

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology consultation document

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

The National Institute for Health and Care Excellence (NICE) is producing guidance on using the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites in the NHS in England. The Medical Technologies Advisory Committee has considered the evidence submitted and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the draft recommendations made by the Committee. NICE invites comments from the public. This document should be read along with the evidence base (see Sources of evidence considered by the Committee).

The Advisory Committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

**Note that this document is not NICE's final guidance on the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites. The recommendations in section 1 may change after consultation.** After consultation the Committee will meet again to consider the evidence, this document and comments from public consultation. After considering these comments, the Committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the [Medical Technologies Evaluation Programme process guide](#) and [Medical Technologies Evaluation Programme methods guide](#).

Key dates:

- Closing time and date for comments: 09:00 17 April 2015
- Second Medical Technologies Advisory Committee meeting: 21 May 2015

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

## **1 Provisional recommendations**

- 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. This 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.
- 1.2 The 3M Tegaderm CHG IV securement dressing should be considered for use in critically ill patients who need a central venous or arterial catheter in intensive care or high dependency units.
- 1.3 The estimated cost saving from using a 3M Tegaderm CHG IV securement dressing (Tegaderm CHG) instead of a standard transparent semipermeable dressing is £73 per patient. These estimates are based on a baseline catheter-related bloodstream infection rate of 1.48 per 1000 catheter days. Tegaderm CHG is estimated to be cost neutral when the baseline catheter-related bloodstream infection rate is 0.24 per 1000 catheter days, and cost incurring when the baseline rate falls below that figure. Estimates of the benefiting population vary from around 88,000 to 226,000 depending on whether adult ICU episodes longer than 48 hours

requiring a central venous catheter, or all adult ICU episodes requiring a central venous catheter, are used. Based on these estimates, if the use of Tegaderm CHG became standard practice, it has the potential to save the English NHS between £6.2 million and £16.5 million each year, assuming the baseline catheter-related bloodstream infection rate is 1.48 per 1000 catheter days.

## **2 The technology**

### ***Description of the technology***

- 2.1 The 3M Tegaderm CHG IV securement dressing (3M, 'Tegaderm CHG') is a sterile transparent semipermeable polyurethane adhesive dressing with an integrated gel pad containing a 2% concentration by weight of chlorhexidine gluconate (CHG).
- 2.2 The Tegaderm CHG dressing is used to secure percutaneous devices and to cover and protect central venous and arterial catheter insertion sites. It aims to provide an effective barrier against external contamination. The dressing and the integrated gel pad are transparent to allow observation of the catheter insertion site. The integrated gel pad is designed to reduce skin and catheter colonisation in order to suppress regrowth of microorganisms commonly related to catheter-related bloodstream infections (CRBSI). The dressing is available in 4 different sizes but the most commonly-used size, accounting for 85% of sales, measures 8.5 cm×11.5 cm.
- 2.3 The Tegaderm CHG dressing was CE-marked as a class III device in April 2009 to cover and protect catheter sites and to secure devices to the skin. There was a modification to the dressing design in 2011 to include a breathable film.
- 2.4 The cost of the Tegaderm CHG stated in the sponsor's submission was £6.21. This cost was based on the list price of the

Tegaderm CHG 1657R (8.5 cm×11.5 cm) dressing; the cost includes VAT.

2.5 The claimed benefits of the Tegaderm CHG presented by the company are:

- A 60% reduction in the incidence of catheter-related bloodstream infections (CRBSI) in critical care patients with intravascular catheters.
- Reduced risk of mortality due to catheter-related infections.
- Reduced incidence of skin and catheter colonisation during treatment with central venous catheters or arterial catheters.
- Reduced length of stay in critical care or high dependency units.
- Reduced costs for diagnosis of CRBSI.
- Reduced material and staff costs for treatment of catheter-related infection.

### ***Current management***

2.6 NICE's guideline on [infection](#) provides guidance on using dressings in adults and children with vascular access devices (central venous catheters or peripherally-inserted central catheters) in primary and community care settings. The guideline recommends that the skin at the central venous catheter insertion site, and the surrounding skin during dressing changes, should be decontaminated with CHG in 70% alcohol and allowed to air dry. If the company's recommendations prohibit the use of alcohol with their catheters, an aqueous solution of CHG should be considered. The guideline further recommends using a sterile, transparent semipermeable membrane dressing to cover the vascular access device insertion site, and changing the dressing every 7 days or sooner if it is no longer intact or if moisture collects under it. A sterile gauze dressing, covered with a sterile transparent semipermeable dressing, should be considered only if the patient has profuse perspiration, or if the vascular access device insertion site is

bleeding or oozing. The guideline states that systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter. It makes no specific recommendations about using CHG-impregnated dressings, although the full guideline notes that they may be cost effective compared with sterile transparent semipermeable membrane dressings based on limited evidence from 1 study, Crawford et al. (2004).

- 2.7 The Department of Health commissioned the [epic3 guideline](#) on preventing healthcare-associated infections in NHS hospitals in England. The guideline recommends using a sterile transparent semipermeable dressing to cover the intravascular insertion point as best practice in both adults and children. The guideline recommends, based on high-quality evidence, a single application of 2% CHG in 70% isopropyl alcohol (or povidone-iodine alcohol for patients with sensitivity to CHG) to clean the central catheter insertion site during dressing changes, and allowing it to air dry. The guideline also recommends, based on evidence of limited quality, that hospitals consider using a CHG-impregnated sponge dressing in adults with a central venous catheter, as a strategy to reduce CRBSI.
- 2.8 NICE's evidence update on [infection](#) concluded that the evidence on which the epic3 recommendation for using CHG-impregnated sponges is based is unlikely to have an effect on NICE's clinical guideline on infection, and that further research is needed to establish the efficacy of CHG dressings applied to CHG-prepared skin to prevent CRBSI in patients with venous access devices. This review was based on evidence from 1 study, Bashir et al. (2012).
- 2.9 Care bundles are a structured way of improving the processes of care and patient outcomes. They consist of a set of simple to implement evidence-based practices, that when performed collectively and reliably, have been proven to improve patient

outcomes. [Central venous catheter care](#) is an exemplar care bundle produced by the Department of Health in 2010.

### **3 Clinical evidence**

#### ***Summary of clinical evidence***

- 3.1 The key clinical outcomes for the 3M Tegaderm CHG IV securement dressing presented in the decision problem were:
- catheter-related bloodstream infections (CRBSI)
  - skin and catheter colonisation
  - length of stay in critical care or high dependency unit
  - mortality caused by catheter-related infections
  - dermatitis
  - local site infection
  - quality of life
  - device-related adverse events.
- 3.2 The company identified 5 studies that met their inclusion criteria. There were 3 studies (Maryniak et al. 2009; Olson et al. 2008; Rupp et al. 2008) that reported nursing satisfaction scores on various aspects of dressing design and performance; these were excluded from the clinical evidence review (see section 3.11). An unpublished study by Scoppettuolo et al. (2012) was also excluded because the results from intensive care unit and non-intensive care unit patients were not reported separately. The company presented the remaining study by Timsit et al. (2012).
- 3.3 The External Assessment Centre agreed with including Timsit et al. (2012) and excluding the 4 remaining studies identified.
- 3.4 The External Assessment Centre carried out a further literature search to identify all prospective comparative studies including at least 2 of the 3 dressing types in the scope: Tegaderm CHG, a semipermeable transparent (standard) dressing and a

chlorhexidine gluconate (CHG)-impregnated dressing. This search returned 1755 records of which 4 were considered relevant. Of the 4 studies identified, 2 involved Tegaderm. One of these 2 studies involving Tegaderm was presented by the company (Timsit et al. 2012); the other was identified by the company as an ongoing study (Karpanen et al. 2014) with interim results published after the company's submission of evidence. The External Assessment Centre considered the Timsit et al. (2012) study to be relevant to the decision problem despite the fact that both the intervention and control groups were not swabbed with 2% CHG in alcohol as specified in the decision problem. The other 2 studies (Timsit et al. 2009; Roberts et al. 1998) compared a CHG-impregnated sponge dressing (Biopatch, Johnson and Johnson) against standard dressings, and were included by the External Assessment Centre to provide an indirect comparison between Tegaderm CHG and a CHG-impregnated dressing (a comparator in the decision problem).

3.5 Timsit et al. (2012) reported a large multicentre randomised controlled trial, based in 12 intensive care units in France, involving 1879 patients and 4163 intravascular catheters (2201 arterial and 1962 central venous catheters). Patients needing intravascular access were randomised to 1 of 3 groups: Tegaderm CHG (938 patients), standard dressing (Tegaderm transparent film dressing; 476 patients) or highly-adhesive dressing (Tegaderm HP transparent film dressing; 465 patients). Assessors were blinded to dressing type. Patients had their skin prepared with povidone-iodine in alcohol or 0.5% chlorhexidine in alcohol. Dressings were replaced after 24 hours and then every 3–7 days depending on the centre, or as needed if there was leaking or soiling. The study follow-up period was 48 hours after discharge from the intensive care unit.

3.6 Outcomes were reported on an intention-to-treat basis. These were reported for each group, and comparative statistical analyses were

done between the Tegaderm CHG group and the 2 non-CHG-dressing groups combined (the standard and highly-adhesive dressing groups), and between the standard dressing group and the highly-adhesive dressing group. Results showed that CRBSI rates were significantly lower in the Tegaderm CHG group, at 0.5 per 1000 catheter days compared with 1.3 for both the highly-adhesive dressing and standard dressing groups (hazard ratio [HR] for CHG compared with non-CHG dressings 0.402; 95% confidence interval [CI] 0.186 to 0.868,  $p=0.02$ ). Catheter and skin colonisation were significantly lower in the Tegaderm CHG group at 4.3 per 1000 catheter days compared with 9.6 for the standard dressing group, 12.5 for the highly-adhesive dressing group, and 10.9 for the 2 non-CHG dressing groups combined (HR for CHG compared with non-CHG dressings 0.412; 95% CI 0.306 to 0.556,  $p<0.0001$ ). Major catheter-related infections (defined as catheter-related sepsis with or without CRBSI), were also significantly lower in the Tegaderm CHG group, at 0.7 per 1000 catheter days compared with 2.3 for the standard dressing group and 1.9 for the highly-adhesive dressing group (HR for CHG compared with non-CHG dressings 0.328; 95% CI 0.174 to 0.619,  $p=0.0006$ ). Patients with a Tegaderm CHG dressing had a significantly higher rate of severe contact dermatitis needing removal of the dressing; 1.1% compared with 0.1% for the standard dressing and 0.5% for the highly-adhesive dressing,  $p<0.0001$ . Also, abnormal International Contact Dermatitis Research Group (ICDRG) scores, measured at each dressing change and at catheter removal, were significantly higher for Tegaderm CHG at 2.3%, compared with 1% for the non-CHG dressings (0.7% for the standard dressing and 1.4% for the highly-adhesive dressing,  $p<0.0001$ ). No systemic adverse events related to any of the dressings were reported. The authors concluded that Tegaderm CHG was associated with a lower rate of major catheter-related infections than either of the non-CHG dressings.

- 3.7 Karpanen et al. (2014) reported interim results, in the form of a poster presentation, of a non-randomised prospective comparative observational study of 273 intensive care unit patients at University Hospitals Birmingham NHS Foundation Trust. Patients had Tegaderm CHG or a standard dressing (Tegaderm IV dressing). Patients in both groups had standard catheter care, including skin preparation with 2% CHG in 70% alcohol. Based on interim results in the 273 patients, there were 10 instances (7.4%) of colonisation of the intradermal section of the central venous catheter in the Tegaderm CHG group compared with 22 (14.6%) in the standard dressing group,  $p=0.037$ . There were 10 instances (7.4%) of tip colonisation of the central venous catheter reported in the Tegaderm CHG group compared with 20 instances (16.1%) in the standard dressing group,  $p=0.08$ . Adverse events were not reported. The authors concluded that adopting Tegaderm CHG reduced bacterial numbers on the skin and reduced the bacterial load at the central venous catheter insertion site compared with the standard dressing.

### **Studies on the comparator technologies**

- 3.8 Timsit et al. (2009) reported on a multicentre, 2×2 factorial randomised controlled trial involving 1636 patients in 7 intensive care units in France. The study had 2 aims: to assess the superiority of a CHG-impregnated sponge on rates of major catheter-related infection; and to determine the effect on outcomes of a 3 or 7-day dressing change. Patients were randomised to 1 of 4 groups by both dressing type (CHG-impregnated sponge [Biopatch] plus a standard dressing [Tegaderm, 3M] or a standard dressing alone) and frequency of dressing change (every 3 or 7 days). In all patients an antiseptic solution of 5% povidone-iodine in 70% ethanol was applied and all dressings were changed 24 hours after catheter insertion. The follow-up period was 48 hours after discharge from the intensive care unit, and all outcomes were based on intention-to-treat analyses.

- 3.9 CRBSI rates were significantly lower in the CHG-impregnated sponge group at 0.4 per 1000 catheter days compared with 1.3 for the standard dressing group (HR 0.24; 95% CI 0.09 to 0.65,  $p=0.005$ ). Catheter and skin colonisation rates were significantly lower in the CHG-impregnated sponge group, 0.6 per 1000 catheter days compared with 1.4 for the standard dressing group (HR 0.36; 95% CI 0.28 to 0.46,  $p<0.001$ ). Major catheter-related infection rates were significantly lower in the CHG-impregnated sponge group, 0.6 per 1000 catheter days compared with 1.4 for the standard dressing group (HR 0.39; 95% CI 0.16 to 0.93,  $p=0.03$ ). There was no statistically significant difference in these outcomes between the 3 or 7-day dressing change groups.
- 3.10 The rate of severe contact dermatitis, needing removal of the dressing, was 0.53% for the CHG-impregnated sponge group and 0% for the standard dressing group (no statistical analyses reported). Abnormal ICDRG scores, measured at each dressing change and at catheter removal, were significantly higher for the CHG-impregnated sponge group at 1.49% compared with 1.02% for the standard dressing group,  $p=0.02$ . No systemic adverse events related to the dressings were reported. The authors concluded that the CHG-impregnated sponge dressing was associated with a reduction in risk of infection, even with low background infection rates compared with the standard dressing.
- 3.11 Roberts et al. (1998) carried out a single-centre randomised controlled trial involving 32 patients with 40 catheters in an Australian intensive care unit. Patients were randomised to have a CHG-impregnated sponge (Biopatch) plus a standard dressing or a standard dressing alone (Opsite IV 3000, Smith and Nephew). Skin was prepared with 0.5% CHG in alcohol and dressings were changed every 3 days. There was 1 CRBSI in the CHG-impregnated sponge group, and 0 in the standard dressing group ( $p$  value not reported). There were 2 instances of catheter

colonisation on the central venous catheter tip, and 4 at the exit site in the CHG-impregnated sponge group compared with 1 case and 3 cases respectively for the standard dressing group; neither difference was statistically significant. Adverse events were not reported. The authors stated that the data were insufficient to draw conclusions from this study.

- 3.12 The External Assessment Centre critically appraised the methodology of each study. It judged that the studies by Timsit et al. (2009 and 2012) were the most relevant and best conducted. The study by Roberts et al. (1998) was underpowered to determine the statistical significance of outcomes; provided few details on the methodology used; included no details on how randomisation was achieved; and only provided information on age and gender of the study population at baseline. The poster presentation by Karpanen et al. (2014) contained insufficient detail for the External Assessment Centre to fully appraise its methodology and accurately judge its relevance to the decision problem.
- 3.13 Overall, the External Assessment Centre considered the company's submission to be reasonably consistent with the scope. The Timsit et al. (2012) study included by the company used internationally-recognised definitions for catheter colonisation and CRBSI. Mortality caused by catheter-related infections, local site infection, and quality of life were not addressed in the company's submission. However, given the evidence for a link between CRBSI and mortality, the External Assessment Centre considered it plausible that if Tegaderm CHG reduced CRBSI, it would have a positive effect on CRBSI-related mortality in practice. The External Assessment Centre noted that the CRBSI rate of 1.3 per 1000 catheter days reported in Timsit et al. (2012) was similar to that reported for the NHS in England in the Matching Michigan study of 1.48 per 1000 catheter days, making its results generalisable to the NHS. However, it also noted that the mortality

of 31% for the intensive care units in France in the Timsit studies was substantially higher than the 9.1% mortality reported for adult critical care units in the NHS. This suggested that whereas their demographics were similar, the intensive care units in France probably had more severely ill patients than the UK intensive care units. The skin preparation protocols followed by the intensive care units in France differed from those recommended for the NHS, which were specified in the decision problem.

### **Adverse events**

- 3.14 The company searched the Medicines and Healthcare Products Regulatory Agency (MHRA) and Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) systems to identify surveillance reports relating to Tegaderm CHG, between 7 January 2000 and 29 July 2013. This revealed 1 result from the MHRA and 109 results from MAUDE. The company also searched their post-marketing surveillance data for reported skin reactions. This identified a marked reduction in reports, both in numbers and relative to increasing sales, after a modification to the dressing design to incorporate a breathable film in 2011.
- 3.15 The External Assessment Centre found that the company's search of the MAUDE and MHRA systems accurately reported, in detail, the adverse events for Tegaderm CHG. Overall, they considered the company's search for adverse events to be robust.
- 3.16 The External Assessment Centre extended the company's search to 28 November 2014 and identified a further 17 results. These results generally described local skin reactions within 48 hours of dressing application, and many were self-limiting. There were 2 deaths reported in MAUDE, but these were not directly linked to Tegaderm CHG.
- 3.17 The company also did a search of the MHRA and MAUDE systems to identify post-marketing surveillance reports for the Biopatch

(CHG-impregnated sponge) and Opsite IV 3000 (standard) dressings, but it did not report the search terms and dates used. The External Assessment Centre did its own searches of these systems between 1 January 2012 and 30 November 2014. These searches identified 73 records for Biopatch, which were similar in nature to the 29 records for Tegaderm CHG over the same period. However, this provides only a crude comparison because it does not allow for numbers of dressings used. One record reported a death; however this was not directly linked to Biopatch. Only 1 minor, self-correcting adverse reaction was found for the Opsite IV 3000 dressing over this period.

### **Committee considerations**

- 3.18 The Committee considered that the evidence showed that Tegaderm CHG was effective in reducing CRBSIs compared with standard semipermeable transparent dressings. It considered that the Tegaderm CHG and CHG-impregnated sponge dressings were clinically equivalent in terms of reducing CRBSIs. However, it noted that Tegaderm CHG offers the additional benefit of visibility of the catheter insertion site. The Committee was advised by clinical experts that visibility of the catheter insertion site allows the 'care bundle' checks that are needed to minimise infection rates. It was also advised that nurses find Tegaderm CHG easier to apply than CHG-impregnated sponge dressings.
- 3.19 The Committee noted that the study evidence was largely from intensive care units in France that followed different skin preparation guidelines and that may have had more severely ill patients than those generally found in the UK. The Committee considered that this evidence was nevertheless generalisable to the UK, based on advice from experts and the External Assessment Centre and on the knowledge of its members.
- 3.20 The Committee heard from clinical experts that different definitions exist for CRBSI. It was advised that variation in the incidence of

CRBSI between hospitals may arise from differences in definitions and measurement methods, making comparison of infection rates difficult.

- 3.21 The Committee was advised by clinical experts that introducing care bundles into intensive care units had significantly reduced rates of CRBSI, but that it is not possible to identify which specific components of a care bundle have led to the reductions in infection rates. It was advised that Tegaderm CHG could be used with existing care bundles as an additional method for minimising rates of CRBSI, but it would not replace the need to use care bundles. The Committee noted that in some hospitals existing infection control procedures may have reduced baseline CRBSI rates to such low levels that they may not be able to realise the benefits from introducing Tegaderm CHG (see section 5.19).

## **4 NHS considerations**

### ***System impact***

- 4.1 The company proposed that using Tegaderm CHG would not result in changes to the current care pathway or need additional resources. The External Assessment Centre agreed with these assumptions.
- 4.2 Using Tegaderm CHG instead of a standard dressing does not need any special additional training. At the topic selection phase, the Committee received expert advice that confirmed that minimal additional training would be needed.
- 4.3 Information provided by the company based on 2012/13 Hospital Episodes Statistics data found 237,710 patient episodes for adult critical care episodes, 92,710 of which involved stays of over 48 hours. Based on expert opinion the company estimated that 95% of these patients would require a central venous catheter, providing

an estimate of the benefitting population of between 88,074 and 225,824.

#### **Qualitative evidence on ease of use and performance**

- 4.4 The company provided supplementary information from 3 randomised controlled trials (Maryniak et al. 2009; Olson et al. 2008; Rupp et al. 2008) on the performance of Tegaderm CHG compared with a standard dressing (either Tegaderm IV or Opsite IV 3000, Smith and Nephew). These studies were not included in the company's main submission because they were not limited to critically ill patients and used non-validated methods in their nurse-reported dressing satisfaction and performance outcome measures.
- 4.5 The External Assessment Centre agreed with the company's decision to exclude these studies from the clinical evidence. The External Assessment Centre collated information on the ease of use and performance of Tegaderm CHG using advice from experts, evidence from the company and from its own searches.
- 4.6 Maryniak et al. (2009) reported a prospective observational study involving 217 inpatients or outpatients (107 patients had Tegaderm CHG and 110 patients had an unspecified standard dressing). Olson et al. (2008) carried out a randomised controlled trial with 63 hospitalised patients (33 patients had Tegaderm CHG and 30 patients had a standard dressing – Tegaderm IV), some of whom were in intensive care units. Rupp et al. (2008) completed a randomised controlled trial with 60 hospitalised patients (30 patients had Tegaderm CHG and 30 patients had a standard dressing – Opsite IV 3000). All these studies were done in the USA, none of them specifically considered critically ill patients and satisfaction with the dressings was judged by the clinical staff. The results showed that the nurses were statistically significantly more satisfied with Tegaderm CHG than with standard dressings in all

3 studies ( $p < 0.05$ ). Tegaderm CHG was reported to provide a more satisfactory dressing securement, was easier to apply and had improved adherence. There were mixed results, and largely insignificant differences, in terms of nurse satisfaction with ease of correct application, transparency (site visibility), ease of dressing removal, and reported patient discomfort levels during dressing wear.

- 4.7 The External Assessment Centre identified a number of studies comparing the ease of use of Tegaderm CHG against a chlorhexidine gluconate (CHG)-impregnated sponge. Eyberg et al. (2008) reported a randomised controlled trial comparing Tegaderm CHG against a CHG-impregnated sponge (Biopatch) in which 12 clinicians were randomly allocated to apply and remove 1 of the dressings on the left or right side of the neck in 12 healthy volunteers. Outcome measures included overall performance, ease of correct application, ease of removal, ability to see the intravenous site, ease of training and intuitive application. Clinicians found that Tegaderm CHG was statistically significantly better than the CHG-impregnated sponge across all outcome measures ( $p < 0.05$ ). There were 2 poster presentations (Zehrer et al. 2009; Deschneau et al. 2008) that reported on questionnaires completed by nurses after using the dressings. In both studies Tegaderm CHG performed significantly better overall than the CHG-impregnated sponge.
- 4.8 Advice provided during evaluation from 3 experts with experience of using both Tegaderm CHG and standard dressings was that, in general, clinician experience of applying and removing Tegaderm CHG was similar to standard dressings. There was 1 expert who stated that it takes longer to remove Tegaderm CHG and that there may be a few incorrect applications at first. The remaining 2 experts stated that the time taken to apply or remove

the dressing is the same or similar for both Tegaderm CHG and standard dressings.

- 4.9 There were 2 experts who had experience of using both Tegaderm CHG and CHG-impregnated sponge dressings. They reported minimal differences between the ease of use of the 2 types of dressings. One expert suggested that applying and removing Tegaderm CHG is quicker than for the CHG-impregnated sponge. The other reported that some nurses had placed the CHG-impregnated sponge upside down and therefore had to use a replacement.

### **Committee considerations**

- 4.10 Based on evidence from the company, the External Assessment Centre and expert advice, the Committee was satisfied that Tegaderm CHG would not involve significant changes to current care pathways and the use of existing care bundles.
- 4.11 The Committee was advised by clinical experts that care bundles are of great importance in minimising infection rates. It was advised that care bundles include many components and that it is difficult to identify any specific components that are driving the improvement in infection rates. The Committee concluded that Tegaderm CHG could contribute to preventing catheter-related bloodstream infections (CRBSI) but it would not replace the need for existing infection control practices.
- 4.12 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.

## 5 Cost considerations

### **Cost evidence**

- 5.1 The company did a literature search and identified 5 studies that met their selection criteria. All of these studies used cost–benefit analyses. Of these, 3 studies were in the USA (Veenstra et al. 1999; Crawford et al. 2004; Ye et al. 2011), 1 study was in the UK (Hockenhull et al. 2008) and 1 study was in France (Schwebel et al. 2012). In 2 of the studies, the comparison was between an antiseptic-impregnated catheter and a standard catheter (Veenstra et al. 1999; Hockenhull et al. 2008). In the remaining 3 studies (Crawford et al. 2004; Schwebel et al. 2012; Ye et al. 2011), the intervention was a chlorhexidine gluconate (CHG)-impregnated dressing and the comparator was a standard dressing. None of the included studies involved the Tegaderm CHG dressing.
- 5.2 The External Assessment Centre considered none of the company’s identified studies to be relevant because they did not compare Tegaderm CHG with either of the comparators. It did additional searches and identified 4 economic studies; all used cost–benefit analyses and compared Tegaderm CHG with a standard dressing (Maunoury et al. 2013, 2014; Palka-Santini et al. 2014a, 2014b). All were published as conference abstracts after the company’s searches. All of the studies were carried out from a perspective of the health service in France, were written by the same authors, and used data from Timsit et al. (2012). Each study used different model structures or reported different results, all involved a non-homogeneous Markov model, and were concerned with various measures of infection. No statistically significant differences in costs were reported between the dressings. The External Assessment Centre was unable to extract any relevant data from the available reports.

## ***Economic model***

- 5.3 The company presented a cost analysis comparing Tegaderm CHG against a standard dressing (Tegaderm IV 1635). The costs of another commonly used but more expensive standard dressing (Opsite IV 3000, Smith and Nephew) were also quoted, but not used in the model. The company did not include the CHG-impregnated sponge dressing in the model because of the lack of direct comparative clinical evidence. The economic model presented by the company was a decision tree with a short time horizon that involved the catheterisation period and any additional length of stay associated with catheter-related bloodstream infections (CRBSI). The model used an NHS perspective. The decision tree simulated intensive care unit patients who had an absolute risk of getting CRBSI, local site infection or dermatitis. Each outcome was a separate health state and the model captured the number of patients in each state and the cost of being in that state (dressings and management costs).
- 5.4 Each time the model was run, Monte Carlo simulation was used to select values at random from the pre-specified distributions associated with each of the input parameters, apart from the unit cost of the dressings. This approach allowed the effects of the joint uncertainty across the parameters of the model to be considered. The company's base-case results were probabilistic, based on 1000 iterations of the model.
- 5.5 The External Assessment Centre considered that the structure of the model was appropriate, capturing the main differences in reported clinical outcomes and cost differences between Tegaderm CHG and standard dressings. However, it noted that the 3 end states did not account for patients who had no complications and it amended the model to include this state. The company did not report any structural assumptions but the External Assessment Centre identified a number of structural assumptions in the model:

- There is no difference in outcomes beyond the short time horizon of the study.
- The length of time a patient has a catheter is not influenced by whether or not they had an infection (CRBSI or local).
- The risk of having any of the study outcomes is mutually exclusive and independent.
- The dressings only affect actual outcomes and not suspected outcomes, which would also incur costs of investigation.
- Infection rates are assumed to be linear regardless of catheter dwell time.
- There are no practical differences in dressing management between the dressings such as time to apply and remove, wastage and training.

5.6 The External Assessment Centre judged that these simplifying assumptions were unlikely to influence the results of the company's model significantly.

5.7 The company used data from Timsit et al. (2012) to populate the parameters for all the clinical end points in the model. The model's time horizon of 10 days was based on the mean duration of catheterisation for critically ill patients reported in the study by Ye et al. (2012). Patients who had a CRBSI incurred an additional length of stay of 3 days in an intensive care unit and 7 days in a ward, with resource use costs based on figures reported in the Hockenhull et al. (2008) study. Baseline risks for the clinical end points were obtained from a number of sources. Those for CRBSI (1.48 per 1000 catheter days) were taken from Bion et al. (2012), based on 2010 final quarter figures from the Matching Michigan study; those for local site infection (0.1 per patient) from Ye et al. (2011); and for dermatitis (0.0026 per catheter) from Schwebel et al. (2012).

5.8 The costs for the Tegaderm CHG and the standard dressing (Tegaderm IV 1635) used in the company's model were based on the cost of the most commonly-used size of dressing, and were

£6.21 and £1.34 respectively. These figures were provided by the company.

- 5.9 The cost for a CRBSI of £9900 was based on the figure reported in the health technology assessment paper by Hockenhull et al. (2010), inflated to 2012/13 prices. This value was used in NICE's guideline on [infection](#). The company produced its own cost estimate for CRBSI based on resource use identified through expert advice, which agreed with this £9900 figure. The cost of dermatitis of £150 used in the company's model was based on the cost of 4 standard dressings, removing the existing catheter, and replacing it with a new catheter. Local site infections were given a cost of £250 based on the US \$400 figure reported in the study by Saint et al. (2000).
- 5.10 The company's base-case results reported an average cost of £99.63 per patient for the Tegaderm CHG dressing compared with £176.89 per patient for the standard dressing. This would give an average saving of £77.26 per patient if Tegaderm CHG were adopted. The probability of Tegaderm CHG being cost saving over standard dressings was calculated at 98.5%. The key driver of this cost saving was avoiding CRBSI through using Tegaderm CHG.
- 5.11 The company presented univariate deterministic analysis on both the cost of CRBSI and its baseline risk, to explore how robust the estimated cost savings of Tegaderm CHG compared with standard dressings were to changes in these key variables. If a low estimate of CRBSI risk of 0.5 per 1000 catheter days was used the cost savings with Tegaderm CHG were £23 per patient; if a high estimate of 5.5 per 1000 catheter days was used the savings with Tegaderm CHG increased to £135 per patient. Based on a low estimate of £5000 for treating a CRBSI and a high estimate of £15,000, Tegaderm CHG generated cost savings per patient of £36 and £119 respectively.

## ***Parameter revisions by the External Assessment Centre***

- 5.12 The External Assessment Centre reviewed the parameters and costs used in the company's model. It contacted clinical experts who validated the company's estimated resource use associated with CRBSI.
- 5.13 The External Assessment Centre revised the company's value for baseline local site infection risk to 0.14 per 1000 catheter days based on 2013 audited rates for NHS Wales published by the Welsh Healthcare Associated Infection Programme (2014).
- 5.14 The External Assessment Centre judged it more appropriate to use the probability of 1 case of dermatitis per 476 patients reported in the Timsit et al. (2012) study. The External Assessment Centre revised the relative risk of dermatitis to 1, based on commercial-in-confidence global event data provided by the company on the reduced rate of dermatitis after design improvements in the breathability of the Tegaderm CHG dressing.
- 5.15 The External Assessment Centre calculated a weighted average cost for the dressings, taken from the NHS Supply Chain costs. For Tegaderm CHG the cost was based on the proportionate sales figures for the 4 dressing sizes and was estimated as £6.26 per dressing. The cost of the standard dressing was based on the proportionate sales figures of 2 commonly-used standard dressings, Tegaderm IV and Opsite IV 3000, and was estimated as £1.54 per dressing. The External Assessment Centre estimated the cost of a CHG-impregnated dressing to be £8.13.
- 5.16 The External Assessment Centre was advised by experts that it was not usual procedure to remove the catheter if a patient developed dermatitis. It therefore considered the company's costs of the consequences of dermatitis overestimated the true cost. The External Assessment Centre therefore estimated a lower value, which involved the costs of dressings only, but assumed, as did the

company, that patients with dermatitis would need more frequent dressing changes. It assumed the use of 1 additional dressing. Therefore the cost of dermatitis was revised to £6.

- 5.17 The study by Saint et al. (2000), which provided the cost for local site infection used in the company's model, provided no details on how that cost was generated. The External Assessment Centre therefore sought expert advice to derive its own cost estimate, £100, which was lower than that used in the company's model.
- 5.18 The External Assessment Centre also sought expert advice on the number of dressings used. This agreed with the company's estimate of 3 dressings over a 10-day catheterisation period.
- 5.19 The External Assessment Centre identified 2 main weaknesses in the company's economic analysis. First, there was a lack of rationale for the choice of distributions and coefficients used in the probabilistic sensitivity analysis done by the company. However, the External Assessment Centre noted that this was not required as part of the submission template. Secondly, the company did not attempt to make any judgement on the comparative cost effectiveness of Tegaderm CHG and a CHG-impregnated sponge dressing. The External Assessment Centre addressed both these concerns in the assessment report.
- 5.20 The External Assessment Centre re-ran the company's model with their revisions to parameter values and distributions. It also ran an additional scenario in which the baseline CRBSI rate for England was substituted with that reported for Scotland in 2013 of 0.3 per 1000 catheter days. Both deterministic and probabilistic sensitivity analyses were done. The External Assessment Centre's deterministic base-case results using CRBSI data from England produced an average per patient cost of £77.75 for Tegaderm CHG and £151.29 for a standard dressing, a cost saving of £73.54. 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. The External Assessment Centre varied the baseline CRBSI rate and identified the threshold value at which Tegaderm CHG was cost neutral as 0.24 per 1000 catheter days.

- 5.21 The External Assessment Centre ran both univariate and multivariate probabilistic sensitivity analyses, varying the model parameters using their ranges and distributions (see table 4.14 of the assessment report). In the probabilistic sensitivity analysis varying all the model parameters, Tegaderm CHG had a 97.8% probability of being cost effective using the baseline CRBSI risk from England, but this fell to 57.9% when the figure from Scotland was used.
- 5.22 The External Assessment Centre also presented an exploratory cost analysis of Tegaderm CHG compared with CHG-impregnated sponge dressings. There were no comparative data and from the limited evidence available (including similar data on adverse events), the External Assessment Centre concluded that it was plausible to assume that the 2 dressings had similar safety and efficacy. Without hard data on outcomes this exploratory work relied on observational studies and expert opinion. This suggested that resource use was similar between the 2 dressings, with any cost differences relying on acquisition cost. Based on NHS Supply Chain costs for Biopatch and the cheapest standard dressing (Tegaderm IV) the cost for a CHG-impregnated sponge dressing was calculated at £8.13, compared with £6.26 for Tegaderm CHG. No sales data were available through the NHS Supply Chain. Expert opinion indicated that NHS trusts would probably purchase through other sources at a lower price than the NHS Supply Chain listed price. Therefore the External Assessment Centre calculated additional costings using the price provided by the company for

Biopatch, of £5.16 per dressing. This resulted in a total price of £6.49, slightly more expensive than Tegaderm CHG.

### ***Committee considerations***

5.23 The Committee noted the cost modelling presented by the company and the adjustments made by the External Assessment Centre. It considered that the revisions made by the External Assessment Centre were plausible. The Committee considered that the External Assessment Centre's sensitivity analyses addressed the uncertainties in the economic model. It concluded that the estimated cost savings for Tegaderm CHG compared with standard semipermeable transparent dressings were likely to be realised in practice, with actual savings dependent on the baseline CRBSI rate.

5.24 The Committee considered that the baseline CRBSI rate was a key driver of the savings in the cost model. It noted that Tegaderm CHG was cost neutral when the baseline CRBSI rate was 0.24 per 1000 catheter days and became cost incurring when the baseline rate fell below that figure. The Committee heard expert opinion that CRBSI rates in England have recently been falling. It heard from both the External Assessment Centre and the experts that there are differences in the definition and measurement of CRBSI between different countries and different hospitals, which makes comparison of infection rates difficult. The Committee concluded that Tegaderm CHG is likely to be cost saving in hospitals where the baseline CRBSI rate is above about 0.24 per 1000 catheter days, and could potentially provide a useful way of reducing infection rates further in those hospitals which have not managed to achieve it by other means alone.

## **6 Conclusions**

6.1 The Committee concluded that the evidence showed that Tegaderm CHG offers better protection against catheter-related

bloodstream infection (CRBSI) than sterile semipermeable transparent dressings. Based on non-comparative evidence the Committee considered that Tegaderm CHG also offers equivalent protection against CRBSI to chlorhexidine gluconate (CHG)-impregnated sponge dressings, but has other advantages, specifically the ability to see the catheter insertion site.

- 6.2 The Committee accepted the External Assessment Centre's revised model and sensitivity analysis which estimated costs in relation to the baseline CRBSI rate. It concluded that Tegaderm CHG could generate cost savings of £73 per patient when the baseline CRBSI rate was 1.48 per 1000 catheter days, as cited in the Matching Michigan study for England intensive care units (based on April 2009 to April 2011 data). However, the Committee was aware of advice that baseline CRBSI rates have fallen in recent years and acknowledged the importance of the External Assessment Centre's estimate that Tegaderm CHG is likely to be cost neutral when the baseline CRBSI rate is 0.24 per 1000 catheter days, and to incur costs when it falls below that level. It therefore concluded that hospitals should take their baseline CRBSI rate into account when making decisions about whether to adopt Tegaderm CHG.

Bruce Campbell  
Chairman, Medical Technologies Advisory Committee  
March 2015

## **7 Committee members and NICE lead team**

### ***Medical Technologies Advisory Committee members***

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

#### **Professor Bruce Campbell (Chair)**

Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

#### **Dr Peter Groves (Vice Chair)**

Consultant Cardiologist, Cardiff and Vale University Health Board

#### **Ms Susan Bennett**

Lay member

#### **Professor Nigel Brunskill**

Professor of Renal Medicine, University of Leicester

#### **Mr Matthew Campbell-Hill**

Lay member

#### **Mr Andrew Chukwuemeka**

Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

#### **Professor Daniel Clark**

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

**Dr Fiona Denison**

Reader / Honorary Consultant in Maternal and Fetal Health, University of Edinburgh

**Professor Tony Freemont**

Professor of Osteoarticular Pathology, University of Manchester

**Professor Shaheen Hamdy**

Professor of Neurogastroenterology, University of Manchester

**Dr Jerry Hutchinson**

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**Dr Cynthia Iglesias**

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**Professor Mohammad Ilyas**

Professor of Pathology, University of Nottingham

**Dr Greg Irving**

GP and Clinical Lecturer, University of Cambridge

**Professor Eva Kaltenthaler**

Professor of Health Technology Assessment, School of Health and Related Research (SchARR), University of Sheffield

**Dr Paul Knox**

Reader in Vision Science, University of Liverpool

**Dr Rory O'Connor**

Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

**Mrs Karen Partington**

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**Mr Brian Selman**

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**Professor Wendy Tindale**

Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

**Professor Allan Wailoo**

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**Mr John Wilkinson**

Director of Devices, Medicines and Healthcare Products Regulatory Agency

**Dr Janelle Yorke**

Lecturer and Researcher in Nursing, University of Manchester

**Dr Amber Young**

Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

## ***NICE lead team***

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

### **Neil Hewitt**

Technical Analyst

### **Bernice Dillon**

Technical Adviser

### **James Bitmead**

Lead Expert Adviser

### **Annette Jeanes**

Lead Expert Adviser

### **Andrew Barton**

Lead Expert Adviser

### **Jerry Hutchinson**

Non-Expert MTAC Member

### **Michelle Jenks**

External Assessment Centre Representative

### **Joyce Craig**

External Assessment Centre Representative

## **8 Sources of evidence considered by the Committee**

The External Assessment Centre report for this assessment was prepared by the Newcastle upon Tyne Hospitals and York Economics Consortium External Assessment Centre:

- Jenks M, Craig J, Arber M, et al. The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites, January 2015

Submissions from the following sponsor:

- 3M Health Care

The following individuals gave their expert personal view on Tegaderm CHG by providing their expert comments on the draft scope and assessment report.

- Dr Linda Kelly, nominated by National Infusion and Vascular Access Society – clinical expert
- Mr James Bitmead, ratified by Royal College of Nursing – clinical expert
- Ms Lisa Dougherty, nominated by National Infusion and Vascular Access Society – clinical expert
- Ms Annette Jeanes, ratified by Royal College of Nursing – clinical expert
- Mr Maurice Madeo, ratified by Infection Prevention Society – clinical expert
- Ms Jackie Nicholson, nominated by National Infusion and Vascular Access Society – clinical expert

The following individuals gave their expert personal view on Tegaderm CHG in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Dr Linda Kelly, nominated by National Infusion and Vascular Access Society – clinical expert
- Mr James Bitmead, ratified by Royal College of Nursing – clinical expert

- Ms Lisa Dougherty, nominated by National Infusion and Vascular Access Society – clinical expert
- Ms Annette Jeanes, ratified by Royal College of Nursing – clinical expert
- Mr Maurice Madeo, ratified by Infection Prevention Society – clinical expert
- Ms Jackie Nicholson, nominated by National Infusion and Vascular Access Society – clinical expert
- Mr Andrew Barton, ratified by Nursing and Midwifery Council – clinical expert
- Dr Justin Roberts, ratified by Royal College of Anaesthetists – clinical expert
- Dr Roland Black, ratified by Royal College of Anaesthetists – clinical expert

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This guidance was developed using the NICE [medical technologies guidance process](#).

It has been incorporated into the NICE pathway on XXX, along with other related guidance and products. [Amend as necessary. Hyperlink to pathway from pathway name. Delete if not relevant.]

We have produced a summary of this guidance for the public [add hyperlink to the UNG page]. Tools [add hyperlink to the guidance summary page] to help you put the guidance into practice and information about the evidence it is based on are also available. [delete any wording that isn't relevant]

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