Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 030 (May 2021)

Antimicrobial barrier caps for use with haemodialysis catheter hubs

HTW Guidance:

The evidence supports the routine adoption of ClearGuard HD antimicrobial barrier caps for use with haemodialysis catheter hubs.

Clinical evidence shows that the use of ClearGuard HD caps reduce the rate of blood stream infections compared to standard caps. Economic modelling suggests that the use of ClearGuard HD has the potential to lead to overall cost savings.

Health Technology Wales recommends the collection of real world audit data around the use of ClearGuard HD caps in Wales.

Why did Health Technology Wales (HTW) appraise this topic?

Chronic kidney disease is usually mild in severity, but in some cases can progress to end-stage renal failure. Haemodialysis is the most common treatment option for people who develop end-stage kidney disease. Although most patients requiring haemodialysis have an arterio-venous fistula created to allow access to the circulation, some patients need to be dialysed through a central venous catheter (CVC) that is placed in a large vein in the chest. Because the dialysis circuit needs to be connected and disconnected from the CVC regularly, there is a risk of blood stream infections (BSIs) which can be serious and lead to hospitalisation, mortality and increased healthcare costs.

ClearGuard HD antimicrobial barrier caps, which incorporate an anti-septic, are screwed on to the end of a catheter hub after haemodialysis has finished and are designed to prevent catheter-introduced BSIs.

HTW identified this topic through HealthTechConnect.

The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.

Evidence Summary

Refer to Evidence Appraisal Report 030 (EAR030) for a full report of the evidence supporting this Guidance.

HTW undertook an evidence review, which aimed to address the following question: What is the effectiveness of antimicrobial barrier caps for use with haemodialysis catheter hubs in reducing catheter-related bloodstream infections?

We identified two large, prospective, cluster-randomised trials from the US that evaluated the use of antimicrobial caps (specifically, ClearGuard HD) for haemodialysis catheters. One study compared ClearGuard HD to standard caps, whereas the second study compared ClearGuard HD to a needle-free connector (Tego) plus disinfectant cap (Curos). All outcomes were reported per 1,000 CVC-days.

ClearGuard HD demonstrated improved overall BSI rates compared to both standard caps and Tego plus Curos. Compared to the Tego plus Curos group, the ClearGuard HD group also reduced catheter-related BSI and central line-associated BSI rates. Hospitalisation outcomes were only reported in the trial comparing ClearGuard HD with standard caps, and it showed that the ClearGuard HD group had lower rates of hospital admissions. However, there was no difference in hospitalisation-days. No device-related adverse events were reported from either study.

No relevant economic evidence was identified in the literature review. HTW conducted an economic analysis to estimate the cost of using ClearGuard HD in comparison to standard caps. The analysis showed that the additional upfront costs for ClearGuard HD caps may be outweighed by savings accrued through a reduction in BSI events. However, there is uncertainty around the baseline BSI rate in Wales and the costs associated with managing BSIs.

Appraisal Panel considerations

- The Appraisal Panel heard from a clinical expert that he is not aware of antimicrobial caps being currently used with haemodialysis catheters in NHS Wales. The expert explained that practice in his centre includes the use of standard caps in combination with a bundle of care to minimise the introduction of infection. The expert also noted that while care bundles are standardised across centres in Wales, there is a variety of practice in regard to the standard caps and antimicrobial lock solution used in these bundles. In considering the place for antimicrobial caps within the clinical pathway, the expert suggested that antimicrobial caps would be used as an alternative to standard caps but in addition to, rather than instead of, antimicrobial lock solutions.

- The clinical expert explained that the diagnosis of catheter-related BSI is, in practice, often an assumption in the absence of an alternative identifiable infection source. Confirmation of the same bacterial growth from the tip of the catheter and from the blood of a patient is rarely achieved and the true incidence of catheter-related BSI is therefore somewhat uncertain. The expert confirmed, however, that this is a potentially serious and life-threatening condition and that a reduction in the incidence of BSI is an important objective.

- The Appraisal Panel noted that the published evidence is from studies that were undertaken in the US and not the UK and the applicability of the results to clinical practice in Wales was considered carefully by the Panel. The Panel heard from the clinical expert that while direct and objective comparisons of care are difficult between the US and the UK, haemodialysis line management is broadly similar across developed countries, as are the characteristics of the patients being treated (including comorbidities). The expert noted that the cluster-randomised trials are likely to be a fair reflection of how antimicrobial barrier caps would be used in clinical practice in Wales, although one cannot exclude an element of performance

bias due to lack of blinding in the clinical studies. Overall, the Appraisal Panel concluded that the published evidence can be considered relevant to practice in Wales.

- The Appraisal Panel were informed by the expert that clinical practice in Wales is moving towards the earlier and wider use of arterio-venous fistulae for vascular access at the time of haemodialysis in order to reduce the risk of infection. Nonetheless, he also explained that there remains a group of patients in whom the use of CVCs cannot be avoided and it is in this group where measures to reduce BSIs further will be most influential.
- The Appraisal Panel concluded that the current evidence shows a reduction in BSI rates with the use of ClearGuard HD antimicrobial caps for haemodialysis catheters compared to standard caps, and that the use of ClearGuard HD antimicrobial caps, in addition to the standard care bundle, offers the potential to reduce BSIs in patients undergoing haemodialysis through a CVC. Furthermore, based on the HTW economic analysis, the use of ClearGuard HD antimicrobial caps has the potential to lead to overall cost savings due to a reduction in BSI rates.
- The Panel noted that the evidence that was available for this evaluation involved the use of ClearGuard HD antimicrobial caps alone. Evidence using other antimicrobial caps for this indication and group of patients was not identified. On this basis, the Panel concluded that this evaluation and guidance should focus only on the use of ClearGuard HD antimicrobial caps but that this should be reviewed in the future if appropriate evidence evaluating other antimicrobial caps becomes available.
- The Appraisal Panel highlighted the importance of collecting real world data about the clinical impact of the use of ClearGuard HD caps in Wales in addition to the standard bundle of measures to reduce the risk of BSI in patients undergoing haemodialysis through CVCs.

Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[1,2] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[3]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.