

ClearGuard HD Antimicrobial Barrier Cap for preventing haemodialysis catheter-related bloodstream infections

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is ClearGuard HD Antimicrobial Barrier Cap. It is a central venous catheter cap with chlorhexidine acetate coated rod and cap threads, used to help prevent catheter-related bloodstream infections in people having haemodialysis.
- The **innovative aspects** are that it could replace the need to clean the connector port with 2% chlorhexidine in 70% alcohol and potentially reduce the risk of catheter-related bloodstream infections.
- The **intended place in therapy** would be as an alternative to using standard central venous catheter caps in people having dialysis.
- The **main points from the evidence** summarised in this briefing are from 2 randomised controlled trials including a total of 4,141 adults in dialysis facilities. They show that ClearGuard HD is more effective than comparators for adults on dialysis.

- **Key uncertainties** around the evidence or technology are that the studies were done in the US, which may limit the generalisability to the NHS.
- The cost of ClearGuard HD is £4 per pair of caps (excluding VAT).

The technology

ClearGuard HD Antimicrobial Barrier Cap (ICU Medical) is a central venous catheter (CVC) cap for haemodialysis catheters. The cap includes a rod that extends into the CVC hub. The rod and cap threads are coated with chlorhexidine acetate, a broad-spectrum antimicrobial agent.

Chlorhexidine acetate is intended to reduce the presence of pathogenic organisms in the CVC lock to reduce the risk of catheter-related bloodstream infections (CRBSI). When the ClearGuard HD cap is inserted into the liquid-filled catheter, chlorhexidine acetate is released from the rod into the catheter lock solution. The antimicrobial agent is held inside the catheter hub in between treatments using the existing catheter clamp. ClearGuard HD caps are used in place of a standard cap or connector and need to be replaced every dialysis session. The recommended maximum use time for the cap is 3 days.

Innovations

The ClearGuard HD cap is intended to replace the need to clean the connector port with 2% chlorhexidine in 70% alcohol and then have to wait for it to air dry. This could save time for healthcare staff and potentially reduce the risk of CRBSI.

Current care pathway

The current standard care makes recommendations about minimising infection risk for vascular access devices. This includes decontaminating the injection port or vascular access device catheter hub before and after accessing the system using 2% chlorhexidine gluconate in 70% alcohol. The hub should be cleaned for 15 seconds and allowed to dry before access. If the manufacturer's recommendations prohibit the use of alcohol with their catheter, an aqueous solution of chlorhexidine gluconate should be considered. The recommendations also state that antibiotic lock solutions and systemic antimicrobial prophylaxis should not be used routinely to prevent CRBSI.

The following publications have been identified as relevant to this care pathway:

- [NICE's guideline on healthcare-associated infections: prevention and control in primary and community care](#)

- [NICE's quality standard on infection prevention and control](#)
- [epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England.](#)

Population, setting and intended user

ClearGuard HD is intended for use in people who need haemodialysis using CVCs. This device would be used mainly by vascular access specialist nurses in dialysis clinics as well as in home dialysis. Users of the ClearGuard HD caps are trained using videos available on the company website. Further training can be requested at no additional cost. Healthcare professionals may need awareness training regarding chlorhexidine allergy according to [national audit projects \(NAP\) 6: perioperative anaphylaxis](#).

Costs

Technology costs

The cost of a pair of ClearGuard caps is £4 per pair of caps. Haemodialysis would normally be needed 3 times a week and the caps would need to be replaced at each dialysis session, leading to a cost of £12 a week. The company have estimated that haemodialysis patients would need a CVC for an average of 132 days (estimated by the company based on [Kwak et al., 2012](#), [Crowley et al., 2017](#) and [Hymes et al., 2017](#)) until a more permanent form of vascular access is established. This would lead to a cost of £226 per person over this period.

Costs of standard care

The cost of a standard CVC cap is around £0.30 to £0.40 per cap. The cap would be disinfected with an alcohol wipe, which costs around £0.02 per wipe (including those containing 2% chlorhexidine gluconate).

Resource consequences

The ClearGuard HD could be used as a replacement to a standard CVC cap, without an overall change in the care pathway. The ClearGuard cap may reduce healthcare professional time by removing the need to clean the connector port. The cap is thought to lower the incidence of CRBSIs, which would reduce the cost and time needed to treat infections.

Regulatory information

ClearGuard HD Antimicrobial Barrier Cap is a CE-marked class IIb medical device. It received its CE mark in 2019.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People on dialysis could benefit from using this device. Disability is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with [NICE's interim process and methods statement for the production of medtech innovation briefings](#). 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 mibs@nice.org.uk.

Published evidence

Two randomised controlled trials are summarised in this briefing. These studies include 4,141 adult patients having dialysis.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence suggests that there is a reduction in positive blood cultures where ClearGuard HD is used. One study showed a decrease in hospitalisation for bloodstream infections, but the other study showed no difference. Both studies were long term, with large group sizes. Baseline measurements were taken to make sure previous bloodstream infection rates were similar between groups. However, both included studies were done in the US, which may limit generalisability to the NHS.

Brunelli et al. (2018)

Study size, design and location

A 13-month, prospective, cluster-randomised, open-label trial including 1,671 adults having dialysis with central venous catheters in 40 dialysis facilities in the US.

Intervention and comparator

Intervention: ClearGuard HD Antimicrobial Barrier Caps.

Comparator: Tego Needlefree Haemodialysis Connector (ICU Medical) used with Curoc Disinfecting Cap for Tego (3M).

Key outcomes

During the 13-month intervention period, the ClearGuard HD group had a significantly lower bloodstream infection rate compared with the comparator group (0.28 compared with 0.75 per 1,000 central venous catheter [CVC] days, respectively; $p=0.001$). The incidence rate ratio for positive blood culture was 0.37 (95% confidence interval [CI] 0.2 to 0.68; $p=0.001$) favouring ClearGuard HD. In people with a new CVC, the incidence rate ratio was 0.28 ($p<0.001$) in the intervention compared with the control group. There was no significant difference in hospitalisation for bloodstream infections between groups.

Strengths and limitations

A run-in phase was used in the study to make sure that bloodstream infection rates were equivalent between study arms. However, there was a small age difference between the study groups and an increased number of people with diabetes in the comparator group (both $p=0.02$). The study was funded by the company.

Hymes et al. (2017)

Study size, design and location

A 12-month, prospective, cluster-randomised, open-label trial in 2,470 adults having dialysis in 40 dialysis facilities in the US.

Intervention and comparator

Intervention: ClearGuard HD Antimicrobial Barrier Caps.

Comparator: Standard CVC caps.

Key outcomes

During the intervention period, there were 0.26 positive blood cultures per 1,000 CVC days in the intervention group and 0.59 per 1,000 CVC days in the control group (56% less in the intervention group; $p=0.01$). The positive blood culture incidence rate ratio of the intervention compared with the control was 0.44 (95% CI 0.23 to 0.83). In people who entered the study with a new CVC, there was lower positive blood culture rate of 0.16 per 1,000 CVC days in the intervention group compared with 0.50 per 1,000 CVC days in control (incidence rate ratio of 0.32 for the intervention compared to control group; $p=0.02$). Hospital admissions for bloodstream infections were lower in the intervention group (0.28 per 1,000 CVC days) compared with the control group (0.47 per 1,000 CVC days; $p=0.04$).

Strengths and limitations

The baseline period showed there was no significant difference between the intervention and control groups in positive blood cultures, hospital admissions and intravenous antibiotic drug usage. The demographics were similar between groups and the study was done across multiple centres. This study was funded by the company.

Sustainability

The company claims to minimise waste and save energy in the facilities used to manufacture the product. There is no published evidence to support these claims.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Expert comments

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

Of the experts, 1 of the 3 was familiar with or had used this technology before.

Level of innovation

Two of the experts stated that the chlorohexidine-coated rod within the cap is novel. One expert stated that this is only a minor variation because there are line locks solutions that can be administered into the dialysis catheter. Another expert noted that comparator caps involved the use of an additional CVC line connector meaning that 2 devices are needed instead of 1.

Potential patient impact

All experts noted that this device could reduce the risk of bloodstream infections. Two experts stated this could additionally reduce the risk of hospitalisation and line removal and 1 expert noted a possible reduction in antibiotic usage. However, 1 expert thought there are other technologies that could have similar benefits. The experts thought that this could benefit specific groups of people including those with recurrent bacteraemia episodes, poor skin hygiene, history of intravenous drug use, and people with difficult vein access.

Potential system impact

All experts commented that a reduction in bloodstream infections could reduce system impact. These included reduced antibiotic usage, hospitalisation, and use of bed space as well as less operator time in removing and replacing dialysis lines. One expert thought the device would cost more than standard care, but 2 experts thought that it would cost less than standard care when factoring in the potential reduction in hospitalisation. All experts stated that the device is unlikely to impact on staff resources and one expert stated that training in using the device is needed.

General comments

One expert commented that line care education could reduce bloodstream infection rates itself. One expert noted that this device is likely to be limited to groups who are at highest risk of bloodstream infection. One expert noted that the caps could lead to increased plastic waste.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Nicola Kumar, consultant nephrologist, Guy's and St Thomas' NHS Trust. Did not declare any interests.

- Dr Partha Das, honorary consultant nephrologist at King's College Hospital NHS Foundation Trust and Chief Medical Officer at Davita International.
- Dr Pritpal Virdee, renal consultant, Epsom and St Helier University Hospitals NHS Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. [NICE's interim process and methods statement for the production of medtech innovation briefings](#) 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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