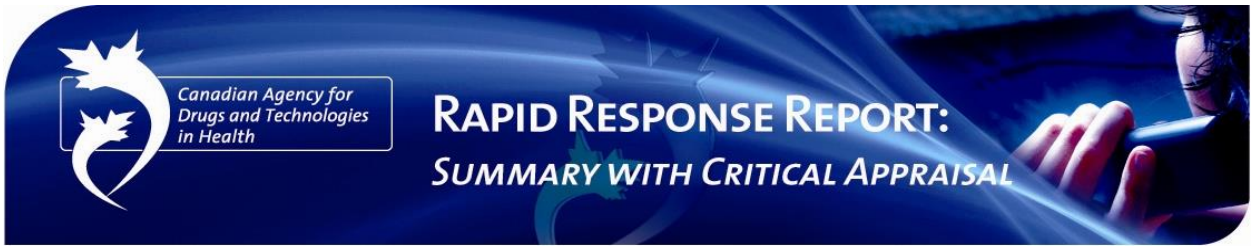

TITLE: Vein Illumination Devices for Vascular Access: A Review of Clinical Effectiveness

DATE: 29 November 2016

CONTEXT AND POLICY ISSUES

Efficient vascular access is an essential treatment procedure in many acute care situations. When this high-priority procedure is prolonged or repeated vascular access attempts are required, patients experience treatment delays in addition to the associated additional pain and trauma with repeated attempts.[1] Repeated attempts may also increase the incidence of complications including arterial occlusion, haematoma, thrombosis, ischaemic damage, or nerve injury.[2]

The standard of care procedure for vascular access is initiated with localization of a suitable vein by visual inspection and palpation.[3] Pediatric patients with smaller veins and increased subcutaneous fat are more likely to present with difficult vascular access. Veins that are not palpable or visible are also predictive factors for difficult vascular access.[4]

To aid in vein visualization, vascular transillumination devices that use near infrared light to produce a 2D image of blood filled structures superimposed upon the skin are available.[4] These devices use infrared light that is not ionizing, can penetrate several centimeters of skin, and can be made portable and lightweight.[4-6] The purpose of these devices is to assist the operator with accurate needle placement thereby decreasing the number of repeated attempts and the time required for vascular access.[6] However, the benefit of these devices remains unclear.

The purpose of this report is to retrieve and the review the existing evidence on the efficacy of vascular transillumination devices for pediatric patients in acute care settings.

RESEARCH QUESTION

What is the clinical effectiveness of vein illumination devices for vascular access procedures for pediatric patients in acute care settings?

KEY FINDINGS

A total of seven randomized controlled trials and three non-randomized studies were identified examining vascular transillumination devices for vascular access in acute care pediatric populations. One unblinded randomized controlled trial without additional significant quality limitations reported evidence of superior clinical efficacy of the Vein Viewer over standard of care for premature infants requiring a peripherally inserted central catheter only when results were adjusted for gestational age. Specific patient gestational ages that may benefit from this device were not established. Additional evidence on mixed pediatric populations was identified in six RCTs and did not support superior clinical efficacy of vascular transillumination devices for vascular access over standard of care. Subgroup analysis in two RCTs reported limited evidence that these devices may have a role for yet undefined patient groups. Results of the three included non-randomized studies were mixed. One study observed a statistically significant improvement in first attempt success with a prototype near infrared imaging device. This study was followed up with a study conducted at the same center on a younger pediatric population which found no statistically significant differences with a similar device. The most recent and largest non-randomized study found standard of care to have statistically significant superiority to the AccuVein Vein Viewer in median time to cannulation, median number of attempts, and first attempt success in patients under 17 years and patients under 72 months.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including Embase, Medline, PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit retrieval by study type for questions 1, 2 and 3. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses and guidelines for questions 4 and 5. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011 and September 29, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citation abstracts and selected studies. Titles and abstracts were reviewed and relevant articles were included in a Rapid Response Summary of Abstracts.[7] The full-text of these articles were retrieved and assessed for inclusion by a second reviewer. A final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Pediatric patients including neonates
Intervention	Vein illumination devices (e.g., vascular access imaging devices such as AccuVein AV400, Vein Viewer, Translite [VeinLite LED], TransLite LLC [VeinLite EMS Pro], Christie [also called Vein Viewer Vision])

Table 1: Selection Criteria	
Comparator	Standard clinical practice, including other vascular access imaging devices (e.g., ultrasound, infrared)
Outcomes	Clinical effectiveness (e.g., harms, benefits, safety, patient and health care practitioner characteristics influencing clinical effectiveness)
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and non-randomized studies

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2011.

Critical Appraisal of Individual Studies

The included randomized studies and non-randomized clinical studies were critically appraised using the Downs and Black Checklist.[8] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

SUMMARY OF EVIDENCE

Details of study characteristics, critical appraisal, and study findings are located in Appendices 2, 3, and 4, respectively.

Quantity of Research Available

A total of 534 citations were identified in the literature search. Following screening of titles and abstracts, 522 citations were excluded and 12 potentially relevant reports from the electronic search were retrieved for full-text review. One relevant publication was retrieved from the grey literature search. Appendix 1 describes the PRISMA flowchart of the study selection.

For the previous Summary of Abstracts,[7] one systematic review with meta-analysis,[9] eight randomized controlled trials,[3,5,6,10-14] and three non-randomized studies,[1,2,15] were identified regarding vascular transillumination devices for vascular access procedures for neonates or adults in acute care settings or in the emergency department. In addition, one evidence-based guideline was identified regarding the use of vascular access imaging devices for patients.[4] No health technology assessments or economic evaluations were identified.

For this summary with critical appraisal three reports were excluded.[4,9,14] Two examined adult populations,[9,14] and one article was a guideline document.[4] Seven randomized controlled trials,[3,5,6,10-13] and three non-randomized studies,[1,2,15] are included in this report.

Summary of Study Characteristics

Study Design

Randomized controlled trials (RCTs)

Seven RCTs met the selection criteria presented in Table 1. Three RCTs were designed as cluster randomized controlled trials.[10-12] This type of design simplified the randomized allocation of the device to operating rooms within the study center. In two of the clustered RCTs the presence of the device in the operating room also determined the device operator(s) for a defined period, either weekly,[10] or daily.[11] Controls were patients where IV cannulation took place in an operating room where the device was not available. The other clustered RCT had one OR and the randomized weekly presence or absence of the device defined the intervention and control groups, respectively.[12] One RCT was a four-arm study,[10] while the others only examined one imaging device and a control.[3,5,6,10,12,13] Two studies were published in 2011,[6,13] two in 2012,[3,5] and three were published in 2013.[10-12]

Non-randomized studies (NRSs)

Three NRSs met the selection criteria presented in Table 1.[1,2,15] One was a retrospective analysis of consecutive patients,[1] while the other two studies were conducted prospectively on consecutive patients.[2,15] In these studies patients were allocated to intervention or control based upon two timeframes, one that used the intervention and one that did not.[1,2,15] All studies were two armed studies, one was published in 2015,[1] one in 2012,[2] and one in 2011.[15]

Country of Origin

RCTs

Four included RCTs were conducted in the US,[3,5,6,13] while three were conducted in the Netherlands.[10-12] The studies from the Netherlands were conducted at, or in collaboration with the University Medical Center, Utrecht, the Netherlands, were all cluster RCTs, and all have at least one common author. The University Medical Centre in Utrecht has filed a patent for the VascuLuminator and the common author is listed as a co-inventor.[10-12] The remaining RCTs conducted in the US do not list common authors or institutions.[3,5,6,13] One RCT from the US also lists collaborators in Beirut and Australia.[5]

NRSs

Two NRSs were conducted in the Netherlands, published in 2011,[15] and 2012,[2] and one was conducted in Germany, published in 2015.[1] The studies from the Netherlands were both conducted at the University Medical Centre in Utrecht which has filed a patent for the VascuLuminator and the first author of both studies is listed as a co-inventor of this device.[2,15]

No included studies were conducted in a Canadian healthcare setting.

Patient Population

RCTs

One RCT examined a population of 120 neonates, 43 of which were at least 1500g and 77 of which were less than 1500g. These enrolled preterm and term neonates were chosen for PICC placement in a level 3 neonatal intensive care facility.[3] Four RCTs examined a mixed pediatric population that included neonates who underwent scheduled surgical interventions in an operating room at a children's,[5,10,11] or general hospital.[12] Two RCTs examined a mixed pediatric population that included neonates who required IV access in the emergency department (ED).[6,13] Inclusion criteria for two of these RCTs were ages 0 to 18 years,[10,11] one included patients aged 0 to 15 years,[12] one included patients aged 0 to 17 years,[13] one included patients less than 20 years old,[6] while one reported an enrolled patient age range of 0.18 to 17.1 years in the study.[5] The largest RCT randomized 1913 patients,[11] followed by 770 randomized patients,[10] 336 randomized patients,[13] 148 randomized patients,[5] 127 randomized patients,[6] and 88 randomized patients,[12] for the smaller included RCTs that examined a mixed pediatric population. One of the studies aimed to evaluate device efficacy in a population with dark skin colour (Fitzpatrick skin colour scale types 5 and 6) and was conducted on the Dutch island of Curacao in the Caribbean.[12] Subgroup analyses were presented in five studies,[5,6,10,11,13] and included patients under three years,[10,11] under two years,[5,13] patients at least two years old,[5] patients less than 17 years,[13] patients between 8 and 17 years,[13] patients with a BMI over the 85th percentile,[10,11] difficult IV access score greater than three,[11] estimated as easy cannulation,[5] estimated as difficult cannulation,[5] dark skin colour (Fitzpatrick scale types 5 & 6),[11] medium or dark skin (undefined),[5] light skin (undefined),[5] profession of device operator,[11] and awake patients.[11] One study provided an extensive analysis of patient subgroups based on age, weight, ethnicity, chronic disease status, the reason for IV access requirement, the use or non-use of topical anesthetic, and the experience of the performer of the device.[6] Exclusion criteria were already a cannula in situ,[10-12] cancelled surgery,[10,11] did not require cannula,[12] cannula gauge other than 22 required,[5] non-English speaking guardians,[13] need for emergent PIV,[13] need for immediate resuscitation,[6] and the presence of malformation or infection at potential insertion site.[5]

NRSs

The three included NRSs examined mixed pediatric populations.[1,2,15] The most recent NRS examined patients 17 years old and younger requiring IV cannulation prior to surgical interventions.[16] In 2012, Cuper et al., examined a mixed pediatric population of three years and younger that required arterial cannulation prior to cardiothoracic surgery,[2] and in 2011, Cuper et al., examined a population six years old and younger that required IV access for blood withdrawal.[15] One study provided an exclusion criteria for patients that already had a cannula in situ, or for patients that had a cannula placed directly in the femoral artery for a clinical reason.[2] No population subgroup analyses were described in the NRSs included in this report.

Interventions and Comparators

RCTs

The RCTs included in this report evaluated three vascular transillumination devices; VeinViewer,[3,6,11,13] VascuLuminator,[10-12] and AccuVein AV300,[5,11] although it is not clear if similarly named devices were identical. One four-armed RCT examined all three of these

devices compared to standard of care,[11] while the other six RCTs compared the use of one device to standard of care.[3,5,6,10,12,13] All RCTs provided a similar brief description of the investigated device and its use, as well as the training provided to the operators during the study. Three RCTs provided equipment supplier information on the VascuLuminator as De Koningh Medical Systems, Arnhem, NL.[10-12] One RCT refers to the VeinViewer as the VeinViewer Vision,[11] one as the Vein Viewer,[3] and two as the VeinViewer.[6,13] Three RCTs listed this device as available from Christie Medical Corporation, Memphis, TN,[3,11,13] and one lists the device supplier as Luminetx Corporation, Memphis TN.[6] One RCT examined the AccuVein AV300 and listed the supplier as AccuVein LLC,[5] and one as Avant Medical,[11] both were reported to be located in Cold Spring Harbor, NT, USA.

NRSs

The most recent NRS compared the efficacy of the AccuVein AV300 (AccuVein LLC, 40 Goose hill Rd, Cold Spring Harbor, NY) to standard of care.[1] The two NRSs, Cuper et al., 2011 and Cuper et al., 2012, examined an unbranded NIR vascular imaging system compared to standard of care.[2,15] However Cuper et al., 2012 stated that the University Medical Centre of Utrecht had filed a patent for the VascuLuminator and that two of the authors were listed as co-inventors.[2] In Cuper et al., 2011 the NIR imaging system was referred to as a prototype device.[15]

Outcomes

RCTs

One RCT examined the successful PICC placement and reported the radiographically confirmed success rate on the first session which included a maximum of four attempts. This RCT also reported the success rate within three sessions and the factors that were associated with successful PICC placement.[3] Five RCTs reported the frequency of success on first attempt for venous access.[5,6,10-12] Four RCTs reported the time required to achieve venous access.[5,10,12,13] Other reported outcomes included the number of attempts required,[13] pain scores on a visual analogue scale (VAS),[13] the perceived usefulness of the device,[11,12] whether a suitable vein was visible with the device,[11] and the success of the procedure over time to assess any effect of experience with the device.[12] None of the RCTs reported any data or methods for data collection on adverse event occurrence.[3,5,6,10-13]

NRSs

Three NRSs reported the frequency of success on the first venous access attempt,[1,2,15] two also reported the time to success and the number of attempts before successful venous access.[1,2] Additionally one NRS reported the time to first flashback of blood,[2] and one reported the time of needle manipulation before venous access.[15] None of the NRSs reported any data or methods for data collection on adverse event occurrence.[1,2,15]

Summary of Critical Appraisal

RCTs

All of the included evidence in this report from RCTs were limited by a lack of blinding in single center trials that did not mention adverse events.[3,5,6,10-13] Additionally, only one RCT provided information on allocation concealment.[3] While all of the included RCTs included some information on patient recruitment and enrollment, two did not include a flow chart of this information.[5,6] Patient characteristics were tabulated in all of the RCTs and a lack of statistically significant differences in these characteristics was reported in two RCTs.[5,13] All of the included RCTs reported statistical methodology, a brief description of randomization, clear patient eligibility criteria, consistent intervention within groups, a discussion on the study's limitations, and clearly defined outcomes.[3,5,6,10-13] Intention-to-treat (ITT) methodology was mentioned in two RCTs.[3,6] One had patients lost prior to randomization and were not included in analysis while one had patients dropout of the study and it is unclear how this data was handled. Two RCTs had considerable (more than 15%) missing and/or excluded data, with similar losses to follow-up between groups and did not include ITT analysis.[10,11] All RCTs provided an a priori statistical power calculation to determine the required sample size for analyses that included the whole population.[3,5,6,10-13] Five RCTs reported subgroup analyses that were therefore statistically under-powered. Additionally, none of these five RCTs reported accounting for multiple comparisons in the a priori statistical power calculation thereby increasing the probability of a spurious finding.[5,6,10,11,13] Three RCTs were cluster RCTs,[10-12] and one of these reported accounting for this study design in the statistical methods including the a priori statistical power calculation.[10] All RCTs provided a COI statement, with five RCTs that reported a potential COI,[6,10-13] and two that reported no COIs.[3,5] Three studies with potential conflicts were the result of patents on the VascuLuminator held by the study center and one study author being listed as a co-inventor of this device.[10-12] Two studies that examined the VeinViewer also reported a potential COI.[6,13] One received an unrestricted gift,[6] while one study was supplied the device in addition to funding for an independent statistical analysis.[13]

NRSs

In addition to the limitations inherent in non-randomized studies, the NRSs were single center studies that did not include mention of adverse events.[1,2,15] One NRS was a retrospective analysis,[1] while the other two studies were non-randomized prospective studies.[2,15] The three NRSs provided tabulated patient characteristics and two of these reported statistically significant differences between groups in these characteristics.[1,15] One NRS did not have any information on the training or experience of the device operator.[15] All three NRSs reported the statistical methodology used, patient eligibility, a consistent intervention between groups, defined reported outcomes, and provided discussion on the study's limitations.[1,2,15] Both NRSs from Cuper et al. reported a potential COI.[2,15]

Summary of Findings

What is the clinical effectiveness of vein illumination devices for vascular access procedures for pediatric patients in acute care settings?

RCTs

One RCT was focused on placement of PICCs in a neonate-specific population and found a trend towards more successful PICC placement when the Vein Viewer was used, however this finding was not statistically significant.[3] This RCT identified gestational age as a statistically significant factor in the overall success rate of PICC placement with or without use of the Vein Viewer.[3] Regression analysis that accounted for the gestational age of all patients and all PICC placement attempts found that the Vein Viewer improved overall successful PICC placement. The authors of this study suggest that the Vein Viewer may provide additional benefits in more mature infants where visualization of vessels is often more challenging.[3] The authors therefore also suggest that future studies should focus on a more mature infant population where the Vein Viewer may demonstrate a significant advantage.

The remaining six RCTs examined a mixed pediatric population perioperatively or in the ED.[5,6,10-13] Five of these RCTs reported an outcome of venous access success on first attempt and none identified a statistically significant advantage of a vascular imaging device for the included patient population.[5,6,10-12] No difference in the time required to achieve venous access was reported in the four RCTs that reported this outcome.[5,10,12,13] No advantage in the number of venous access attempts, or VAS pain scores was identified for the included patient population in the one RCT that reported these outcomes.[13] Van der Woude et al. reported no change in first attempt success over time and also found that 32/43 operators found the VascuLuminator as at least partly helpful.[12] The one RCT that compared devices found the VeinViewer Vision and AccuVein AV300 devices visualized the vein of first choice more frequently and were rated as valuable by operators more frequently than the VascuLuminator. These findings did not translate into any significant clinical efficacy outcome improvements over standard of care for these three devices.[11] Subgroup analyses of included patient populations did not identify any statistically significant advantage of vascular imaging devices for patients under three years,[10-12] patient age categories,[6] patient weight categories,[6] patient ethnicity,[6] chronic disease status,[6] purpose of IV access,[6] use of topical anesthetic,[6] nurse experience,[6] patients with a BMI over the 85th percentile,[10,11] Fitzpatrick skin grade 5 & 6,[11,12] awake patients,[11] when the operator was a trainee,[11] or for patients with a difficult IV access score of over 3,[11] for outcomes of venous access success on first attempt. One RCT, Van der Woude et al., found a statistically significant increase in successful first attempt for venous access in patients with an anticipated venous access difficulty of hard or very hard when the VascuLuminator was used.[12] Subgroup analyses of included patient populations did not identify a statistically significant decrease in the time required for vascular access for patients under three years,[10,12] patients with a BMI over the 85th percentile,[10] or with an anticipated venous access difficulty of hard or very hard.[12] One RCT, identified a statistically significant decrease in the mean time to place PIV, and in nurse assessments of pain for patients under two years old when the VeinViewer was used.[13] Pain assessment outcomes by parents and nurses were not different when the VeinViewer was used, as compared to standard of care, for other analyzed patient age subgroups including patients under two years as assessed by parents.[13]

NRSs

The NRSs included in this report did not identify any consensus of statistically significant advantages of vascular imaging devices for vascular access in the mixed pediatric populations examined.[1,2,15] Standard of care demonstrated superior time to vascular access as compared to the AccuVein AV300 in all included patients, and patients less than 72 old in one study.[1] This study also demonstrated advantages of standard of care in outcomes of number of vascular

access attempts, and the rate of success for first attempt for vascular access. These advantages were statistically significant for both all included patients and patients less than 72 months old.[1] In 2011, Cuper et al., found a greater success in vascular access upon first attempt using a NIR imaging device as compared to standard of care.[15] In 2012, Cuper et al. did not find any statistically significant advantage to a NIR imaging device and suggested that vessel localization may not be a limiting factor in the time required and success rate of arterial cannulation in small children.[2]

Limitations

The ten included studies were limited by the inability to blind the intervention to the operator and increased the likelihood of operator bias. While vascular transillumination devices may not present significant probability of adverse event occurrence on their own it is possible that adverse events due to operator use of the device are of interest. No included studies reported methodology for adverse event observation that may have been relevant to the use of these devices.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

The evidence identified and included in this report that addressed the question of vascular imaging device clinical efficacy consisted of seven adequately powered, unblinded RCTs and three unblinded NRSs.[1-3,5,6,10-13,15] One well-conducted RCT examined a neonate-specific population with an average gestational age of 28 weeks. This RCT identified increased gestational age as a significant factor in vascular access success for both groups. When findings accounted for gestational age for all attempts an improvement in overall vascular access success was identified when the Vein Viewer was used over standard of care, though this difference was not observed for unadjusted findings.[3] The remainder of identified RCT evidence on vascular imaging devices was on mixed pediatric populations for which no consistent evidence supported improvements in objective clinical efficacy outcomes such as venous access success on first attempt and time required to achieve venous access. Most specific patient subgroup analyses including patients under three years,[10-12] patient age category,[6] and patient skin type[11,12] did not reveal any statistically significant differences in these objective measures of clinical efficacy. While one cluster RCT identified a statistically significant increase in successful first attempts for venous access in patients with anticipated difficult venous access when the VascuLuminator was used,[12] another larger cluster RCT found that patients predicted to have difficult venous access did not have a greater rate of successful venous access on first attempt when the VascuLuminator was used as compared to standard of care, AccuVein AV300 or VeinViewer Vision, and none of these devices were superior to the standard of care.[11] A subgroup analysis in one other RCT revealed a significant decrease in the average time to achieve venous access in patients under two years when the VeinViewer was used.[13] Two RCTs reported a lack of statistical power for the subgroup analyses conducted which may have resulted in a type II error.[5,6] Evidence from two NRSs identified in this report examined similar mixed pediatric populations, had more quality limitations than the RCT evidence, and reported no consistent evidence to support the superiority of vascular imaging devices over standard of care for objective clinical efficacy outcomes.[1,2] Rothbart et al.'s adequately powered retrospective study published in 2015 reported evidence for the superiority of standard of care over the AccuVein AV300 in all included patients and a subgroup analysis of patients under 72 months.[1] A NIR imaging device demonstrated greater successful vascular access upon first attempt than standard of care that reached statistical significance in one NRS.[15] As suggested by the authors of four RCTs future research may identify a role for these

devices in particular patient populations.[3,6,10,12] The evidence identified and included in this report however does not support superior clinical efficacy of VascuLuminator, AccuVein AV300, or VeinViewer over standard of care in general pediatric populations in acute care settings.

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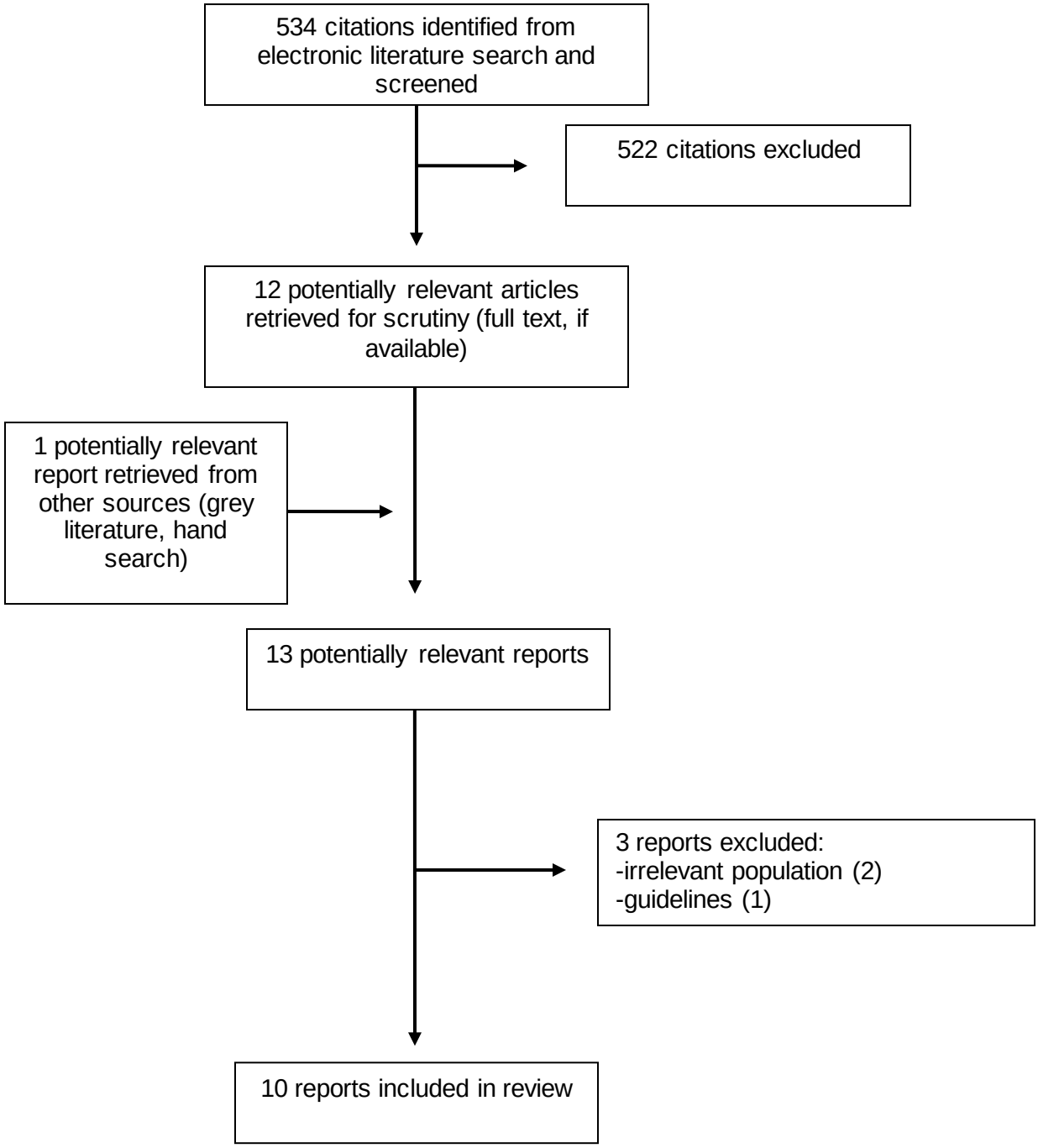
APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A2.1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
Randomized Controlled Trials				
Neonate-Specific Population				
Phipps et al., 2012[3] USA	120 premature neonates: 77 < 1500g, and 43 ≥ 1500g Average gestational age 28.0 weeks Exclusions: change in medical plan	Vein Viewer for PICC placement (n = 59)	Standard of care (n = 56)	• Successful placement with radiographic confirmation on first session (≤ 4 attempts) • Successful placement with radiographic confirmation within three sessions • Factors associated with successful placement
Mixed Pediatric Population (Includes Neonates)				
Cuper et al., 2013[10] Netherlands	Mixed pediatric population (0 – 18 years) receiving IV cannulation in a children's hospital OR (n = 770 randomized) Exclusions: already a cannula in situ, cancelled surgery Subgroup analysis of patients • < 3 years • BMI ≥ 85th percentile	VascuLuminator (De Koningh Medical Systems, Arnhem, NL) a NIR vascular imaging system (n = 248)	Standard of care (n = 246)	• Successful line placement on first attempt • Time to successful cannulation
de Graaf et al., 2013[11] Netherlands	Mixed pediatric population (0 – 18 years) receiving IV cannulation in a children's hospital OR for elective surgery (n = 1913 randomized) Exclusions: already a cannula in situ, cancelled surgery Subgroup analysis of patients • < 3 years • BMI ≥ 85th percentile	• VeinViewer® Vision (n = 357) • AccuVein® AV300 (n = 292) • VascuLuminator® (n = 290)	Standard of care (n = 444)	• Successful line placement on first attempt • Perceived device usefulness

Table A2.1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
	• Difficult IV access score >3 • Predicted difficult (score >3) • Dark skin (Fitzpatrick grad 5 & 6) • Performer (trainees, residents) • Device rated valuable • Suitable vein not visible without device • Awake patient			
Van der Woude et al., 2013[12] Netherlands	Mixed pediatric population (0 – 15 years) receiving IV cannulation in a general hospital OR (n = 88 randomized) in Curacao where 85% of the population has dark skin (Fitzpatrick skin colour scale type 5 and 6) Exclusions: already a cannula in situ, did not require IV cannula	VascuLuminator (n = 43)	Standard of care (n = 45)	• Successful line placement on first attempt • Time to successful cannulation • Perceived device usefulness • Success of procedure over time
Kaddoum et al., 2012[5] USA	Mixed pediatric population (0.18 – 17.1 years) receiving IV cannulation in a children's hospital OR (n = 148 randomized) ASA physical I, II, or III; scheduled elective surgery, examination or diagnostic imaging under anesthesia, already a cannula in situ Exclusions: cannula gauge other than 22 required, malformation or infection at potential insertion site Subgroup analysis of patients • ≥ 2 years • < 2 years • Difficulty of cannulation	AccuVein AV300 (AccuVein LLC, Cold Spring Harbor, NT, USA) (n = 72)	Standard of care (n = 74)	• Successful line placement on first attempt • Time to successful cannulation

Table A2.1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
	'Easy' • Difficulty of cannulation 'Difficult' • Light skin (undefined) • Medium or dark skin (undefined)			
Pediatric Population in ED				
Chapman et al., 2011[13] USA	Mixed pediatric population (0 – 17 years) receiving non-emergent PIVC in a tertiary care pediatric ED (n = 336 randomized) Exclusions: non-English-speaking patients or guardians, need for emergent PIV Subgroup analysis of patients for pain outcome • < 17 years • < 2 years • 8 – 17 years	VeinViewer (Christie Medical, Cypress, CA) (n = 160)	Standard of care (n = 163)	• Time to successful cannulation • Number of cannulation attempts • Pain scores (VAS)
Perry et al., 2011[6] USA	Mixed pediatric population (<20 years) requiring IV access in ED (n = 127 randomized) Inclusion: previously healthy or with chronic medical conditions Exclusions: need for immediate resuscitation Subgroup analysis of • Patient age ranges • Patient weight ranges • Patient ethnicity • Presence or absence of chronic disease patients • Purpose of IV access requirement • Use of topical anesthetic • Experience of performer	VeinViewer (Luminetx Corporation, Memphis, Tenn) (n = 61)	Standard of care (n = 61)	• Successful line placement on first attempt
Non-Randomized Studies				
Mixed Pediatric Population (Includes Neonates)				
Rothbart et al., 2015[1] Germany	Mixed pediatric population (0 – 17 years) receiving IV cannulation prior to surgical interventions	AccuVein® AV300 (AccuVein® LLC, 40 Goose hill Rd, Cold Spring Harbor, NY) (n = 114)	Standard of care (n = 124)	• Time to successful cannulation • Number of cannulation

Table A2.1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
				attempts • Successful line placement on first attempt
Cuper et al., 2012[2] Netherlands	Mixed pediatric population (0 – 3 years) requiring arterial cannulation prior to cardiothoracic surgery Exclusions: already a cannula in situ, cannula placed directly in femoral artery for a clinical reason	NIR vascular imaging system (n = 39) (VascuLuminator)	Standard of care (n = 38)	• Time to successful cannulation • Time to first flashback of blood • Successful line placement on first attempt • Number of cannulation attempts
Cuper et al., 2011[15] Netherlands	Mixed pediatric population (0 – 6 years) receiving venipuncture for blood withdrawal	NIR vascular imaging system (n = 45)	Standard of care (n = 80)	• Successful line placement on first attempt • Time of needle manipulation

ED = emergency department; IV = intravenous; NIR = near-infrared; OR = operating room; PICC = peripherally inserted central catheters; PIVC = peripheral intravenous catheter; RCT = randomized controlled trial; VAS = visual analogue scale

APPENDIX 3: Critical Appraisal of Included Publications

Table A3.1: Strengths and Limitations of Randomized Controlled Trials using Downs and Black checklist[8]

Strengths	Limitations
Neonate-Specific Population	
Phipps et al., 2012[3]	
• CONSORT diagram for patient recruitment/enrollment • Patient characteristics tabulated • Allocation concealment methodology described • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes – one outcome assessment was blinded • Statistical power determined a priori • Provided ITT analysis • Mention of equipment training level • Discussion on study limitations • Statement of no potential COIs	• Single center study • Not possible to blind • No mention of adverse events
Mixed Pediatric Population (Includes Neonates)	
Cuper et al., 2013[10]	
• CONSORT diagram for patient recruitment/enrollment • Patient characteristics tabulated • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Statistical power determined a priori – accounted for cluster randomization and used prior findings • Mention of equipment training level • Discussion of limitations • COI statement	• Single center study • Cluster RCT (by daily OR) • Allocation concealment methodology not described • Not possible to blind • Considerable amount of missing/excluded data • No ITT analysis • No mention of adverse events • Potential COI • Significant difference between patient groups in performer of cannulation (nurse anesthetist vs anesthesiologist)
de Graaf et al., 2013[11]	
• Compared NIR systems • CONSORT diagram for patient recruitment/enrollment • Patient characteristics tabulated • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Examination of confounding (performer of	• Single center study • Cluster RCT (by daily OR) • Patient characteristics not evaluated for significant differences • Allocation concealment methodology not described • Not possible to blind • Considerable amount of missing/excluded data • No ITT analysis • No mention of adverse events

Table A3.1: Strengths and Limitations of Randomized Controlled Trials using Downs and Black checklist[8]

Strengths	Limitations
cannulation (nurse anesthetist vs anesthesiologist)) • Statistical power determined a priori • Mention of equipment training level • Discussion on study limitations • COI statement	• Potential COI
Van der Woude et al., 2013[12]	
• CONSORT diagram for patient recruitment/enrollment • Patient characteristics tabulated • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Statistical power determined a priori • Mention of equipment training level • Discussion on study limitations • COI statement	• Single center study • Cluster RCT (by weekly OR) • Patient characteristics not evaluated for significant differences • Allocation concealment methodology not described • Not possible to blind • No ITT analysis • No mention of adverse events • Potential COI
Kaddoum et al., 2012[5]	
• Patient characteristics tabulated - no statistically significant differences between groups • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Statistical power determined a priori • Discussion on study limitations • Mention of equipment training level • Statement of no COIs • Mention of equipment training level	• Single center study • Allocation concealment methodology not described • Not possible to blind • No ITT analysis • No mention of adverse events
Pediatric Population in ED	
Chapman et al., 2011[13]	
• CONSORT diagram for patient recruitment/enrollment • Patient characteristics tabulated - no statistically significant differences between groups • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Statistical power determined a priori • Discussion on study limitations • COI statement	• Single center study • Allocation concealment methodology not described • Not possible to blind • No ITT analysis • No mention of adverse events • Potential COI

Table A3.1: Strengths and Limitations of Randomized Controlled Trials using Downs and Black checklist[8]	
Strengths	**Limitations**
• Mention of equipment training level	
Perry et al., 2011[6]	
• Patient characteristics tabulated • Mention of equipment training level • Allocation concealment methodology described • Statistical methods described • Randomization methodology described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Statistical power determined a priori • Discussion on study limitations • ITT analysis • COI statement	• Single center study • Patient characteristics not evaluated for significant differences • Not possible to blind • No mention of adverse events • Potential COI

COI = conflict of interest; ED = emergency department; NIR = near infrared; OR = operating room; RCT = randomized controlled trial;

Table A3.1: Strengths and Limitations of Non-Randomized Controlled Trials using Downs and Black checklist[8]

Strengths	Limitations
Mixed Pediatric Population (Includes Neonates)	
Rothbart et al., 2015[1]	
• Patient characteristics tabulated • Mention of equipment training level • Statistical methods described • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Discussion on study limitations • Statement of no COIs	• Retrospective observational study • Single center study • Significant differences between patient groups • Open-label study • No mention of adverse events
Cuper et al., 2012[2]	
• Patient characteristics tabulated - no statistically significant differences between groups • Mention of equipment training level • Statistical methods described • Statistical power determined a priori • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Discussion on study limitations • COI statement	• Observational study • Single center study • Open-label study • Potential COI • No mention of adverse events
Cuper et al., 2011[15]	
• Patient characteristics tabulated • Clearly defined patient eligibility • Clearly defined intervention • Clearly defined outcomes • Discussion on study limitations • Statistical methods described • COI statement	• Observational study • Single center study • Significant differences between patient groups • Potential COI • Open-label study • No mention of adverse events • No mention of equipment training level

APPENDIX 4: Main Study Findings and Author's Conclusions

Table A4.1: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Randomized Controlled Trials	
Neonate-Specific Population	
Phipps et al., 2012[3]	
Overall successful PICC placement n/N (%) (p = 0.08) Vein Viewer 51/59 (86%) Standard of care 41/56 (75%) [sic] First session (≤ 4 attempts/session) successful PICC placement n/N (%) (p = 0.55) Vein Viewer 38/59 (64%) Standard of care 33/56 (59%) After two sessions (≤ 4 attempts/session) additional successful PICC placement n/N (%) (p = 0.32) Vein Viewer 7/16 (44%) Standard of care 4/15 (27%) After three sessions (≤ 4 attempts/session) additional successful PICC placement n/N (%) (p = 0.25) Vein Viewer 3/3 (100%) Standard of care 4/5 (80%) Gestational age on first attempt (weeks) (p = 0.008) Successful 28.8 ± 4.3 Unsuccessful 31.2 ± 4.8 Gestational age overall (weeks) (p = 0.04) Successful 29.5 ± 4.7 Unsuccessful 31.6 ± 4.8 Gestational age adjusted VeinViewer OR (95%CI) First attempt 1.57 (0.71, 3.50) Overall 3.05 (1.10, 8.42)	"Use of the Vein Viewer was associated with a trend toward more successful placement (P = 0.08). The benefit was most clearly seen in more mature infants in whom visualization of vessels is the most challenging." (pp. 500) "Further studies using imaging technology are needed to evaluate the benefits of a smaller, more easily accessible device with a focus on larger more mature infants." (pp. 501)
Mixed Pediatric Population (Includes Neonates)	
Cuper et al., 2013[10]	
Success at first attempt n/N (%) – All patients NIR Imaging 171/246 (69.5%) Standard of care 175/245 (71.4%) RD (95% CI) 1.9% (-6.1, 9.9) Success at first attempt n/N (%) – Patients <3 years NIR Imaging 47/86 (54.7%) Standard of care 52/99 (52.5%) RD (95% CI) 2.1%% (-12.1, 16.2)	"Visualization of veins with NIR light by the VascuLuminator did not improve the clinical success rate of intravenous cannulation in a general pediatric population." (pp. 197) "There are 3 possible explanations for this result:

Table A4.1: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
Success at first attempt n/N (%) – Patients ≥ 85% BMI NIR Imaging 28/40 (70.0%) Standard of care 21/28 (75.0%) RD (95% CI) 5.0% (-16.9, 24.8) Time to Cannulation (seconds (±SD)) – All patients NIR Imaging 162 (±14) Standard of care 143 (±15) HR (95% CI) 0.90 (0.75, 1.08)* Time to Cannulation (seconds (±SD)) – Patients < 3 years NIR Imaging 257 (±33) Standard of care 228 (±35) HR (95% CI) 0.78 (0.65, 1.17)* Time to Cannulation (seconds (±SD)) – Patients ≥ 85% BMI NIR Imaging 179 (±36) Standard of care 118 (±23) HR (95% CI) 0.74 (0.45, 1.21)* *HR > 1 favours NIR Imaging	first, it could be that localization of the vein is not the main problem, and therefore visualization is not a solution; second, the type of system used in this study could be less than optimal; and, third, the choice of the patient population in this study could be inappropriate." (pp. 191)
de Graaf et al., 2013[11]	
Visibility of Vein of Choice with device (n/N (%; 95% CI))) – All Patients (p = 0.01) VeinViewer 307/322 (95.3%; 92.4, 97.4) AccuVein 239/254 (94.1%; 94.1, 96.7) VascuLuminator 229/257 (89.1%; 89.1, 92.9) Cannulation success at first attempt (p > 0.05) The following subgroup analyses demonstrated no significant differences between Standard of care, VeinViewer, AccuVein, and VascuLuminator: All patients (p = 0.94) Number of punctures (p = 0.95) Age < 3 years (p = 0.91) BMI or weight-to-age z-score > 85th percentile (p = 0.81) Difficult IV access score > 3 (p = 0.58) Predicted difficult (score > 3/10) (p = 0.28) Dark skin (Fitzpatrick grade 5 & 6) (p = 0.49) Trainees (p = 0.94) Device value rating >3 (p = 0.49) Suitable vein not visible without device(p = 0.30) Awake patient (p = 0.90)	"In conclusion, views of veins with near-infrared light did not improve the clinical success rate at the first attempt of peripheral intravenous cannulation in a general paediatric surgical population." (pp. 844) "Suitable veins for cannulation were more easily visible with the VeinViewer (307/322 (95.3%)) and AccuVein (239/254 (94.1%)) devices than with VascuLuminator (229/257 (89.1%)) (p = 0.03)." (pp. 835)
Van der Woude et al., 2013[12]	
Success at first attempt (n/N (%; 95% CI)) – All Patients (p = 0.27) VascuLuminator 27/43 (63%; 47, 77) Standard of care 23/45 (52%; 36, 66)	"In conclusion, this study showed limited value of the VascuLuminator in facilitating IV cannulation in

Table A4.1: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
Success at first attempt (n/N (%; 95% CI)) – Patients < 3 years (*p* = 0.08) VascuLuminator 14/23 (61%; 32, 85) Standard of care 8/23 (35%; 12, 63) Success at first attempt (n/N (%; 95% CI)) – Hard or very hard anticipated difficulty (*p* = 0.03) VascuLuminator 8/16 (50%; 19, 81) Standard of care 1/13 (8%; 0, 45) Success at first attempt (n/N (%; 95% CI)) – Fitzpatrick skin type 5 & 6 (*p* = NS) VascuLuminator 20/32 (63%; 38, 83) Standard of care 17/33 (52%; 29, 74) Median time to successful cannulation (seconds (IQR)) – All Patients (*p* = 0.54) VascuLuminator 53 (34, 154) Standard of care 68 (40, 159) Median time to successful cannulation (seconds (IQR)) – Patients < 3 years (*p* = 0.21) VascuLuminator 66 (40, 248) Standard of care 120 (47, 390) Median time to successful cannulation (seconds (IQR)) – Hard or very hard anticipated difficulty (*p* = 0.07) VascuLuminator 102 (40, 664) Standard of care 310 (132, 660) Perceived usefulness of VascuLuminator Helpful 23/43 Partly helpful 9/43 No change in success at first attempt over the course of the study was observed	a subgroup of children with dark skin color who are anticipated to be difficult to cannulate." (pp. 1270) The authors also use their results to suggest cohort sizes required to confirm or refute an advantage for the VascuLuminator with an α = 0.05 and power = 0.08
Kaddoum et al., 2012[5]	
Success at first attempt (n/N (%; 95%CI)) – All Patients (*p* = 0.85) AccuVein 54/72 (75%; 64, 84) Standard of care 54/74 (73%; 62, 82) Median time to successful IV cannulation (units are assumed to be minutes although authors do not define) (range)) – All Patients (*p* = 0.10) AccuVein 1.18 (0.25, 5.03) Standard of care 1.00 (0.38, 4.75)	"Although the AV300 was easy to use and improved visualization of the veins, we found no evidence that it was superior to the standard method of intravenous cannulation in unselected pediatric patients under anesthesia." (pp. 884)

Table A4.1: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
Cannulation success at first attempt ($p > 0.05$) The following subgroup analyses also demonstrated no significant differences between control and AccuVein AV300: Patients ≥ 2 years ($p = 0.55$) Patients < 2 years ($p = 0.62$) Estimated difficult of cannulation "Easy" ($p = 0.36$) Estimated difficult of cannulation "Difficult" ($p = 0.68$) Light skin (undefined criteria) ($p = 0.66$) Medium or Dark skin (undefined criteria) ($p = 1.00$)	
Pediatric Population in ED	
Chapman et al., 2011[13]	
Geometric mean time to place PIV (seconds) – All Patients ($p = 0.40$) VeinViewer 132 Standard of care 145 Geometric mean time to place PIV (seconds) – Patients < 2 years ($p = 0.047$) VeinViewer 121 Standard of care 167 Median number of attempts to place PIV (seconds(IQR)) – All Patients ($p = 0.5$) VeinViewer 1 (1, 1) Standard of care 1 (1, 1) Median number of attempts to place PIV (seconds(IQR)) – Patients < 2 years ($p = 0.23$) VeinViewer 1 (1, 2) Standard of care 1 (1, 2) Nurse assessed pain for patients < 2 years (VAS; IQR) ($p = 0.01$) VeinViewer 34 (20, 50) Standard of care 46 (31, 62) VAS pain for the following subgroups demonstrated no significant difference ($p > 0.5$) between VeinViewer and Standard of care Patients 8 – 17 years as assessed by patients ($p = 0.37$) Patients < 17 years as assessed by parents ($p = 0.34$) Patients < 17 years as assessed by nurses ($p = 0.16$) Patients < 2 years as assessed by parents ($p = 0.8$)	"Our study suggests that the VeinViewer may decrease the time to IV catheter placement in young children and infants. However, it did not demonstrate significant benefits in older children." (pp. 970) "There was a significant difference in nurse reporting of the child's pain in the 0- to 2-year-olds, although parents did not perceive this difference." (pp. 970) The authors suggested multiple potential sources of bias for this finding.
Perry et al., 2011[6]	
Success at first attempt (% (95%CI) – All Patients ($p = 0.361$) VeinViewer 79.0% (66.8, 88.3) Standard of care 72.1% (59.2, 82.9) Subgroup analyses of the following were underpowered and did not identify any groups where the 95% CIs did not overlap	"First-attempt success rate for IV placement was non-significantly higher without than with the assistance of a near-infrared light device in a high-volume pediatric ED.

Table A4.1: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
Patients 0 - 1 year Patients 2 – 3 years Patients 4 – 8 years Patients 8 + years Patient weight < 10 kg Patient weight 10 – 20 kg Patient weight 20 – 30 kg Patient weight > 30 kg Hispanic patients African American patients White patients Other ethnicity patients Chronic disease patients Patients without chronic disease Patients requiring IV for blood specimen Patients requiring IV for IV medication Patients requiring IV for IV fluids Topical anesthetic Without topical anesthetic Nurse experience < 5 years Nurse experience 5 – 10 years Nurse experience 10 + years	Nurses placing IVs did report several benefits to use of the device with specific patient groups, and future research should be conducted to demonstrate the role of the device in these patients." (pp. 5)
Non-Randomized Studies	
Mixed Pediatric Population (Includes Neonates)	
Rothbart et al., 2015[1]	
Median time to cannulation (minutes (IQR)) – All patients ($p < 0.01$) AccuVein 2 (1, 5) Standard of care 1 (0.2, 2) Median time to cannulation (minutes (IQR)) – Patients < 72 months ($p < 0.01$) AccuVein 2 (1, 6) Standard of care 1 (1, 2) Median number of attempts (IQR) – All patients ($p < 0.01$) AccuVein 2 (1, 3) Standard of care 1 (1, 2) Median number of attempts (IQR) – Patients < 72 months ($p < 0.01$) AccuVein 2 (1, 4) Standard of care 1 (1, 2) Success at first attempt (n/N (%; 95%CI)) – All Patients ($p < 0.01$) AccuVein 51/114 (45%; 35, 54) Standard of care 90/124 (73%; 65, 81) Success at first attempt (n/N (%; 95%CI)) – Patients < 72 months ($p <$	"In our study the use of the Accuvein® Vein Viewer was not able to reduce neither time nor number of attempts until a successful venous cannulation. Thus, its use in standard procedures with easy cannulations cannot be recommended within the limitations of this study." (pp. 5 of 6)

Table A4.1: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
0.01) AccuVein 32/85 (38%; 27, 48) Standard of care 57/86 (66%; 56, 76)	
Cuper et al., 2012[2]	
Mean time to successful cannulation (seconds (range)) – All patients (p = 0.76) NIR Imaging 464 (174, 996) Standard of care 547 (171, 1183) Mean time to first flashback of blood (seconds (range)) – All patients (p = 0.38) NIR Imaging 219 (59, 447) Standard of care 171 (96, 522) Success at first attempt (n/N (%)) – All patients (p = 0.29) NIR Imaging 12/38 (31.6%) Standard of care 7/39 (17.9%) Mean number of punctures (mean (range)) – All patients (p = 0.10) NIR Imaging 3 (1, 7) Standard of care 6 (2, 12)	"We conclude from the present study that the use of NIRVIS does not significantly improve time and success rate of arterial cannulation in small children, although there is a tendency in favour of success at first attempt and number of punctures. Future developments should probably be aimed at the insertion of the arterial cannula after penetration of the vessel wall and most likely not at the localization of the artery. (pp. 425)
Cuper et al., 2011[15]	
Success at first attempt (n/N (%)) – All patients (p = 0.05) NIR Imaging 44/45 (98%) Standard of care 70/80 (87%) Median time of needle manipulation (seconds (IQR)) – All patients (p = 0.07) NIR Imaging 1 (1, 4) Standard of care 2 (1, 10)	"This study is the first study to investigate the use of NIR light for venipuncture. It showed promising results in facilitating venipunctures in young children. The NIR vascular imaging system was able to decrease the number of failed punctures and was considered as a valuable tool by the users." (pp. 512)

BMI = body mass index; CI = confidence interval; HR = hazard ratio; IQR = interquartile range; NIR = near infrared; NS = not significant; OR = odds ratio; PIV = peripheral intravenous catheter; PICC = peripheral intravenous central cannulas; RD = risk difference; SD = standard deviation