National Institute for Health and Care Excellence

External Assessment Centre correspondence

3M Tegaderm CHG IV Securement Dressing to provide transparent, antiseptic coverage at central venous and arterial catheter insertion sites

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Fifteen initial clarification questions to 3M. Tegaderm CHG Sponsor, Martin Arrowsmith and Steve Foster. Submitted by EAC for discussion at sponsor introductory teleconference 24/11/2014, hosted by NICE: 1) Is initial training required for ICU nurses to use Tegaderm CHG dressing where standard dressings or CHG sponges are already in use? If so, who is this provided by?	**Written and verbal responses from Martin Arrowsmith and Steve Foster to these fifteen initial clarification questions. Summarised in this log by the EAC:** Yes training on application and removal is provided by 3M Health Care employees. Materials are provided as aide memoires for ongoing use of the product and to support training of new starter staff. Training covers application and removal of dressings (note: removal of Tegaderm CHG is no different to other dressings). It involves 3M health care employees going into trusts for a period of time and catching nurses usually at the start, or end, of their shift.	Noted with thanks.
	2) Is there any ongoing training required for nurses using Tegaderm CHG? If so, who is this provided by?	Training for new staff is required but update training for existing staff is not required. There are no plans to change the dressing design nor recommendations for application or removal.	Noted with thanks.
	3) Are you aware of any CHG impregnated dressings other than Tegaderm CHG and Biopatch?	We are not aware of any other CHG impregnated dressings that are available for sale in Europe that are positioned for vascular	Noted with thanks.

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		access site care.	
	4) We note that poster presentations regarding Tegaderm CHG have been made at Healthcare Infection Society Conference and Association for Vascular Access. Are there any other key conferences where research in this area (including on Tegaderm CHG) is presented?	Yes, other key conferences are: WOCOVA (World Congress of Vascular Access), SHEA (Society of Hospital Epidemiologists of America), NIVAS (National Infusion and Vascular Access Society)	To inform EAC grey literature search. One additional study was identified by the EAC during the grey literature searches. This study was identified as on ongoing study by the sponsor (Karpanen *et al*., 2014).
	5) In the ongoing studies section you refer to a health economic study awaiting publication. Was this written by 3M? If so, is the economic analysis for the economic submission based on this study?	This study was sponsored by 3M and 3M employees are listed as co-authors. The lead authors are independent of 3M. There is a lot of overlap between this study and the modelling for the economic evidence submission.	Noted with thanks.
	6) Please could you provide information on the proportion of total sales by Tegaderm CHG dressing size	1660R 7 x 8.5cm < 5% 1657R 8.5 x 11.5cm 85% - largely CVC 1659R 10 x 15.5cm 13% - largely PICC 1658R 10 x 12cm < 5%	Noted with thanks.
	7) Please describe the key differences between Tegaderm CHG and Biopatch	Tegaderm CHG dressing is an integrated I.V. securement dressing with antimicrobial activity containing 2% CHG in an aqueous gel that is	Noted with thanks.

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		positioned over the insertion site. Biopatch requires an additional cover dressing to be applied over with separate purchase. Biopatch contains approx. 18% dry CHG that requires a certain amount of humidity to facilitate release on to the skin, while Tegaderm CHG contains 2% CHG in solution and therefore readily active for delivery to the skin with no dependency on under dressing moisture. Tegaderm CHG gel patch is glassy clear allowing inspection of the site without dressing disturbance. Biopatch is a fully opaque disk of 2 cm diameter around the insertion site.	
	8) In order to analyse the data from FDA MAUDE we would like to know when the modified design with a high breathability film for Tegaderm CHG was introduced into the United States?	**Answer received via email on 24th November:** Approval for sale in US market was Feb 2011. It is estimated that supplies would be in use with a majority of US customers by end of June 2011.	
	9) Please can you provide the adverse event rate for severe contact dermatitis associated with the modified design from the 3M Health Care post market surveillance database.	[redacted]	Noted with thanks.

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	10) In the study by Timsit (2012) please advise, for each of the three arms, the: a) Number of dressings per patient? b) Number of dressings dislodged per patient? c) Number of dressings soiled and dislodged per patient? We note that this information is provided for all 3 dressing types combined.	**Answer received via email on 27th November:** Please be advised that following consultation with my Clinical Research colleagues in Germany, we are able to offer the information that is published in Table 3 of the Timsit 2012 publication. I have pasted the screen shot into this email that shows the median number of dressing changes per catheter for the three dressing types. Catheter dwell time is also described. Together this data allows calculation of median no. of dressings in each dressing group. I appreciate that this does not address the detail you requested in this question.	Noted with thanks.
	11) What proportion of patients have an allergy to CHG?	Sorry we are unaware of any information about this. We are aware it varies from country to country and it has been suggested this is due to different levels of public exposure to chlorhexidine through its propensity for use in cosmetics and toiletries.	Noted with thanks.
	12) Please describe the use of the Tegaderm HP transparent dressing within the NHS. Is the dressing listed on NHS supply chain and if so, what is the product code?	Tegaderm HP dressing is not listed in NHS Supply Chain catalogue due to low sales. Use in NHS in UK is restricted to one hospital account. In view of this 3M are discontinuing the product in UK in 2015. Tegaderm HP dressing does have significant sales in France where patient recruitment for the Timsit 2012 study took place.	Noted with thanks.

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	13) The clinical evidence submission states that 'In general, the risk of an anaphylactic reaction in patients treated with any CHG-containing medicine or device needs to be assessed in those with known or unknown sensitivity to CHG.' How is this achieved?	By standard methods: discussion with the patient or reading their medical notes, to dermine any previous experience of CHG, latex of penicillin allergy.	Noted with thanks.
	14) Please describe current use of Tegaderm CHG in NHS England – we note use was about 36,000 in Q3 2013 and welcome information on: a. The number of trusts using the dressing; b. If the dressing is used only in an ICU or CCU setting.	a) [redacted] b) We are aware of use in Haematology, dialysis (renal), HDU as well as critical care. It is believed the highest use is in renal dialysis.	Noted with thanks.
	15) On the 18th November the sponsor sent on two documents to the EAC – a poster presentation (Karpenden, 2014) and additional results from Timsit (2012). Are these documents in the public domain, or are there any copyright implications?	We are aware that the publication Timsit 2012 Study is now open access. I have discussed the Karpenen poster with the copyright owner and they have stated that they are perfectly happy for the EAC to receive a copy.	Noted with thanks. The EAC confirmed that the information in the public domain published as supplementary material to Timsit, 2012 matched the document provided by the sponsor.
	An additional question was asked verbally by the EAC to 3M. Tegaderm CHG Sponsor, Martin Arrowsmith and Steve Foster. Submitted by EAC for discussion at	Most dressings are made by 3M (Tegaderm) or Smith and Nephew (Opsite IV 3000). Other brands producing wound care dressings may be used in this indication, but these make up a	Noted with thanks.

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	sponsor introductory teleconference 24/11/2014: 16) Please name the brands of standard dressings used in critically ill adult patients requiring a central venous or arterial catheter.	small part of the market share. These include: - Bioclusive; - C view; - Hartmann.	
	On 24/11/2014, a list of sixteen questions was sent by the EAC to 7 Expert Advisors named by NICE for this project.	**By 20/01/2015, 4 responses had been received and collated by the EAC into a single documented response: see Appendix 1. One of these was subsequently redacted due to a conflict of interest. An additional expert responded to say they would be unable to assist due to other commitments. The remaining two experts were chased up by telephone, but no response was received (as of 20/01/15).**	To inform EAC report on the Clinical and Economic Evidence Submission
	On 04/12/14 additional information was requested from Dr Timsit (corresponding author of Timsit et al. 2009 and Timsit et al. 2012). The following questions were asked: I note that in Timsit et al. (2012) there is a total of 34,339 catheter-days, could you please provide the breakdown of: 1) Number of catheter days in CHG impregnated dressing group 2) Number of catheter days in highly adhesive dressing	**On 05/12/14 a response was received from Dr Timsit and Stephane Ruckly:** Here is the information you requested: In Timsit et al. (2012) there is a total of 34,339 catheter-days 1. Number of catheter days in CHG impregnated dressing group: 17,303 2. Number of catheter days in highly adhesive	Noted with thanks and used to inform Section 3.6.2 of the report.

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	group 3) Number of catheter days in standard dressing dressing group I also note than in Timsit et al. (2009) there is a total of 28,931 catheter-days, could you please provide the breakdown of: 1) Number of catheter days in CHGIS group 2) Number of catheter days in standard dressing group	dressing group: 7,732 3. Number of catheter days in standard dressing group: 9,304 In Timsit et al. (2009) there is a total of 28,931 catheter-days 1. Number of catheter days in CHGIS group: 15,479 2. Number of catheter days in standard dressing group: 13,452	
	On 17/12/2014, a list of fourteen further questions was sent by the EAC to 5 Expert Advisors named by NICE for this project (Professor Tom Elliott and Ms Jackie Nicholson were withdrawn).	**By 20/01/2015, 2 responses had been received and collated by the EAC into a single documented response: see Appendix 1. An additional expert responded to say they would be unable to assist due to other commitments. The remaining two experts were chased up, via email and telephone, but no response was received (as of 20/01/15).**	To inform EAC report on the Clinical and Economic Evidence Submission
	On 17/12/2014, a list of 7 further questions was sent by the EAC to 3M. Tegaderm CHG Sponsor, Martin Arrowsmith and Steve Foster: 1) Do you have an ISO (13485) certificate for Tegaderm CHG?	Yes – see attached (Appendix 2)	Noted with thanks.

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	2) Does the shelf life of Tegaderm CHG differ to standard Tegaderm dressings? If so, please explain the differences and reasons behind this.	The shelf life for Tegaderm CHG dressing is two years whereas the shelf life of Tegaderm I.V. dressings (non-antimicrobial) is 3 years. We have decades of experience in the aging of the components used in Tegaderm I.V. dressings and understand the interaction of different parts and the effect that radiation sterilization has. This gives 3M confidence in offering a 3 year shelf life for these non-antimicrobial dressings. When new products are first brought to the market we introduce based on accelerated aging studies including analysis of products stored at higher temperatures and humidities than ambient. Successful completion of these programmes offers a two year shelf life. At introduction to the market, the first manufacturing batches are placed on ambient testing and in due course and where appropriate the shelf life is extended as aging data is acquired beyond two years. As yet the most recent design of Tegaderm CHG dressing has not completed the full aging and validation process to enable shelf life extension beyond 2 years.	Noted with thanks.
	3) We note there are two ongoing studies listed on clinicaltrials.gov with unknown status. These are NCT01142934 and NCT01733940. Would you be able to provide any updates on the status of these studies?	Regarding NCT01142934, we have no further information on this investigator led study beyond that included in Section 7.3.2 of Part B of the application. Regarding study no. NCT01733940 we are unaware of the status of this study and have contacted our colleagues in 3M Spain. We will respond to the expert centre when we have this	Noted with thanks.

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		information. Email then received on 08/01/15: "Regarding Study No. NCT01733940 on Clinical trials.gov, we have had contact with the author of this study who made two documents available. 1. Please find attached (Appendix 3) the study report authored by the lead investigator by the investigator. The study was conducted and finished during 2012. 2. The results were presented in the 2013 Congress of the Spanish Society of Preventive Medicine (Appendix 4). As you will see both these papers are in Spanish. I have checked with a native Spanish speaker that the following is an representative summary of the study outcomes: The study report is dated July 2012. The objective of the study was to compare catheter tip colonisation in ICU patients with short term CVCs. Patients were randomised to receive site care with either Tegaderm I.V. (non-medicated) or Tegaderm CHG dressings. Data from126 patients were included in the analysis. The outcome from multivariate analysis was that use of the Tegaderm CHG dressing reduced the risk of catheter tip colonisation by 73% compared to the non-medicated I.V. dressing.	

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	4) Please provide a clinical definition of local site infection and CRBSI.	a. Local site infection: Exit Site Infection Erythema or induration within 2 cm of the catheter exit site, in the absence of concomitant BSI and without concomitant purulence[1] b. CRBSI is a clinical definition, used when diagnosing and treating patients, that requires specific laboratory testing that more thoroughly identifies the catheter as the source of the BSI. A full definition is provided in HICPAC Guidelines of 2002.[2] The pivotal clinical study, Timsit et al 2012 used a slightly different definition where: CR-BSI was a combination of (i) one or more positive peripheral blood cultures sampled immediately before or within 48 hours after catheter removal; (ii) a positive quantitative catheter-tip culture positive for the same microorganisms (same species and same susceptibility pattern) and (iii) no other infectious focus explaining the positive blood cultures. Many clinical centres find that it is problematic to precisely establish if a BSI is a CRBSI due to the clinical needs of the patient.[1] Simpler definitions are often used for surveillance purposes. For example, central line associated blood stream infection (CLABSI) is a term used by many NHS critical care centres to report their infection rates.[3] A CLABSI is a primary BSI in a	Noted with thanks.

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		patient that had a central line within the 48-hour period before the development of the BSI and is not bloodstream related to an infection at another site. However, since some BSIs are secondary to other sources other than the central line, the CLABSI surveillance definition may overestimate the true incidence of CRBSI.[1] In view of this CRBSI has been used in the economic model to better represent the value that might be obtained following implementation of a catheter site care protocol utilising Tegaderm CHG. References 1. O'Grady, N.P., Alexander, M., Burns, L.A., Dellinger, E.P., et al. Guidelines for the prevention of intravascular catheter-related infections. American Journal of Infection Control 2011; 39(4 SUPPL.), S1-S34. 2. O'Grady, N.P., Alexander, M., Burns, L.A., Dellinger, E.P. et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections. Pediatrics 2002 110 (5) 1-24. 3. Bion J, Richardson A, Hibbert P, et al. 'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in	

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		England. BMJ Qual Saf 2013 Feb;22(2):110-23.	
	5) In the model are the event rates for CRBSI and local site infections mutually exclusive?	Yes they are	Noted with thanks.
	6) Please could you provide further information on why it is appropriate to use HR for CRBSI for local site infections given the local audit of the ICU at University Hospital Birmingham did not show any differences in rates of suspected sepsis between those patients who had Tegaderm CHG dressings as compared to those who received non-antimicrobial dressings?	The assumption that HR of local site infection is the same as that of HR for CRBSI is also used in Ye et al. Thus, we felt it was a valid assumption. Also, our expert clinical expert group (Professor Tom Elliott, Consultant Microbiologist / Deputy Medical Director and Dr Tony Whitehouse, Consultant Critical Care and Anaesthesia, both at University Hospital Birmingham (UHB)) suggested that local site infections are different from suspected sepsis. There is no difference in rates of suspected sepsis observed in UHB, hence, we excluded them from the model. But, the clinical expert group felt that there would be a difference in local site infections, hence their inclusion.	Noted with thanks.
	7) Please advise on the reference for the cost per day in CCU and general wards used to estimate the cost of a CRBSI. We acknowledge that the cost from Hockenhull was actually used within the model.	These cost were derived from discussions with the clinical experts cited in see 6a and based on local experience at UHB.	Noted with thanks.
	FOI request was made on 24/11/2014 to NHS supply chain requesting the following information: Could I please have some information relating to the following devices (each should be	**A response was received on 18/12/2014 and the information provided is shown in Appendix 5.**	Noted with thanks.

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	supplied in different sizes, catalogue numbers provided): 1. Aquilant Surgical: IV3000 (ELW 041, 054, 099, 112, 363) 2. 3M Healthcare: Tegaderm IV (ELW104, 071, 056, 074) 3. 3M Healthcare: Tegaderm IV advanced (ELW 334, 335, 624) 4. 3M Healthcare: Tegaderm CHG (ELW 294, 295, 366, 625) 5. Vygon UK: Bioptach (ELW 708, 709, 710) For each dressing I would be grateful if you could provide the following information: 1. The unit purchased (for example a box of 50 dressings); 2. The selling price including VAT per box; 3. Total sales value; 4. Total number of boxes issued in 2012 and 2013		

Correspondence between the EAC and Tegaderm CHG clinical experts

Newcastle and York EAC Questions to Tegaderm Clinical Experts
24/11/2014 to 17/12/2014 Responses & ~~Nil Response~~

MT 238 - 3M Tegaderm CHG IV Securement Dressing to provide transparent, antiseptic coverage at central venous and arterial catheter insertion sites

Expert Adviser Responses:

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Mr Maurice Madeo	Deputy Director for Infection Prevention and Control	Infection Prevention Society	Sponsor	~~Y~~
~~Ms Annette Jeanes~~	~~Consultant Nurse, Infection Control~~	~~Royal College of Nursing~~	~~Sponsor~~	~~Y~~
~~Prof Tom S J Elliott~~	~~Consultant Microbiologist~~	~~Royal College of Physicians~~	~~Sponsor~~	Y
~~Ms Jackie Nicholson~~	~~Consultant Nurse in Vascular Access~~	~~National Infusion & Vascular Access Society~~	~~Specialist Society~~	-
Ms Linda Kelly	Lecturer in Adult Health	National Infusion & Vascular Access Society	Specialist Society	-
Ms Lisa Dougherty	Consultant Nurse, Intravenous Therapy	National Infusion & Vascular Access Society	Specialist Society	-
Mr James Bitmead	IV Lead nurse Infection control	Royal College of Nursing	NICE	Y

Question 1: *If the 3M Tegaderm CHG IV Securement Dressing ('Tegaderm CHG') was introduced into the care pathway of critically ill adult patients (who require a central venous or arterial catheter) in replacement of either a standard securement dressing, or standard securement dressing plus Biopatch, would any of the following be required:*

a) Initial training on use of the Tegaderm CHG dressing;
b) Ongoing training on use of the Tegaderm CHG dressing?

If you answered 'yes' to any of the above, please provide more detail including the time required for the training per nurse, how many nurses would be involved and who provides the training

Expert Adviser	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**a) Yes. All nurses should be trained as there is need to get dressing positioned correctly and also the removal is different. Hard to say time frame but 10 – 15 minutes. Reps to start with to do training and then other nurses** **b) No**
Ms Linda Kelly, Lecturer in Adult Health	**a) Yes. It should not take long for the training of dressing application (20 mins approx.). All nurses who provided vascular access care and maintenance should be trained. This could be provided by either the companies educational staff / or cascaded down by the trust staff who are responsible for education and training regarding general vascular access care once they had been trained** **b) No**
Mr James Bitmead, IV Lead nurse Infection control	**a) The same as standard dressing, less than Biopatch** **b) Minimal. Training given by myself (IV nurse, other infection control nurses, nurse educators and staff provided by 3M)**

Question 2: *If the Tegaderm CHG has been introduced into the care pathway of critically ill adult patients (who require a central venous or arterial catheter) in replacement of a standard securement dressing , were there changes in any of the following:*

a) Frequency of incorrect applications of dressing which require re-application;
b) Time taken to apply or remove the dressing;
c) Frequency of dressing changes;
d) Number of dressings dislodged per patient;
e) Number of dressings soiled and dislodged per patient?

If you answered 'yes' to any of the above, please provide more detail.

Expert Adviser	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**a) Unsure** **b) Yes. It does take longer to remove, not sure how many incorrect applications – probably a few when first starting** **c) No** **d) No** **e) No**
Ms Linda Kelly, Lecturer in Adult Health	**a) Minimal** **b) Minimal** **c) No** **d) No** **e) No**

Expert Adviser	Comment
Mr James Bitmead, IV Lead nurse Infection control	**a) No** **b) No** **c) No** **d) No** **e) No**

Question 3*: If the Tegaderm CHG has been introduced into the care pathway of critically ill adult patients (who require a central venous or arterial catheter) in replacement of a standard securement dressing plus Biopatch , was there changes in any of the following:*

a) Frequency of incorrect applications of dressing which require replication;
b) Time taken to apply the dressing;
c) Frequency of dressing changes;
d) Number of dressings dislodged per patient
e) Number of dressings soiled and dislodged per patient?

If you answered 'yes' to any of the above, please provide more detail.

Expert Adviser	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**Have never used Biopatch so can't comment**

Ms Linda Kelly, Lecturer in Adult Health	**a) No** **b) Quicker** **c) No** **d) No** **e) No**
Mr James Bitmead, IV Lead nurse Infection control	**a) Less than Biopatch, a number of nurses had put Biopatch upside down** **b) No** **c) No** **d) No** **e) No**

Question 4: *Which brands of standard sterile semi-permeable transparent dressings are used in critically ill adult patients (who require a central venous or arterial catheter) patients in your hospital?*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**Opsite IV 3000**
Ms Linda Kelly, Lecturer in Adult Health	**Tegaderm**
Mr James Bitmead, IV Lead nurse Infection control	**Main dressing is tegaderm CHG, have a few others for any patient who develops sensitivity**

Question 5: *Is it standard practice to prepare skin with 2% CHG in 70% isopropyl alcohol (in line with epic 3 guidelines) prior to catheter insertion:*

a) *In your trust?*
b) *In the NHS more generally?*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**a) Yes** **b) Yes**
Ms Linda Kelly, Lecturer in Adult Health	**a) Yes** **b) Yes**

Mr James Bitmead, IV Lead nurse Infection control	**a) Yes** **b) Yes**

Question 6: *Have you had any experience of or concerns about adverse events relating to Tegaderm CHG?*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**There have been concerns about increase exposure to chlorhexidine and potential increased sensitivity**
Mr James Bitmead, IV Lead nurse Infection control	**No**

Question 7: *Please provide an estimate of the proportion of patients who have an allergy to chlorhexidine gluconate (CHG).*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**I am unable to give estimation but at the moment I believe this to still be 'rare'. I have however experienced one patient who had an allergic reaction to chlorhexidine so the number may be rising due to increased exposure**

Mr James Bitmead, IV Lead nurse Infection control	**Very few patients, more seem to develop an allergy to the tegaderm**

Question 8: *Please describe the standard procedure and time taken for results of suspected catheter or skin colonisation in your hospital.*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**Unsure**
Mr James Bitmead, IV Lead nurse Infection control	**We only screen for MRSA, we use a PCR test which is back the same day**

Question 9: *In the randomised control trial comparing Tegaderm CHG to standard dressings, dressings were changed 24 hours after catheter insertion (Day 1) then every 3 or 7 days according to standard practice in each ICU (Timsit et al., 2012). Is it standard practice in your hospital to change dressings 24 hours after catheter insertion?*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**Yes**

Mr James Bitmead, IV Lead nurse Infection control	**Yes if the patient bleeds after insertion, sometimes the line inserter uses surgical glue to prevent bleeding and then we leave dressing in place for up to 7 days. If they do not use surgical glue then lines are dressed with gauze and plain tegaderm and after 24 hours dressing changed to CHG**

Question 10: *Please provide information on your Trust or departmental policy for:*

a) Suspected infection in critically ill patients in ICU or CCU with arterial or central venous catheters;

b) Changing of catheters in critically ill patients in ICU or CCU with arterial or central venous catheters.

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**a) Different policies for site and systemic infection** **Site infection – swab taken and if necessary specific antibiotic administered** **Catheter related blood stream infections need to be confirmed by blood cultures taken from the device and from a peripheral vein. Unless required antibiotics not administered until the strain is confirmed and the relevant antibiotic is then administered** **Device only removed on advice from microbiologist and depending on patient presentation and need for access** **b) Acute catheters are changed after 72 hours (clinical judgement used)**
Mr James Bitmead, IV Lead nurse Infection control	**a) Review by microbiologist, usually this will lead to line change** **b) As required**

Question 11: *Please describe the resources required for the diagnosis and treatment (including any additional length of stay in ICU/CCU and in hospital and also including any NHS resources utilised post-discharge) of:*

a) Catheter related blood stream infections;
b) Skin colonisation;
c) Catheter colonisation;
d) Local infection;
e) Severe dermatitis.

We are aware the care post ICU or post discharge may be undertaken by another care provider, but would be grateful if you were able to check this with colleagues.

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**Unfortunately, I was unable to get this information**
Mr James Bitmead, IV Lead nurse Infection control	**Unsure of this**

Question 12: *Please describe the impact on quality of life, and an indication of the severity, of:*

a) Catheter related blood stream infections;
b) Skin colonisation;
c) Catheter colonisation;
d) Local infection;
e) Severe dermatitis

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**a) This can be devastating as it is associated with mortality. Patients can become desperately ill. Increases hospital stay and compounds existing conditions. Although patients' often recover I would suggest that it is something you could not forget** **b) Not too severe** **c) Not very severe** **d) Not very severe if treated promptly (can cause pain and discomfort)** **e) This could have an effect on quality of life it is ongoing**
Mr James Bitmead, IV Lead nurse Infection control	**Unsure of this**

Question 13: *Please advise on whether the following characteristics (taken from Timsit et al., 2012) are typical of ICU within a UK NHS setting?*

a)Median age of 64 years;
b)Mechanical ventilation in 71% of patients;
c)Median length of stay in ICU setting of 9 days;
d) ICU death in 31% of patients.

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**a) Possibly lower in parts of Scotland** **b) Yes if not slightly higher** **c) Yes** **d) Yes**
Mr James Bitmead, IV Lead nurse Infection control	**No response**

Question 14: *Are there any particular patients who are at a higher risk of catheter related infection than the ICU patient population generally?*

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**

Ms Linda Kelly, Lecturer in Adult Health	**Oncology patients who often have low neutrophils making them more susceptible**
Mr James Bitmead, IV Lead nurse Infection control	**Yes – patients with haematological cancers**

Question 15: ***Are data collected within your hospital around infection rates and whether these change over time? If not, are you aware of any such nationally collected data?***

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**
Ms Linda Kelly, Lecturer in Adult Health	**Yes**
Mr James Bitmead, IV Lead nurse Infection control	**No response**

Question 16: ***Please advise on any other factors you consider could be relevant to an assessment of Tegaderm CHG versus standard care in an ICU or CCU setting.***

Expert Advisers	Comment
Ms Lisa Dougherty, Consultant Nurse, Intravenous Therapy	**No response**

Ms Linda Kelly, Lecturer in Adult Health	**I think that it is important to look at the overall care (bundle) as one technology alone does not ensure reduction in CVC infections**
Mr James Bitmead, IV Lead nurse Infection control	**No response**

Question 17: *What is the average number of dressings per patient with a central venous catheter during an ICU stay? The sponsor has used 3 dressings, based on 9 days catheter use in ICU. Is this reasonable in your experience?*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**This seems an appropriate estimate made by the sponsor.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Yes**

Question 18: *Please advise on the definition your trust adopts for local site infection.*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**Inflammation associated with localised erythema, tenderness and purulent discharge.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Redness, local inflammation with possible discharge - no systemic symptoms**

Question 19: *Would you expect the use of Tegaderm CHG to reduce the incidence of local site infection compared with standard dressings (with no CHG)?*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**Yes**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Yes**

Question 20: *What proportion of local site infections are mutually exclusive to CRBSI?*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**I believe any local site infection can lead to a CRBSI**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**?**

Question 21: *Please describe the process involved in the diagnosis and treatment of local site infections. For example:*

- *a. How is a local site infection diagnosed and are any lab tests required?*
- *b. Are catheters removed, if so, for which patients and for how long?*
- *c. What proportion of patients would require a new catheter?*
- *d. How would patients be treated, for example, which antibiotics would typically be provided?*
- *e. Are any further lab tests required?*

Question 22: *Please provide an estimate of the cost of the diagnosis and treatment of local site infections.*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**I do not know the cost of laboratory tests.** **a) Usually this is a visual diagnosis. Usually systemic antibiotic therapy is not required. A swab can be taken if deemed necessary.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**£100 – depends on severity** **b) Catheters do not routinely need to be removed. Usually the removal of the catheter will depend on the patient condition and with consultation with a microbiologist.**
	c) Of the patients with a localised infection – the number who would get a new catheter would be approx. 70% **d) This would depend on the sensitivity. Broad spectrum antibiotic therapy is no longer the normal** **e) Not for a localised site infection**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**a) Clinical decision +/- skin swab** **b) Not usually – depends on severity of local infection** **c) Unknown** **d) Local infections not usually treated with systemic antibiotics but if CRBSI then vancomycin usual first line agent – depending on organism cultured** **e) If temp blood cultures – paired samples, skin site swab and if catheter removed tip for culture if CRBSI suspected**

Question 23: *Is it reasonable to suggest the treatment of contact dermatitis comprises four standard dressings, removal of the catheter and insertion of a new catheter? If not, what does treatment comprise?*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**I don't think a new catheter would be required but an alternative dressing would be if that was the cause of the dermatitis.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Possibly**

Question 24: *Please advise definition your trust adopts for CRBSI.*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**This would be diagnosed when blood cultures match between a peripheral sample and one from the catheter**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**+ve blood culture (paired/time to positivity and no other obvious source)**

Question 25: *Is it reasonable to assume that an average length of stay for a CRBSI patient will vary between 6 days (first 2 days in ICU and rest of the 4 days in general medical ward) and 10 days (first 3 days in ICU and the rest of the 7 days in general medical ward)?*

Expert Advisers	Comment

Ms Linda Kelly, Lecturer in Adult Health	**This seems reasonable**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Yes**

Question 26: ***Is it reasonable to assume that in clinical practice approximately 50% of intravascular catheters are removed due to suspected CRBSI? How many may subsequently be replaced?***

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**That figure seems very high and I understand that the number of CRBSIs has decreased a lot since the use of care bundles. The figure will vary greatly across Trusts. In ICU the patients would generally require another catheter until they are able of take oral medication.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Half (50% of the catheters that are removed would be replaced)**

Question 27: ***Would an XRAY be used to confirm position of catheter?***

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**The position of a catheter has to be confirmed by xray or with one of the new tip locating devices (ECG or Magnet).**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Or ultrasound**

Question 28: *Please provide the brand name of the central venous catheter that is used in your trust for intravascular access in critically ill patients.*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**? Arrow**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Vygon/Bard**

Question 29: *Which staff member(s) would carry out catheter insertion and what is the mean time of this?*

Expert Advisers	Comment
Ms Linda Kelly, Lecturer in Adult Health	**Medical or nursing staff (approx. 30 – 40 mins)**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**Anaesthetists, PICC nurse team in radiology – time depends on urgency PICC1-2 days on ICU/theatre immediately if required. Time depends on complexity – approx. 30 mins.**

Question 30: *What is the treatment for patients with a CRBSI?*

Expert Advisers	Comment

Ms Linda Kelly, Lecturer in Adult Health	**Treatment with targeted antibiotics. Catheter removal if indicated.**
Mr Maurice Madeo, Deputy Director for Infection Prevention and Control	**See above**