NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Report for Review Decision

Review of MTG25: The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites

This guidance was issued in July 2015.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However, the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance and do not consult on the review proposal.

Produce a medtech innovation briefing on the use of Tegaderm CHG IV securement dressings for indications that lie outside of the scope of the original guidance (such as people undergoing haemodialysis and oncology patients). Signpost this from the guidance landing page.

2. Original objective of guidance

To assess the case for adoption of the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites.

3. Current guidance

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. It reduces 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 adults 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. This estimate is 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 population for Tegaderm CHG based on adult intensive care episodes needing a central venous or arterial catheter vary from around 88,000 to 226,000 depending on whether episodes longer than 48 hours, or all episodes, are used. Based on these estimates, if the use of Tegaderm CHG became standard practice, it has the potential to save the NHS in England between £4.2 million and £10.8 million each year, assuming the baseline catheter-related bloodstream infection rate is 1.48 per 1000 catheter days.

4. Rationale

The dressings have undergone 2 minor changes aimed at improving the ease of removal and the conformability around wide bore lumens. The company claim that these changes do not affect the mode of action or function of the original version evaluated.

The new clinical evidence identified appears to support the committee's conclusions from the original guidance that Tegaderm CHG reduces catheter-related bloodstream infections and local site infections compared with semipermeable transparent (standard) dressings. In the updated cost modelling, Tegaderm CHG is shown to be more cost-saving than was considered at the time of guidance (£93 rather than £73 per patient, based on a baseline CRBSI rate of 1.48 per 1000 catheter days). As the new evidence and cost update is unlikely to materially change the recommendations of the original guidance, it is proposed that the guidance be amended without consulting on the review proposal.

Since the guidance has been published, the use of Tegaderm CHG has expanded to include people undergoing haemodialysis and oncology patients. It is therefore proposed that the medical technology topic oversight group (MTTOG) consider developing a medtech innovation briefing, providing advice on the use of the technology for those indications that lie outside of the scope of the original guidance.

5. New evidence

The search strategy from the original assessment report was re-run. References from August 2013 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available to the NHS. Since the guidance was published in July 2015, minor changes have been made to the technology. According to the company the current version still performs the same function and uses the same mode of action as the original version. The current model does not have a new CE mark. The current model differs from the original in the following ways:

I. A small (to be used as an option) perforation has been incorporated into the keyhole notch to enable conformability around wide bore lumens

II. A perforation has also been added to the wide secural strip to aid ease of removal.

The price for Tegaderm CHG has reduced from £6.21 to £6.09 per dressing.

5.2 Clinical practice

NICE guideline Healthcare-associated infections: prevention and control in primary and community care was published in March 2012. Minor updates were made to the clinical guideline in 2013 and 2017, none of which impact the MTG recommendations for Tegaderm CHG.

As stated in MTG25, 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. It also 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. As stated in the original guidance, 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).

Expert advice was received from 3 experts, 2 of whom use the technology in their NHS practice. All the experts contacted noted that, since the MTG25 was published, the care pathway had not changed sufficiently to alter the original recommendations.

5.3 NICE facilitated research

None.

5.4 New studies

Results from the NICE literature search as well as information from the company and clinical experts were used to assess new relevant evidence. A total of 4 clinical studies were identified as being relevant to this guidance review, all of which are comparative studies (Eggimann et al. 2019; Karpanen et al 2016a; Karpanen et al. 2016b; Scheithauer et al. 2014). The new studies included information on catheter related bloodstream infection (CRBSI), skin or catheter colonisation and device-related adverse events. Two of the studies were conducted in an NHS setting; a prospective study done at University Hospitals Birmingham (Karpanen et al. 2016a) and a clinical staff evaluation study from the same centre (Karpanen et al. 2016b). The remaining studies were conducted in Switzerland (Eggimann et al. 2019) and Germany (Scheithauer et al. 2014). Further details on the study design, population and key results of each study are summarised below:

Eggimann et al. (2019) reported results from a prospective randomised controlled study evaluating the impact of incrementally introducing chlorhexidine dressings (Biopatch or Tegaderm CHG) in addition to an ongoing catheter bundle on the rates of CRBSI. The study was conducted in a single centre in Switzerland, and it enrolled all consecutive adult patients admitted to the ICU from January 2006 to December 2018 (n=18,286). The study reported a progressive but significant decrease in CRBSI rates when Tegaderm CHG was used, from 1.48 episodes per 1,000 catheter days without CHG dressings to 0.23 episodes per 1,000 catheter days with Tegaderm ($p<0.001$). A non-significant lower rate of infection occurred with Tegaderm CHG compared to Biopatch (CRBSI was 0.69 episodes per 1,000

catheter days with Biopatch). Both types of dressings were associated with a similar rate of allergic skin reactions (0.3 per 1,000 catheter days).

Karpanen et al (2016a) reported results from a single-centre, prospective observational study conducted at University Hospitals Birmingham. The study included a total of 273 patients (Tegaderm CHG n=136; standard dressing n=137) and aimed to determine if Tegaderm CHG decreases CVC and insertion site microbial colonization compared to standard nonantimicrobial dressing in adult patients in critical care. Results reported a significant reduction in the number of microorganisms recovered from the CVC insertion site, suture site, sutures, and catheter surface in the Tegaderm group compared to the standard dressing group. There was no significant difference in susceptibility to CHG between the microorganisms isolated from the CHG and standard dressing patients. Interim results from this study were discussed in the original guidance.

Karpanen et al. (2016b) reported results from a clinical staff evaluation study which was conducted following a 9-month trial period in which Tegaderm CHG was introduced to critical care patients at Birmingham University hospital. 70 out of 81 respondents considered the performance of Tegaderm CHG to be better or much better than the standard dressing, and 77 out of 78 of the respondents recommended continuing its use.

Scheithauer et al. (2014) reported a prospective single-centre observational study comparing Tegaderm CHG to standard dressing in a single tertiary care centre in Germany; involving a medical ICU and a cardiology ICU. The study involved 1,298 patients admitted between November 2010 to May 2012. Overall, 40 CRBSIs occurred in 34 patients. The use of Tegaderm CHG was associated with significantly lower rates of CRBSI compared to standard dressing (1.51 episodes per 1,000 catheter days vs. 5.87 episodes per 1,000 catheter days; $p<0.0001$).

Three economic studies were also identified (Maunoury et al., 2015, Thokala et al., 2016; Heimann et al. 2018):

Maunoury et al. (2015) conducted a cost-effectiveness analysis comparing Tegaderm CHG to standard dressings. It utilised a Markov model with a time horizon of 30 days and one-day cycles. The analysis showed an incremental cost-effectiveness ratio of €12,046 per catheter-related bloodstream infection prevented, and an incremental net monetary benefit of €344.88 per patient.

The incremental net monetary benefit was calculated by multiplying the difference in effectiveness per patient by the willingness to pay (WTP), minus the difference in cost per patient. The WTP was considered as the mean cost for treating one patient with CRBSI included in the reference dressing arm (€41,424).

Thokala et al. (2016) conducted a study to assess the economic impact of Tegaderm CHG compared with standard dressing in critically ill patients. They developed a decision analytical cost-consequence model and showed that Tegaderm CHG provided an average cost-saving of £77 per patient, with a 98.5% probability of being cost-saving compared to standard dressings.

Heimann et al. (2018) conducted a cost and resource utilisation analysis of Tegaderm CHG compared with standard dressing from a German societal perspective. The micro-costing health-economic analysis was based on published data evaluating the incidence of CRBSI in neutropenic high-risk patients (Biehl et al. 2016). Only direct treatment cost factors were considered, including treatment on general ward, treatment in intermediate care unit, treatment on bone marrow transplant ward, treatment in intensive care unit, mechanical ventilation, imaging, diagnostic measures, laboratory tests, CVC dressings, antimicrobial agents, antifungal agents and antiviral agents. The study included relevant health-economic data until the end of inpatient stay. The study reported similar results in overall direct treatment costs for the 2 dressing types (€13,881 for Tegaderm CHG and €13,929 from standard dressings).

5.5 Cost update

The EAC reviewed the cost case and updated the model parameters. An error was noted in the calculations of expected costs of CRBSI and expected costs of local site infection in the original assessment. According to the EAC, the incidence rates in the original assessment were treated as probabilities, meaning the true effect of time on actual risk was not captured. The EAC noted that the impact of this error was small as it appears in both arms. The error was amended in the updated cost model by converting incidence risk to cumulative incidence rate in the calculation of expected costs for CRBSI and local site infection. The EAC analysed the evidence provided by the company and the clinical experts contacted for this guidance review and concluded that, given the clinical pathway has not changed since the initial assessment, the

overarching model structure and assumptions remain valid. Table 1 summarises the parameter values utilised in the updated base case scenario.

Table 1. Updated cost model parameters

Model parameter	Value used in the original model	Updated value	Distribution and SE	Source of updated parameter
Baseline rate for CRBSI	0.3 per 1,000 catheter-days	0.28 per 1,000 catheter-days	Gamma (SE = 0.12)	Scottish Intensive Care Society Audit Group (2018)
Effectiveness of Tegaderm CHG to prevent CRBSI	0.402 (reported as hazard ratio)	0.45 (reported as relative risk)	Lognormal (SE = 0.11)	Safdar et al (2014)
Baseline local site infection rate	0.14 per catheter-days	0.4 per 1000 catheter-days	Gamma (SE = 0.12)	Scottish Intensive Care Society Audit Group (2018)
Baseline dermatitis rate	0.002 1-year probability	0.3 per 1000 catheter-days	Gamma (SE=0.70)	Eggimann et al (2019)
Length of stay with catheterisation	10 days	13 days	Gamma (SE=6.5)	NICE MTG44 Curos for preventing infections when using needleless connectors
Cost of Tegaderm CHG	£6.26	£6.14	Fixed	Estimated in the basis of cost reduction provided by manufacturer
Cost of standard dressing	£1.54	£1.72	Fixed	Uplifted from the original report

Cost of CRBSI	£9,990	£10,199.86	Gamma (SE=3000)	Uplifted from the original report
Cost of local site infection	£100	£103.03	Gamma (SE=30)	Uplifted from the original report
Cost of dermatitis	£6	£6.18	Gamma (SE=3)	Uplifted from the original report

The total costs associated with use of Tegaderm CHG and standard dressing are higher in the updated cost model than the original model. This increase is higher in the standard dressing arm. Consequently, the base case cost savings in the updated model are greater than in the original model (£93 rather than £73 per patient, based on a baseline CRBSI rate of 1.48 per 1000 catheter days). In a scenario analysis using estimates of baseline CRBSI incidence rates from Scottish ICUs (0.28 per 1000 catheter days), the magnitude of the estimated savings with Tegaderm CHG decreased to £7.50 per patient. The EAC undertook univariate deterministic sensitivity analysis (DSA) around all model inputs and probabilistic sensitivity analysis (PSA). Univariate sensitivity analysis using the updated cost model showed that Tegaderm CHG is cost neutral when the baseline catheter-related bloodstream infection rate is 0.18 per 1,000 catheter days (reduced from 0.24 per 1,000 catheter days in initial guidance), and cost incurring when the baseline rate falls below that figure. Other key drivers were: the cost of treating CRBSI, the effectiveness of Tegaderm CHG for preventing CRBSI infections, and catheter dwell time. The parameters did not change the direction of the results when utilising English data. The PSA showed the results are robust, resulting in cost-savings in 98.9% of the iterations. When the Scottish data for baseline CRBSI incidence rate was used, mean number of dressing per patient and the unit cost of Tegaderm CHG also became important drivers of cost-savings. Results from the PSA using Scottish data showed cost-savings in 50.3% of iterations.

6. Summary of new information and implications for review

The new clinical evidence identified appears to support the committee's conclusions from the original guidance. The updated cost modelling shows that the cost savings for Tegaderm CHG compared with standard dressings has increased since the original guidance was published. The threshold baseline CRBSI at which Tegaderm becomes cost neutral has also decreased. Overall, the new evidence identified for

Tegaderm CHG is unlikely to have a material effect on the recommendations in the published guidance.

7. Implementation

The company have confirmed that a total of 50 NHS Trusts are currently using Tegaderm CHG.

8. Equality issues

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

No potential equality issues have been identified.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

NICE guideline Healthcare-associated infections: prevention and control in primary and community care

In progress

None

Registered and unpublished trials

Trial name and registration number	Details
Use of Chlorhexidine-gel-Impregnated Dressing Compared to Transparent Polyurethane Film Dressing as Coverage of the Site of Insertion of Central Venous Catheter, in the Evaluation of Catheter Colonization in Critically Ill Adults Patients: A Randomized Controlled Trial Trial NCT02472158; Chlorhexidine-Impregnated Sponge Dressing: A Clinical Trial (CISDCT).	Recruitment Status: Unknown (last updated May 2016) Estimated study completion date: September 2016 Estimated enrolment: 120 participants Location: São Paulo, Brazil

Additional information

Expert advice was received from 3 specialists, 2 of whom use the technology in their NHS practice. Expert advice was that the technology is also used in other IV services and in kidney dialysis patients. One expert highlighted the risk of chlorhexidine resistance as a controversy around the technology/care pathway. They also said that healthcare professionals may need awareness training regarding chlorhexidine allergy which was said to be highlighted in national audit projects (NAP) 6: perioperative anaphylaxis. The greatest benefit of using the technology was said to be in ward areas where infection rates are higher than more controlled areas such as intensive care. One expert said that in their hospital, kidney dialysis patients have benefitted from the technology.

Additional studies were identified by the company and clinical experts however, these studies involved populations that were outside of the original scope, including: paediatric ICU patients (Düzkaya et al. 2016; Ergul et al. 2018), people with ventricular drains (Roethlisberger et al. 2018) or epidural and peripheral regional catheters (Kerwat et al. 2015), patients with chemotherapy-induced neutropenia

(Biehl et al. 2016) and people undergoing haemodialysis (Apata et al. 2017; Righetti et al. 2016).

The EAC acknowledged that, although the clinical pathway has not changed since the initial assessment, there is increasing evidence showing that the use of the technology prevents CRBSI in other populations. This includes the use in non-intensive care IV services such as haemodialysis, chemotherapy, haematology, and in infants (Biehl et al. 2016; Gerceker et al. 2017; Waters et al., 2019). The EAC state that further analyses are needed in order to assess the cost-effectiveness of the technology in the different services. This is because key parameters are likely to differ to those of the population evaluated under the scope of the original assessment report.

Appendix 3 – changes to guidance

Table 2: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Page 4, 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. This estimate is 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 population for Tegaderm CHG based on adult intensive care episodes needing a central venous or arterial catheter vary from around 88,000 to 226,000 depending on whether episodes longer than 48 hours, or all episodes, are used. Based on these estimates, if the use of Tegaderm CHG became standard practice, it has the potential to save the NHS in England between £4.2 million and £10.8 million each year, assuming the baseline catheter-related bloodstream infection rate is 1.48 per 1000 catheter days.	The estimated cost saving from using a 3M Tegaderm CHG IV securement dressing (Tegaderm CHG) instead of a standard transparent semipermeable dressing is £93 per patient. This estimate is 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 0.18 per 1000 catheter days, and cost incurring when the baseline rate falls below that figure. [2019 – see section 5.25].
2.4	The cost of Tegaderm CHG stated in the company'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.	The cost of Tegaderm CHG stated in the company'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. The cost has been updated in the 2019 revision to £6.09 per dressing [2019 – see section 5.25].
5.8		
2019 guidance review		For the guidance review, the external assessment centre revised the model to reflect 2019

5.25		costs (original guidance values given in brackets). The main parameter changes were: baseline incidence rate of CRBSI for Scottish ICUs, 0.28 per 1,000 catheter-days (0.3 per 1,000 catheter-days); baseline incidence rate of local site infection, 0.4 per 1000 catheter-days (0.14 per catheter-days); baseline incidence rate of dermatitis, 0.3 per 1000 catheter-days (0.002 1-year probability); the effectiveness of Tegaderm CHG for preventing CRBSI, 0.402 hazard ratio (0.45 relative risk); length of stay with catherization, 13 days (10 days). The cost of Tegaderm CHG was also updated to reflect the 2% decrease in the cost of the dressing (from £6.21 to £6.09). The EAC assumed this reduction was implemented in all sizes of Tegaderm CHG and estimated an updated weighted average of £6.14 (£6.26), using the sales proportions from the original cost model. Other costs from the original model were adjusted for inflation. Deterministic base-case results for the 2019 revised model produced an average per patient cost of £106.62 (£77.75) for Tegaderm CHG and £199.69 (£151.29) for a standard dressing, a cost saving of £93.07 (£73.54) when considering a baseline CRBSI rate of 1.48 per 1,000 catheter days. When CRBSI data from Scotland were used, Tegaderm CHG had an average per patient cost of £35.80 (£30.79) and a standard dressing cost of £43.30 (£34.47); a cost saving of £7.50 (£3.68) per patient. In the probabilistic sensitivity analysis, Tegaderm CHG had a 98.9% (97.8%) probability of being cost saving using the baseline CRBSI rate for England, but this fell to 50.3% (57.9%) when the figure for Scotland was used. The External Assessment Centre varied the baseline CRBSI rate and identified the threshold at which Tegaderm

		CHG was cost neutral as 0.18 (0.24) per 1000 catheter days. Further details of the 2019 revised model are in the cost model update report [2019].

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