AccuVein AV400 for vein visualisation

Medtech innovation briefing
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www.nice.org.uk/guidance/mib6
### Summary

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>Adverse events and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Evidence is based on 2 randomised controlled trials and 2 cohort studies on the AccuVein AV300; no studies were found specifically for the AV400 device.</td>
<td>• No adverse event or safety concerns were reported in the clinical studies.</td>
</tr>
<tr>
<td>• The studies compared the AccuVein AV300 with the standard method of palpation and visualisation for vein location and with 2 other infrared devices.</td>
<td></td>
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<tr>
<td>• The clinical studies reported an increase in vein visualisation but no statistically significant increase was found in first attempt cannulation rates.</td>
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<table>
<thead>
<tr>
<th>Cost and resource use</th>
<th>Technical factors</th>
</tr>
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<tbody>
<tr>
<td>• The AccuVein AV400 has an NHS acquisition cost of £3300 excluding VAT.</td>
<td>• The AccuVein AV400 uses an infrared laser imaging technique to help visualise and locate suitable veins for venepuncture and cannulation.</td>
</tr>
<tr>
<td>• No evidence on cost or resource use was available.</td>
<td>• The currently available version, the AccuVein AV400, differs from the predecessor device (the AccuVein AV300, on which all of the clinical evidence is based) in having technical enhancements that are intended to make the device easier to use.</td>
</tr>
</tbody>
</table>
Introduction

Peripheral venous access may be needed in a variety of clinical settings to obtain one-off blood samples (venepuncture) or to provide prolonged access to the bloodstream for blood sampling or giving intravenous infusions (cannulation).

It can be more difficult to access veins in certain groups of patients such as older people, or those with darker skin. There may be multiple attempts before cannulation is successful, which can cause pain or discomfort. Delays in cannulation can cause delays in diagnosis and treatment, and multiple attempts at cannulation by different practitioners reduces hospital productivity (Crowley et al. 2011). If a peripheral vein cannot be accessed, patients may need central venous catheterisation, which poses greater risks and is more time consuming.

There is limited evidence on the percentage of patients whose veins are difficult to access. It is likely that the experience and ability of the practitioner affects the success rate of the procedure (Crowley et al. 2011).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

AccuVein LLC received a CE mark for the manufacture of non-invasive vein illumination devices on 23 June 2009. The AccuVein AV400 is a non-invasive class 1 active medical device.

The laser in the AccuVein AV400 is a class 2 laser, which generally needs no precautions because the blink reflex is sufficient to protect the eye. However these blink reflexes may be inhibited or reduced by some diseases, drugs or other medical conditions. The
manufacturer recommends a protective eye shield for people with an impaired blink reflex. It is also considered unsafe for a person to stare into the laser beam for longer than 0.25 seconds.

**Description**

The AccuVein AV400 system comprises:

- a handheld AV400 unit and rechargeable battery (removable), weighing 275 g
- a charging cradle unit and power supply.

The device can be hand held or used with a hands-free option. The hands-free option is needed if a healthcare professional wishes to use the AccuVein AV400 while performing venepuncture. The additional hands free options are:

- A clamp and flexible arm kit for supporting the device. This can be attached to a bed rail or other suitable furniture.
- A wheeled stand, which can be moved to the patient.

There are no disposable parts.

Superficial veins are detected using an infrared laser light emitted by the device, and an image of the veins in real time is projected back onto the skin surface. The standard projected image is a red illuminated background with the veins shown darker in colour. This can be inverted to improve vein visibility if needed. The device allows improved visualisation of noticeable veins and allows the identification of previously undetected veins in the arm. The maximum depth of vein visible using this technology depends on the patient and it can be affected by factors such as scarring in the area and the presence of adipose tissue. A typical visible depth is 10 mm for the AV400 device. Additionally if the device is not held directly over the vein, the resulting image will be displaced from the true position. Therefore, to position the device correctly to carry out a cannulation, it should be perpendicular to the skin surface, between 10 and 45 cm away and with the vein display light centred above the central line of the vein of interest. The width of the displayed vein may not be the same as the width of the actual vein.

The rechargeable battery lasts for approximately 180 minutes, which is estimated to be around 90 standard viewing procedures. A full charging of the battery is estimated to take
3 hours. The lifespan of the battery pack under normal operational use is expected to be 2 years, and the expected lifespan of the device is 5 years.

The operating manual states that no routine or preventative maintenance is needed with the AccuVein AV400 and that the device contains no user-serviceable parts. Any servicing or repair needed, for example if the vein light window is scratched, would need to be carried out by an authorised AccuVein repair department.

The device is not designed to come into contact with the patient. The lens and optical surfaces on the back of the device can be cleaned using an alcohol wipe or similar. The device body must not be submerged in liquid but can be cleaned using a cloth and alcohol disinfectant, diluted bleach or soapy water. The device cannot be sterilised using heat or pressure.

The model available to the NHS is the AccuVein AV400, which differs from its predecessor, the AV300, in 3 main ways:

- The AccuVein AV400 is capable of showing all the veins in the field of view and therefore does not need to be rotated. The AV300 was only able to show those in which blood flowed in the same direction as the long axis of the unit and therefore needed rotating to view all the veins in the field of view.

- The AV300 had 3 vein display settings, whereas the AV400 has a single setting. These settings were related to the depth of veins. The AV400 only has the deepest of the 3 settings from the AV300. The manufacturer stated this was the setting most often used. This simplifies the operation of the device.

- The AV400 has a fully digitised signal processing chain, whereas the AV300 had analogue electronics. This change to the AV400 should reduce the presence of shadows in the image (Qmed, 2013).

**Intended use**

The AccuVein AV400 is intended to help find superficial veins for venepuncture and cannulation.

The technology is marketed for use with any patient and particularly those in whom venous access is difficult, including but not limited to:
• children and young people
• older people
• people with darker skin
• people who are obese
• people with renal failure
• people having intravenous chemotherapy.

The AccuVein AV400 is used in addition to the standard practice of visualisation and palpation, and must be used by a qualified healthcare professional. The manufacturer suggests that it could either be used to identify the most suitable veins before venous access is attempted, or to confirm the location of an identified vein.

Setting and intended user

The likely setting where the AccuVein AV400 will be used is a hospital. Departments with a higher than average proportion of patients with difficult venous access would be the most likely places to identify a need for the device. These include paediatric and bariatric surgery units.

The AccuVein AV400 can be used by any qualified healthcare professional trained in intravenous cannulation including nurses, surgeons, radiographers and phlebotomists. The distributor provides initial training and education in using the device.

Current NHS options

The current standard practice before performing a venepuncture is visualisation of the vein and palpation of the skin. A tourniquet is used to restrict venous flow (Lavery and Ingram, 2005).

Methods used with patients with difficult venous access include clenching of the fist, tapping the skin, warm compresses, positioning the arm below the heart to increase blood volume and ultrasound guidance (Whitehead, 2010; Mbamalu and Banerjee, 1999).

NICE is aware of the following CE marked devices that appear to fulfil a similar function to the AccuVein AV400:
• Vasculuminator (deKoningh Medical Products)
• VeinViewer (Christie Medical Holdings)
• Veinsite (VueTek Scientific).

Costs and use of the technology

Information on the cost of using the technology and alternative treatment options has been provided by the device's UK distributor (Q Medical Technologies Ltd). The AccuVein AV400 device has an NHS acquisition cost of £3300 excluding VAT. Additional costs of £285, £400 and £120 (excluding VAT) are needed respectively for a flexible support arm with a bed rail clamp, a 5-wheeled, hands-free, powered stand, and additional clamps for use with the flexible arm.

The anticipated lifespan of the device is 5 years. The number of patients on whom the device could be used during its lifespan is not known, so the average cost per treatment could not be estimated.

No practical difficulties have been identified in using or adopting the technology.

Alternative treatment options available in the NHS include visual inspection and palpation, the cost of which is dependent on staff time and consumables for the procedure. Ultrasound guidance needs acoustic coupling gel and contact with the patient, so the injection site needs to be cleaned afterwards. There are no publically available studies comparing the costs involved in using AccuVein AV300 or AccuVein AV400 to other infrared devices or ultrasound scanners for when cannulation is expected to be difficult.

Likely place in therapy

The AccuVein AV400 would be used in addition to the standard practice of visualisation and palpation in the standard clinical pathway for people whose veins are difficult to access. It would either be used to identify the most suitable vein before attempting venous access or to confirm the location of an identified vein.

Specialist commentator comments

Although visual inspection may be part of the process of identifying a suitable vein, it is
the palpation of that vein that is essential for deciding if cannulation should be attempted.

Some patients have clearly visible veins, but without palpation of vein elasticity or 'bounce', they may be liable to collapse when cannulation is attempted. Palpation is also important in locating and avoiding valves. It is therefore important not to give undue emphasis to visualising a vein, especially if it cannot be palpated.

Devices that facilitate quick and efficient cannulation can be important in reducing anxiety for patients.

If help with imaging is needed, ultrasound is the method of choice and has the advantage of being routinely available in accident and emergency departments.

Equality considerations

NICE is committed to promoting equality and eliminating discrimination. As a public authority NICE must also comply fully with legal obligations to promote race and disability equality and equality of opportunity between men and women; and to eliminate unlawful discrimination on the grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief. This is in accordance with the NICE Equality Scheme.

Some of the intended patient populations for the AccuVein AV400 are covered under the Equality Act, 2010. These include older people, children and minority ethnic groups. Using this device may improve clinical care for these groups of people.

Evidence review

Clinical and technical evidence

No publicly available evidence was found on the AccuVein AV400 model.

Two randomised controlled trials in children and 2 poster presentations on the AccuVein AV300 (provided by the device's UK distributor) were assessed.

Kaddoum et al. (2012) compared intravenous cannulation assisted by the AV300 device with the standard method of palpitation and visualisation alone (table 1).
<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
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<tbody>
<tr>
<td>Objectives/ hypotheses</td>
<td>To evaluate the efficacy of the AccuVein AV300 device in improving the first-time success rate of intravenous cannulation of anesthetised children. Use of the AV300 device was compared with the standard method of locating veins with palpation and visualisation alone.</td>
</tr>
<tr>
<td>Study design</td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>Conducted at a tertiary referral centre for children with cancer in the USA.</td>
</tr>
</tbody>
</table>
| Inclusion/exclusion criteria    | **Inclusion:** Patients had been referred for surgery or diagnostic imaging under anaesthesia, age <18 years, American Society of Anesthesiologists physical status I, II or III, no existing intravenous access, no need for interpreter.  
**Exclusion:** Malformation or infection at potential insertion site, anticipated to need an intravenous cannula size other than 22 gauge. |
| Primary outcomes                | First time success of intravenous cannulation as defined by an absence of signs of tissue infiltration after rapid administration of 5 ml of crystalloid solution via the cannula.                                                                                                               |
| Statistical methods             | An age stratified (<2 versus ≥2 years) block randomisation scheme was implemented to assign patients to a group.  
A Fischer’s exact test was used to calculate the sample size (146) and predicted a 90% power, a 5% probability of a Type I error and a CI of 95%.                                                                                                                                     |
<p>| Participants                    | 146 children with cancer who had been referred for surgery or diagnostic imaging under anaesthesia.                                                                                                                                                                                  |
| Results                         | <strong>Visualisation and palpation alone</strong> | <strong>AccuVein AV300</strong> | <strong>Analysis</strong> |
|                                 |                                                                                                       |                                                                 |                                                                 |</p>
<table>
<thead>
<tr>
<th></th>
<th>Randomised n=74</th>
<th>Randomised n=72</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean [range])</strong></td>
<td>5.4 [0.2–16.8]</td>
<td>5.7 [0.5–17.1]</td>
</tr>
<tr>
<td><strong>BMI (mean [range])</strong></td>
<td>17.9 [13.9–31.6]</td>
<td>17.3 [14–26.2]</td>
</tr>
<tr>
<td><strong>Anticipated difficulty:</strong></td>
<td>Easy 31, moderate 36, difficult 17.</td>
<td>Easy 33, moderate 20, difficult 9.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Efficacy n=54</th>
<th>Efficacy n=54</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome:</strong>&lt;br&gt;First attempt success rate</td>
<td>73% (54/74)</td>
<td>75% (54/72)</td>
</tr>
<tr>
<td><strong>95% CI 62 to 82% for visualisation and palpation alone</strong></td>
<td>95% CI 64 to 84% for AccuVein AV300</td>
<td>p=0.85</td>
</tr>
</tbody>
</table>

### Selected secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>Mean=1.26 SD=0.75</th>
<th>Mean=1.33 SD=0.75</th>
<th>p=0.86</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of skin punctures</strong></td>
<td>Mean=1.26 SD=0.75</td>
<td>Mean=1.33 SD=0.75</td>
<td>p=0.86</td>
</tr>
<tr>
<td><strong>Time to successful cannulation (minutes)</strong></td>
<td>Median=1.00 Range=0.38–4.75</td>
<td>Median=1.18 Range=0.25–5.03</td>
<td>p=0.10</td>
</tr>
</tbody>
</table>

**Conclusions**

The trial found no statistically significant difference in first attempt success rates, number of skin punctures or the time to successful cannulation between the standard method of visualisation and palpation alone and the use of the AV300 device.

**Abbreviations:** CI, confidence interval; n, number of patients; SD, standard deviation.
Subgroups were identified from the trial population based on 3 factors generally associated with potential ease of cannulation. These were age (<2 versus ≥2 years), prior assessment of cannulation difficulty (easy versus difficult) and skin colour (light skin versus medium or dark skin).

No statistically significant differences in the first time success rates were found for these subgroup pairings. However, it should be noted that at least 1 subgroup in each of these pairings consisted of a small number of patients (11 or fewer) and therefore statistical power would have been low.

The authors reported that the AV300 device was easy to use and despite not being able to demonstrate any superiority to the standard method they did feel that visualisation of the veins was improved. They offered several possible reasons as to why this did not translate to a statistically significant increase in the cannulation success rate, including the lack of vein depth information and their perception that the device overestimated the size of superficial veins.

de Graaff et al. (2013) compared intravenous cannulation assisted by 3 devices that use infrared light. These were the VeinViewer Vision, the AccuVein AV300 and the Vasculuminator. The standard method of palpitation and visualisation alone was used as a control. This trial is summarised in table 2.

Table 2 Summary of the de Graaff et al. trial (2013)

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To evaluate the effectiveness of 3 near-infrared devices in facilitating peripheral intravenous cannulation in children.</td>
</tr>
<tr>
<td>Study design</td>
<td>Cluster randomised clinical trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>Conducted at a tertiary referral centre for children in the Netherlands.</td>
</tr>
</tbody>
</table>
| Inclusion/exclusion criteria | **Inclusion:** Patients had been referred for non-cardiac surgery under anaesthesia, age <18 years.  
                          | **Exclusion:** Cannula already in situ.                                    |
### Primary outcomes
Successful peripheral intravenous cannulation at the first attempt. An attempt was defined as a penetration of the skin with the needle.

### Statistical methods
The Kruskal–Wallis test was used for comparison of continuous data. The chi-squared test was used for dichotomous data. Logistic regression analysis was used to calculate crude and adjusted odds ratios and correct for any bias on the profession of the operator.

### Participants
1913 children who had been referred for non-cardiac surgery.

### Results

<table>
<thead>
<tr>
<th>Results</th>
<th>Control Group (visualisation and palpation alone)</th>
<th>AccuVein AV300</th>
<th>VeinViewer</th>
<th>Vascu-luminator</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised</td>
<td>n=444</td>
<td>n=292</td>
<td>n=357</td>
<td>n=290</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>n=328 Age (median [range]) 5 [0–18] Dark skin/light skin: 20/436 (4.6%) Anticipated difficulty: (median [range]) 2 [0–10]</td>
<td>n=218 Age (median [range]) 6 [0–17] Dark skin/light skin: 15/289 (5.2%) Anticipated difficulty: (median [range]) 2 [0–10]</td>
<td>n=267 Age (median [range]) 5 [0–18] Dark skin/light skin: 23/344 (6.7%) Anticipated difficulty: (median [range]) 2 [0–10]</td>
<td>n=211 Age (median [range]) 5 [0–18] Dark skin/light skin: 10/287 (3.5%) Anticipated difficulty: (median [range]) 2 [0–10]</td>
<td></td>
</tr>
<tr>
<td>Selected secondary outcomes</td>
<td></td>
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<td>----------------------------</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of skin punctures (median, range)</td>
<td>1, [1–11]</td>
<td>1, [1–8]</td>
<td>1, [1–11]</td>
<td>1, [1–10]</td>
<td>p=0.95</td>
</tr>
<tr>
<td>Suitable vein not visible without device but visible with device</td>
<td>14.3% (5/35)</td>
<td>23.7% (9/38)</td>
<td>40.0% (6/15)</td>
<td>p=0.14</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

The trial found no statistically significant difference in first attempt success rates or the median number of skin punctures between the standard method of palpation and visualisation alone and the use of the AV300 device.

Abbreviations: CI, confidence interval; n, number of patients.

de Graaff et al. concluded that although vein visibility was reported as enhanced, the near-infrared devices did not improve cannulation.

The investigators also divided their population into subgroups to see if improvements in cannulation rates were only improved if cannulation was deemed to be difficult. The subgroups used were: pre-assessed difficulty of cannulation (>3 on a 1–10 range [10 being extremely difficult] versus <3), age (<3 years versus ≥3 years), skin colour (Fitzpatrick types 5 and 6 [dark] versus other Fitzpatrick types) and BMI (>85th percentile versus <85th percentile). No statistically significant benefit in first time cannulation rates was found for any of these subgroups.
Frame et al. was a study presented at the Royal Medical Society's National Student Conference in Edinburgh 2012 in the form of a poster (table 3).

### Table 3 Summary of the Frame et al. (2012) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To evaluate the impact of a vein illumination device on the peripheral intravenous cannulation technique in the emergency department.</td>
</tr>
<tr>
<td>Study design</td>
<td>Prospective cohort study comparing the AccuVein AV300 device with a control of the standard technique of visualisation and palpation alone. This was actioned as a first audit cycle using the standard technique, and then a second audit cycle using the AV300.</td>
</tr>
<tr>
<td>Setting</td>
<td>Conducted in an emergency department. The patient age range was reported as 16–97 years with a mean age of 61 years.</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>None stated</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>Compliance to the University Hospitals of Leicester's guidelines on peripheral intravenous cannulation.</td>
</tr>
<tr>
<td></td>
<td>In particular whether there was re-palpation of the insertion site after the skin had been cleaned.</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Simple percentages and median values were compared. The difference in whether there was re-palpation of the insertion site after cleaning is reported as significant but the method used and confidence interval was not reported, so it is not clear if this is a statistical significance.</td>
</tr>
<tr>
<td>Participants</td>
<td>200 patients, split into 2 cycles of 100 patients each.</td>
</tr>
<tr>
<td>Results</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; cycle (without the AV300)</td>
</tr>
<tr>
<td></td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; cycle (with the AV300)</td>
</tr>
<tr>
<td></td>
<td>Analysis</td>
</tr>
</tbody>
</table>
There was no randomisation in this study.

<table>
<thead>
<tr>
<th>Grouping</th>
<th>n=100</th>
<th>n=100</th>
<th>There was no randomisation in this study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome: Re-palpation of injection site after skin cleaning</td>
<td>41% (41/100)</td>
<td>24% (24/100)</td>
<td>Reported as significant, but no confidence intervals were given. The target was 0%</td>
</tr>
</tbody>
</table>

Selected secondary outcomes

| First time success rate | 84% | 76% | None reported. |

Conclusions

The study reported a significant decrease in the re-palpation of the injection site after the skin clean when the AV300 device was used. This is an improved rate of compliance with the University Hospitals of Leicester’s guidelines.

Abbreviations: n, number of patients.

Two more clinical trials were identified on ClinicalTrials.gov during the production of this briefing:

- ID. NCT01434537 – Evaluation of a Touchless Vein Scanner for Venepuncture and Cannulation in Paediatric Patients. This trial has been completed, but results have not yet been reported.
- ID. NCT02015845 – Evaluation of AccuVein in Obese Patients. This trial is currently in the recruitment phase.

Costs and resource consequences

It is not possible to estimate the likely NHS usage because information on the number of patients for whom the technology would be used is not available or quantifiable.

No published evidence on resource consequences for either the AccuVein AV300 or the AccuVein AV400 devices was identified in literature searches. In the study by Kaddoum et al. (2012), there was no statistically significant difference in the time to successful cannulation with AccuVein AV300 compared with the standard methods by experienced paediatric anaesthetists without the device.
No evidence on the resource consequences of adopting the AccuVein AV400 was identified.

According to the manufacturer, both the AccuVein AV300 and the AccuVein AV400 can be used with minimal training, implying no substantial additional costs. There would be no need to change the way in which current services are organised. No additional facilities or equipment are needed to adopt the AccuVein AV300 or AV400 into practice.

**Strengths and limitations of the evidence**

**Kaddoum et al. (2012)**

Kaddoum et al. (2012) did not show a statistically significant improvement in efficacy with the device. The trial was a single centre study using a sample size of 146, and predicted a statistical power of 90%, a 5% probability of a type I error and a confidence interval of 95%. This would suggest that, if any improvement is offered by the device, this study had a 90% chance of observing it.

First attempt success rate is considered the most clinically relevant primary outcome. A recognised validation technique was used to verify the success of the cannulation. The secondary outcome of number of skin punctures is probably the most relevant to patient experience, and time to successful cannulation is useful for resource analysis.

Cannulation was performed by paediatric anaesthetists with a minimum of 8 years' intravenous cannula insertion experience and therefore all were considered experts. This may affect the generalisability of this study and may be a source of bias against the device, as any advantage over palpation may be minimised. The patients' arms and hands were inspected and a likely site was identified. Randomisation was by computer program and the assigned group revealed immediately before the first cannulation attempt. A separate observer recorded the results.

Only a 22 gauge cannula size was used in this study. This would have been a small size to use in older children and may have introduced a bias for this group as it would have been relatively easier to insert.
de Graaff et al. (2013) was a larger, single centre trial involving a total sample size of 1913, with 292 allocated to the AV300 group and 444 allocated to the control group. The other patients were allocated to groups using other vein visualisation devices. The predicted statistical power of this study was 80% with a level of significance of 0.05 (assuming 2-sided testing).

The primary outcome was first attempt success rate, which would be considered the most clinically relevant. The use of a validation technique was not recorded in the study method, but it is standard practice to validate each cannulation. The secondary outcome of number of skin punctures is relevant for patient satisfaction.

Cannulation was performed by clinical staff with various professional roles, which may make this study more generalisable. Before the start of the study a 1-month familiarisation period was used to acquaint all users with the devices even if they had previous experience. Logistic regression analysis was used to correct the outcomes for any potential bias by profession of the operator. The probability of a prolonged learning phase was assessed by checking for any trend in the time taken to cannulate the first 3 successive cohorts of patients. Randomisation was performed immediately before the first cannulation attempt and after the assignment of a team member to perform the cannulation. Recording of results was performed by a separate observer. Subgroups were assigned by each individual operator, which may have introduced some variability.

One of the authors of this study has declared that they have filed a patent for one of the other vein visualisation devices (Vasculuminator).

Frame et al. (2012) concludes that using the AV300 device improved compliance with a hospital's guidelines on intravenous cannulation by substantially reducing the rate at which the insertion site was re-palpated after the skin was cleaned. No confidence interval or details of the statistical method used to assess significance were provided for this finding, so it is not clear if this is a statistical significance. It was noted that the first time success rate of cannulation, when using the AccuVein, decreased by 8% compared with when AccuVein was not used, but no analysis was performed on this result to see if it was statistically significant.

Patient populations in both audit cycles were reported to be of a similar age, but additional factors that may influence the ease of cannulation, such as skin colour and BMI, were not
considered. The study did not use randomisation and did not state whether these were consecutive patients. The study did not state whether cannulation was being attempted by the same group of people and does not correct for any operator bias. The study did not report who was responsible for recording the results.

The primary outcome in this study is relevant for compliance with good clinical practice, but its findings are limited in usefulness because the operators may have been aware of the auditing process. If so, or if additional interventions were applied between the 2 auditing cycles, then the improvement may not be entirely attributable to the use of the AV300.

**Version of device**

All of the evidence relates to the AV300 device and not the currently available AV400 device. Although there is uncertainty about whether the evidence for the AV300 is relevant to the AV400, it seems unlikely that the stated differences between the 2 devices would change the basic functionality of the unit. The modifications in the AV400 may improve usability and visualisation as veins with blood flow in all directions can be seen at once without adjusting the position of the device. No published evidence directly comparing the performance of the 2 models has been identified. There is no published economic evidence relating to either device.

**Relevance to NICE guidance programmes**

The use of AccuVein AV400 is not currently planned into any NICE guidance programme.

**References**


OECD (2013). PPPs and exchange rates [online; accessed 10 March 2014].

Qmed (2013) Vein finding can be illuminating [online; accessed 11 March 2014]


Search strategy and evidence selection

Search strategy

The following databases were searched on 18 February 2014 with the stated search criteria.

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) 1946 to Present and Embase 1974 to 2014 February 14

For clinical evidence

1. Cannulation/

2. venepuncture/
3. ((intravenous or intravascular) and (catheterisation or catheterization)).mp.

4. 1 or 2 or 3.

5. (AccuVein or AV300 or AV400).mp.

6. (infrared or infra-red or infra red).mp.

7. near-infr*.mp.

8. 5 or 6 or 7

9. 4 and 8

For economic evidence

1. cannulation/

2. Cannulation.mp.

3. venepuncture/

4. Venepuncture.mp.

5. intravenous.mp.

6. intravascular.mp.

7. catheterisation.mp.

8. catheterization.mp.

9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

10. AccuVein.mp.

11. AV300.mp.
12. AV400.mp.

13. infrared.mp.

14. infra-red.mp.

15. infra red.mp.

16. near-infr*.mp.

17. 10 or 11 or 12 or 13 or 14 or 15 or 16

18. cost$.mp.

19. economic$.mp.

20. 18 or 19

21. 9 and 17 and 20

22. limit 21 to english language

23. limit 22 to human

**PUBMED**

For clinical evidence

1. Cannulation/

2. venepuncture/

3. intravenous catheterization.mp.

4. intravascular catheterization.mp.

5. #1 or #2 or #3 or #4.
6. AccuVein

7. AV300

8. AV400

9. infrared

10. infra-red

11. infra red

12. near-infr*

13. #6 or #7 or #8 or #9 or #10 or #11 or#12

14. #5 and #13

For economic evidence

(((Cannulation OR Venepuncture OR Intravenous OR Intravascular OR Catheterisation OR Catheterization)) AND (AccuVein OR AV300 OR AV400 OR Infrared OR Infra-red OR Infra red OR Near-infr*)) AND (cost$ OR economic$)

Cochrane Database of Systematic Reviews : Issue 2 of 12, February 2014, and Cochrane Central Register of Controlled Trials : Issue 1 of 12, January 2014

For clinical evidence

#1 Cannulation

#2 Venepuncture

#3 Intravenous

#4 Intravascular

#5 Catheterisation
AccuVein AV400 for vein visualisation (MIB6)

#6 Catheterization

#7 #1 or #2 or #3 or #4 or #5

#8 AccuVein

#9 AV300

#10 AV400

#11 Infrared

#12 Infra-red

#13 Infra red

#14 near-infr*

#15 #8 or #9 or #10 or #11 or #12 or #13 or #14

For economic the following terms were added to those listed above.

#16 cost$

#17 economic$

#18 #16 or #17

#19 #7 and #15 and #18

DARE (Database of Abstracts of Reviews of Effects), NHS EED (National Health Service Economic Evaluation Database), and HTA (Health Technology Assessment) databases

For economic evidence only

(Cannulation OR Venepuncture OR Intravenous OR Intravascular OR Catheterisation OR Catheterization) AND (AccuVein OR AV300 OR AV400 OR Infrared OR Infra-red OR Infra red OR Near-infr*) AND (cost$ OR economic$) IN DARE, NHSEED, HTA FROM 1960 TO
Clinical Trials.gov

Clinical evidence only

AV300 or AV400 or AccuVein

Evidence selection

Clinical:

Total number of abstracts: 486

Duplicates: 28

Titles and abstracts reviewed: 458

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/abstracts, animal studies, and non-English language studies, not using the AccuVein AV300 or AV400 device for the purposes of locating blood vessels.

Studies for review: 2

Economic:

Total abstracts: 71

Duplicates: 16

Abstracts reviewed: 55

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/abstracts, animal studies, and non-English language studies

Studies for review: 0
About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech Innovation Briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are not formal NICE guidance.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC), King's Health Partners. The Interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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The following specialist commentators provided comments on a draft of this briefing:

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- Andrew Jessup, Deputy Imaging Manager, Dartford and Gravesham NHS Trust