Healthcare Improvement Scotland | SHTG Advice on health technologies

Innovative Medical Technology Overview

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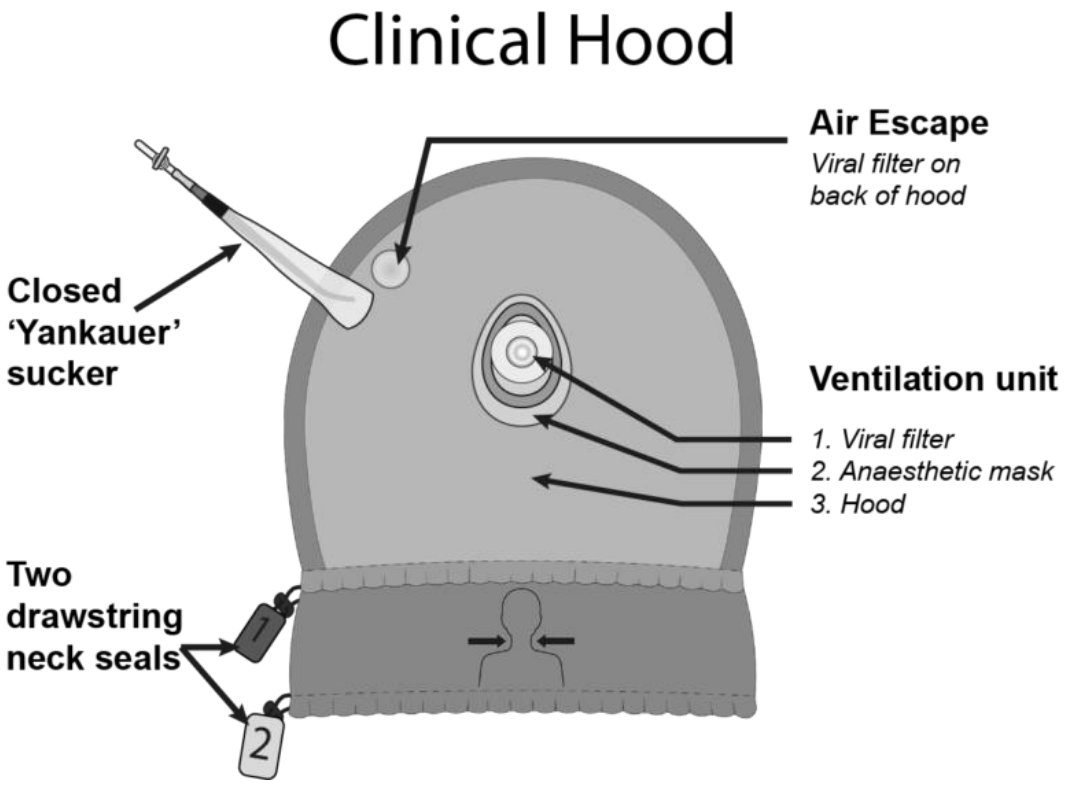
The SARUS (safer - airway - resuscitation) - CPR hood™ to protect first responders from biohazards



Executive summary

The Scottish Health Technologies Group (SHTG) was asked by the developers of the SARUS-CPR hood™ to assess the evidence for its use. Following initial exploration, the relevance of an IMTO received support from various stakeholders including clinical networks and clinical experts.

The SARUS-CPR hood™ is a single use containment/exposure-control solution worn by the patient and designed to improve safety for personnel during traditional 'bag and mask' ventilation, as part of cardiopulmonary resuscitation (CPR) by Basic Life Support (BLS)-trained responders.

In a small, unpublished randomised crossover trial, the technical tasks of performing CPR using a manikin were conducted equally well with the SARUS-CPR hood™ employed when compared with the use of standard CPR equipment. The time taken to complete the first three chest compressions was longer when using the SARUS-CPR hood™ (63 seconds compared with 42 seconds for standard CPR equipment).

In unpublished experiments using aerosol particles, less than 1% of particle concentration was detected at the breathing zone of the resuscitator. This may indicate protection from aerosol-borne viral and bacterial infections. The SARUS-CPR hood™ also offers protection from contamination of skin and eyes by large coughed droplets, saliva, blood and vomitus.

Potential safety issues associated with the use of the SARUS-CPR hood™ include reduction in internal jugular venous outflow and the risk of emotional distress to the patient in regaining consciousness within the confining SARUS-CPR hood™.

Further assessment relating to the efficacy, safety, ease of use and clinical impact of the device under intended conditions of use is required.

Technology and innovative aspect

The single use SARUS-CPR hood™ is an engineered containment/exposure-control device designed to improve safety for personnel and patients during traditional 'bag and mask' ventilation, as part of CPR by BLS-trained responders.

The SARUS-CPR hood™ is designed to protect emergency responders from biohazards contained in aerosols and coughed droplets, and reduce transmission of infection such as COVID-19, when carrying out CPR.[1]

The SARUS-CPR hood™ incorporates an anaesthetic facemask, viral filter, oral suction catheter and viral air escape port within a clear plastic-textile hood. During resuscitation the patient's head is lifted gently and the hood slipped down to cover the neck. Two tension-controlled drawstrings are tightened around the base of the hood. A version without the suction catheter is also available.

The SARUS-CPR hood™ can be quickly applied to the patient and may reduce the time to initiating airway ventilation when compared with the alternative of accessing and donning the

level of responder personal protective equipment (PPE) required for aerosol generating procedures (AGP).

The sealed hood reduces the risk of inhalation of aerosols and droplets by responders and provides protection from direct skin or eye contact with blood, saliva and vomitus.

The SARUS-CPR hood™ is CE-marked as a Class I medical device.

Target patient group

SARUS-CPR hood™ may be used as part of the emergency response when a person experiences a cardiac arrest in a hospital or community setting, including GP surgeries, lifeboat and mountain rescues, first aid at major events and first responder contexts in remote and rural environments.[2]

The SARUS-CPR hood™ is intended for adult use only. It cannot be used: in patients with major head and neck injury, on account of potential vascular/airway compromise; in patients with suspected raised intracranial pressure, on account of reduced internal jugular venous return; or in situations of fire and extreme heat, on account of the device being made of plastic materials.

A cardiac arrest occurs when the heart stops pumping blood around the body, commonly because of a problem with the electrical signals in a person's heart. Immediate resuscitation after arrest offers the best chance of patient survival.

The UK National Cardiac Arrest Audit 2019-2020 reported 13,211 in-hospital cardiac arrests across 175 participating hospitals. Although the audit is not complete, it allows an estimate for Scotland of approximately 1,300 events annually.[3]

Cardiac arrest is a significant healthcare challenge and ensuring as many people as possible survive an out-of-hospital cardiac arrest is a specific priority for the Scottish Government. Every year, over 3,000 people in Scotland experience an out-of-hospital cardiac arrest.[2]

Current practice: comparators and use of technology in pathway of care

Clinical use

In the context of the COVID-19 pandemic, Scottish Government guidance is that CPR in acute hospital settings and as carried out by the Scottish Ambulance Service (SAS) should be considered as a continuum which is likely to include an AGP as part of airway management. Professional judgement should be used to determine whether to apply airborne precautions based on the likely outcome of CPR; this would include FFP3 face mask, long-sleeved gown, gloves and eye protection.[4]

The developers of the SARUS-CPR hood™ propose that it may facilitate more rapid initiation of CPR in the hospital and SAS setting.

First responder use

Guidance for first responders undertaking chest compressions and early defibrillation states that a fluid resistant surgical facemask, disposal apron, gloves and eye protection should be worn where appropriate. Where such PPE is not available, the Resuscitation Council UK (RCUK) notes that rescuers should place a cloth/towel over the victim's mouth and nose, and attempt compression-only CPR and early defibrillation until the ambulance (or advanced care team) arrive.[4]

The developers of the SARUS-CPR hood™ suggest it could be used to protect first responders in the community who may be carrying out chest compressions or cardioversion whilst awaiting emergency support or where there is limited access to AGP PPE. Citizens near the patient may also be protected.

Product performance: data submitted for journal publication

A study submitted for publication [supplied without figures/tables] included a randomised crossover trial (n=15) (randomisation procedure not described) of the SARUS-CPR hood™. The study was conducted by the developers of the device within their NHS organisation, with volunteer participants opting in to the study following an approach by email.

Study participants were surgical foundation doctors considered to be novices with respect to CPR. Participants were randomised to undertake mock resuscitation on a plastic high-fidelity simulator using SARUS-CPR hood™ or standard bag and mask equipment for the first procedure. A second procedure was carried out one week later, with each participant swapping 'intervention' and acting as their own control. Procedures were videoed with only the participant's hands shown to attempt blinding their identity. Three expert assessors measured performance using a bespoke locally developed and validated nine-point checklist of important technical tasks of resuscitation.

No difference in the performance scores for tasks of mock resuscitation were identified between the procedures using SARUS-CPR hood™ and standard bag and mask equipment. Mean (standard deviation) checklist scores were, 7.3 (1.4) versus 7.3 (1.1) respectively, difference (90% confidence interval (CI) 0.0 (-0.3 to 0.3, p=0.90). This met the pre-defined study definition of equivalence.

There was no difference identified in the proportion of participants recording a score <7 using either the hood or standard equipment (0.67 versus 0.54 respectively, difference in proportions 0.13 (95% CI -0.20 to 0.43, p=0.98).

Resuscitation (time to achieve three chest inflations) took longer using the hood (median 63 seconds) compared with the standard equipment (median 42 seconds). Difference between medians 21s (95% CI 13 seconds to 28 seconds, p<0.0001).

Foundation doctors were chosen because they had received one half day's basic CPR training at medical school, but had no formal experience of resuscitation as part of a cardiac arrest team. It was assumed that they had similar skills and training as lifeboat operators, fire and ambulance crew, as well as members of the public who attend life-saving classes.

Product performance: unpublished and local data

Preliminary clinical evaluation/clinical opinion

The company provided the results of two preliminary clinical evaluations that were carried out to inform the effectiveness and safety of the device. The evaluations were limited to use of the SARUS-CPR hood™ on one person. These indicated that:

- There is a risk of venous outlet obstruction with the tight seal required to operate the hood. An ultrasound study in a healthy volunteer measured 80% occlusion of both internal jugular veins, meaning that the device should be avoided in head injured patients or those where obstruction in cerebral venous drainage and subsequent rise in intracranial pressure pose significant risks to the patient.
- Full anaesthetic monitoring, with full neck compression over a 5 minute period identified that there was no change in airway or arterial diameters and no physiological or neurological changes as a result of jugular venous outflow obstruction.
- Under the pressures tested and achieved, which were equivalent to those that would reasonably be used during manual bag-valve-mask ventilation, mask seal pressures above 30 cmH_2O were achieved.
- There was no concern that the hood increased rebreathing of expired gases.
- The integrated Yankeur suction catheter performed well in providing adequate safe suction ability.
- The hood was effective in containing simulated vomit to a considerable level of individual rescuer protection, shielding rescuer face and eyes.

Aerosol studies

An unpublished study conducted by the Institute of Occupational Medicine (IOM) introduced sodium chloride (NaCl) aerosol (majority of particles <1 micro metre) into the SARUS-CPR hood™ whilst worn by two volunteers. Using two detection methods, the relative concentration of NaCl was measured at three points around the breathing zones of CPR responders (5 cm from the hood-wearer's mouth, 75 cm above the hood-wearer, and at standing height above the hood-wearer). The wearer simulated three coughs during the tests to mimic patient activity. Relative concentrations ranged from 0.09% to 0.54% at the three positions in the five minutes following introduction of the aerosol.

Relative concentrations of NaCl detected around the neck seal on the front of the hood and the drawstring area ranged from 0.64% to 77.22%.

The study authors concluded that the resuscitator breathing zone is protected from the patient's aerosol during CPR when wearing the safety hood but some potential leak exposures may be possible from the neck and drawstring areas. The impact and significance of these must be determined from a clinical perspective.

Follow-up tests using the same methods were undertaken on five wearers of varying neck dimensions (diameter 13 cm to 19 cm), shaved/not shaved and differing hair lengths (short, long with ponytail exposed at rear seal, long with hair exposed at front and rear seal). For all five wearers, the relative concentrations of NaCl particles detected at 5 cm from mouth and 75 cm above wearer were less than 1%, ranging from 0.23% to 0.93%.

The study authors concluded that no notable releases were detected outside of the safety hood at the two breathing zones of the resuscitator during the experiments.

The generated NaCl was used as a proxy for potential hazardous biological aerosols due to size range of particles produced. No information was provided on the likelihood that the test aerosol behaves similarly to an aerosol containing infective microorganisms.

Safety

Jugular venous outflow obstruction presents a theoretical risk to the patient and to the effectiveness of resuscitation. Training is a pre-requisite for use. Clinician-led web-based training for trainers on safe use and correct application of the device is offered to CPR lead trainers by the developers.

It is recommended that AGP PPE should be worn during the removal and disposal of the SARUS-CPR hood™ into clinical waste. There are no commonly recognised allergy generating materials in the exposed components of the hood. The elasticated draw strings contain latex enclosed within other materials and so not in direct contact with the patient's skin.

There is a risk of emotional distress to the patient in regaining consciousness within the confining hood.

Economic and cost considerations

The current cost to NHS Tayside is £15 to £20 per device.

Keela International Ltd. will produce the SARUS-CPR hoods™ at their Dunfermline factory.

Future research

A single arm observational study is planned within a cardiac care setting to explore the ease of application, use and disposal of the SARUS-CPR hood™.

Conclusions

Based on the limited assessment undertaken to date (n=15), CPR using the SARUS-CPR hood™ can be performed to the same technical standard as that using traditional bag and mask equipment. In a test situation, particles introduced into the hood as aerosol did not reach the breathing zone of the rescuer. The potential of the device to reduce the risk of transmission of infection to personnel performing CPR and improve the speed of initiation of resuscitation to benefit the patient experiencing cardiac arrest should be explored.

It may be used both in hospital and by rescuers/first responders across a diverse range of community settings. The SARUS-CPR hood™ is not suitable for all patients.

Further assessment relating to the efficacy, safety, ease of use and clinical impact of the device under intended conditions of use is required.

References

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Acknowledgment of professional commentators and fact checking

Professional commentary was provided by:

- A consultant in intensive care medicine and anaesthesia, NHSScotland
- A consultant anaesthetist, NHSScotland
- A academic anaesthetist, NHSScotland
- Three anaesthetists, NHSScotland
- Two cardiopulmonary resuscitation lead trainers, NHSScotland
- A senior resuscitation officer, NHSScotland and
- A acting senior charge nurse, NHSScotland

Declarations of interests were obtained from professional commentators.

Fact checking was conducted by an ENT surgeon (NHSScotland) responsible for clinical design and oversight of the device.

What is an IMTO?

An IMTO provides a high-level summary of the evidence surrounding health and care innovation in Scotland. IMTOs may include:

- a review of local evaluation(s) undertaken within NHSScotland
- an appraisal of the evidence, based on the health technology assessment framework
- bespoke analysis and advice towards the development of evidence.

The purpose of an IMTO is to raise awareness of promising innovations and to assist local decision making by health and care colleagues. Further information about the IMTO process can be found on the SHTG webpage.