NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

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

1 Technology

1.1 Description of the technology

The 3M Tegaderm CHG IV Securement Dressing ('Tegaderm CHG') is a sterile transparent semi-permeable polyurethane adhesive dressing with an integrated gel pad containing a 2% concentration by weight of chlorhexidine gluconate (CHG). It is used to secure percutaneous devices and to cover and protect central venous and arterial catheter insertion sites with the aim of providing an effective barrier against external contamination. The dressing and the integrated gel pad are transparent to allow continual observation of the percutaneous device and 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) at the catheter insertion site.

1.2 Regulatory status

The 3M Tegaderm CHG IV securement dressing received a CE mark in April 2009 to cover and protect catheter sites and to secure devices to the skin.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor for use of Tegaderm CHG dressing compared with the current recommended practice of using a sterile transparent semi-permeable, non-CHG impregnated dressing are:

- A 60% reduction in the incidence of catheter related bloodstream infection (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.

The benefits to the healthcare system claimed by the sponsor for use of Tegaderm CHG dressing compared with current recommended practice are:

- Reduced length of stay in critical care/high dependency units
- Reduced costs for diagnosis of CRBSI
- Reduced material and staff costs for treatment of catheter related infection

1.4 Relevant diseases and conditions

Tegaderm CHG dressing is intended for use in critically ill adult patients in intensive care or high dependency units who require a central venous or arterial catheter. Hospital Episodes Statistics (HES) data for 2012/13 show that there were 237,710 adult ICU episodes in England, 92,710 of which involved a stay of over 48 hours.

1.5 Current management

Infection (NICE clinical guideline 139, March 2012) provides guidance on the using dressings in adults and children with vascular access devices (central venous catheter (CVC) or peripherally inserted central catheter (PICC)) in primary and community care settings. The guideline recommends that the skin at the CVC insertion site, and the surrounding skin during dressing changes, should be decontaminated with chlorhexidine gluconate in 70% alcohol and be allowed to air dry. Where the manufacturer's recommendations prohibit the use of alcohol with their catheters, an aqueous solution of chlorhexidine

gluconate should be considered for use. It further recommends using a sterile, transparent semipermeable membrane dressing to cover the vascular access device insertion site, and that the dressing should be changed every 7 days or sooner if it is no longer intact or moisture collects under it. A sterile gauze dressing, covered with a sterile transparent semipermeable dressing, should be considered for use 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 colonization or CRBSI, either before insertion or during the use of a central venous catheter.

CG139 made no recommendations on CHG impregnated dressings. The full guideline states that they may be cost effective compared with sterile transparent semi-permeable membrane dressings. However, the evidence was limited to a single study, where the costs used for transparent dressings were not reported, making it impossible to analyse costs incrementally. The evidence was, therefore, considered to have potentially serious limitations and partial applicability.

The epic3 guideline (Healthcare Infection Society, 2013) on preventing heathcare-associated infections in NHS hospitals in England recommends using a sterile transparent semi-permeable dressing to cover the intravascular insertion point as best practice in both adults and children. The guideline recommends, based on high-quality evidence (stated as Grade A), 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 allow to air dry. The guidance also recommends, based on evidence of limited quality, that hospitals consider the use of a CHG impregnated sponge dressing in adults with a CVC, as a strategy to reduce CRBSI.

NICE evidence update 64, Infection (September 2014) states that the evidence on which the epic3 recommendation (on CHG impregnated sponges in adults with a CVC) is based is unlikely to have an impact on NICE clinical

guideline 139, and that further research is needed to establish the efficacy of CHG dressings applied to CHG-prepped skin to prevent CRBSI in patients with venous access devices.

2 Reasons for developing guidance on Tegaderm CHG for critically ill patients requiring a central venous line

The Committee recognised that Tegaderm CHG may offer benefits to patients and the healthcare system. It considered that the target population should be critically ill adult patients in intensive care or high dependency units who require a central venous or arterial catheter. The Committee thought that the standard care comparator should be the use of a sterile semi-permeable transparent dressing following decontamination of the skin with a CHG solution. The Committee also considered that the use of a CHG impregnated dressing such as Biopatch should also be included as an additional comparator because these dressings are used as standard care in some hospitals.

3 Statement of the decision problem

	Scope issued by NICE	
Population	Critically ill adult patients in intensive care or high dependency units who require a central venous or arterial catheter.	
Intervention	Swabbing with 2% chlorhexidine gluconate (CHG) in alcohol and Tegaderm CHG IV securement dressing	
Comparator(s)	• Swabbing with 2% CHG in alcohol and sterile semi-permeable transparent dressing • Swabbing with 2% CHG in alcohol and CHG impregnated dressing	
Outcomes	The outcome measures to consider include: • Catheter related bloodstream infection (CRBSI) and associated antimicrobial use • Skin and catheter colonisation • Length of stay in critical care/high dependency units • Mortality caused by catheter related infections • Dermatitis • Local site infection • Quality of life • Device-related adverse events, including adverse events caused by contact with chlorhexidine	
Cost analysis	Two comparators will be considered: • Swabbing with 2% CHG in alcohol and a sterile semi-permeable transparent dressing • Swabbing with 2% CHG in alcohol and a CHG impregnated dressing Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	None identified	
Special considerations, including those related to equality	None identified	
Special considerations, specifically related to equality issues		
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No

	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Infection prevention and control. Nice Quality Standard, QS61, April 2014. Available from: http://www.nice.org.uk/guidance/QS61
- Infection: Prevention and control of healthcare-associated infections in primary and community care. NICE Clinical Guideline, CG139, March 2012. Available from: http://guidance.nice.org.uk/CG139
- Prevention and control of healthcare-associated infections: Quality improvement guide. NICE Public Health Guidance, PH36, November 2011. Available from: http://guidance.nice.org.uk/PH36
- Surgical site infection: Prevention and treatment of surgical site infection. NICE Clinical Guideline, CG74, October 2008. Available from: http://www.nice.org.uk/CG74

Evidence update

- Infection: A summary of selected new evidence relevant to NICE clinical guideline 139. Evidence update 64, September 2014. Available from: http://www.evidence.nhs.uk/about-evidence-services/bulletins-and-alerts/evidence-updates/evidence-updates-by-date

Under development

None identified

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Surgeons in Primary Care
- British Association of Critical Care Nurses
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- Intensive Care Society
- National Infusion and Vascular Access Society
- Royal College of Nursing
- Royal College of Physicians
- The Royal College of Anaesthetists

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Anaesthetists of Great Britain and Ireland
- British Association of Critical Care Nurses
- British Association of Parenteral and Enteral Nutrition
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- Intensive Care Society
- National Infusion and Vascular Access Society
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Surgeons of England (RCSeng)

- The Royal College of Anaesthetists

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary. After selection they were alerted to the availability of the draft scope for comment:

- Critical Care Patient Liaison Committee (CritPaL)
- Fiona Elizabeth Agnew Trust
- ICU Steps
- MRSA Action UK
- The Patients Association
- United Kingdom Sepsis Trust