Airglove air warming system for venous access

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Summary

- The technology described in this briefing is Airglove. It is used to warm and raise the veins in the arm to help with cannula insertion.
- The innovative aspects are claimed to be that there are no other devices available which warm the arm to help with cannula access.
- The intended **place in therapy** would be anywhere patient venous access is needed, especially for people with hidden or fragile veins that are difficult to cannulise.
- The main points from the evidence summarised in this briefing are from 1 service evaluation in 80 adults in 1 NHS oncology centre in whom vascular access was judged to be difficult. It shows that using Airglove helped successful cannulation in most cases.
- Key uncertainty around the technology is that the clinical evidence is very limited in quantity and quality. Further well-designed comparative studies that report all relevant outcomes would be helpful.
- The cost of Airglove is £795 for the warming unit, and £0.80 per disposable glove (excluding VAT). The resource impact would be an additional cost compared with current practice which could be offset if using Airglove in selected patients saved staff time and allowed use of fewer consumables from failed attempts at cannulation.

The technology

Airglove (Green Cross Medico Ltd) is an air warming system to improve access to veins for the delivery of drugs such as chemotherapy. It consists of a heating unit and tube containing a heat outlet, and single-use disposable double-walled polythene 'gloves'. The glove is placed on the tube and over the forearm; the glove seals on the forearm and heats it using warm air. Airglove has 3 temperature settings (31.5°C, 35.5°C, and 38.5°C) designed for sensitive, normal and heavier skin types as well as a timer that automatically switches off the unit after 3 minutes. Warming the forearm raises the veins allowing for easier cannula insertion.

Innovations

The company claims that there are no other technologies available that warm the arm to help with improved cannula access. No similar technology was identified during the development of this briefing.

Current care pathway

There is no guidance on how to perform cannulation in people with hard-to-access veins. <u>Mbamalu</u> <u>et al. (1999)</u> reviews the evidence for methods of getting peripheral venous access in difficult situations. These include milking the vein, increasing pressure using tourniquets, warming the arm with hot water or pads, and using ultrasound to identify veins.

Population, setting and intended user

The technology would be used by healthcare professionals, including vascular access specialists, in settings where regular venous access is needed. It would likely be used when access was anticipated to be difficult, or after failed attempts, including in patients with hidden or fragile veins, such as in oncology. However, it is suitable for use in any setting - inpatient, outpatient or GP surgeries - where venous access is needed.

Minimal training is expected to be needed.

Costs

Technology costs

The heating unit costs £795, has an estimated lifespan of 3 years, and comes with a 1-year guarantee.

A single-use disposable glove costs £0.80.

Costs of standard care

The technology could potentially avoid repeated unsuccessful cannulation. The company estimates that it can take 3 attempts for successful cannulation in an oncology patient. The costs of the consumables (2 each of cannula, saline solution, needles, syringes, and sterilisation packs) for each attempted cannulation is estimated by the company to be £1.45.

Resource consequences

The technology has been used in a clinical trial at Maidstone and Tunbridge Wells NHS Trust hospital, and is currently used in 5 NHS hospitals in England.

The company has calculated potential annual cost savings of $\pm 57,627$ for a typical oncology unit using the following assumptions:

- It does 9,100 chemotherapy cycles a year.
- Using Airglove avoids 2 unsuccessful cannulation attempts, each taking 6 minutes of an oncology nurse's time (at £1.44 for 6 minutes) and £1.45 in consumable costs.
- For successful cannulation, using Airglove takes 6 minutes of an oncology nurse's time but avoids the need for warming with hot water, which takes 12 minutes of their time.
- No changes in facilities or additional infrastructure are needed.

Regulatory information

Airglove is a CE-marked class I medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Some people in whom vascular access is difficult may, because of their underlying condition (such as cancer), be classified as disabled under the Equality Act. The technology may help with quicker access to intravenously administered chemotherapy agents in these patients and improve their experience of care.

Clinical and technical evidence

A literature search was done for this briefing in accordance with the <u>interim process and methods</u> <u>statement</u>. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting <u>mibs@nice.org.uk</u>.

Published evidence

One service evaluation in 80 patients is summarised in this briefing. A further unpublished study in 2 adult volunteers was identified and no other evidence on the technology was identified.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence base is very limited in quantity and quality, consisting of a service evaluation which is not peer reviewed and is missing details on the outcomes reported in particular. It showed that most patients in whom access was difficult had a successful cannulation using Airglove.

Table 1 Summary of selected studies

Service evaluation of the Airglove Patient Warming Device (2017)

Study size, design and location	80 patients in whom cannulation is difficult; observational; 1 oncology ward in England.
Intervention and comparator(s)	Intervention: Airglove warming device. No comparator.
Key outcomes	Cannulation after 1 heating was successful in 70 out of 80 attempts using Airglove. Two of the 10 patients had a further unsuccessful attempt, and 1 patient had 3 unsuccessful attempts at cannulation using Airglove.
	Reasons for unsuccessful cannulation included veins not being visible or palpable, or being damaged. Staff and patient satisfaction with the device (when sought) is reported as being high, and preferred to the warm water method of raising the veins.
	Two patients were recorded as having an adverse event; no cause was recorded; both had successful cannulation. No patients had a burning sensation and none experienced pain.
Strengths and limitations	The study includes a large sample of patients, who it is claimed were chosen randomly. The study methodology is basic. This is a hospital evaluation not published in a peer-reviewed journal and the information reported on patient and nursing feedback in particular is limited.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three specialists and 1 additional reviewer commented on the technology.

Level of innovation

The additional reviewer had used the technology, and 2 specialists were aware of it. All considered the technology to be innovative, and were not aware of any similar technologies.

Potential patient impact

The commentators agreed that the technology would benefit patients if it improved the rate of successful cannulation. One further identified improved patient satisfaction and enhanced sterility as other potential benefits. Oncology patients, those with diabetes, peripheral arterial disease, the young and elderly were cited as examples of patient groups who would particularly benefit from this technology.

Potential system impact

A reduction in staff time spent on getting venous access and a better patient experience were identified as potential system benefits. One expert further noted that repeated failed attempts at cannulation can increase the risk of infection and thrombosis. The technology was considered likely to be cost saving by 1 expert, cost incurring by 2, and cost neutral to potentially saving by the additional reviewer.

General comments

No specific infrastructure and only limited training needs were identified. One expert cited the need for further evidence but considered that if the technology provided a consistent level of heat for a predefined time it would have patient benefits. One was of the opinion that while the technology is likely to increase costs, this has to be weighed against potential improvements in the patient experience and savings in staff time spent securing venous access. Around 20% of patients needing venous access was identified as an estimate of the eligible patient population.

Patient organisation comments

Forty-three patient organisations were contacted, of which 2 replied.

Prostate Cancer UK were uncertain if this technology would offer advantages over existing treatments, warm water and warm pads. It noted that it is important to help accurate cannulation in its patient group because chemotherapy can cause blisters and burn if it is delivered into the tissue rather than diluted rapidly into the blood stream. With each cycle of chemotherapy, the

blood vessels can deteriorate, so it is important to avoid failed cannulation attempts. There is also the potential problem of leakage out of holes left from failed cannulation.

Chronic Lymphocytic Leukaemia Support Association (CLLSA) noted that it is very distressing for patients, and their care giver, when there are multiple painful and unsuccessful attempts at cannulations. This anxiety is particularly severe for those with poor veins. CLLSA discussed methods of warming the arm, warm pads and hot water, and noted that these are not standardised in terms of timing or temperature, risk damage to the patient, and can be time consuming. It considered that Airglove offered a simple non-invasive solution to the issue of difficult cannulation and would be particularly suitable in elderly patients with fragile skin and veins, and anyone with a communication or learning disability, who may struggle to understand what is happening to them, and would therefore benefit from a smoother and quicker cannulation process.

Specialist commentators

The following clinicians contributed to this briefing:

- Andrew Barton, advanced nurse practitioner vascular access and intravenous therapy, Frimley Health. Did not declare any interests.
- Terence Wong, consultant dermatologist, NHS Forth Valley. Did not declare any interests.
- Catherine Plowright, acute care nurse consultant and British Association of Critical Care Nurses professional advisor, East Kent Hospitals University NHS Foundation Trust. Did not declare any interests.

Additional reviewer:

• Leon D'Cruz, research associate in rheumatology and entrepreneurial lead, University of Ulster. Did not declare any interests.

Representatives from the following patient organisations contributed to this briefing:

- Prostate Cancer UK
- Chronic Lymphocytic Leukaemia Support Association.

Development of this briefing

This briefing was developed by NICE. The <u>interim process and methods statement</u> 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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