

**National Institute for Health and Care Excellence
Centre for Health Technology Evaluation**

Pro-forma Response

External Assessment Centre Report factual check

**The 3M Tegaderm CHG IV Securement Dressing for central
venous and arterial catheter insertion sites**

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from Newcastle upon Tyne Hospitals (NUTH) and York Health Economics Consortium (YHEC) to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 10am, Monday 26 January 2015 using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Link to reference 64	Replace with: http://www.documents.hps.scot.nhs.uk/hai/sshqip/publications/icu-surveillance/icu-annual-report-2014.pdf	Link is to a general audit publication that contains no occurrence data regarding CRBSI. Correct link provided.	Thank you – this link has been updated within the reference list.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
The assumption that the CRBSI data published in ref 64 is an accurate reflection of the levels of catheter related infections prevalent in Scottish ICUs. The words of the report authors and previous surveillance data strongly indicate this is not the case.	This model and cost effectiveness comparison using a rate of 0.3 CRBSI/1000 catheter days should be excluded from the document. The sensitivity analysis employed in the sponsor's and EAC's models based on incidence reported by Bion et al, covers likely levels of catheter related infection in English HDUs/ICUs and should be presented exclusively in the document.	The sensitivity analysis employed in the sponsor's model covers likely clinical occurrence of levels of catheter related infection in English HDUs/ICUs. The authors of ref 64 state that current practices in culturing catheter tips in Scotland lead them to believe that their reported levels of CRBSI can be criticised for being an inaccurate reflection of the true levels of catheter related infections (page 19). The authors state "the lack of routine tip culturing across Scotland remains an issue for the surveillance system, making it difficult to fulfil the infection definition for CRBSI". As a proportion of total BSI, the levels of CRBSI seen in Europe are three times higher than those reported from Scotland. Indeed, previous editions of this document covering data collected in 2011 and 2012, have estimated the true CRBSI rate as being five to six times higher than the reported levels of CRBSI. In view of this it may be	Thank you for highlighting this. The EAC has reviewed the reports from Scotland and Wales on CRBSI rates within ICUs. The EAC agrees that the authors of the Scottish report do note caveats with the data resulting in the potential under reporting of CRBSI. The authors of the Welsh report provide no such caveats around their data. The EAC has updated the assessment report to highlight the limitation with the Scottish data, specifically in the following places: <ul style="list-style-type: none"> • Summary; • Section 4.2.3; • Section 4.5.1;

		<p>concluded that the “low” level of infection presented in ref 64 underestimates the size of the problem of catheter related infections in Scotland and thereby significantly undervalues the contribution that Tegaderm CHG can make in preventing this issue.</p> <p>In contrast the methods of <i>Bion et al</i> (reference 8) use broad, clinically relevant definitions of catheter related infection that include both CRBSI and CLABSI that do not exclusively rely on perhaps, sporadic application of tip cultures. Therefore these data have a stronger relationship to the picture of BSI in patient care that is seen by ICU/HDU clinicians in NHS England. Models utilising this data are the most relevant to NHS England and in the absence of anything more up to date, these alone should be included in the document.</p>	<ul style="list-style-type: none"> • Section 4.6; • Section 5. <p>This includes referencing the larger cost savings that are generated had the Scottish ‘confirmed and probable CRBSI’ (rather than confirmed alone) been used in the model.</p> <p>The EAC has not removed the scenario analysis using the Scottish data from the report as although these may underestimate the rate of CRBSI on average, the data can still provide a useful exploratory analysis for ICU/HDUs with CRBSI rates lower than those reported by <i>Bion et al</i> in reference 8.</p>
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Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response