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**NEEDLELESS VACUTAINER SYSTEM  
FOR BLOOD COLLECTION**

HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS)  
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**DISCLAIMER**

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## **DISCLOSURE**

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

## **EXECUTIVE SUMMARY**

### **Background**

Healthcare workers (HCW) are exposed to occupational hazard of sharp injuries, commonly referred to as needle stick injuries. World Health Organization (WHO) reported that of the 35 million health-care workers, two million experience percutaneous exposure to infectious diseases each year. According to Ministry of Health (MOH) Malaysia, needle stick injury was the major cause of injuries among the MOH personnel which contributes to a total of 74.9% of all injuries in 2005. Vacuum extraction tube system was reported to be a safer option than using hypodermic needle and syringe. The system eliminates blood transfer and allows numerous blood samples to be collected through single venepuncture. Vacutainer system is a type of vacuum extraction tube system specifically designed for the collection of single or multiple blood samples under closed conditions. Vacuum extraction tube systems are widely available in most well-resourced countries. The system has been reported to reduce needle stick injuries in HCW. However, if the system is not correctly used, it may create risk for needle stick injuries to the HCW. Therefore, this systematic review was requested by the Medical and Endocrinology Consultant, Hospital Ipoh to evaluate safety, efficacy and cost-effectiveness of needleless Vacutainer system for blood collection.

### **Objective/aim**

To evaluate the safety, efficacy, cost-effectiveness, organizational and psychological/social/ethical issues of needleless Vacutainer system for blood collection.

### **Results and conclusions**

A total of 383 titles were identified through the Ovid interface and PubMed. There were six articles included in this review; one RCT, two pre and post intervention studies, and three cross sectional studies.

#### **Effectiveness**

##### **1) Needle sticks injuries**

There was limited fair level of retrievable evidence to suggest that Vacutainer blood collection system were effective in preventing needle stick injuries among HCW. Combination of Vacutainer tube with safety devices significantly decreased needle stick injuries compared to conventional devices with reduction rates between 38.7% to 81%.

##### **2) Sample Hemolysis**

The evidence on sample hemolysis is inconclusive whereby one RCT reported a lower hemolysis rate of blood samples drawn from Vacutainer venepuncture compared to IV catheter (via syringe). On the other hand, two cross sectional studies reported that blood hemolysis was found to be higher

in samples drawn with a Vacutainer system compared to a syringe-needle transfer system (hemolysis rate with Vacutainer: 35.8% to 77.0%).

### **Safety**

There was no retrievable evidence on the safety of needleless Vacutainer system for blood collection. The BD Vacutainer Systems had received 510(k) from US Food and Drug Administration.

### **Psychological / Social / Ethical**

There was limited fair level of retrievable evidence to suggest the preference and compliance of Vacutainer system among HCW. One study reported a slightly higher proportion of safety devices preference over conventional equipment while another study reported only 35.8% of HCW always used Vacutainer for blood sampling. Among the reason cited for not using Vacutainer were difficult venous access and the absence of a flashback.

### **Organizational**

Healthcare workers who are using needleless Vacutainer system need to be trained.

### **Cost / Cost-Effectiveness**

Based on the available data, cost-effectiveness of needleless vacutainer system could not be determined. However, it is estimated that needleless vacutainer system will require additional investment of approximately MYR 134 to MYR 282 million for its utilisation within MOH.

### **Methods**

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EMBASE – 1996 to March 2018, EBM Reviews - Cochrane Central Register of Controlled Trials – August 2017, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to August 2017, EBM Reviews - Health Technology Assessment – 4<sup>th</sup> Quarter 2016, EBM Reviews – NHS Economic Evaluation Database 1<sup>st</sup> Quarter 2016. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 20 January 2019.

# NEEDLELESS VACUTAINER FOR BLOOD COLLECTION SYSTEM

## 1. BACKGROUND

Healthcare workers (HCW) are exposed to occupational hazard of sharp injuries, commonly referred to as needle stick injuries. Needle stick injuries is defined as injury caused by needles such as hypodermic needles, blood collection needles, intravenous (IV) stylets, and needles used to connect parts of IV delivery systems.<sup>1</sup> World Health Organization (WHO) reported that of the 35 million health-care workers, two million experience percutaneous exposure to infectious diseases each year.<sup>2</sup> According to Ministry of Health (MOH) Malaysia, needle stick injury was the major cause of injuries among the MOH personnel which contributes to a total of 74.9% of all injuries in 2005.<sup>3</sup> Most reported needle stick injuries involve nursing staff; but laboratory staff, physicians, housekeepers, and other HCW are also injured.<sup>1</sup>

Needle stick injuries may cause a number of serious and potentially fatal infections with blood borne pathogens. According to WHO, 37.6% of Hepatitis B, 39% of Hepatitis C and 4.4% of HIV/AIDS in health-care workers around the world are due to needle stick injuries.<sup>2</sup> These injuries are preventable and under the Occupational Safety and Health Act 1994 (OSHA), employers, employees and self employed persons have a duty of care towards their own safety and health, and to that of others at their workplace. Elements of a successful sharps injury prevention programmes include promoting an overall culture of safety in the workplace, eliminating the unnecessary use of needles and other sharp devices, using devices with sharps injury prevention features (safety devices), employing safe workplace practices and training health care personnel.<sup>3</sup>

Safety devices such as vacuum extraction tube system or winged needle sets was reported to be a safer option than using hypodermic needle and syringe. Safety features (eg: needle covers, needleless transfer systems or adaptors, and retractable lancets) can further reduce the risks associated with manual recapping, needle removal, disassembly and transfer of blood syringes to tubes.<sup>4</sup> Vacutainer system is a type of vacuum extraction tube system specifically designed for the collection of single or multiple blood samples under closed conditions. The closed system reduces the risk of direct exposure to blood and has made it easier to draw blood from a single venepuncture. The ability to withdraw blood in volumes ranging from one to 50 ml into several bottles with different anticoagulants makes the system versatile.<sup>5</sup>

Vacuum extraction tube systems are widely available in most well-resourced countries. The system has been reported to reduce needle stick injuries in HCW. However, if the system is not correctly used, it may create risk for needle stick injuries to the HCW. If a blood sample is poorly collected, the results may be inaccurate and misleading to the clinicians.<sup>4</sup> Therefore, this systematic review was requested by the Medical and Endocrinology Consultant, Hospital Ipoh to

evaluate safety, efficacy, cost-effectiveness and organizational issues of needleless Vacutainer system for blood collection.

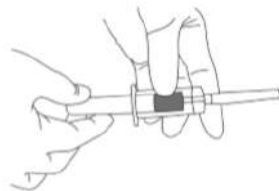
## 2. OBJECTIVE / AIM

To evaluate the safety, efficacy, cost-effectiveness, organizational and psychological/social/ethical issues of needleless Vacutainer system for blood collection.

## 3. TECHNICAL FEATURES

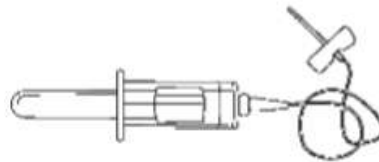
### Vacuum extraction tube systems

The use of vacuum extraction tube systems (Figure 1) as closed systems for blood collecting reduces the risk of direct exposure to blood and has made it easier to take multiple samples from a single venepuncture. Double-ended needles are available in several recommended gauge sizes. The end covered by a rubber cuff is screwed into the barrel (also known as the tube holder, evacuated tube needle holder or bulldog). The barrel holds the sample collection tube in place and protects the phlebotomist from direct contact with blood. The sample tube is under vacuum. Once the needle is in the vein, the tube is pressed on to the needle and the blood is drawn automatically into the sample tube by vacuum until the required amount is collected. This system comes complete with needle, barrel and the laboratory sample tubes with appropriately coloured tops for different types of samples. Tubes for adult and paediatric specimens are available. The barrel and syringe are discarded as a single entity where possible. If there is a need to reuse the barrel, one-hand scoop technique is used to cover the sharp end of the needle and thus to safely remove the needle from the barrel. Alternately, sharps container with a needle removal hold can be used, again employing a one-handed technique. Some systems have a mechanism that can be activated once the needle has been used; the mechanism retracts the used needle into the barrel and snaps it shut. Others have a quick release mechanism to dislodge the used needle into the sharps container. Vacuum systems may also be used with a winged butterfly needle (Figure 2) and luer-lock connectors. Winged butterfly needles are also available with safety-engineered devices.<sup>4</sup>



**Figure 1. Vacuum Extraction System**

The barrel holds the sample collection tube in place and protects the HCW from direct contact with blood.



**Figure 2. Winged butterfly system**

A vacuum system combined with a winged butterfly needle.

Vacutainer is a registered brand of test tube specifically designed for venipuncture. It was developed in 1947 by Joseph Kleiner, and is currently

marketed by Becton, Dickinson (BD) and company. Vacutainer also known as vacuum blood collection tubes.<sup>6</sup>

The BD Vacutainer Blood Collection System consists of:

- a) BD Vacutainer Safety Lok Blood Collection Set with Pre-attached Holder (Figure 3)
- b) BD Vacutainer Blood Collection Tubes (Figure 4)<sup>7</sup>



**Figure 3: BD Vacutainer Safety Lok Blood Collection Set with Pre-attached Holder**



**Figure 4: BD Vacutainer Blood Collection Tubes**

### **Needleless system**

A needleless system refers to a device that does not use needles for the collection of body fluids or administration of medication or fluid after initial IV access is established.<sup>8</sup> There are two types of needleless devices that can be used in phlebotomy:

#### **a) Needleless connector**

Needleless connectors (Figure 5), also known as “end caps”, “injection caps”, “catheter caps”, “luer activated devices”, injection ports” and “mechanical valves” are an integral component of an infusion system. Needleless connectors were initially designed to reduce needles tick injuries among HCW and to provide safer workplace environment.<sup>9</sup> Several needleless connectors are available in the market, varying in both design and function. The needleless connectors are different in the visual appearance (clear, coloured, flat, concave), and different in the internal mechanisms that are responsible for the way the devices function. Needleless connectors are typically defined as being simple or complex. Simple devices are described as having no internal moving parts (such as split-septum), whereas complex devices contain internal moving components (such as mechanical valve).<sup>10</sup> Needleless connectors can be used with syringe or Vacutainer for blood collection. The BD Vacutainer Luer-Lok access device (Figure 6) is a direct access collection device used for needleless collection of blood. It is a holder with preattached multiple sample and male adapter that is compatible with female luer

connections or IV ports designed for luer access. It allows specimens to be collected into an evacuated tube.<sup>11</sup>



**Figure 5: Needleless Connectors**



**Figure 6: BD Vacutainer Luer-Lok access device**

**b) Needleless transfer device**

Needleless transfer device facilitates a safe transfer of blood from a syringe into a blood collection tube. The syringe is attached to the top of the device; the tubes are then inserted into the holder until the stopper is punctured by the needle inside the holder. The vacuum in the tube causes blood to be drawn into the tube. The BD Vacutainer® Blood Transfer Device (Figure 7) is a sterile, single-use device that can reduce the risk of spill and transfer-related injuries.<sup>12</sup>



**Figure 7: BD Vacutainer® Blood Transfer Device**

## 4. METHODS

### 4.1. Searching

Electronic databases were searched through the Ovid interface:

- Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present
- EMBASE – 1996 to March 2018
- EBM Reviews - Cochrane Central Register of Controlled Trials – August 2017
- EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to August 2017
- EBM Reviews - Health Technology Assessment – 4<sup>th</sup> Quarter 2016
- EBM Reviews – NHS Economic Evaluation Database 1<sup>st</sup> Quarter 2016

Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 20 January 2019.

Appendix 1 shows the detailed search strategies.

### 4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

#### Inclusion criteria

Population	Healthcare workers/Health Personnel
Interventions	Needleless Vacutainer system for blood collection
Comparators	Syringe/No comparator
Outcomes	i. Effectiveness/Efficacy: Reduction in needle stick injuries, sample hemolysis, ii. Safety: Bruising, haematoma, nerve injury iii. Psychological/Social/Ethical: Compliance, preference iv. Organizational: Training v. Economic: Cost-effectiveness, cost-analysis
Study design	Health Technology Assessment (HTA) reports, Systematic review (SR) and Meta-analyses, Randomised Controlled Trials (RCT), Non-randomised controlled trials (NRCT), cohort studies, cross-sectional studies, case control studies, case series

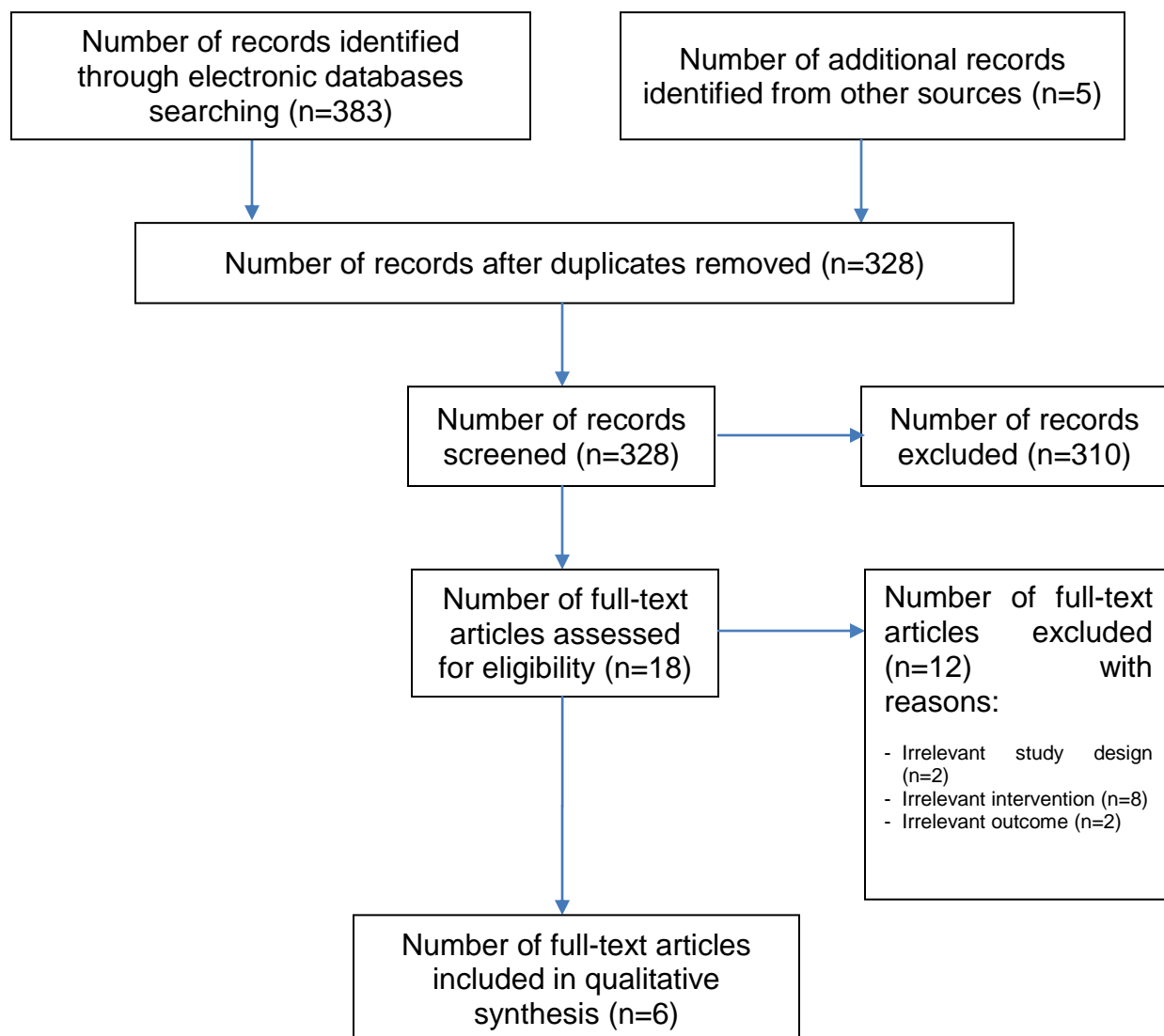
#### Exclusion criteria

Study design	Studies conducted in animals, narrative reviews, pilot studies, case reports
	Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

## 5. RESULTS AND DISCUSSION

A total of 383 titles were identified through the Ovid interface and PubMed. There were six articles included in this review; one RCT, two pre and post intervention studies, and three cross sectional studies, as shown in Figure 8. However, there was no retrievable evidence from the scientific databases on cost-effectiveness of this technology. The studies retrieved and included in this review were conducted in United States, United Kingdom, France and Singapore.



**Figure 8: Flow chart of study selection**

## 5.1. CRITICAL APPRAISAL OF THE LITERATURES

### Assessment of risk of bias

One of the tools that are being used by MaHTAS to assess the risk of bias is the CASP checklist which consists of eight critical appraisal tools designed for SR, RCT, cohort studies, case control studies, economic evaluations, diagnostic studies, qualitative studies, and clinical prediction rule. This is achieved by answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias as either:

+	Indicates YES (low risk of bias)
?	indicates UNKNOWN risk of bias
-	Indicates NO (high risk of bias)

### Assessment using Cochrane Collaboration's Tools for Randomised Controlled Trials (RCTs)

One RCT was included in this assessment and the risk of bias is summarised in Figure 9a. The RCT had either low or unclear risk of bias for the six domains assessed. The method of generating the randomisation sequence, allocation concealment and blinding was classified as unclear as the methods were not mentioned in detail. Incomplete outcome data and all outcomes were clearly stated, thus were judged to have low risk of bias.

Criteria assessed	Adequate sequence generation	Allocation concealment	Blinding of participants and personnel	Incomplete outcome data addressed	Free of selective reporting	Free of other bias
Kennedy et al. <sup>15</sup>	?	?	?	+	+	?

**Figure 9a: Assessment of risk of bias of RCT (Cochrane)**

## Assessment using Quality Assessment Tool for Pre-Post Studies With No Control Group (NIH)

Two pre and post intervention studies were included in this assessment and the risk of bias is summarised in Figure 9b. Both studies have low risk of bias for all domains assessed with the exception of blinding and loss to follow-up, which was classified as unclear as the methods were not mentioned in detail.

Criteria assessed	Rogues et al. <sup>13</sup>	Centers for Disease Control and Prevention <sup>14</sup>
Question or objective clearly stated?	+	+
Eligibility/selection criteria for study population clearly described?	+	+
Were participants representative for those who would be eligible for the test/ service/intervention in the population of interest?	+	+
Were all eligible participants that met the prespecified entry criteria enrolled?	+	+
Sample size sufficiently large to provide confidence in findings?	+	+
Test/service/intervention clearly described and delivered consistently?	+	+
Outcome measures prespecified, valid, reliable, and assessed consistently?	+	+
People assessing the outcome measures blinded to participants exposure/ interventions?	?	?
Loss to follow-up after baseline 20% or less? Loss to follow-up accounted for in the analysis?	?	?
Statistical methods examine changes in outcome measures from before to after intervention? p value?	+	+
Outcome measures taken multiple times before and after intervention? Use interrupted time-series design?	+	+
If intervention conducted at group level, did statistical analysis take into account of individual level data to determine effects at group level?	+	+

**Figure 9b: Assessment of risk of bias of pre-post studies with no control (NIH)**

## 5.2. EFFICACY / EFFECTIVENESS

Five studies reported the effectiveness of needleless Vacutainer system for blood collection, of which one was RCT, two pre and post intervention studies, and two cross sectional studies.

### 5.2.1. Needle stick injuries

Rogues et al. conducted a pre and post intervention study to assess the effectiveness of winged steel needles and vacuum tube phlebotomy needle in preventing needles stick injuries to HCW. Sharps injury data were collected over a seven-year period (1993 to 1999, n=4624 sharp injuries) in a 3600-bed tertiary care university hospital in France. Two protective devices for blood drawing, Vacutainer blood collecting tube with recapping sheath (SafetyLok, BD, Figure 10) and resheathable winged steel needles (SafetyLok, BD, Figure 11) were introduced throughout the hospital on June 1996. Nurses were trained on how to activate the safety mechanism following removal of the needle from the patient. Pre and post intervention rates were compared after the implementation of the safety devices for preventing percutaneous injuries related to phlebotomy procedure. From 1993 to 1999, an overall decrease in the needle stick-related injuries was noted. Phlebotomy procedures accounted for 19.4% (n=320) of all needle-related injuries in the pre intervention period, and 12% (n=127) in the post intervention period [Relative risk (RR): 0.62; 95% CI: 0.51, 0.72; p<0.001]. Reported phlebotomy-related percutaneous injuries declined from 191 on pre intervention period to 117 for post intervention period for vacuum-tube blood collection needles (reduction of 38.7%), and from 53 to 10 for winged steel needles (reduction of 81%). There was an overall reduction of 48% in percutaneous injuries per 100,000 phlebotomies.<sup>13, level II-2</sup>



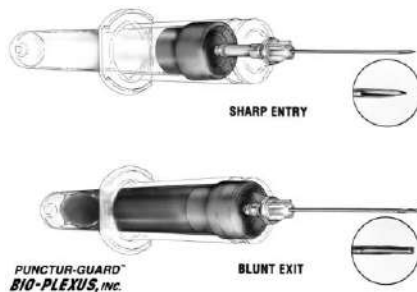
**Figure 10. Vacutainer blood collecting tube with recapping sheath (SafetyLok, BD)**



**Figure 11. Resheathable winged steel needles (SafetyLok, BD)**

Centers for Disease Control and Prevention (CDC) conducted a pre and post intervention study to evaluate safety devices for phlebotomy. The study was conducted in two phases during 1993 to 1995 at six university-affiliated hospitals in United States. The assessment compared three safety devices;

resheathable winged steel needle (SafetyLok, BD, Figure 11), blunable vacuum tube blood collection needle activated in patients's vein (Punctur-Guard, Bio-plexus, Figure 12) and vacuum tube blood collection needle with a hinged recapping sheath (Venipuncture Needle-Pro, Smith Industries, Figure 13) with conventional devices. Before introducing the safety devices, each hospital conducted a 'hands-on' training program for HCW. During phase I (nine to 12 months), hospital used conventional devices and conducted enhanced surveillance for injuries. A survey was distributed to HCW to estimate their rates of percutaneous injuries. During phase II (six to 15 months), conventional devices were replaced with safety devices and enhanced surveillance for injuries was continued. A survey was repeated one to two months before the end of phase II, and the estimated percutaneous injuries rates for safety and conventional devices were compared. The overall response rate for each of the two surveys was approximately 75%, based on estimates of the number of HCW who received survey forms; 1699 HCW responded in phase I and 1421 in phase II. Compared with conventional devices, percutaneous injuries rates were lower for safety devices (Table 1). Of the 41 percutaneous injuries associated with safety devices, 34 (83%) involved winged steel needles and seven (17%) involved vacuum-tube blood-collection needles. Twenty-five (61%) involved an injury before activation of the safety feature was appropriate or possible (eg: within seconds after the device was removed from the vein); six (15%) occurred during activation of the safety feature (all with SafetyLok). For eight (20%), the safety feature had not been activated, and for two (5%), the mechanism of injury was unknown. There was a significant reduction ( $p<0.05$ ) in phlebotomy-related percutaneous injuries associated with use of each of the vacuum tube blood collection devices.<sup>14</sup>, level II-2



**Figure 12. Blunable vacuum-tube blood collection needle activated in patients's vein (Punctur-Guard, Bio-plexus)**



**Figure 13. Vacuum-tube blood collection needle with a hinged recapping sheath Venipuncture Needle-Pro, Smith Industries**

**Table 1. Evaluation of three safety devices used in phlebotomies**

<b>Characteristics</b>	<b>Winged steel needle</b>	<b>Vacuum-tube blood-collection device</b>	
	<b>Safety-Lok™<sup>†</sup></b>	<b>Punctur-Guard™<sup>***</sup></b>	<b>Venipuncture Needle-Pro™</b>
<b>Study site (no. hospitals)</b>	Minneapolis-St. Paul (3) New York City (1) San Francisco (2)	Minneapolis-St. Paul (3)	Minneapolis-St. Paul (1) New York City (1) San Francisco (2)
<b>No. phlebotomy-related percutaneous injuries (PIs)</b>			
Unadjusted			
Conventional device	53	14	19
Safety device	34	2	5
Adjusted for underreporting by occupation			
Conventional device	102	19	33
Safety device	58	4	8
<b>Estimated no. phlebotomies performed</b>			
Conventional device	2,540,500	523,561	895,054
Safety device	1,875,995	501,596	628,092
<b>Estimated no. PIs per 100,000 phlebotomies</b>			
Conventional device	4.0	3.6	3.6
Safety device	3.1	0.9	1.2
<b>Percentage reduction in PI rate with safety device<sup>††</sup></b>	23% (p=0.07)	76% (p=0.003)	66% (p=0.003)

\*Safety-Lok™ (Becton Dickinson, Franklin Lakes, New Jersey), Punctur-Guard™ (Bio-Plexus, Inc., Tolland, Connecticut), and Venipuncture Needle-Pro™ (Smith Industries [Concord Portex], Keene, New Hampshire).

<sup>†</sup>Phlebotomists; nurses on representative medical and surgical wards, intensive-care units, and the emergency department; medical, pediatric, and surgical residents; and third- and fourth-year medical students.

<sup>‡</sup>This study was not designed to compare one safety device with another.

<sup>¶</sup>Use of trade names and commercial sources is for identification only and does not imply endorsement by the Public Health Service of the U.S. Department of Health and Human Services.

<sup>\*\*</sup>According to the manufacturer, the design of this product has been modified since study completion.

<sup>††</sup>Safety versus conventional device.

### 5.2.2.

### Sample Hemolysis

Kennedy et al. conducted a RCT to compare the rate of hemolysis in blood samples obtained by an IV catheter versus the rate in samples obtained by venipuncture (Vacutainer tubes and needles; BD Vacutainer Systems). Patients who came to the emergency department (ED) and required both an IV infusion and blood sampling for determination of electrolyte levels and complete blood cell count (CBC) were randomly assigned to either group A or B. A total of 165 patients participated in this study, 87 patients were enrolled in group A while 78 patients were enrolled in group B. The blood samples for patients in the A group were obtained through the IV catheter (via syringe) at the time of insertion. The IV catheters ranged in size from 24 gauge to 14 gauge. Patients in the B group also had insertion of an IV line, but their blood samples were obtained by Vacutainer venipuncture at a separate site. The Vacutainer needle was standardized at 21 gauge. All blood samples were collected by experienced ED nurses. In group A, 12 of 87 (13.7%) blood samples hemolyzed. The electrolytes were hemolyzed in all 12. Three of these 12 samples also had a hemolyzed CBC. In group B only 3 of 78 (3.8%) blood samples hemolyzed. Of these three, one CBC and all three electrolyte tests were hemolyzed. Group A was found to have a statistically higher hemolysis rate than group B ( $\chi^2=4.89$ ,  $p=0.03$ ). The rate of hemolysis declined with larger IV catheter diameter (the larger the catheter diameter the smaller the IV gauge number) (Regression coefficient,  $R=+0.82$ ,  $p=0.047$ ).<sup>15</sup>, level II-2

Grant conducted a cross sectional study to identify venipuncture and blood draw factors associated with hemolysis of ED blood samples. A convenient sample of ED blood samples was studied for degree of hemolysis and phlebotomy technique using data obtained from surveys completed by ED nurses and/or ED clinical technicians. The questionnaire cover four areas: 1) the venepuncture technique (IV catheter or straight needle), 2) the blood-draw methods (Vacutainer or syringe), 3) the blood transfer method if drawn with a syringe (needle-to-tube or needleless connector-to-Vacutainer), and 4) the identity of phlebotomist and lab technician. The level of hemolysis per sample was designated by laboratory technicians. A total of 598 surveys were collected, and 76% ( $n=454$ ) were complete enough to be included in the analysis (Table 2). The predominant technique for drawing blood in new venipunctures ( $n=372$ ) was by IV catheters [69% ( $n=255$ )], versus straight needles [31% ( $n=117$ )]. Thirty-two percent ( $n=144$ ) of the samples had some degree of hemolysis; 13% ( $n=59$ ) were so hemolyzed that tests were cancelled by the laboratory. Blood drawn through IV catheters resulted in significantly more hemolysis and test cancellation than that drawn with a straight needle (20% versus <1%,  $p<0.001$ ). Analysis of blood-draw method revealed that combination of IV catheter/Vacutainer had a large amount of hemolysis, 77% with 23% requiring test cancellation. In contrast, for the IV catheter/syringe combination, only 28% of samples were hemolyzed with 9% requiring test cancellation. This difference was significant at  $p=0.002$ .

For straight needle/Vacutainer combination, only 3% of samples were hemolyzed with no test cancellation. For straight needle/syringe combination only 9% were slightly hemolyzed. The authors concluded that combination of IV catheter and Vacutainer cause more hemolysis than using and IV catheter with a syringe.<sup>16, level II-3</sup>

**Table 2. Hemolysis levels by various factors**

Technique	Total n (%)	Samples with hemolysis (hemolysis levels 1-4) n (%)	Samples requiring test cancellation (hemolysis levels 3 and 4) n (%)
Venipuncture method			
Intravenous catheters			
Existing	82 (100)	20 (24)	8 (10)
New	255 (100)	126 (49)	50* (20)
Straight needles	117 (100)	4 (3)	1* (<1)
Intravenous catheter gauge			
14 and 16 gauge	4 (100)	2 (50)	0 (0)
18 gauge	139 (100)	65 (47)	28 (21)
20 gauge	116 (100)	59 (51)	22 (19)
Blood draw method			
New intravenous catheters			
With Vacutainer	195 (100)	151 (77)	44† (23)
With syringe	60 (100)	17 (28)	5† (9)
Straight needle			
With Vacutainer	105 (100)	3 (3)	0 (0)
With syringe	11 (100)	1 (9)	0 (0)

\*Difference between the new intravenous catheters and straight needles is significant at  $P < .001$ .

†Difference between the intravenous catheters/Vacutainers and catheters/syringes is significant at  $P = .02$ .

Ong et al. conducted a cross sectional study to determine which factors in blood sampling was associated with higher rates of hemolysis. Blood samples taken from patients presenting to the ED requiring blood urea and electrolyte analysis were included in this study. Questionnaires were distributed to the doctors and nurses conducting blood sampling to determine the method used and outcome data were collected after the samples were processed. Various factors, including method (IV cannulation or venepuncture), system (syringe or Vacutainer), operator, rate of blood flow, difficulty of cannulation/venepuncture and source of blood (arterial or venous), were analysed. A total of 227 blood samples and completed questionnaires were collected and included in analysis (Table 3), out of which 45 (19.8%) were hemolysed. The size of the needle, operator, and perceived rate of blood flow and difficulty of cannulation had poor associations with sample hemolysis rates ( $p > 0.05$ ). Both the use of Vacutainer and IV cannulation appeared to be associated with the highest rates of hemolysis [Odd ratio (OR): 4.5, 95% CI: 2.3, 9.0 and OR: 4.4, 95% CI: 1.5, 13.0] respectively. However, after adjustment with a logistic regression model with hemolysis as the outcome, the use of the Vacutainer was associated with significantly higher rates of hemolysis (adjusted OR: 6.0, 95% CI: 2.3, 15.1).<sup>17, level II-3</sup>

**Table 3. Various factors related to blood sampling and their association with hemolysis rates**

Characteristic	Option	Sample lysed (%)	OR (95%CI)
Method	Venepuncture	4 (6.8)	
	IV cannula	41 (24.4)	4.4 (1.5, 13.0)
System	ABG, Syringe	16 (11.0)	
	Vacutainer	29 (35.8)	4.5 (2.3, 9.0)
Size of needle	<=21G cannula	15 (17.4)	
	>21G cannula	30 (21.3)	1.3 (0.6, 2.5)
Operator	Registrar	2 (11.1)	
	Medical officer	22 (16.1)	1.5 (0.3, 7.1)
	Consultant	4 (22.2)	2.3 (0.4, 14.4)
	Student/Nurse	17 (31.5)	3.7 (0.8, 17.8)
Blood flow	Fast	14 (15.2)	
	Moderate	23 (22.5)	1.6 (0.8, 3.4)
	Slow	8 (24.2)	1.8 (0.7, 4.7)
Difficulty of venepuncture/ cannulation	Hard	4 (13.8)	
	Easy	27 (18.5)	1.6 (0.8, 3.4)
	Moderate	14 (26.9)	1.8 (0.7, 4.7)
Source	Arterial	1 (14.3)	
	Venous	44 (20.1)	1.5 (0.2, 12.9)

### 5.3. SAFETY

There was no retrievable evidence on the safety of needleless Vacutainer system for blood collection. The BD Vacutainer Systems had received 510(k) from US Food and Drug Administration.<sup>18</sup>

### 5.4. PSYCHOLOGICAL / SOCIAL / ETHICAL

Two studies reported the preference and compliance of Vacutainer system for blood collection.

Centers for Disease Control and Prevention (CDC) reported the preference of HCW on safety devices over conventional equipment. Among 1108 HCW, 1879 responses were related to one or more of the three safety devices. A higher proportion 822 (44%) responded yes, 435 (23%) responded unsure and 622 (33%) responded no.<sup>14, level II-2</sup>

Little et al. identified factors associated with use of Vacutainer and gloves while taking blood among staff in ED who routinely performed percutaneous venepuncture. During January 2006, a prospective survey was conducted to capture data on occupation, place of work, time since attaining professional qualification, frequency of performing percutaneous venepuncture, training received, preferred venepuncture technique, use of gloves when performing venepuncture, number of sharps injuries suffered and number of sharps injuries reported. Fifty-three responses were received, giving a response rate of 76%. Doctors comprised 64% (34/53) of the HCWs, the remainder being nurses and healthcare assistants, 36% (19/53). Most of the study group worked in the medicine department, 62.3% (33/53). Of those studied, 74% (39/53) had undergone formal venepuncture training. Vacutainer use was common in the study group, with 90.6% reporting at least some use (Table 4). Only 35.8%, however, reported using a Vacutainer all the time with 64.2% reporting needle and syringe use at least sometimes. The reason given for preference of a non-Vacutainer approach was usually that it was easier for patients with difficult venous access (n=12) or that the absence of a flashback made venepuncture more difficult (n=5). Other reasons given were that needle and syringe were less painful for the patient (n=2), they were easier to handle (n=2), there was a better selection of needle size (n=1) or they were simply out of habit (n=1). The use of Vacutainer was high among non-doctors (63% always use Vacutainer), whereas only 20% of doctors reported using Vacutainer all the time (p=0.001). Eighty-percent of doctors and 37% of nurses and healthcare assistants performing routine percutaneous venepuncture admitted to not exclusively using the BD Vacutainer system provided. Formal training increased the probability of always using a Vacutainer from 7% to 46%, and decreased the probability of never using one from 14% to 5%, (p<0.01). Doctors qualified less than three years were particularly likely to prefer needle and syringe. The use of Vacutainer have no effect on the reported sharp injuries rate (p=0.9).<sup>19, level II-3</sup>

**Table 4. Phlebotomy technique and glove use among respondents**

		Frequency	Percentage (%)
Phlebotomy technique	Always Vacutainer	19	35.8
	Mixed usage	29	54.8
	Always needle and syringe	5	9.4

## 5.5. COST / COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of needless Vacutainer system for blood collection. The price of BD Vacutainer SafetyLok

Blood Collection Set ranges between USD 2.22 to 2.44 per set (RM 9.04 to RM 9.94 per set).<sup>19</sup> The price of BD Vacutainer Luer-Lok access device is around USD 1.22 per piece (RM 4.97 per piece) and the price of BD Vacutainer® Blood Transfer Device is around USD 1.25 per piece (RM 5.09 per piece).<sup>11,20</sup>

A financial implication associated with the use of needleless vacutainer system for blood collection was estimated using internally acquired data. Based on the analysis, the needleless vacutainer system will require additional investment of approximately MYR 134 to MYR 282 million for its utilisation within the Ministry of Health. This estimation has taken into consideration the potential cost saving from avoiding 100% needles related sharps injury. High budget implication were possibly contributed by huge differences in the estimated unit price between conventional method for blood collection and needleless vacutainer systems with relatively low number of reported seroconversion among the healthcare workers.

## **5.6. ORGANIZATIONAL**

Education and training is necessary for all staff carrying out phlebotomy to prevent unnecessary risk of exposure to blood and to reduce adverse events for patients. Staff should receive training and demonstrate proficiency on the specific methods that they will use in blood drawing.<sup>4</sup> Healthcare worker noting technical difficulties or adverse patient effects when handling safety devices (5 to 44%).<sup>14</sup> Formal training in Vacutainer may increased Vacutainer used among HCW.<sup>19</sup> Safety devices are more expensive, so if resources are limited, their use may need to be restricted to procedures associated with the greatest rates or risk of sharps injury.<sup>4</sup>

## **5.7. LIMITATIONS**

This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English full text articles were included in this review.

# **6. CONCLUSION**

## **6.1. EFFECTIVENESS**

### **Needle stick injuries**

There was limited fair level of retrievable evidence to suggest that Vacutainer system were effective in preventing needle stick injuries among HCW. Combination of Vacutainer tube with safety devices significantly decreased needle stick injuries compared to conventional devices with reduction rates between 38.7% to 81%.

### **Sample Hemolysis**

The evidence on sample hemolysis is inconclusive whereby one RCT reported a lower hemolysis rate of blood samples drawn from Vacutainer venepuncture compared to IV catheter (via syringe). On the other hand, two cross sectional studies reported that blood hemolysis was found to be higher in samples drawn with a Vacutainer system compared to a syringe-needle transfer system (hemolysis rate with Vacutainer: 35.8% to 77.0%).

### **6.2. SAFETY**

There was no retrievable evidence on the safety of needleless Vacutainer system for blood collection. The BD Vacutainer Systems had received 510(k) from US Food and Drug Administration.

### **6.3. PSYCHOLOGICAL / SOCIAL / ETHICAL**

There was limited fair level of retrievable evidence on the preference and compliance of Vacutainer system among HCW. One study reported a slightly higher proportion of safety devices preference over conventional equipment while another study reported only 35.8% of HCW always used Vacutainer for blood sampling. Among the reasons cited for not using Vacutainer were difficult venous access and the absence of a flashback chamber.

### **6.4. ORGANIZATIONAL**

Healthcare workers who are using Vacutainer system need to be trained. Formal training in Vacutainer was shown to increase Vacutainer used among HCW.

### **6.5. COST / COST-EFFECTIVENESS**

The cost-effectiveness of needleless vacutainer system could not be determined. However, it is estimated that needleless vacutainer system will require additional investment of approximately MYR 134 to MYR 282 million for its utilisation within the MOH.

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## 8. APPENDIX

### 8.2. Appendix 1: LITERATURE SEARCH STRATEGY

**Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1946 to present**

1. health personnel/
2. field worker\*.tw.
3. (provider adj2 (health care or healthcare)).tw.
4. health personnel.tw.
5. nurses/
6. registered nurse\*.tw.
7. Vacutainer.tw.
8. blood specimen collection/
9. blood specimen collection.tw.
10. specimen handling/
11. (specimen adj1 (handling or collection)).tw.
12. phlebotomy/
13. phlebotom\*.tw.
14. venesection\*.tw.
15. blood draw device.tw.
16. blood collection system.tw.
17. blood transfer device.tw.
18. needleless.tw.
19. needle free.tw.
20. 1 or 2 or 3 or 4 or 5 or 6
21. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
22. 20 and 21

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	} Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
EBM Reviews - NHS Economic Evaluation Database	

## **PubMed**

("health personnel"[MeSH Terms] OR field worker[Title/Abstract]) OR healthcare provider[Title/Abstract]) OR "nurses"[MeSH Terms]) OR (registered nurse[Title/Abstract] OR registered nurseries[Title/Abstract] OR registered nurses[Title/Abstract])) AND (((((((Vacutainer[Title/Abstract] OR blood specimen collection[Title/Abstract]) OR specimen handling[Title/Abstract]) OR phlebotomy[Title/Abstract]) OR venesection[Title/Abstract]) OR (("blood specimen collection"[MeSH Terms] OR ("blood"[All Fields] AND "specimen"[All Fields] AND "collection"[All Fields]) OR "blood specimen collection"[All Fields] OR ("blood"[All Fields] AND "draw"[All Fields]) OR "blood draw"[All Fields]) AND device[Title/Abstract])) OR blood collection system[Title/Abstract]) OR (("blood"[Subheading] OR "blood"[All Fields] OR "blood"[MeSH Terms]) AND transfer device[Title/Abstract])) OR needleless[Title/Abstract]) OR needle free[Title/Abstract])

## **8.2. Appendix 2**

### **DESIGNATION OF LEVELS OF EVIDENCE**

- I Evidence obtained from at least one properly designed randomised controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

**SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)**

Evidence Table : Efficacy  
Question : Is Vacutainer effective for blood collection?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>1. Rogues AM, Verdun-Esquer C, Buisson-Valles I et al. Impact of safety devices for preventing percutaneous injuries related to phlebotomy procedures in health care workers. Am J Infect Control. 2004;32(8):441-444.</p> <p>France</p>	<p>Pre and post intervention study</p> <p>Objective: To assess the effectiveness of winged steel needles and vacuum-tube phlebotomy needle in preventing needles stick injuries to HCW.</p> <p>Method: Sharps injury data were collected over a 7-year period (1993-1999) in a 3600-bed tertiary care university hospital in France. Two protective devices for blood drawing were introduced throughout the hospital on June 1996. Nurses were trained on how to activate the safety mechanism following removal of the needle from the patient. Pre and post intervention rates were compared after the implementation of the safety devices for preventing percutaneous injuries related to phlebotomy procedure.</p>	II-2	n=4624 sharps injuries	<p>Vacutainer blood collecting tube with recapping sheath (SafetyLok, BD)</p> <p>Resheathable winged steel needles (SafetyLok, BD)</p>	Vacuum-tube blood collection with Vacutainer needle or with winged steel needle (conventional method)	-	<ul style="list-style-type: none"> <li>From 1993 to 1999, an overall decrease in the needlestick-related injuries was noted. Phlebotomy procedures accounted for 19.4% (n=897) of all needle-related injuries in the pre intervention period, and 12% in the post intervention period (RR: 0.62; 95% CI: 0.51,0.72; p&lt;0.001).</li> <li>Reported phlebotomy-related percutaneous injuries declined from 191 on pre intervention period to 117 for post intervention period for vacuum-tube blood collection needles (reduction of 38.7%), and from 53 to 10 for winged steel needles (reduction of 81%).</li> <li>There was an overall reduction of 48% in percutaneous injuries per 100,000 phlebotomies.</li> </ul> <p>Author's conclusion: The implementation of these safety devices apparently contributed to a significant decrease in the percutaneous injuries related to phlebotomy procedures, but they constitute only part of a strategy that includes education of health care workers and collection of appropriate data that allow analysis of residuals percutaneous injuries.</p>	Reduction in NSI

**Evidence Table : Efficacy**  
**Question : Is Vacutainer effective for blood collection?**

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>2. Centers for Disease Control and Prevention (CDC). Evaluation of safety devices for preventing percutaneous injuries among health-care workers during phlebotomy procedures-- Minneapolis-St. Paul, New York City, and San Francisco, 1993-1995. MMWR Morb Mortal Wkly Rep. 1997;46(2):21-25.</p> <p>United States</p>	<p>Pre and post intervention study</p> <p>Objective: To evaluate safety devices for phlebotomy.</p> <p>Method: The study was conducted in two phases during 1993 to 1995 at six university-affiliated hospitals in United States. The assessment compared three safety devices with conventional devices. Before introducing the safety devices, each hospital conducted a 'hands-on' training program for HCW. During phase I (nine to 12 months), hospital used conventional devices and conducted enhanced surveillance for injuries. A survey was distributed to HCW to estimate their rates of percutaneous injuries. During phase II (six to 15 months), conventional devices were replaced with safety devices and enhanced surveillance for injuries was conducted. A survey was repeated one to two months before the end of phase II, and the estimated percutaneous injuries for safety and conventional devices were compared.</p>	II-2	<p>Phase 1 n=1699 respondent</p> <p>Phase 2 n=1421 respondent</p>	<p>1. Resheathable winged steel needle (Safety-Lok,BD)</p> <p>2. Bluntable vacuum-tube blood collection needle activated in patients's vein (Punctur-Guard, Bio-plexus)</p> <p>3. Vacuum-tube blood collection needle with a hinged recapping sheath (Venipuncture Needle-Pro, Smith Industries)</p>	Conventional device	10-12 months	<ul style="list-style-type: none"> <li>• The overall response rate for each of the two surveys was approximately 75%.</li> <li>• Compared with conventional devices, percutaneous injuries rates were lower for safety devices (86 vs 41).</li> <li>• Of 41 of percutaneous injuries associated with safety devices, 34 (83%) involved winged steel needles and seven (17%) involved vacuum-tube blood-collection needles.</li> <li>• Twenty-five (61%) involved an injury before activation of the safety feature was appropriate or possible (e.g., within seconds after the device was removed from the vein); six (15%) occurred during activation of the safety feature (all with Safety-Lok). For eight (20%), the safety feature had not been activated, and for two (5%), the mechanism of injury was unknown.</li> <li>• There was a significant reduction in phlebotomy-related percutaneous injuries associated with use of each of the vacuum tube blood-collection devices and a reduction in percutaneous injuries associated with use of the winged steel needles.</li> </ul>	

**Evidence Table : Efficacy**  
**Question : Is Vacutainer effective for blood collection?**

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Kennedy C, Angermuller S, King R et al. A comparison of hemolysis rates using intravenous catheters versus venipuncture tubes for obtaining blood samples. J Emerg Nurs. 1996;22(6):566-569.  United States	<p>RCT</p> <p>Objective: To compare the rate of hemolysis in blood samples obtained by an IV catheter versus the rate in samples obtained by venipuncture (Vacutainer tubes and needles; BD Vacutainer Systems).</p> <p>Method: Patients who came to the emergency department and required both an IV infusion and blood sampling for determination of electrolyte levels and complete blood cell count (CBC) were randomly assigned to either group A or B. The blood samples for patients in the A group were obtained through the IV catheter at the time of insertion. The IV catheters ranged in size from 24 gauge to 14 gauge. Patients in the B group also had insertion of an IV line, but their blood samples were obtained by Vacutainer venipuncture at a separate site. The Vacutainer needle was standardized at 21 gauge. All blood samples were collected by experienced ED nurses.</p>	II-2	<p>n=165</p> <p>Group A : 87 Group B : 78</p>	Group A - Blood samples from IV catheter (via Syringe)	Group B- Blood samples from venepuncture site (via Vacutainer)		<ul style="list-style-type: none"> <li>• In group A, 12 of 87 (13.7%) blood samples hemolyzed. The electrolytes were hemolyzed in all 12. Three of these 12 samples also had a hemolyzed CBC.</li> <li>• In group B only 3 of 78 (3.8%) blood samples hemolyzed. Of these three, one CBC and all three electrolyte tests were hemolyzed.</li> <li>• Group A was found to have a statistically higher hemolysis rate than group B (<math>\chi^2=4.89</math>, <math>p=0.03</math>).</li> <li>• The rate of hemolysis declined with larger IV catheter diameter (the larger the catheter diameter the smaller the IV gauge number) (<math>R=+0.82</math>, <math>p=0.047</math>).</li> </ul> <p>Author's conclusion: Hemolysis of blood samples obtained by an IV catheter was significantly higher than when blood was obtained through Vacutainer venipuncture. There is an inverse correlation between IV catheter diameter and the rate of hemolysis.</p>	Lower hemolysis rate with Vacutainer venepuncture

**Evidence Table : Efficacy**  
**Question : Is Vacutainer effective for blood collection?**

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>4. Grant MS. The effect of blood drawing techniques and equipment on the hemolysis of ED laboratory blood samples. J Emerg Nurs. 2003;29(2):116-121.</p> <p>United States</p>	<p>Cross sectional study</p> <p>Objective: To identify venipuncture and blood draw factors associated with hemolysis of ED blood samples.</p> <p>Method: A convenience sample of ED blood samples was studied for degree of hemolysis and phlebotomy technique using data obtained from surveys completed by ED nurses and/or ED clinical technicians. The questionnaires were submitted with each blood sample sent to the laboratory for diagnostic testing. The questionnaire cover four areas: 1) the venepuncture technique (IV catheter or straight needle), 2) the blood-draw methods (Vacutainer or syringe), 3) the blood transfer method if drawn with a syringe (needle-to-tube or needleless connector-to-Vacutainer), and 4) the identity of phlebotomist and lab technician. The level of hemolysis per sample was designated by laboratory technicians. Completed questionnaires were gathered and analyzed. Chi-square analysis was used to determine significant relationships.</p>	II-3	n=598	<p>1. Venepuncture method – IV catheter</p> <p>2. Blood draw method – Vacutainer</p> <p>3. Blood transfer method-needle-to-tube</p> <p>4. Phlebotomist</p>	<p>1. Venepuncture method – Needle</p> <p>2. Blood draw method – Syringe</p> <p>3. Blood transfer method-needleless connector</p> <p>4. Lab technician</p>		<ul style="list-style-type: none"> <li>• 598 surveys were collected, and 76% (n = 454) were complete enough to be included in the analysis.</li> <li>• The predominant technique for drawing blood in new venipunctures (n = 372) was by IV catheters (69% [n = 255]), versus straight needles (31% [n = 117]). Thirty-two percent (n=144) of the samples had some degree of hemolysis; 13% (n=59) were so hemolyzed that tests were canceled by the laboratory.</li> <li>• Blood drawn through IV catheters resulted in significantly more hemolysis and test cancellation than that drawn with a straight needle (20% versus &lt;1%, significant at p &lt;0.001).</li> <li>• Analysis of blood-draw method revealed that combination of IV catheter/Vacutainer had a large amount of hemolysis, 77%(n=151) with 23%(n=44) requiring test cancellation. In contrast, for the IV catheter/syringe combination, only 28%(n=17) of samples were hemolyzed with 9%(n=5) requiring test cancellation. This difference was significant at p=0.002.</li> <li>• For straight needle/Vacutainer combination, only 3%(n=3) of sample were hemolyzed with no test cancellation. For straight needle/syringe combination only 9%(n=1) were slightly hemolyzed.</li> </ul>	Higher hemolysis rate with IV catheter+ Vacutainer

Evidence Table : Efficacy  
Question : Is Vacutainer effective for blood collection?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
							Author's conclusion: Drawing blood through intravenous catheters was associated with significantly more hemolysis than drawing blood with straight needles. Using a combination of intravenous catheter and Vacutainer caused more hemolysis than using an intravenous catheter with a syringe.	

**Evidence Table : Efficacy**  
**Question : Is Vacutainer effective for blood collection?**

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
5. Ong ME, Chan YH, Lim CS. Observational study to determine factors associated with blood sample haemolysis in the emergency department. Ann Acad Med Singapore. 2008;37(9):745-748.  Singapore	<p>Cross sectional study</p> <p>Objective: To determine which factors in blood sampling were associated with higher rates of haemolysis.</p> <p>Method: Blood samples taken from all patients presenting to the ED requiring blood urea and electrolyte analysis were included in this study. Questionnaires were distributed to the doctors and nurses conducting blood sampling to determine the method used and outcome data were collected after the samples were processed. Various factors, including method (IV cannulation or venepuncture), system (syringe or Vacutainer), operator, rate of blood flow, difficulty of cannulation/venepuncture and source of blood (arterial or venous), were analysed.</p>	II-3	n=227	IV cannulation, Vacutainer	Venepuncture, Syringe		<ul style="list-style-type: none"> <li>• A total of 227 blood samples and completed questionnaires were collected and included in analysis, out of which 45 (19.8%) were haemolysed.</li> <li>• The size of the needle, operator, and perceived rate of blood flow and difficulty of cannulation had poor associations with sample haemolysis rates (<math>p&gt;0.05</math>).</li> <li>• Both the use of Vacutainer and IV cannulation appeared to be associated with the highest rates of haemolysis [Odd ratio (OR): 4.5, 95% CI: 2.3, 9.0 and OR: 4.4, 95% CI: 1.5,13.0] respectively. However, after adjustment with a logistic regression model with haemolysis as the outcome, the use of the Vacutainer was associated with significantly higher rates of haemolysis (adjusted OR: 6.0, 95% CI: 2.3, 15.1).</li> </ul> <p>Author's conclusion: Blood sampling with the Vacutainer system increased rates of haemolysis. This could potentially change attitudes towards equipment used for blood sampling in the ED.</p>	Higher hemolysis rate with IV catheter and Vacutainer

Evidence Table : Psychological/Social  
Question : Is Vacutainer a preferred device for blood collection?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size														
6. Little MA, Hussein T, Lambert M. Percutaneous venepuncture practice in a large urban teaching hospital. Clin Med (Lond). 2007;7(3):243-249.  London	<p>Cross sectional study</p> <p>Objective: To identify factors associated with use of an evacuated blood collection system (BD Vacutainer) and gloves while taking blood.</p> <p>Method: During January 2006, staff in the accident &amp; emergency (A&amp;E) department and acute admission unit who routinely performed percutaneous venepuncture was observed. A prospective survey was conducted among the HCWs to study the use of BD Vacutainer and gloves during clinical practice. A questionnaire was developed to capture data on occupation, place of work, time since attaining professional qualification, frequency of performing percutaneous venepuncture, training received, preferred venepuncture technique, use of gloves when performing venepuncture, number of sharps injuries (SIs) suffered and number of SIs reported.</p>	II-3	n=53	BD Vacutainer	-	-	<ul style="list-style-type: none"><li>Fifty-three responses were received, giving a response rate of 76%.</li><li>Doctors comprised 64% (34/53) of the HCWs, the remainder being nurses and healthcare assistants, 32% (19/53). Most of the study group worked in the medicine department, 62.3% (33/53). Of those studied, 74% (39/53) had undergone formal venepuncture training.</li></ul> <p>Table 1. Phlebotomy technique and glove use among respondents</p> <table><tr><th></th><th></th><th>Frequency</th><th>Percentage (%)</th></tr><tr><td rowspan="3">Phlebotomy technique</td><td>Always Vacutainer</td><td>19</td><td>35.8</td></tr><tr><td>Mixed usage</td><td>29</td><td>54.8</td></tr><tr><td>Always needle and syringe</td><td>5</td><td>9.4</td></tr></table> <ul style="list-style-type: none"><li>BD Vacutainer use was common in the study group, with 90.6% reporting at least some use (Table 1). Only 35.8%, however, reported using a Vacutainer all the time with 64.2% reporting needle and syringe use at least sometimes. The reason given for preference of a non-Vacutainer approach was usually that it was easier for patients with difficult venous access (n=12) or that the absence of a flashback made venepuncture more difficult (n=5).</li><li>The use of Vacutainer was high among non-doctors (63% always use Vacutainer), whereas only 20% of doctors reported using Vacutainer all</li></ul>			Frequency	Percentage (%)	Phlebotomy technique	Always Vacutainer	19	35.8	Mixed usage	29	54.8	Always needle and syringe	5	9.4
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Evidence Table : Psychological/Social  
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							<p>the time (<math>p=0.001</math>). 80% of doctors and 37% of nurses and healthcare assistants performing routine percutaneous venepuncture admitted to not exclusively using the BD Vacutainer system provided.</p> <ul style="list-style-type: none"> <li>• Formal training increased the probability of always using a Vacutainer from 7% to 46%, and decreased the probability of never using one from 14% to 5%, (<math>p&lt;0.01</math>).</li> <li>• Doctors qualified less than three years were particularly likely to prefer needle and syringe.</li> <li>• The use of Vacutainer have no effect on the reported SI rate (<math>p=0.9</math>).</li> </ul> <p>Author's conclusion:            This study suggests that HCWs may not always perform their duties in the safest manner possible. There is considerable room for improvement in phlebotomy technique, particularly among junior doctors. Formal training in percutaneous venepuncture results in higher uptake of the evacuation blood collection system and therefore safest practice.</p>