **Direct**	**Study (3 max)**: **2** As noted, lack of control for potential confounders	**Practice (2 max)**: **2**	**Outcome (2 max)**: **2**	**Results/findings (3 max)**: **3**

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Lisa Dugan, BC, Lida Leech; Karen Gabel Speroni; Joy Corriher **– Year**: 2005 **– Publication**: Journal of Emergency Nursing **– Affiliations**: Loudoun Hospital Center, Leesburg, VA – **Funding**: Internal	– **Design**: (0) Cross-Sectional Observational – **Facility/setting**: (0) ED — 21-bed unit with 33,000 patients/year — 40% having blood drawn, average between 3 – 4 tubes — thus, approximately 52,800 tubes/year – **Time period**: (0) 36 day period from 6/3 to 7/9, 2004 **– Population/sample**: (1) 100 randomly selected ED patients 18 years or older with orders for IV blood draw (excluding blood cultures). N = 382 drawn by RN, LPN or technician (others excluded). – **Comparator**: (0) 1) Syringe vs. vacuum tube 2) Antecubital vs. other 3) ≤21 vs >21 gauge catheter **– Study bias**: (2) Counted multiple tubes from one patient (~4) as independent samples; potential bias by order. Also, study observed regular (unregulated) practices and recorded rates of hemolysis for various main effects, but did not provide data allowing control for potential confounding factors	**–** **Description**: (0) Practices Evaluated: For IV starts: 1) Syringe vs. vacuum tube 2) Placement (AC, forearm, hand) 3) Needle size All practices recorded on a report form. – **Duration**: (0) 36 days — 100 patients — 382 blood draws. – **Training**: (0) Minimal – **Staff/other resources**: (0) Minimal – **Cost**: (0) Not provided	**– Description**: (0) Hemolysis determined by subjective comparison to color charts **– Recording method**: (0) Laboratory technician completed a report form providing information on level of hemolysis and whether the sample was rejected.	**– Type of findings**: (0) Rates of hemolysis – **Findings/effect size**: (0) 1) *Syringe vs. vacuum tube* 14/104 (13.5%) vs. 35/278 (12.6%) 2) *Antecubital vs. distal site* 26/296 (8.8%) vs. 23/86 (26.7) Forearm: 11/52 (21.2%) Hand: 12/34 (35.3%) 3) *≤21 vs. >21 gauge catheter* 40/367 (10.9%) vs. 9/15 (60.0%) 18 gauge: 15/183 (8.2%) 20 gauge: 25/184 (13.6%) 22 gauge: 9/15 (60.0%) *Other findings — tube size* 1.8 mL tube: 0/3 (0.0%) 3 mL tube: 15/162 (13.6%) 3.5 mL tube: 7/70 (10.0%) 4.5 mL tube: 11/57 (19.3%) 5 mL tube: 11/71 (15.5%) 6 mL tube: 5/19 (26.3%) – **Statistical significance/test(s)**: (0) Logistic regression too ambitious for sample size — not useful. **– Results/conclusion biases**: (1) No information to control for confounding factors. Potentially useful results for main effects are compromised by potential for bias.
Quality rating: **7 (fair)** **Effect rating**: **Minimal/ none, substantial, substantial** **Relevance**: **Direct**	**Study (3 max)**: **1** As noted, used multiple tubes per patient as independent samples. Also, lack of control for confounding	**Practice (2 max)**: **2**	**Outcome (2 max)**: **2** As noted, lack of information process	**Results/findings (3 max)**: **2** Small sample size, potential confounders and non-independence of outcomes when multiple tubes collected.

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Giavarina, D; Pasquale, L; Mezzena, G; Soffiati, G. **– Year**: 2010 **– Publication**: Rivista Italiana Della Medicina Di Laboratorio (Italian) –	– **Design**: (0) Cross-Sectional Random assignment – **Facility/setting**: (0) ED is a 21-bed unit with 33,000 patients/year — 40% having blood drawn, average between 3 and 4 tubes — thus, approximately 52,800 tubes/year – **Time period**: (0) 78 consecutive days. **– Population/sample**: (0) 363 consecutive ED patients requiring blood chemistry draws randomly assigned to four different IV catheter brands. All used 18 gauge catheters. 100 consecutive straight needle venipuncture draws from the intensive care department. All used 21 gauge needle. – **Comparator**: (0) 1) *Straight needle vs. IV start* **– Study bias**: (1)	**–** **Description**: (0) Practices evaluated: 1) Straight Needle vs. IV Start – **Duration**: (0) 78 consecutive days. – **Training**: (0) Minimal – **Staff/ other resources**: (0)	**– Description**: (0) Hemolysis — quantitatively measured by automatic lab instrument. **– Recording method**: (0) Not described	**– Type of findings**: (0) Rates of hemolysis – **Findings/effect size**: (1) 1) *Straight needle vs. IV start* Compares ICU straight needle venipuncture to ED IV start: Light hemolysis: 3/100 = 3% vs. 64/321 = 19.9% Severe hemolysis: 0/100 = 0% vs. 17/321 = 5.3% *Other findings*: Rates for IV types: not a practice of interest — see chart abstracted and attached. – **Statistical significance/test(s)**: (0) None presented for comparison of interest. **– Results/conclusion biases**: (1) Clear difference in rates for straight needle venipuncture vs any of the IV start types used. However, comparison is with ICU. Other potential

(*continued*)

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
Affiliations: San Bortolo Hospital, Vicenza – **Funding**: Internal	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).	Minimal – **Cost**: (0) Not provided		confounders not addressed are: 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).
Quality rating: 7 (fair) **Effect rating**: Substantial **Relevance**: Direct	**Study (3 max)**: **2** As noted, potential confounding by comparing different populations	**Practice (2 max)**: **2**	**Outcome (2 max)**: **2** As noted, lack of information process	**Results/findings (3 max)**: **1** Comparison between ED and ICU. Also, missing information on potential confounders

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Marian Sue Grant **– Year**: 2003 **– Publication**: Journal of Emergency Nursing **– Affiliations**: Johns Hopkins Hospital, Baltimore, MD – **Funding**: Internal	– **Design**: (0) Cross-sectional Observational – **Facility/setting**: (0) Adult ED of a major teaching hospital – **Time period**: (0) 19 days from May 21 to June 8, 2001 **– Population/sample**: (0) Convenience sample of 454 blood draws with sufficient information — draws conducted by ED nurse or ED technician — no information on experience level. – **Comparator**: (0) **1) Straight needle vs. IV start**: **2) For IV starts**: **Syringe vs. vacuum tube**: Regular (unregulated) practices and hemolysis rates for both main effects and some within practice parameters. However, did not control for location or tourniquet use or training. **– Study bias**: (1) Did not discuss number of tubes per draw — reported only one result per draw. Lack of control for other practice parameters Potential bias: hemolysis determined by visual inspection (subjective) without blinding of lab technicians to draw technique.	**– Description**: (0) Practices evaluated: – Straight needle vs. IV start – Vacuum tube vs syringe Other practices: – Needle size (none>20 gauge) – Transfer techniques – Personnel (nurse vs technician) All practices recorded on a form. – **Duration**: (0) 19 days from May 21 to June 8, 2001 — 598 blood draw forms collected — 454 complete enough for analysis. Participation voluntary and participation estimated to be only 31%. Only one result per draw recorded — no mention of how multiple tube draws were analyzed. – **Training**: (0) None – **Staff/other resources**: (0) Minimal – **Cost**: (0) Not reported	**– Description**: (0) Hemolysis determined subjectively by lab technicians who were not blinded as to collection method **– Recording method**: (1) Laboratory technician completed a report previously completed by the person conducting the draw– therefore not blinded	**– Type of findings**: (0) Rates of hemolysis – **Findings/effect size**: (0) Main effects and sub-practices (see attached table). Meaningful results are shown here: 1) *Straight needle vs. IV start* Any hemolysis 4/117 = 3% vs. 126/255 = 49% Requiring re-draw 1/117 = <1% vs. 50/255 = 20% (p<0.001) 2) *For IV starts: syringe vs. vacuum tube*: Any hemolysis" 17/60 = 28% vs. 151/195 = 77% Requiring re-draw 5/60 = 9% vs. 44/195 = 23% (p = 0.02) *Other findings*: – **Statistical significance/test(s)**: (0) Chi-square significance tests using SAS. **– Results/conclusion biases**: (1) Sufficient population. It is likely that more than one sample was drawn per patient. Thus, either result was reported on multiple samples per patient or on only one sample per patient, without discussion about how this was handled in protocol or analysis. Good discussion of confounders. Potential confounding associated with subjective hemolysis measures without blinding for lab techs.
Quality rating: 7 (fair) **Effect rating**: Substantial **Relevance**: Direct	**Study (3 max)**: **2** As noted, no control for potential confounders. No information on # of tubes drawn..	**Practice (2 max)**: **2**	**Outcome (2 max)**: **1** Subjective determination — no blinding of lab technicians.	**Results/findings (3 max)**: **2** Not clear how hemolysis was calculated across multiple tubes.

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Kathryn E. Hamilton; Cheryl Orr **– Year**:	**– Design**: (0) Cross-Sectional Observational **– Facility/setting**: (0) 60-bed ED — very busy — draws	**– Description**: (0) Phlebotomist draw (usually straight needle venipuncture at antecubital site) — located in ED, also has draw room for patients waiting to be triaged.	**– Description**: (0) Automated colorimetric measures report hemolyzed	**– Type of findings**: (0) Rates of Hemolysis **– Findings/effect size**: (0) **IV start vs. straight needle** Rate IV start (nurse);

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
2011 **– Publication**: Unpublished **– Affiliations**: Mary Washington Hospital, Fredericksburg, VA **– Funding**: Internal	conducted by first person to see patient: Nurse, paramedic, respiratory therapist or phlebotomist. **– Time period**: (0) Jan–July, 2011 **– Population/sample**: (0) All ED patients — all ages. **– Comparator**: (0) Nurse draw (usually IV start) — Note — nurse refers to all non-phlebotomist draws. **– Study bias**: (0) None observed — informant states that both nurse and phlebotomist have similar severity of patients.	**– Duration**: (0) Jan–July, 2011 **– Training**: (0) None **– Staff/other resources**: (0) None **– Cost**: (0) Minimal	samples. **– Recording method**: (0) Standard records.	216/6455 = 3.35% Rate venipuncture (Phleb.): 255/22,273 = 1.14% RR = 3.35/1.14 = 2.76 **– Statistical significance/test(s)**: (0) None conducted **– Results/conclusion biases**: (1) Results based on large numbers. Demonstrates a large RR for IV draws despite the relatively low rate of hemolysis among the nurses. While this study compares the two practices, they are conducted by differently trained people. This may modify the comparison to other studies.
Quality rating: **9 (good)** **Effect rating**: **Substantial** **Relevance**: **Direct**	**Study (3 max)**: **3**	**Practice (2 max)**: **2**	**Outcome (2 max)**: **2**	**Results/findings (3 max)**: **2** Conducted by differently trained staff.

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Cindy Hudson **– Year**: 2011 **– Publication:** Unpublished **– Affiliations:** University of Minnesota Medical Center, Fairview, MN **– Funding:** None	**– Design:** (0) Observational Two site (two practices): Compared ED centers within the University system and using identical machines and protocols for measuring hemolysis. **– Facility/setting**: (0) Two University ED departments with different practices. One routinely collects samples from IV starts while the other routinely uses straight needle venipuncture. In both cases, nurses do the draws **– Time period:** (0) Weekly data from August 2006 to June 2009 **– Population/Sample:** (0) All ED patients at two University EDs **– Comparator:** (0) University ED — routinely use IV starts **– Study bias:** (1) None observed, but potential for other differences between two sites	**– Description:** (0) Riverside ED — routinely use straight needle venipuncture **– Duration:** (0) 8/2006 to 6/2009 **– Training:** (0) None **– Staff/other resources:** (0) None **– Cost:** (0) Minimal	**– Description:** (0) Vitros instrumentation direct reading of hemolysis **– Recording method:** (0) Weekly electronic reports.	**– Type of findings:** (0) Rates of hemolysis **– Findings/effect size:** (0) **1) IV starts vs. straight needle** IV start: 355/8022 = 4.43% Straight N: 38/5797 = 0.66% RR = 6.71 **– Statistical significance/test(s):** (0) Not done. **– Results/conclusion biases:** (1) No bias observed. Despite relatively low rates with IV starts, RR is still quite high.
Quality rating: 8 (good) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 2** Potential for unmeasured differences between two sites	**Practice (2 max): 2**	**Outcome (2 max): 2**	**Results/findings (3 max): 2** Large sample overcomes most problems (unless systematic) with lack of control for variation in other practices

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s) Kennedy C; Angermuller S; King R; Noviello S; Walker J; Warden J; Vang S.	– **Design:** (0) Random assignment experiment – **Facility/setting**: (0) ED — restricted to patients 16 years or older. Conducted by 7 experienced ED nurses. – **Time period:** (0) Not Given **– Population/sample:** (0)	**– Description:** (0) Practices evaluated: – **IV draws**: with 14–24 gauge needles and syringe and transfers using 18 gauge needle **– Straight needle venipuncture**: with 21	**– Description:** (1) Hemolysis determined by lab technologist — no description given. **– Recording method:** (0) Nurse performing	**– Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) See tables below for details. **1) IV start (w syringe) vs. straight needle (w vacuum tube)** 12/87 = 13.8% vs. 3/78 = 3.8% **2) For IV start: ≤21 vs >21 gauge catheter**

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Year: 1996 **– Publication:** J Emergency Nursing **– Affiliations:** The Medical Center Columbus, GA – **Funding:** Internal	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). – **Comparator:** (0) **1) IV start (w syringe) vs. straight needle (w vacuum tube)** **2) For IV start: ≤21 vs >21 gauge catheter** **– Study bias:** (1) Lopsided loss of subjects may reflect bias on part of nurses — otherwise difficult to explain. No control for location of draw.	gauge needle and vacuum tube. **– IV gauge:** Note — Not controlled for location of draw 7 experienced ED nurses were responsible for patient selection. – **Duration:** (0) Not Given – **Training:** (0) Minimal – **Staff/Other resources:** (0) Minimal – **Cost:** (0) Not Given	draw responsible for recording data.	10/82 = 12.2% vs. 2/5 = 40.0% – **Statistical significance/test(s):** (0) Chi-Square comparisons for IV draw vs. needle & vacuum tube: p = 0.03 Regression on gauge of IV: p = 0.047 **– Results/conclusion biases:** (1) Lopsided loss of subjects may introduce some bias. Sample size fairly small. No control for site of venipuncture — particularly difficult for comparison between rates for various IV gauge sizes.
Quality rating: 7 (fair) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 2** Lopsided loss of bloods for random samples (p<.02). No control for location of draw.	**Practice (2 max): 2**	**Outcome (2 max): 1** No description of how hemolysis determined	**Results/findings (3 max): 2** Potential for bias, small study size, did not control venipuncture location for gauge size comparisons.

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Glynnis Lowe; Rose Stike; Marc Pollack; Jenny Bosley; Patti O'Brien; Amy Hake; Greta Landis; Natalie Billings; Pam Gordon; Steve Manzella; Tina Stover **– Year:** 2008 **– Publication:** J Emergency Nursing **– Affiliations:** York Hospital, York PA – **Funding:** Internal	– **Design:** (0) Randomized control-cross over study – **Facility/setting**: (0) ED of 450 bed level II trauma center in a community teaching hospital with 64,000 annual visits/year. – **Time period:** (0) 4/5 to 5/30, 2006 **– Population/sample:** (0) 11 experienced (>2 years) ED registered nurses randomly assigned to first collect 70 samples using either IV start or butterfly needle, then switch over to other method. Out of total 857 samples collected, 4 had incomplete information and were excluded. Analysis included 853 samples) – **Comparator:** (0) **1) Straight needle (butterfly) vs. IV start:** **2) For IV start: antecubital vs. other** **– Study bias:** (0) None observed — however, the cross-over design provided only limited control as each nurse only collected, on average, 78 samples (857/11). Study not implemented as designed — stopped when investigators realized they would not achieve those numbers due to 1 nurse dropping out (bereavement), scheduling, and EMS patients arriving with IVs	**– Description:** (0) Detailed protocol provided. Selection of site and needle/catheter gauge decisions was up to nurse (both recorded). Analysis evaluated confounding (not shown) for nurse, shift, and gauge. Analysis of confounding by location was shown. Needle gauge was 21 or 23. Range for catheter gauge was not given, but reported as non-significant – **Duration:** (0) April 5 to May 30, 2006 – **Training:** (0) Minimal – **Staff/other resources:** (0) Minimal – **Cost:** (0) Not given	**– Description:** (0) Hemolysis defined as any visually detectable level. Level of hemolysis determined by automatic reader. Lab blinded to experimental status. **– Recording method:** (0) Standardized data collection form completed by nurses — trained in completing form.	**– Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) **1) Straight needle (butterfly) vs. IV start:** 1/355 (<1%) vs. 28/498 (5.62%) p<0.001 **2) For IV start: antecubital vs. other** 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%) – **Statistical significance/test(s):** (0) Chi-square using SPSS. **– Results/conclusion biases:** (0) Semi-controlled randomized cross over experiment was well reported. Main problem is that cross-over design did not have enough time to work. This should have been discussed in more detail. Also, while use of pneumatic tube was specified in the protocol, the discussion seemed to suggest that it was not controlled for.
Quality rating: 8 (good) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 2** Cross-over study should be more balanced; not implemented as designed	**Practice (2 max): 2**	**Outcome (2 max): 2**	**Results/findings (3 max): 2** Sample size too small to control for potential confounders — can only calculate main effects. Unclear why level of hemolysis was not used in the analysis — adds subjectivity.

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Munnix; ICA; Schellart, M; Gorissen, C; Kleinveld, HA. **– Year:** 2010 **– Publication:** Ned Tijdschr Klin Chem Labgeneesk **– Affiliations:** Atrium Medical Center, Heerlen, Netherlands – **Funding:** Internal **Quality rating: 8 (good)** **Effect rating: Substantial** **Relevance: Direct**	– **Design:** (0) Cross-Sectional Observational – **Facility/setting**: (0) Emergency and outpatient depts. Last half of 2008 lab processed 8710 samples from ED and 9754 from internal med. – **Time period:** (0) 3 months in 2009 **– Population/sample:** (1) 4 blood draws each from 100 ED patients (all IV draws). 50 straight needle draws from outpatients were not used in analysis because not from ED. No description provided of who drew the samples or how subjects were selected. – **Comparator:** (0) **1) Antecubital vs. other** **2) ≤21 vs >21 gauge catheter** Observed regular (unregulated) practices — did not provide data allowing control for potential confounding factors. **– Study bias:** (0) None observed. Although multiple tubes collected — primary results reported for first tube only **Study (3 max): 2** No description of how subjects were selected or who drew sample (training/position)	**– Description:** (0) Practices of interest include: – Placement (AC, forearm, hand) – Needle size (only 18 & 20 gauge) so not useable for this analyses. Notes: All IV starts, but not clear if vacuum tubes or syringe is used. Person who conducted draw recorded practices on a report form. Had straight needle vs. IV draw comparison, but not within ER — so not reportable for this evaluation. – **Duration:** (0) 36 days — 100 patients – **Training:** (0) Minimal. – **Staff/other resources:** (0) Minimal – **Cost:** (0) Not provided. **Practice (2 max): 2**	**– Description:** (0) Hemolysis determined by automated colorimetric reader — hemolysis defined as an index of 300 or more. **– Recording method:** (0) Standardized data collection form completed by person drawing sample. **Outcome (2 max): 2**	**– Type of findings:** (0) Rates of hemolysis **1) Antecubital vs. other** 5/54 (9.3%) vs. 11/45 (24.4%) Forearm: 6/37 (16.2) Hand: 5/8 (62.5) **2) ≤21 vs >21 gauge catheter** No data on >21 g. catheters 18 gauge: 5/34(14.7) 20 gauge: 11/65 (16.9) *Note: Missing data on one subject.* – **Statistical significance/test(s):** (0) Not done. **– Results/conclusion biases:** (0) Limited sample size and did not provide information to control for confounding factors. **Results/findings (3 max): 2** Small sample size, no way to control for potential confounders — can only calculate main effects

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Marcus EH Ong; Yiong Huak Chan; Chin Siah Lim. **– Year:** 2008 **– Publication:** Ann Acad Med Singapore **– Affiliations:** Singapore General Hospital, Singapore – **Funding:** Internal **– Author(s):** Marcus EH Ong; Yiong Huak Chan; Chin Siah Lim. **– Year:** 2009	– **Design:** (0) Cross-Sectional with follow-up – **Facility/setting**: (0) No description. Estimated an average of 200 UE samples collected daily – **Time period:** (1) Not described. **– Population/sample:** (0) Convenience population of 227 patients. All patients requiring blood urea and electrolytes (UE) during study time period were eligible. No requirements put upon personnel drawing blood – **Comparator:** (0) 1) *Straight needle vs. IV start* 2)*Syringe vs. vacuum tube* 3) *≤21 vs. >21 gauge needle* Other comparisons not being evaluated: operator, blood flow, difficulty of draw, source (venous vs. arterial) **– Study bias:** (1) None observed — only used UE samples. Did not control for other parameters (but did state no statistical influence by operator).	**-Description:** (1) Scanty protocol provided. No description of patients selection (N seemed small) or time period. No controls put on methods or participation of operators. Follow-up study evaluated change in numerous practices parameters and overall hemolysis rates, but did not provide rates by practice parameters. – **Duration:** (0) Not specified. – **Training:** (0) None in Phase 1 — Education in phase 2. – **Staff/other resources:** (0) Minimal – **Cost:** (0) Not specified.	**– Description:** (0) Hemolysis defined using standard laboratory procedure — not defined. **– Recording method:** (0) Questionnaire on blood draw parameters with patient label matched to reported laboratory outcomes (hemolysis	**– Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) Phase 1: N = 227. Straight needle vs. IV start: 4 (6.8%) vs. 41 (24.4%) OR = 4.4 (1.5–13.0) Syringe vs. Vacuum tube: ***Insufficient control*** ≤21 gauge needle vs. >21 gauge: ***Insufficient control*** Logistic regression analysis has inadequate data to provide much information. Phase 2: N = 204 Significant changes in practices including straight needle vs. IV starts and syringe vs. vacuum tube resulted in reduction of hemolysis rates for 19.8% before to 4.9% after. However, no rates by practice provided – **Statistical significance/test(s):** (0) ORs and CIs provided. **– Results/conclusion biases:** (1) Convenience sample with little description and no data provided to control for other practice parameters.

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– **Publication:** Am 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**	**Results/findings (3 max): 2** Lack of control for other practice parameters and sample size does not support logistic regression

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– **Author(s):** Raisky, F; Gauthier C; Marchal, A; Blum, D. – **Year:** 1994 – **Publication:** Ann de biologie clinique – **Affiliations:** CHG Louis-Pasteur, Dole Cedex, France – **Funding:** Internal	– **Design:** (0) Random Assignment experiment – **Facility/setting**: (0) Hospital ED in France — No other description – **Time period:** (0) July and August, 1992 – **Population/sample:** (1) 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 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. – **Comparator:** (0) **1) Straight needle vs. IV start.** Also evaluated two types (Teflon and Vialon) of catheters. – **Study bias:** (0) None observed — usual practice introduced confounding by location, needle size.	– **Description:** (0) 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 73–77%, 18 g in 83–90% (also 20 & 16 g) All samples collected in 5 mL glass vacuum tubes. Groups comparable in age and gender (tests for randomness). All data recorded on randomization form. – **Duration:** (0) July and August, 1992 – **Training:** (0) None – **Staff/other resources:** (0) Minimal — used standard collection conditions – **Cost:** (0) Not reported.	– **Description:** (0) Hemolysis determined by both visual and calibrated automatic photometric reader (detection limit of 0.05 g/l of plasma). Hemolysis status of patient determined by the tube used for electrolytes and enzymes — tests most sensitive to hemolysis. – **Recording method:** (0) Data collected on randomization form which was sent to lab with sample. Lab blinded to status.	– **Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) Final N = 853. **Straight needle vs. IV start:** 11/95 (11.6%) vs. 97/200(48.5%) For the two catheters: Teflon: 42/100 (42%) Vialon: 55/100 (55%) – **Statistical significance/test(s):** (0) ANOVA by ranks — Kruskal–Wallis (non-parametric). Note: all comparisons between groups (3-way and pairwise) had significance of $p<0.00001$ – **Results/conclusion biases:** (0) Randomized subject assignment to collection technique. Very detailed description of protocol and testing methods. No biases observed, although conclusion is tempered by differences in site and needle gauge for the two compared techniques
Quality rating: 9 (good) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 2** Although randomized, clear differences in site and gauge by method.	**Practice (2 max): 2**	**Outcome (2 max): 2**	**Results/findings (3 max): 3**

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Sixsmith, DM; Weinbaum, F; Weinbaum F; Chan, SYA; Nussabaum M; Magdich, K. **– Year:** 2000 **– Publication:** SAEM 2000 Annual Meeting Abstracts (abstract only) **– Affiliations:** NY Hospital Medical Center of Queens, Flushing NY – **Funding:** Internal	– **Design:** (0) 3-Period crossover trial. 2 week baseline (standard practice with regular vacuum tubes); 2 week practice trial with low vacuum tubes; 2 weeks back to standard practice – **Facility/setting**: (0) Hospital ED – **Time period:** (0) 3×2 week consecutive periods in 1999 **– Population/sample:** (1) All patients in ED getting blood chemistry tests: Total N = 2743: Period 1) 1050; period 2) 725; period 3) 968. – **Comparator:** (0) **1) Regular vs. low vacuum tubes.** Usual practice using regular vacuum tubes. No description of regular practice given beyond types of vacuum tubes used. No information or control for straight needle vs. IV starts or who drew sample. **– Study bias:** (0) None observed.	**– Description:** (0) Use of low vacuum tubes for blood chemistries. – **Duration:** (0) 6 weeks broken into 2 week segments: baseline with regular practice; test period with new practice; re-evaluation of baseline with regular practice – **Training:** (0) None – **Staff/other resources:** (0) Minimal – **Cost:** (0) Not provided.	**– Description:** (1) Hemolysis — no description of how it was measured. **– Recording method:** (0) No description.	**– Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) **1) Regular vs. low vacuum tubes.** Baseline (**regular vac**.): 1: N = 1050 Hemolysis rate = 120/1050 = 11.4% Trial period (**low vacuum**): N = 725 Hemolysis rate = 19/725 = 2.6% Baseline 2 (**regular vac**.): N = 968 Hemolysis rate = 128/968 = 13.2% Overall ratio for regular vs. low vacuum is 4.36 (CI: 2.45–7.77) p<0.0001. – **Statistical significance/test(s):** (0) Fisher's exact test — 2 tailed **– Results/conclusion biases:** (1) Evidence for a reduction in hemolysis based solely on type of vacuum tube used. Real world experience with comparison made on complete separation of practice, but with no controls for other practices.
Quality rating: 7 (fair) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 2** Real world comparator is a pure practice (regular vacuum tubes), but uncontrolled for other practices (e.g. straight needle vs. IV start). Cross-over design minimizes any observation bias.	**Practice (2 max): 2**	**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

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Christine Schmotzer **– Year:** 2011 **– Publication:** Unpublished **– Affiliations:** Case Western Reserve University Hospitals, Cleveland Ohio – **Funding:** Internal	**– Design:** (0) Small experiment + Cross-sectional observation **– Facility/setting**: (0) ED in a 1000 bed Academic Medical Center **– Time period:** (0) A) One day — Experiment: 8 syringe and 7 vacuum tube draws — no hemolysis observed. B) 10 days after education — 752 results observed C) 10 days immediately after removal of syringes and exclusive use of vacuum tubes (660 observations) and after elapse of 1.5 months (715 observations) **– Population/Sample:** (0) Adult ED patients requiring Potassium blood draws — all conducted using IV starts. **– Comparator:** (0) **1) For IV starts: syringe vs. vacuum tube** **– Study bias:** (0) None observed — no control for patient characteristics, gauge of catheters, # tubes drawn, or staff conducting draw.	**– Description:** (0) Removal of syringes from ED forcing exclusive use of vacuum tubes. **– Duration:** (0) A) one day — 6/13/11 B) Training completed 6/13/11. Observed for 10 days C1) Syringes removed 7/14/11. Observed for 10 days. C2) 1.5 months later — observed for 10 days **– Training:** (0) One day (6/13/11) **– Staff/other resources:** (0) Minimal. **– Cost:** (0) Minimal.	**– Description:** (0) Hemolysis measured on all potassium samples using an automated analyzer. H index of ≥3 were considered hemolyzed. **– Recording method:** (0) Laboratory electronic information system results reviewed for relevant dates.	**– Type of findings:** (0) Rates of hemolysis **– Findings/effect Size:** (0) From observations before/after removal of syringes: **Note:** Baseline rate taken from period (B) with 752 observations. Effect rate take from period (C 1&2) with 660 and 715 observations **For IV starts: syringe vs. vacuum tube** **1) immediate after (N = 660):** 18.4% vs. 19.8% **2) at 1.5 months (N = 715):** 18.4% vs. 17.6% ***Other observations***: Education — two 10 day periods before/after (752 observations after education): Hemolysis: 18.0% vs. 18.4% **– Statistical significance/test(s):** (0) None done

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Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
				– Results/conclusion biases: (0) No bias observed. Based upon usual practice with isolated change. No major effects observed.
Quality rating: 10 (good) **Effect rating: Minimal/ none** **Relevance: Direct**	**Study (3 max): 3**	**Practice (2 max): 2**	**Outcome (2 max): 2**	**Results/findings (3 max): 3**

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

Bibliographic information Overall rating	Study* Category (points deducted)	Practice* Category (points deducted)	Outcome measures* Category (pts deducted)	Results/findings* Category (points deducted)
– Author(s): Shannon M. Straszewski; Leon Sanchez; Daniel McGillicuddy; Kirsten Boyd; Jane DuFresne; Nina Joyce; Richard Wolfe; Alice W. Lee; Jonathan Fisher; John L. Mottley **– Year:** 2011 **– Publication:** Intern Emerg Med **– Affiliations:** Beth Israel Deaconess Medical Center, Boston, MA – **Funding:** Internal	– **Design:** (0) Before/after experiment mandating use of separate straight needle venipuncture for lab studies – **Facility/setting**: (0) Level 1 trauma center with ED volume of 55,000/year. – **Time period:** (0) 5-week time period: 1 week baseline and 4-week test period. **– Population/sample:** (1) Adult ED patients — provided only number of blood samples — not specified if there could be more than one sample per patient. N samples = 2879 (315 baseline, 2564 trial) – **Comparator:** (0) **Straight needle vs. IV start** Baseline involved mixed use of separate straight needle venipuncture (21 gauge butterfly with vacuum tube) and IV starts (mixed gauge with vacuum tubes) for lab potassium studies. **– Study bias:** (1) None observed. Difficult to calculate ORs given no indication of % needle vs. IV distribution at baseline. Also confounded by some minimal training and impact of being observed/forced change of practice.	**– Description:** (0) Intervention: all lab draws conducted with straight needle (21g butterfly) and vacuum tube. Some education on how to minimize hemolysis. – **Duration:** (0) 5-week time period: 1 week baseline and 4-week test period. – **Training:** (0) Some on reducing hemolysis. – **Staff/other resources:** (0) Draws conducted by normal staff — ED nurses and technicians — modest amount of training on how to minimize hemolysis. – **Cost:** (0) Not provided	**– Description:** (0) Hemolysis determined by visual inspection and reported as none, moderate and gross. Critical hemolyzed sample was defined as having potassium levels > 5.1 mEq/L (outside normal range),) which requires re– sampling. **– Recording method:** (0) Study relied only on hemolysis data reported by laboratory — change in practice was universal and compliance was not reported (assumed 100%).	**– Type of findings:** (0) Rates of hemolysis – **Findings/effect size:** (0) N total = 2879. Baseline week N = 315 4-Week trial N = 2564 (641/week) **Straight needle vs. IV start** *Baseline rate*: Hemolyzed– 23% (CI: 16.7—29.1) Critical = 6,7% *Trial rate (100% straight needle)*: Hemolyzed = 6.6% (CI: 5.5—7.5) Critical = 2.0% – **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.
Quality rating: 7 (fair) **Effect rating: Substantial** **Relevance: Direct**	**Study (3 max): 1** Comparator is a mixed practice. Unexplained disparity between baseline and trial volume of tests	**Practice (2 max): 2**	**Outcome (2 max): 2**	**Results/findings (3 max): 2** Discordant patient volume between baseline and trial. Training adds confounding

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