National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT238 The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites

Consultation Comments table

MTAC date: 21 May 2015

There were 44 consultation comments from 7 consultees (3 NHS professionals, 2 manufacturers, 1 Department of Health and 1 professional society). The comments are reproduced in full, arranged in the following themes: CRBSI, Evidence, Benefit of visualisation, MTEP Process/ Guidance, Cost model, Adverse events, and Miscellaneous.

In comments 13 to 25; 27, 28 31, 32, 35, 39 and 42, the consultee included the full text of the sections on which the comment was made in their submission. These have been removing in the interests of document length and clarity. The full text of the medical technologies consultation document is at: http://www.nice.org.uk/guidance/gid-mt238/resources/the-3m-tegaderm-chg-iv-securement-dressing-for-central-venous-and-arterial-catheter-insertion-sites-consultation-document2

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			CRBSI	
1	2. 3M Health Care	1.1 page 2	A revised text of the provisional Recommendation to inform the reader that the local measure of blood stream infection that best represents infection burden due to CVCs and arterial catheters should be used. In view of this 3M Health Care suggests the following footnote be added to make this transparent. “The case for adopting the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites is supported by the evidence. This	Thank you for your comment The Committee decided to change section 3.20 to clarify the definition of CRBSI.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			technology allows observation and provides antiseptic coverage of the catheter insertion site, reducing catheter related bloodstream infections* and local site infections compared with semipermeable transparent (standard) dressings. It can be used with existing care bundles." Proposed Additional Footnote: *the term "catheter related blood stream infection (CRBSI)" as used in this document, is a collective description for any measure of the incidence of blood stream infections in critically ill patients in intensive care and high dependency units where a CVC or arterial catheter is viewed as the probable source and expressed in occurrences per 1,000 catheter days.	
2	2. 3M Health Care	Overall comments on document	Our discussion with NHS clinical experts strongly indicates differences in the way English acute trusts measure and report events under the terminology CRBSI. Certainly in some NHS Trusts there is sporadic use of the essential culture techniques to properly make a diagnosis of actual CRBSI. Also in some Trusts it's apparent that only those blood stream infections due to MRSA bacteria are collected and reported. True numbers of catheter related infections are collected only through prospective studies where the resources for proper diagnosis and microbiological testing are made available. Audit data is generally a significant under estimate of the impact on patients of CVC/arterial catheter related infections. It is apparent that there is no consensus on the nature of data collected under the term CRBSI in general clinical practice in the NHS. It is our view that in order to enable proper interpretation of the Recommendation, it should be made clear that the term "catheter related blood stream infection (CRBSI)" as used in the document, is a collective description for any measure of the incidence of blood stream infections in critically ill patients in intensive care and high dependency units where a CVC or arterial catheter is viewed as the	Thank you for your comment The Committee decided to change section 3.20 to clarify the definition of CRBSI.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			probable source. We have made appropriate comments to support this concern.	
3	2. 3M Health Care	4.12 page 17	It is known that in routine clinical practice the microbiological tests* used for confirmation of CRBSI are often not available due to the needs of patient care or the resources available. Consequently the rate that should be used for informing the significance of the problem when considering the use of Tegaderm CHG dressing is central line associated blood stream infection (CLABSI). Proposed revised paragraph 4.12 to read: The Committee noted that the cost savings associated with adopting Tegaderm CHG instead of standard dressing depend on baseline CRBSI rates (see section 5.24). The Committee considered that it was important for intensive care and high dependency units to review their local CRBSI rates when considering whether to adopt Tegaderm CHG. Where CRBSI data is viewed to be incomplete i.e. where tip and/or peripheral blood cultures are not systematically taken, the central line associated blood stream infection (CLABSI) rate is the more informative data to review.	Thank you for your comment The Committee carefully considered this comment and decided not to update section 4.12 in response. The Committee was advised by the External Assessment Centre, please see Appendix 3, that the definition of CRBSI requires culturing the tip or blood, whilst CLABSI is a primary bloodstream infection (i.e. there is no apparent infection at another site) that develops in a patient with a central line in place. Hence CLABSI is more practical than the CRBSI definition for surveillance, but may overestimate the true rate of CVC–related infections (http://www.jointcommission.org/assets/1/18/CLABSI_Monograph.pdf). The Committee decided to update section 3.20 in response to this and other comments on CLABSI/CRBSI.
4	2. 3M Health Care	5.20 page 23 to 24	NHS National Services Scotland have stated that whilst they report both probable and confirmed CRBSI it is not possible to determine what proportion of “probable CRBSI” are true CRBSI. The true incidence of CRBSI in Scotland therefore lies somewhere between 0.3 and 2.4/1000 catheter days. Also, the EAC has acknowledged that the authors of the report on Infections in Scottish ICUs state that the figure of 0.3 per 1,000 catheter days is likely to be a significant under estimate of the level of	Thank you for your comment The External Assessment Centre noted that the rate from Scotland of 0.3 CRBSI per 1000 catheter days refers to those blood stream infections with a positive microbiological catheter tip culture. A 'probable and confirmed' rate of 2.4 CRBSI per 100 catheter days (95% CI: 1.9 - 3.0) was also provided. This rate refers

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			infections due to CVCs and arterial catheters in Scottish intensive care. The higher figure for "probable and confirmed" CRBSI is reported as 2.4 per 1,000 catheter days2. Cost data based on 0.3/1,000 catheter days should not be presented as the Scottish national incidence unless balanced by inclusion of cost data based on 2.4 per 1,000 catheter days. In view of this we propose the deletion of the following sentence from paragraph 5.20: "When CRBSI data from Scotland were used, Tegaderm CHG had an average per patient cost of £30.79 and a standard dressing cost of £34.47; a cost saving of £3.68 per patient." Reference 1. NHS National Services Scotland, Personal communication 2. Health Protection Scotland. Surveillance of Healthcare Associated Infections in Scottish Intensive Care Units. Annual report of data from January - December 2013. (August 2014). http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/icu-surveillance/icu-annual-report-2014.pdf	to bloodstream infections occurring where a catheter was *in situ,* but no tip culture was taken to confirm the infection was catheter related. Where the model is run using the 'probable and confirmed' Scottish CRBSI rate, cost-savings with Tegaderm CHG increase compared with standard dressings. The Committee decided not to change section 5.20 because it judged that presentation of cost modelling outcomes across the full range of CRBSI rates was important.
5	2. 3M Health Care	5.20 page 23 to 24	NHS National Services Scotland have stated that whilst they report both probable and confirmed CRBSI it is not possible to determine what proportion of "probable CRBSI" are true CRBSI. The true incidence of CRBSI in Scotland therefore lies somewhere between 0.3 and 2.4/1000 catheter days. Also, the EAC has acknowledged that the authors of the report on Infections in Scottish ICUs state that the figure of 0.3 per 1,000 catheter days is likely to be a significant under estimate of the level of infections due to CVCs and arterial catheters in Scottish intensive care. The higher figure for "probable and confirmed" CRBSI is reported as 2.4 per 1,000 catheter days2. In our view cost data based on 0.3 per 1,000	Thank you for your comment. Please see the response to comment 4.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			catheter days should not be presented as representative of the incidence in Scotland unless balanced by cost data based on 2.4 / 1,000 catheter days. In view of this we propose amending the following sentence from paragraph 5.20: "When confirmed CRBSI data from Scotland were used, Tegaderm CHG had an average per patient cost of £30.79 and standard dressing a cost of £34.47; a cost saving of £3.68 per patient. However where probable and confirmed CRBSI data from Scotland were used, Tegaderm CHG had an average per patient cost of £XX.XX* and a standard dressing cost of £XX.XX* the cost savings were £XX.XX* per patient." Reference 1. NHS National Services Scotland, Personal communication 2. Health Protection Scotland. Surveillance of Healthcare Associated Infections in Scottish Intensive Care Units. Annual report of data from January - December 2013. (August 2014). http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/icu-surveillance/icu-annual-report-2014.pdf *cost to be calculated from EAC cost model using 2.4/1,000 catheter days.	
6	1. Consultant Microbiologist	5.2, referring to 5.20, error confirmed by consultee	As in the supporting documentation it would be helpful to consider adding the caveats about the Scotland CRBSI rates of 0.3/ 1000 catheter days. This could include the lack of routine microbiological monitoring eg catheter tip cultures and paired blood cultures as well as the possible use already of CHG dressings.	Thank you for your comment. The Committee carefully considered this comment and decided not to change the guidance. Please see response to comments 2 and 5
7	2. 3M Health Care	5.21 page 24	The EAC in its revisions to the their report, have acknowledged that the report on Healthcare Associated	Thank you for your comment The Committee considered that the

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			Infections in Scottish ICUs states that the figure of 0.3 per 1,000 catheter days is likely to be a significant under estimate of the level of infections due to CVCs and arterial catheters in Scottish intensive care1. The higher figure for "probable and confirmed" CRBSI is reported as 2.4/1,000 catheter days. Cost data based on 0.3/1,000 catheter days should not be presented as the Scottish national incidence unless balanced by inclusion of cost data based on 2.4 per 1,000 catheter days. In view of this we propose deleting the final part from paragraph 5.21: "but this fell to 57.9% when the figure from Scotland was used." Or alternatively rewording this text as follows: "but this fell to 57.9% when a lower CRBSI rate of 0.3/1,000 catheter days was used." Reference 1. Health Protection Scotland. Surveillance of Healthcare Associated Infections in Scottish Intensive Care Units. Annual report of data from January - December 2013. (August 2014). http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/icu-surveillance/icu-annual-report-2014.pdf	meaning was clear from the current wording and decided not to change section 5.21.
8	2. 3M Health Care	Overall comments on document	Another concern is the referral to a CRBSI rate of 0.3/1,000 catheter days to be representative of the national incidence for Scottish ICUs. The likely under reporting of infection in the 2013 CRBSI rate for Scotland (1) has been acknowledged by the EAC in its response to 3M's Factual Check document. In view of this the EAC made modifications to five sections of their Assessment Report and made this reply to the sponsor: "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." However, no acknowledgement of these changes to the EAC Report	Thank you for your comment The Committee decided not to change the guidance because the rate identified in the Culshaw paper was already included in the cost modelling. The assessment report was updated in response to the company's factual check. Page 107 of the assessment report describes the EAC's considerations on the Scottish CRBSI figures.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			nor this remark can be found in the draft Recommendations document. This omission should be addressed in the published Recommendations document. A recent report from a major London tertiary referral centre indicates the catheter linked blood stream infection rate to be 1.19/1,000 catheter days (2) which is four times higher than the rates reported in either Scotland or Wales. This rate of infection is perhaps a better reflection of the progress that has been made in reducing CRBSI in English ICUs in the period since Matching Michigan and preferable to using data from other parts of the UK. In the event that levels of CRBSI in Scottish ICUs are verified as being lower than in those reported by Bion (1.48 per 1,000 catheter days) (3) it should be acknowledged that the Scottish national care bundle includes the use of chlorhexidine containing dressings (4). In view of this we conclude that the rates of CRBSI reported from Scottish intensive care units already include an impact of using Tegaderm CHG dressing or a CHG sponge dressing. Consequently it would seem illogical to use the Scottish data as a benchmark for baseline infection rates in the cost model. In view of these factors it is our recommendation that all references to national figures as the benchmark of current levels of CRBSI be deleted from the Recommendations and reporting of two scenarios alone should be included. These are: 1. Cost effectiveness based on 1.48/1,000 catheter days 2. The level of CRBSI at which use of Tegaderm CHG dressing to prevent CRBSI, is no longer cost effective. References:	The External Assessment Centre noted that the Culshaw et al (2014) study reports the CRBSI and CLBSI for patients within ICU at Guy's and St. Thomas' NHS Foundation Trust between December 2009 and November 2013 The patients included within the study are critically ill and therefore match the scope. This study reports the catheter linked blood stream infection (CLBSI) incidence rate as 1.19 per 1,000 catheter days and CRBSI as 0.66 per 1,000 catheter days, which was recorded in line with the definitions used in Matching Michigan. The rate of 0.66 per 1,000 catheter days falls between the Matching Michigan (1.48 per 1,000 catheter days) and Scottish rates (0.3 per 1,000 catheter days) considered in the revised economic modelling carried out by the the External Assessment Centre, based on the company's submission. The study does not provide any information on the trend in infection rates over time within Guy's and St. Thomas' NHS Foundation Trust (i.e. whether these have gone up or down since Matching Michigan). The study is limited in that chlorhexidine-impregnated dressing sponges were one of a number of precautions used against CLBSI, and the proportions of use are unclear. The External Assessment Centre acknowledges that this limitation is a common problem when attempting to determine baseline infection rates.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			1. Health Protection Scotland. Surveillance of Healthcare Associated Infections in Scottish Intensive Care Units. Annual report of data from January - December 2013. (August 2014). http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/icu-surveillance/icu-annual-report-2014.pdf 2. Culshaw N et al. Healthcare-associated bloodstream infections in critically ill patients: descriptive cross-sectional database study evaluating concordance with clinical site isolates. Annals of Intensive Care 2014 4:34 3. Bion JF, Richardson A, Hibbert P, et al. 'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheterblood stream infections in intensive care units in England. BMJ Quality and Safety. 2013;22:110-23.	
9	2. 3M Health Care	5.21 page 24	NHS National Services Scotland do not publish unit level data so it is impossible to know the variance of incidence of CRBSI within their hospitals. Therefore the low CRBSI rates reported for example in audits of Scottish ICUs, may have been achieved partially or wholly due to the use of chlorhexidine containing dressings and therefore should not be used in cost models to represent the baseline opportunity for Tegaderm CHG to improve on. That baseline has been achieved by widespread use of a care bundle that includes the option for use of CHG containing dressings. In view of this we propose deleting the final part sentence from paragraph 5.21: "but this fell to 57.9% when the figure from Scotland was used."	Thank you for your comment The External Assessment Centre noted that it is understood that trusts in England and Scotland use CHG impregnated dressings; hence baseline rates of CRBSI will include some patients with CHG impregnated dressings in both settings. In Matching Michigan this was reported to be 17%. The External Assessment Centre acknowledged in Section 4.6 (page 144) of their assessment report that this is a limitation of the analysis. The External Assessment Centre believes that the probabilistic sensitivity analysis using the Scottish data should be included within the guidance to represent the potential cost savings for hospitals with low infections rates not using CHG impregnated

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
				dressings. The Committee decided not to change the guidance because the Committee agreed with the EAC's assessment. Please also see response to comments 4 and 7
10	2. 3M Health Care	5.24 page 25	3M Health Care fully support the way that the cost effectiveness of the product has been presented in this paragraph and would encourage that this way of presenting the information be used throughout rather than referral to potentially misleading individual country data.	Thank you for your comment
11	1. Consultant Microbiologist	6.2	The decision to adopt this technology based on current rates of CRBSI is reasonable with 0.24/1000 catheter days being cost neutral. However it is important that hospitals derive their current rates of CRBSI using recognised accepted definitions with appropriate microbiological investigations. Otherwise, there may be concern that some units would not use this technology based on erroneous audit data. The need for accurate data to establish CRBSI rates could be highlighted.	Thank you for your comment The Committee decided to change section 3.20 to further clarify that a diagnosis of CRBSI should involve tests to confirm that the catheter was the source of the bloodstream infection and to note the risks of using less rigorous definitions such as CLABSI.
12	2. 3M Health Care	6.2 Page 25 to 26	The following footnote should be added to this otherwise excellent paragraph: Final sentence to be amended to read: "It is therefore concluded that hospitals should take their baseline CRBSI or CLABSI* rate into account when making decisions about whether to adopt Tegaderm CHG. *Where CRBSI data is viewed to be incomplete i.e. where tip and/or peripheral blood cultures are not systematically taken, the CLABSI rate is the more informative data to review."	Thank you for your comment The Committee noted the advice from the External Assessment Centre (please see response to comment 3) and decided to update section 3.20 to further clarify the distinction between CLABSI and CRBSI.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			EVIDENCE	
13	3. Johnson & Johnson	1.1	Timsit et al 2012 is the only study that met the inclusion criteria of the company and The External Assessment Centre. This leads Johnson & Johnson to conclude that all recommendations are based solely on this single study. Johnson & Johnson would like to highlight the disclosure on the funding of Timsit et al 2012: "Timsit et al 2012 was sponsored by the University of Grenoble 1/Albert Michallon university hospital. An unrestricted research grant was obtained by university Grenoble 1/Albert Michallon university hospital from 3M Company. "	Thank you for your comment The Committee decided not to change the guidance. Timsit et al. 2012 was one of the four studies included by the External Assessment Centre, two of which related to Tegaderm CHG. Table 3.5 of the assessment report (page 53) specifies the funding source of Timsit et al. 2012 as 3M.
14	3. Johnson & Johnson	2.7	Johnson & Johnson challenge the committee's decision to label the epic3 recommendation as "based on evidence of limited quality": The evidence that the recommendations in the epic3 guideline is described by the guidelines themselves as follows: "The evidence for these guidelines was identified by multiple systematic reviews of peer-reviewed research. In addition, evidence from expert opinion as reflected in systematically identified professional, national and international guidelines was considered following formal assessment using a validated appraisal tool. All evidence was critically appraised for its methodological rigor and clinical practice applicability, and the best-available evidence in influenced the guideline recommendations." Further, epic3 states: Consider the use of a chlorhexidine	Thank you for your comment The Committee decided to change section 2.7to clarify the evidence categories used to develop the epic 3 guideline.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			impregnated sponge dressing in adult patients with a central venous catheter as a strategy to reduce catheter related bloodstream infection. New recommendation Class B A class B recommendation was based on based on systems developed by the Scottish Intercollegiate Guideline Network (SIGN) for study quality assessment. Defined as: B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+ Given the accreditation from NICE for the epic3 guideline, Johnson & Johnson question the decision of the committee to undermine the guideline with this statement.	
15	3. Johnson & Johnson	2.8	Johnson & Johnson would seek to clarify that it is the evidence of Bashir et al 2012 that is not of sufficient quality to effect NICE's clinical guideline on infection. Johnson & Johnson would ask the committee to clarify how this statement is to be interpreted? Does the committee disagree with the recommendation in epic3?	Thank you for your comment. The Committee decided to change section 2.8 to clarify that the outcome of the surveillance review in September 2014 was to not update the NICE infection guideline; and to remove the reference to the evidence considered within the review.
16	3. Johnson & Johnson	3.4	What did the External Assessment Centre conclude from their review of Timsit et al. 2009 and Roberts et al. 1998 Was Biopatch more/less/equally effective as Tegaderm? What reductions in CRBSI rates were reported for each technology?	Thank you for your comment The Committee decided not to change the guidance because sections 3.8 to 3.11 report the findings of the Timsit et al. 2009 study and section 3.12 reports the Roberts et al. 1998 study. Pages 45 to 65 of the External Assessment Centre report contains further details on the External Assessment Centre's appraisal of this evidence.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
17	3. Johnson & Johnson	3.7	Johnson & Johnson question the inclusion of section 3.7 in the draft. The evidence is of low quality: • Reporting interim findings only • The result reported was not statistically significant Would this poster have met the evidence threshold for inclusion in the epic3 guideline?	Thank you for your comment The External Assessment Centre judged that the Karpanen et al. (2014) study was relevant to the scope and its limitations are described in section 3.12. The process and methods for developing medical technologies guidance provide for consideration of all relevant evidence including unpublished data. The process and methods for developing the epic3 guideline are outside the scope of this evaluation.
18	3. Johnson & Johnson	3.8	When reviewing the evidence on comparator technologies, Johnson & Johnson would like to draw the committee's attention to the studies published by: Maki et al 2000 Rushculte et al 2009 Chambers et al 2005 Egol et al 2006 Mann et al 2001 Shapiro et al 1990 Schebwel et al 2012 Foglia et al 1993 Karwowska 1995	Thank you for your comment The Committee decided not to change the guidance because none of the studies cited by the consultee were relevant to the decision problem. The External Assessment Centre provided a summary of the reasons why it excluded the studies cited from detailed consideration in its assessment report. This is included in Appendix 1 of this document

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			Additionally the following systematic reviews & Meta-analysis may be helpful: Ho et al 2010 Huanget al 2011 Crnich et al 2002 Crawford et al 2004	
19	3. Johnson & Johnson	3.9	Did the committee conclude that CHG-impregnated sponge (Biopatch, Johnson & Johnson) demonstrated a clinically significant reduction in CRBSI? If so: • What was the reduction How did that compare to any reduction demonstrated by Tegaderm CHG IV securement dressing?	Thank you for your comment. The Committee decided not to change section 3.9 because the findings of the Timsit study relating to the CHG-impregnanted sponge are summarised in section 3.9; and the Committee's considerations are described in sections 3.18 and 6.1.
20	3. Johnson & Johnson	3.11	Johnson & Johnson would like to ask the committee why recommendation 3.11 has been included given: The evidence is of poor quality: • Low numbers • No P-values reported Additionally, The authors stated that the data were insufficient to draw conclusions from this study. What is the purpose of including this in the evaluation given the recognised low quality?	Thank you for your comment The Committee decided not to change the guidance. Section 3.11 is a factual summary of the Roberts et al. (1998) study and not a recommendation. This study was identified by the External Assessment Centre as being relevant to the decision problem specified in the scope therefore its findings are summarised here. Section 3.12 contains a summary of the strengths and limitations of the evidence.
21	3. Johnson &	3.12	Johnson & Johnson would like to ask the committee to	Thank you for your comment

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
	Johnson		clarify which studies are included, and from which studies recommendations are based. Johnson & Johnson would then ask the committee what benefit discussing the findings of studies excluded by the committee due to poor quality adds to this process?	The Committee carefully considered this comment and decided not to change the guidance. The process and methods for developing medical technologies guidance provide for consideration of all relevant evidence, including unpublished data. The committee considers all relevant evidence in developing its recommendations. Section 3.12 summarises the External Assessment Centres critical appraisal of the evidence it identified as relevant to the decision problem. The Committee considerations about the evidence are reported in sections 3.18-3.21.
22	3. Johnson & Johnson	3.13	Johnson & Johnson would like to seek clarity on the statement “reasonably consistent with the scope”. It would be helpful to know if the submission is consistent or not and if not in what way?	Thank you for your comment The Committee decided to change section 3.13 of the guidance to further clarify the External Assessment Centre’s assessment of the company’s submission. Further information on the consistency of the company submission with the evaluation scope is in section 2.3 of the Assessment Report
23	3. Johnson & Johnson	3.13	Johnson & Johnson would question the recommendations made on one paper that is not generalizable to the NHS in terms of current guidance on skin preparation. Is this consistent with strong and directive statement in section 1.1: “The case for adopting the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites is supported by the evidence?” The committee states that the skin preparation protocols followed by the intensive care units in France differed from	Thank you for your comment The Committee discussed the skin preparation protocols and the mortality rates reported in the Timsit et al. (2012) study and their generalisability to the NHS. It judged that the evidence relating to Tegaderm CHG (from two studies - one set in France and one in England) was sufficient to support the recommendations (see section 3.19) and decided not to

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			those used in the NHS recommended. Is this significant? Additionally, the committee has noted the difference in the mortality rates which infers a difference in the level of severity of illness in French critical care units to that of the UK. This is another inconsistency that lends further doubt to relying on generalizing the findings from the single study of Timsit et al (2012) in setting UK guidance.	change the guidance.
24	3. Johnson & Johnson	3.17	Johnson & Johnson would ask the committee to clarify the significance of this statement given that the records are unadjusted for usage proportions in the NHS and therefore have no denominator to provide statistical comparison?	Thank you for your comment The limitation of reporting the number of events over a fixed period for Tegaderm CHG and Biopatch without knowledge o**f** the numbers of dressings used is noted in section 3.17. The Committee did not reach any conclusions based on this data and decided not to change the guidance.
25	3. Johnson & Johnson	3.19	Does one study constitute the weight of evidence inferred in statement 1.1	Thank you for your comment Please see response to comment 23.
26	5. Clinical Nurse Specialist Infection Prevention and Control	General	The research at hierarchal level for this dressing still needs to be developed in supporting this dressing and in reducing blood stream infections to compared to other similar CHG dressings.	Thank you for your comment.
27	3. Johnson & Johnson	General	Over the past 15 years BIOPATCH Protective Disk with CHG has been evaluated in multiple studies and controlled randomized trials. It is the only device of its kind with an FDA-cleared indication to reduce local infection CRBSIs and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters. In addition many highly regarded international guidelines including CDC, Health Protection Scotland, SARI and EPIC3 all specifically recommend following detailed review of the evidence	Thank you for your comment

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			available a “chlorhexidine-containing sponge dressing” be considered.	
			BENEFIT OF VISUALISATION	
28	3. Johnson & Johnson	3.18,	With regard to visualization, Johnson & Johnson would like to draw the attention of the committee to the Center for Disease Control (CDC) guidelines from the United States: 12. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and MSB [93, 96–98]. Category 1B 13. No recommendation is made for other types of chlorhexidine dressings. Unresolved issue 14. Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site [99–101]. Category IB In addition the conclusion of the combination of 2 randomised trials involving 1,263 central venous catheters was that inflammation at the insertion site was not indicative of infection (Safdar, Maki 2002). Many types of bacteria responsible for CRBSI do not cause visible site reaction i.e. coagulase negative staph bacteria. Biopatch was specifically designed to be 1.25 cm in diameter when the CDC states that an indication of a	Thank you for your comment The Committee was advised by clinical experts that the ability to see the catheter insertion site was important, and relevant to the NICE guideline which recommends the use of a sterile *transparent* semi-permeable dressing, and decided not to change section 3.18. The additional expert advice is summarized in appendix 2 of this document. The Committee was also advised that, subject to appropriate training, removal of Tegaderm CHG is straightforward. Please see pages 75-76 of the Assessment Report for additional information on ease of use.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			systemic infection would be >2cm from the exit site. Johnson & Johnson note the committee's consideration on ease-of-application. Did the committee also consider the importance of ease of removal?	
29	5. Clinical Nurse Specialist Infection Prevention and Control	General	Even though clinical staff can observe the invasive device, this leads to them not actually completing a full assessment for line infection and not carrying out other examination skills like palpation and asking the patient if there is pain.	Thank you for your comment Please also see the response to comment 28. The Committee's considerations on the benefits of being able to see the insertion site are in summarised in section 4.12
30	2. 3M Health Care	6.1 page 25 to 26	Modify text to include why the ability to see the CVC site is important to clinicians and patient: "…but has other advantages, specifically the ability to see the catheter insertion site that provides clinicians with the opportunity to see the early onset of local symptoms of infection or dermatitis."	Thank you for your comment Section 6.1 contains the overall conclusions. The Committee's considerations about the benefit of seeing the wound site are described in section 4.12.
MTEP PROCESS / GUIDANCE				
31	3. Johnson & Johnson	3.18,	We commend the committee for recognizing that CHG-impregnated sponge dressings (Biopatch, Johnson & Johnson) are clinically equivalent But question why this isn't reflected in section 1.1 of the guidance. Johnson & Johnson would like to understand who the clinical experts who informed the committee were? Were the experts a representative sample of Tegaderm and Biopatch users?	Thank you for your comment. NICE medical technologies guidance provides recommendations on a single technology notified to NICE. Please see the MTEP Process Guide for further details. Section 1 of the guidance describes the recommendations about the notified technology which for this evaluation is Tegaderm CHG. Please refer to Appendix B, pages 39 to 41, of the assessment report overview for

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
				details of the experts involved in this topic and a summary of their advice. The MTEP Process Guide (section 3.7) describes the way in which expert advisers are identified and engaged.
32	3. Johnson & Johnson	3.20	Johnson & Johnson would like to seek clarity on the following points: • How did they select the experts? • Were they all selected by the manufacturer? • Given Biopatch, Johnson & Johnson is referenced extensively in the document we would like to understand whether NHS professionals with experience of using the product were contacted? • Did the committee approach the Infection Prevention Society for comment given the significant role that organization has in authoring epic3 guidelines?	Thank you for your comment Expert advisers are identified according to the processes described in Section 3.7 of the MTEP Process Guide. Appendix B of the assessment report overview describes the source of the nominations. The expert advice which the Committee received included professionals who had experience of using Biopatch. The Infection Prevention Society was asked to nominate expert advisers for the selection and routing stage of the evaluation and is a stakeholder for this evaluation and so was invited to comment on both the draft scope and on the provisional recommendations. Please also see the response to comment 31.
33	7. Professional Lead, Royal College of Nursing	General	The evidence presented refers to adults and children however the recommendation is not clear as to whether it applies to both groups of patients. The use of the product in neonates is not mentioned and requires clarification in the recommendation.	Thank you for your comment The Committee decided to change sections 1.2 and 2.5 to further clarify that the recommendations and the company claims are for adults
COST MODEL				

MT238 The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
34	2. 3M Health Care	5.22 page 24	Please note that several NHS customers purchase Tegaderm CHG dressings using alternative procurement routes to NHSSC. These NHS customers may receive associated price differences which in some cases are lower than the average price reported from the analysis of NHSSC data.	Thank you for your comment The Committee decided not to changed section 5.22 because the External Assessment Centre analysis showed that there was insufficient information on which to base any different cost estimates. Please see Appendix 4 for the detailed response provided by the External Assessment Centre.
35	3. Johnson & Johnson	5.22	The UK list price of Biopatch (Johnson & Johnson) is £5.33 inclusive of VAT This price is available to all Trusts, with volume based discounts available where applicable. The stated price by the manufacturer for Tegaderm CHG is is £6.26. Johnson & Johnson recommend the committee remove or amend section 5.22 Any subsequent recommendations on cost-effectiveness may also wish to take this into consideration.	Thank you for your comment The Committee decided not to changed section 5.22 because the External Assessment Centre analysis showed that there was insufficient information on which to base any different cost estimates. Section 5.22 includes two cost estimates for Biopatch (with a standard dressing), one based on NHS supply chain costs (£8.13), and a lower estimate based on information provided by 3M (£6.49). In cost modelling, using either price, Tegaderm CHG was cost saving overall compared with Biopatch and a standard dressing. The lower estimate for Biopatch supplied by 3M is less than the value of £5.33 referred to in the comment.
36	5. Clinical Nurse Specialist Infection Prevention and Control	General	Economically we have not had an increase in cost by switching over and the cost has reduced as we had to treat the skin reactions. The price which is listed in the consultation document is much higher than the price our Trust pays for the sponge CHG and lower than the cost of the CHG gel, therefore there was a cost saving when we switched.	Thank you for your comment

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			ADVERSE EVENTS	
37	5. Clinical Nurse Specialist Infection Prevention and Control	General	Within our Trust there has been reported numbers of skin reactions with the CHG gel therefore this is one of the many reasons why we have changed this to a 2nd line dressing and the sponge CHG dressing as 1st line as since this change over a year we have not had any reported incidences of skin reactions to the sponge CHG dressing. It also was noted that there have been a larger number of skin reactions reported to FDA than the sponge CHG dressing. There was also a high incident of lines being pulled out when using the gel CHG dressing and residue left behind of the gel on the lines which in its self would increase the risk of infection.	Thank you for your comment The consultee has confirmed that Tegaderm CHG is described as CHG gel in this comment. The adverse event data for this technology was reviewed by the External Assessment Centre and the company (see sections 3.14-3.17). A high incidence of lines being pulled out was neither reported in the qualitative evidence or by clinical experts.
38	7. Professional Lead, Royal College of Nursing	General	The material presented is a fair and comprehensive review of the evidence available. The provisional recommendations are sound and applicable to the NHS, however members have expressed concern as to the implications of the evaluation having made decisions to use Biopatch. The rationale for choice specifically relates to experience of skin reactions with Tegaderm products. Whilst it is acknowledged that the evaluation produces a recommendation only and how this is implemented is not within the remit of NICE, it is important that the implications of the recommendation are monitored and evaluated.	Thank you for your comment NICE medical technology guidance evaluates a single medical technology. Specific recommendations in the medical technologies guidance on individual technologies are not intended to limit the use of other relevant technologies which may offer similar advantages.
			MISCELLANEOUS	
39	4. Johnson and Johnson	3.8	When referencing Biopatch please include manufacturer name: Johnson & Johnson	Thank you for your comment NICE style is to refer to the manufacturer only at the first mention of the technology only. This is done for Biopatch in section

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
				3.4.
40	2. 3M Health Care	2.7 page 5	3M are in discussion with the authors of the EPIC3 Guideline regarding the recommendation for use of CHG sponge dressings, so that the guidance is revised to better reflect the clinical evidence reviewed in the EPIC3 publication.	Thank you for your comment
41	2. 3M Health Care	Overall comments on document	3M Health Care generally supports the provisional recommendations of the consultation document with a number of caveats regarding the baseline CRBSI data used for cost models. These are provided in detail in the comments on the relevant parts of the draft Recommendations.	Thank you for your comment
42	3. Johnson & Johnson	General	Johnson & Johnson Medical (J&J) welcome the opportunity to contribute to the consultation on the draft proposals for the Tegaderm CHG Medical Technology Evaluation Programme. In considering our response, we are drawing on our company's experience as a Global Healthcare organisation providing a breadth of products, services and solutions focused on the improvement of patients' outcomes. The Johnson & Johnson family of companies are committed to delivering innovative and market relevant medical devices, diagnostics and solutions; a diverse range of over the counter products to support self-treatment and well-being as well as medicines which make an important difference to the lives of patients with serious health conditions such as HIV, schizophrenia, diabetes and prostate cancer.	Thank you for your comment

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			We believe this unique perspective means we are well placed to offer a balanced opinion on the implications for this draft.	
43	4. Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment
44	7. Deputy Director for Infection Prevention and Control (Expert Adviser)	General	The document does not take into consideration the impact of CRBSI in those patients receiving Parenteral feeding. As a trust we have been utilising the CHG IV securement dressing for over 4 years and seen a dramatic reduction in CRBSI in this population. http://www.journalofhospitalinfection.com/article/S0195-6701%2811%2900341-0/abstract. Whilst the majority of intravascular devices will be utilised within a critical care environment it should not be overlooked that a significant number of patietns will have such a device in non specialist areas e.g. surgical wards, orthopaedic units etc which may reflect a higher CRBSI than those currently published.	Thank you for your comment The Committee decided not to change the guidance because the study population was not considered to be relevant to the scope. The External Assessment Centre stated that the scope issued by NICE defined the population of interest for this assessment as "critically ill adult patients in intensive care (ICU) or high dependency units (HDU) who require a central venous or arterial catheter". Therefore, patients who were not critically ill were outside the scope of the evaluation and any clinical evidence which was not specific to critically ill patients was excluded. Hence the study the consultee has cited was excluded. The clinical evidence that was used to generate the guideline, included critically ill patients in ICU or HDU with a CVC or arterial catheter. The reason for requiring a catheter was not specified in the selection criteria. Therefore, within the included clinical evidence patients were included who had CVCs for parenteral

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
				nutrition. In Timsit (2009) 37.9% of patients had lipids and in Timsit (2012) 47.8% of patients had lipids, which suggests they received parenteral feeding. No further information on the use of lipids was provided in either paper.

Appendix 1: EAC exclusion of studies – comment 18

Study	Reason for exclusion
Maki et al 2000	Abstract only and did not specify in critically ill patients (in ICU, CCU or HDU).
Rushculte et al 2009	Did not specify critically ill patients (in ICU, CCU or HDU).
Chambers et al 20005	Haematology unit patients rather than in critically ill patients (in ICU, CCU or HDU).
Egol et al 2006	Patients did not have a CVC or arterial catheter, but rather external fixation for fracture.
Mann et al 2001	Patients are not critically ill and do not have a CVC or arterial catheter.
Shapiro et al 1990	Patients do not have a CVC or arterial catheter.
Schwebel et al 2012	This is an economic evaluation built on clinical data from Timsit 2009 which was considered as evidence by MTAC. As reported in the EAC's assessment report, only economic evaluations which included Tegaderm CHG as a comparator were considered within the economic evidence review.
Karwowska et al 1995	Study was in neonates not critically ill adults.
Ho et al 2010	Not specific to critically ill patients (systematic review). Included studies were assessed for relevance.
Huang et al 2011	Specific to children (outside the scope of this guideline)
Crnich et al 2002	Study type (review/opinion article).
Crawford et al 2004	Not specifically in critically ill patients.

Appendix 2 Additional expert advice (comments 3, 12 and 28)

Question 1 (comments 3, 12): Expert advisers were asked about the validity of using CLABSI rates where CRBSI data were incomplete or unavailable

Expert Adviser	*Comment*
Dr Justin Roberts	*I agree with your recommendation on the use of CLABSI, as this looser definition is becoming more widespread (CDC standard in the US), and I expect will become the standard reporting incidence soon in the UK.*
Jackie Nicholson	*I would agree with this.*

Question 2. Expert advisers were asked to comment on comment 28 and about the advantage for Tegaderm CHG of being able to see the infection site (compared to other CHG impregnated dressings)

Expert Adviser	*Comment*
Dr Justin Roberts	*The issues around viewing the site are interesting, and of course it has to be remembered that it is possible to have a normal appearance at the catheter insertion site, and yet the patient can develop sepsis related to in-situ cannula tip contamination. In practice at my institution an ability to view the insertion site is still considered important, as erythema will raise the index of suspicion, if evidence of sepsis subsequently develops.*
Jackie Nicholson	*I think that the NICE guidance can only state that the CHG dressing allows visible inspection of the site - it is then for people to decide (based on the evidence) whether this is an important element of product use.*
Lisa Dougherty	*Re seeing the site – I don't think it is just about infection and I understand what they are saying re degree of redness spreading past patch and whether indicative of an infection, but there are other complications that can occur such as infiltration, dislodgement etc and being able to see the site allows visual inspection of all of these without having to remove the dressing when using CHG dressing. If we are asking nurses to document at least daily on inpatients about the CVAD insertion site then we need to be able to see it.*

Appendix 3: External Assessment Centre (EAC) response on Central Line Associated Bloodstream Infections (CLABSI) and Catheter-related Bloodstream Infections (CRBSI) (comment 3)

1. Consultation comment

A comment was received during the consultation period from the Tegaderm CHG sponsor stating that "It is known that in routine clinical practice the microbiological tests used for confirmation of CRBSI are often not available due to the needs of patient care or the resources available. Consequently the rate that should be used for informing the significance of the problem when considering the use of Tegaderm CHG dressing is central line associated blood stream infection (CLABSI)." A revision to section 4.12 of the guideline was suggested, advising hospitals to review CLABSI rates where CRBSI rates are unavailable.

2. Definition of CLABSI and CRBSI

The Joint Commission provide a definition of both CLABSI and CRBSI (Joint Commission, 2012):

- "CLABSI is the term used by the US Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network. A CLABSI is a primary bloodstream infection (that is, there is no apparent infection at another site) that develops in a patient with a central line in place within the 48-hour period before onset of the bloodstream infection that is not related to infection at another site. Culturing the catheter tip or peripheral blood is not a criterion for CLABSI."
- "CRBSI is a more rigorous clinical definition and requires specific laboratory testing to identify the catheter as the source of the bloodstream infection, such as culturing the catheter tip or a more elaborate method such as time-to-positivity."

The CLABSI definition is a more practical definition for surveillance than the CRBSI definition. However, CLABSI may overestimate the true rate of catheter related bloodstream infections due to difficulties in determining whether infections are due to the catheter or are unrelated e.g. urinary tract infections or pneumonia (Joint Commission, 2012).

3. Comparison of CLABSI and CRBSI incidence rates

The Joint Commission report on preventing CLABSI provides no comparison of CLABSI and CRBSI rates and therefore the magnitude of over estimation of CRBSI when using CLABSI as a proxy measure cannot be determined from this report (Joint Commission, 2012). The Centre for Disease Control and Prevention (CDC) also report that CLABSI may overstate the true incidence of CRBSI, although again no magnitude of this is provided (CDC, 2011).

The EAC have therefore conducted a pragmatic literature review to identify studies comparing the incidence rates of CLABSI and CRBSI in order to gain an understanding of the magnitude of over estimation of true CRBSI when CLABSI incidence is used. One study was identified that was set up to compare CRSBI and CLABSI incidence rates in the same group of adult patients (Chen *et al.*, 2014). This retrospective, observational study considered patients in a Taiwanese hospital. Cases of CLABSI for which there was a corresponding catheter tip culture were included within the study. Of the 64 cases of CLABSI, 31 cases of CRBSI were identified (48.4%). Therefore the results of this study suggest that the incidence of CLABSI is approximately double that of CRBSI

(Chen *et al.*, 2014). The generalisability of the results of this study to the Tegaderm CHG guidance are limited in that the study was not restricted to critically ill patients and because infection rates may vary between Taiwan and the UK NHS.

A second study was identified that compared the rates of CRBSI and catheter-linked bloodstream infection in patients in an intensive care unit (ICU) at Guy's and St. Thomas' NHS Foundation Trust (Culshaw *et al*., 2014). Catheter-linked bloodstream infections comprise both CRBSI and catheter-associated bloodstream infection. The definition of catheter-linked bloodstream infection appears to be in line with that provided for CLABSI in Section 2. Over a 48 month study period comprising 36,838 central venous catheter (CVC) days, the three-month rolling average mean CRBSI rate was 0.66 per 1,000 catheter days and catheter-linked bloodstream infection rate was 1.19 per 1,000 catheter days. Therefore, this study again suggests that the rate of CRBSI is roughly half that of catheter-linked bloodstream infection rate (Culshaw *et al*., 2014).

4. Implications for clinical and economic evidence

The clinical and economic evidence submitted by the sponsor and assessed by the EAC referred to CRBSI rather than CLABSI. Clinical evidence reported the hazard ratio of CRBSI with Tegaderm CHG compared with standard dressings (Timsit *et al*., 2012). The hazard ratio of CLABSI with Tegaderm CHG compared with standard dressings is likely to differ to that reported for CRBSI. This is because infections included within the broader CLABSI definition, which do not originate from the catheter, cannot be influenced by Tegaderm CHG. The economic modelling conducted by both the sponsor and the EAC utilised baseline CRBSI rates from the UK NHS (Bion *et al*., 2012) and applied the hazard ratio of CRBSI with Tegaderm CHG compared with standard dressings to this baseline rate. Therefore the cost-savings reported in the draft guidance relate to CRBSI rather than CLABSI.

The consultation comment on section 4.12 of the guideline proposes that where hospitals do not collect CRBSI rates, they should use their CLABSI as a substitute. In doing so, hospitals are at risk of overestimating potential cost-savings with Tegaderm CHG. The economic modelling conducted by the sponsor and EAC showed that higher baseline CRBSI rates equate to higher cost-savings. Where CLABSI baseline rates are substituted in, the effectiveness of Tegaderm CHG may be overstated. That is, the hazard ratio of reduction in CRBSI will be applied to a falsely high baseline infection rate.

The EAC recommends based on the evidence identified that the suggested adjustment should not be made. If the adjustment is made, the caveats associated with the data be clearly stated, including the potential for the overestimation of cost-savings.

References

Bion JF, Richardson A, Hibbert P, et al. 'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheterblood stream infections in intensive care units in England. BMJ Quality and Safety. 2013; 22: 110-23.

CDC. 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections. Available from: http://www.cdc.gov/hicpac/BSI/04-bsi-background-info-2011.html [last accessed 5th May 2015]

Chen X, Lo Y, Lin-Hui S, Chin-Lu C. Investigation of the case numbers of catheter-related bloodstream infection overestimated by the central line-associated bloodstream infection surveillance definition. Journal of Microbiology, Immunology and Infection. 2014; doi: 10.1016/j.jmii.2014.03.006.

Culshaw N et al. Healthcare-associated bloodstream infections in critically ill patients: descriptive cross-sectional database study evaluating concordance with clinical site isolates. Annals of Intensive Care. 2014; 4:34.

The Joint Commission. Preventing Central-Line Associated Bloodstream Infections: A Global Challenge, A Global Perspective. Available from: http://www.jointcommission.org/assets/1/18/CLABSI_Monograph.pdf [last accessed 5th May 2015]

Timsit JF, Mimoz O, Mourvillier B, Souweine B, Garrouste-Orgeas M, Alfandari S, et al. Randomized controlled trial of chlorhexidine dressing and highly adhesive dressing for preventing catheter-related infections in critically ill adults. American Journal of Respiratory and Critical Care Medicine. 2012; 186(12): 1272-8

Appendix 4: External Assessment Centre (EAC) response on Tegaderm CHG dressing costs (Comment 34)

The costs that the EAC used were taken from NHS supply chain. We calculated a weighted average cost based on the proportion of sales of each dressing size (sales data provided by 3M in their submission).

The following table outlines the costs from the sponsor's submission and costs used by the EAC from NHS supply chain.

Dressing size	Cost stated by 3M	NHS supply chain cost	Proportion of total sales
Tegaderm CHG 1660R 7 x 8.5cm	5.68	5.68	<5% (EAC assumed 1% in weighted average)
Tegaderm CHG 1657R 8.5x11.5cm	6.21	6.14	85%
Tegaderm CHG 1659R 10.5 x 15.5cm	7.17	7.17	13%
Tegaderm CHG 1658R 10 x 12cm	5.52	5.52	<5% (EAC assumed 1% in weighted average)

The weighted average cost that the EAC used in the cost modelling was £6.26 per dressing. The cost that the sponsor used was £6.21 (based on the list prices of the most commonly used dressing size). No alternative costs were provided by the sponsor during their submission.

During the assessment process we attempted to validate the NHS supply chain costs with those paid by Newcastle upon Tyne Hospitals NHS Foundation Trust. Unfortunately, Tegaderm CHG is not used there, so an alternative cost could not be identified. No other costs for Tegaderm CHG aside from those provided by the manufacturer and those on NHS supply chain were identified during the assessment process. We note that there are 3 distributors of the dressing listed on the 3M website:

- 3M direct – Tegaderm CHG is not listed on this website (price unavailable);
- Bunzl healthcare – we rang this distributor for the cost of Tegaderm CHG. For Tegaderm CHG 1657R (8.5x11.5cm) they charge £176.61 for a box of 25, which equals £7.06 per dressing (this price is for customers who do not hold an account with Bunzl, prices may be lower for those who do);
- NHS supply chain – see costs above.

We received information from the NHS supply chain regarding the number of Tegaderm CHG dressings sold via this source (section 2.1.2 of assessment report). In 2012/13, 108,200 dressings were sold and in 2011/12 84,900 dressings were sold.

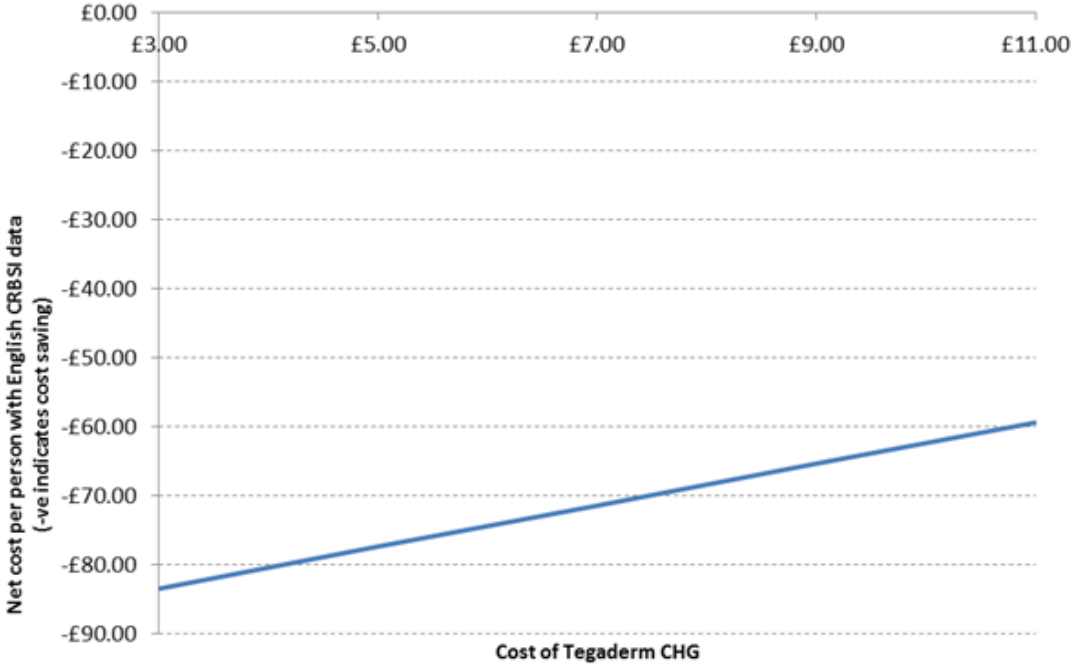
MT238 The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites

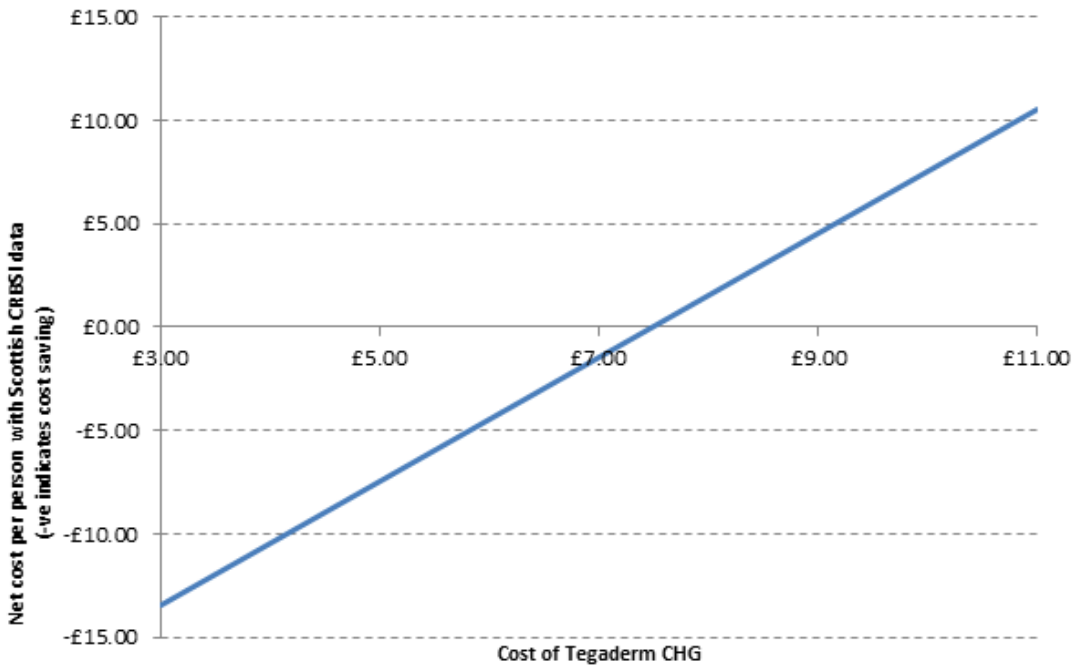
Within the sponsor's submission (figure 9, business confidential), the volume of sales of Tegaderm CHG to the NHS is provided. In the following table we have extracted data from that graph.

Time period	Volume of sales of Tegaderm CHG	Rolling annual total (based on current quarter and 3 previous quarters)
2013 Q3	[redacted]	[redacted]
2013 Q2	[redacted]	[redacted]
2013 Q1	[redacted]	[redacted]
2012 Q4	[redacted]	[redacted]
2012 Q3	[redacted]	[redacted]
2012 Q2	[redacted]	N/A
2012 Q1	[redacted]	N/A
2011 Q4	[redacted]	N/A

From this analysis it appears that the vast majority of sales are through NHS supply chain. In 2012/13 of the [redacted] total sales, [redacted] were through NHS supply chain [redacted]. We appreciate that this data is a couple of years old so the manufacturer may now sell more dressings through other means.

Finally, we have conducted a one-way sensitivity analysis on the cost of Tegaderm CHG to assess its impact on the results of the economic analysis. The figures below show the one-way analysis using the English CRBSI baseline rate and then the Scottish CRBSI baseline rate (note the line appears steeper on the Scottish graph only because the scale on the y axis is smaller). As we would expect, where the cost of Tegaderm CHG is lower, cost savings increase and vice versa. Using the Scottish data provided the cost of Tegaderm CHG is below £7.50 the dressing is estimated to be cost saving. Without a weighted average cost from 3M it is difficult to know exactly what hospitals are paying and how this influences the cost savings.


£0.00
£3.00
£5.00
£7.00
£9.00
£11.00
-£10.00
-£20.00
-£30.00
-£40.00
-£50.00
-£60.00
-£70.00
-£80.00
-£90.00
Net cost per person with English CRBSI data
(-ve indicates cost saving)
Cost of Tegaderm CHG



Given that around [redacted] of the 2012/13 sales were through the NHS supply chain and therefore from hospitals paying the list price, we are confident of the costs used within the modelling. If the savings given to the other [redacted] are vast, our confidence would reduce.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."