National Institute for Health and Care Excellence

4-year surveillance (2016) – Healthcare-associated infections: prevention and control in primary and community care (2012) NICE guideline CG139

Appendix B: stakeholder consultation comments table

Consultation dates: 15 August to 26 August 2016

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
3M	Disagree	We view the proposal not to update CG139 last updated in 2012 as incorrect. In the area of vascular access there have been advances in available technologies and the evidence base associated with them some of which are acknowledged in the proposal document and others that are not. Epic 3 guideline was updated in 2014 with changes to the recommendations for choice of dressings for central venous catheters to include consideration of chlorhexidine sponge dressings. This change is referenced in the Surveillance proposal consultation document. However, subsequent to the publication of NICE Medical Technologies Evaluation Programme guidance on Tegaderm CHG dressing (MTG 25), epic3 guidance was updated via a publication in the Journal of Hospital Infection (Loveday et al 2015). This letter acknowledges the effectiveness of both CHG sponge *and gel* dressings in reducing numbers of blood stream infections in patients receiving central venous therapy and modified the recommendation to read: *Consider the use of a 2% chlorhexidine-impregnated sponge or gel dressings in adult patients with a central venous catheter as a strategy to reduce catheter-related bloodstream infection.* Under the section Reason for the proposal, New Evidence that in the	Thank you for your comment. The 4 year surveillance review searched for and considered evidence published from April 2014 to April 2016. The references provided were either published before these search dates, and would have been considered during previous surveillance reviews, or in hospital settings. MTG25 considered the use of the intervention within ICU/HDU therefore this is not transferrable to primary and community care settings. No evidence in these setting was identified during the 4 year surveillance or through stakeholder consultation.

		following citation of the opinion of the clinical expert was perhaps misinterpreted since it erroneously implies that *all* CVCs cared for in the community are tunneled or otherwise implanted: "*Regarding the use of chlorhexidine impregnated dressings, one topic expert highlighted that in community settings this would be relevant only when using peripheral intravenous lines but not in central venous catheters. In community settings, most of the central venous catheters are impacted (or healed) so a dressing is not required.*" Continued from page 3… It is true that tunneled catheters such as Hickman lines may not require a dressing for infection control purposes after several weeks *in situ*. However, when initially placed and cared for in the community infection is a risk for patients with tunneled catheters and a dressing is certainly required for the secural of the line before tissue is fully integrated with the cuff. Also there are a number of other CVC lines used in patients cared for in the community where dressings are an integral part of the catheter site care and infection prevention. These include temporary haemodialysis catheters, midlines and peripherally inserted central venous catheters (PICCs). Each of these are nontunnelled (or not impacted), and are percutaneously inserted above the vein and are therefore liable to catheter colonization and blood stream infection from the microorganisms on the skin at the catheter site. The financial benefits to the NHS of enabling earlier hospital discharge by facilitating care of patients with a CVC in the community is leading to more prevalent use of the vascular access devices mentioned above in primary care patients. In these circumstances it is important to have appropriate and up to date guidance on choice of dressings for vascular access devices cared for in the community. CHG containing dressings (both gel and sponge) are supported by high quality evidence and epic 3 guidance for their use in acute care. The Proposal document rightly points out that the evidence supporting this technology comes from the hospital environment. However, since there is scant evidence from primary care for most areas of infection prevention and control practice, Guideline CG139 would be a very thin document if this view was generalised to the current text.	

		This stakeholder strongly disagrees with the proposal not to update this guideline as there have been significant changes in the evidence base supporting choice of catheter site dressings since its last publication: Continued from page 4 NICE 2015, The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites. NICE medical technology guidance [MTG25] Published date: July 2015. https://www.nice.org.uk/guidance/mtg25 Loveday H.P., Wilson J.A., Prieto J., Wilcox M.. 2015. epic3: revised recommendation for intravenous catheter and catheter site care. Journal of Hospital Infection 92 (2016) 346-348 Jenks M., Craig J., Green W., Hewitt N., Arber M., Sims A. 2015. Tegaderm CHG IV Securement Dressing for Central Venous and Arterial Catheter Insertion Sites: A NICE Medical Technology Guidance. Appl Health Econ Health Policy http://rd.springer.com/article/10.1007/s40258-015-0202-5/fulltext.html Timsit, J.F., Mimoz, O., Mourvillier, B., Souweine, B., Garrouste-Org, Alfandari, S., Plantefeve, G., Bronchard, R., Troche, G., Gauzit, R., Antona, M., Canet, E., Bohe, J., Lepape, A., Vesin, A., Arrault, X., Schwebel, C., Adrie, C., Zahar, J.R., Ruckly, S., Tournegros, C., & Lucet, J.C. 2012. Randomized controlled trial of chlorhexidine dressing and highly adhesive dressing for preventing catheter-related infections in critically ill adults. Am.J.Respir.Crit Care Med., 186, (12) 1272-1278	
British Infection Association	Disagree	The Clinical context of the guideline states : “Healthcare-associated infections can occur in otherwise healthy individuals, especially if invasive procedures or devices are used….” The guidance claims the Audience is : “Primary care setting, such as…..dental clinics….” This CG then focuses on; Standard Principles (No issue there), Hand decontamination (No issue there), Long term urinary catheters (No issue there), Vascular access devices (missed IV sedation) but the biggest gap is omission of any guidance on minor surgery	Thank you for your comment. The 4 year surveillance review did not identify evidence in the areas highlighted in your comment in primary and community care settings; therefore no impact on recommendations was identified. The general recommendations in CG139 would cover the specific gaps referred to in your comment for primary and community care settings.

		(including bone grafting) & dental implant placement. These gaps should be recognized and addressed with appropriate guidance.	
Royal College of Nursing	Disagree	The guideline advice only references C. diff and MRSA. Moving forward there will be a greater focus on gram negative bacteria which are currently not referenced. We believe that the guideline should be updated and review the evidence for the recommendations in the light of this change in epidemiology and clinical significance of these organisms.	Thank you for your comment. The guideline recommendations refer to Clostridium difficile as an example and therefore the guideline is not limited to that organism only. The 4 year surveillance review did not identify any published evidence which would impact on the current recommendations.
South Eastern HSC Trust	Additional clarity and inclusion of new legislation from 2012 version	I would like to suggest that there is a clear reference and recommendation added or amended within the Safe use and Disposal of Sharps section. C/f 1.1.4.2 bullet 3 “In Dentistry, if recapping or disassembly is unavoidable, a risk assessment must be undertaken and appropriate safety devices should be used”. The above is the only mention of modest reference to the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 (the Sharps Regulations). There should be a clear mention of the objective of these new regulations which have been issued since the 2012 issue of this NICE Guideline 139. There should be a prompt for all healthcare providers (not only dentistry) to ensure that there are risk assessments for safe handling and use of sharps and that safer sharps items are used when risk have been identified and are available on the market. The example to be considered here are that safety needles or retractable syringe and needle units should be used where a HCW is required to undertake a procedure involving a clinical sharp. If taking blood, inserting a peripheral cannula or if administering /assisting in the administration of insulin to a patient / or other injecting these safer sharps pieces of equipment should be used to reduce and in most cases avoid the risk of sharps injury to the healthcare worker. I consider these NICE guidelines an essential means of generating awareness of this legislation to those private healthcare providers especially those providing care in the community either in residential facilities or to patients in their own homes. This legislation must be included here within this update/re-issue of NICE 139 with a widening of the statement quoted above to include all groups if there is not to be any review of the other included recommendations.	Thank you for your comment. A footnote providing a link to the Health and Safety regulations 2013 will be added to the guideline.
UK Clinical Pharmacy Association (UKCPA)	Agree	There is no significant new evidence therefore the decision to not update the guideline is logical.	Thank you for your comment.

Royal College of Paediatrics and Child Health	Agree	None	Thank you for your comment.
NHS England	None	None	Thank you for your comment.
Astellas Ltd.	Disagree	Astellas welcomes the opportunity to comment on the provisional review decision and disagrees with the decision of not updating the NICE CG139 Healthcare-associated infections: prevention and control in primary and community care based on the following: The rates of healthcare-transmitted infections (HCAI) have fallen over the years in the UK. However, and in spite of this decrease, there has been an increase in morbidity and mortality associated with HCAI. Infections such as Clostrium Difficile infection (CDI) occurs most commonly in elderly patients and recently discharged patients, outpatients, and those in long-term care facilities. In the UK, there were 14,165 cases of CDI reported to PHE in 2014/15, and 2,267 of these patients died within 30 days of a positive specimen being taken, giving a Case Fatality rate (CFR) of 16.2%. Further, in 2007 MRSA bloodstream infections and CDI were recorded as the underlying cause of, or a contributory factor in, approximately 9000 deaths in hospital and primary care in England.1 These figures demonstrate the magnitude of this infection on a national basis. Healthcare associated CDI is therefore associated with significant mortality and measures to reduce death and onward transmission are of extreme importance. Each one of these infections means additional use of NHS resources, greater patient discomfort and a decrease in patient safety. Furthermore, inappropriate HCAI control leads to unnecessary use of antibiotics, increasing the risk of CDI and development of multi-resistant organisms, as well as limiting treatment choices. The UK Five Year Antimicrobial Resistance Strategy recommends the use of the right drug, right dose at the right time and for the right duration to limit unnecessary antibiotic exposure and fidaxomicin fulfils these criteria.2 Astellas as part of the pharmaceutical industry wishes to continue supporting work to improve antimicrobial resistance surveillance and infection prevention and control in the NHS. Therefore, Astellas would like to present the following evidence supporting that treatment with fidaxomicin reduces infection-related CDI cases and subsequently reduces CDI-related deaths.	Thank you for your comment. The guideline recommendations refer to Clostridium difficile as an example and therefore the guideline is not limited to that organism only. The 4 year surveillance review did not identify any published evidence which would impact on the current recommendations. The 4 year surveillance review searched for and considered evidence published from April 2014 to April 2016. The references provided were either published before these search dates, and would have been considered during previous surveillance reviews, or were in hospital settings and therefore not included in this guideline. This area is considered outside the scope of the guideline which is for primary and community care settings.

		• A case study suggested that independent predictors of C. Difficile infection-related mortality included admission either from another acute hospital or from a long-term care facility. 3 Further, results from additional regression analysis based on an UK cohort associated CDI with an 50% increase of death. 4 • Fidaxomicin is a narrow spectrum macrocyclic compound which has been shown in randomised clinical trials to successfully treat and reduce recurrence of C. Difficile infection.5-6 • A recent real world analysis evaluated the impact of the introduction of fidaxomicin treatment vs. current practice on the management of C. Difficile infection in seven NHS secondary care hospitals. In the two hospitals where fidaxomicin was positioned for all primary and recurrent episodes, the recurrence rate and the 28-day all-cause mortality were significantly reduced. 7 • C. Difficile forms spores that survive for months in dust and on surfaces therefore eradication can be difficult. Fidaxomicin has been shown in vitro to reduce sporulation of C. Difficile. In contrast, the other tested treatments vancomycin, metronidazole, and rifaximin (at similar sub-MICs) did not inhibit sporulation. 8 • With respect to the importance of transmission via environmental surfaces, in a prospective study, it was found that acquisition of CDI spores even with gloved hands was as likely after contact with commonly touched environmental surfaces as after contact with commonly examined skin sites. 9 Surface decontamination, hand hygiene, isolation precautions, restricted use of antibiotics and glove protection are important infection control strategies. 10 • Another study investigated whether fidaxomicin treatment of patients reduced C. Difficile environmental contamination in hospitalised patients. Treatment with fidaxomicin was associated with reduced environmental contamination with C. Difficile in patients treated with fidaxomicin compared with metronidazole and/or vancomycin. 11 In conclusion, based on the data that has become available since the last review of this guideline, Astellas would like to suggest that the sections “Drug recommendations” and “Related NICE guidance” in the NICE CG139 are updated and fidaxomicin should be considered as a treatment helping to minimise the risk of infection by reducing sporulation and transmission of CDI, as well as contributing to improvements reducing the need for antibiotics, limit the emergence and spread of multi-drug resistant organisms, and finally HCAI- related deaths.	

		References 1. NICE CG 139 Prevention and Control of Healthcare-Associated infections in primary and community care. http://www.nice.org.uk/guidance/cg139/chapter/1-guidance 2. Department of Health 2013. UK 5 year antimicrobial resistance strategy 2013 to 2018 3. Chopra et al. Predictors of Clostridium difficile infection–related mortality among older adults. Am J Infect Control. 2016 Jul 13. pii: S0196-6553(16)30475-8. doi: 10.1016/j.ajic.2016.04.231. [Epub ahead of print] 4. Reach et al. Excess Mortality Attributable to Clostridium difficile and Risk Factors for Infection in an Historic Cohort of Hospitalised Patients Followed Up in the United Kingdom Death Register. PLoS One. 2016 Mar 21;11(3):e0149983 5. Louie TJ et al. Fidaxomicin versus vancomycin for Clostridium difficile infection. N Engl J Med. 2011; 364(5):422-31 6. Cornely OA et al. Fidaxomicin versus vancomycin for infection with Clostridium difficile in Europe, Canada, and the USA: a double-blind, non-inferiority, randomised controlled trial. Lancet Infect Dis. 2012; 12(4): 281-9 7. Goldenberg SD et al. The impact of the introduction of fidaxomicin on the management of Clostridium difficile infection in seven NHS secondary care hospitals in England: a series of local service evaluations. Eur J Clin Microbiol Infect Dis. 2016 Feb;35(2):251-9. 8. Babakhani et al. Fidaxomicin inhibits spore production in Clostridium difficile. Clin Infect Dis. 2012 Aug;55 Suppl 2:S162-9	

		9. Guerrerro et al. Acquisition of spores on gloved hands after contact with the skin of patients with Clostridium difficile infection and with environmental surfaces in their rooms. American Journal of Infection Control 40 (2012) 556-8 10. Gould et al. Prevention and control of clostridium difficile infection. Nurs Older People. 2010 Apr;22(3):29-34; 11. Biswas et al. Reduction in Clostridium difficile environmental contamination by hospitalized patients treated with fidaxomicin. J Hosp Infect. 2015 Jul;90(3):267-70.	
PHE	Disagree	1. There is no mention of the Health and Social Care Act (2008) Code of Practice on the prevention and control of infections and related guidance. There is reference to the Health and Social Care Act (2008) but no mention of the Code, which is the standard that registered providers are measured against by CQC. There should be some mention of this and how the two should work together. 2. It is disappointing that there is a focus on MRSA and CDI throughout the guidelines given the changing epidemiology of healthcare associated infection and the significant increase of infections caused by Gram-negative organisms, many of which are multi-drug resistant. 3. The terminology around aseptic technique, aseptic non-touch technique, non-touch technique, clean technique is confusing and should be clarified. 4. Healthcare worker safety should also be included in the assessment of the need/type of respiratory protective equipment in accordance with the relevant Health and Safety regulations.	Thank you for your comment. The Health and Social Care Act (2008) was available when the guideline was developed and would therefore have been considered at the time the guideline was produced. The 4 year surveillance review searched for and considered evidence published from April 2014 to April 2016. The guideline recommendations refer to Clostridium difficile as an example and therefore the guideline is not limited to that organism only. The 4 year surveillance review did not identify any published evidence which would impact on the current recommendations. The terminology for aseptic technique, aseptic non-touch technique, non-touch technique, clean technique will be considered and amended if required to ensure clarity. The guideline references Health and Safety regulations; no evidence was identified during the 4-year surveillance review suggesting no impact to these recommendations.
Royal College of General Practitioners	Disagree	The RCGP does not agree with the decision not to update the guideline Healthcare-associated infections: prevention and control in primary care and community care, and place NICE guideline CG139 on the static list. Infection prevention and control is fundamental in improving the safety and quality of care provided to patients. National and local health care associated infection reduction plans	Thank you for your comment. The proposal to transfer CG139 to the static list means that the guideline will be reviewed every 5 years to determine if they should remain on the static list and routine surveillance would not be carried out. However the guideline will still

		are vital as the UK population ages as we enter a period of increased antimicrobial resistance (AMR) with no substantial new antimicrobial treatments The guidance needs updating to consider the a. situation of infections where there is no effective antimicrobial treatments using the lessons of history and the ebola outbreak b. design of GP and improvement of GP facilities and equipment to drive improvement in services and will contribute to the further development of the nationwide work to combat AMR. (MH)	remain available and in use for the NHS. The 4 year surveillance review did not identify evidence in the areas highlighted in your comment in primary and community care settings, therefore no impact on recommendations was identified.

Do you agree with the proposal to put the guideline on the static list?

Stakeholder	Overall response	Comments	NICE response
3M	Disagree	This Guideline is the only national guidance to advice primary care healthcare professionals on best evidence based practice in for the prevention and control of infections in the community setting. Its role should be to set standards and identify research questions in its subject area. With the constant pressure for earlier discharge of acute care patients it is of paramount importance that this Guideline is maintained to lead infection control and prevention practice in the community to the bnefit of patients and the protection of healthcare professionals.	Thank you for your comment. The proposal to transfer CG139 to the static list means that the guideline will be reviewed every 5 years to determine if they should remain on the static list and routine surveillance would not be carried out. However the guideline will still remain available and in use for the NHS.
British Infection Association	Disagree	See comments above – gaps in the guidance need addressing	Thank you for your comment, please see our response to your previous comment.
Royal College of Nursing	Disagree	See above comments	Thank you for your comment, please see our response to your previous comment.
South Eastern HSC Trust	Agree if action recommended at No one above is undertaken	Yes if above comments is included	Thank you for your comment.

UK Clinical Pharmacy Association (UKCPA)	None	None	Thank you for your comment.
Royal College of Paediatrics and Child Health	Agree	None	Thank you for your comment.
NHS England	None	None	Thank you for your comment.
Astellas Ltd.	Agree	Astellas consider appropriate to move the guideline to the static list.	Thank you for your comment.
PHE	Disagree	As above. There is an opportunity to update the guidelines of in light of the changing epidemiology of healthcare associated infection and the significant increase in infections caused by Gram-negative organisms.	Thank you for your comment. The guideline recommendations refer to Clostridium difficile as an example and therefore the guideline is not limited to that organism only. The 4 year surveillance review did not identify any published evidence which would impact on the current recommendations.
Royal College of General Practitioners	None	None	Thank you for your comment.

Do you agree with the proposal to remove the research recommendation:

When clean running water is not available, what is the clinical and cost effectiveness of using wipes, gels, handrubs or other products to remove visible contamination?

Stakeholder	Overall response	Comments	NICE response
3M	Agree	None	Thank you for your comment.
British Infection Association	Agree	This question is not of high clinical or cost-effectiveness importance in the opinion of those members who responded.	Thank you for your comment.
Royal College of Nursing	Disagree	Taking into account the recent UK contribution to the Ebola epidemic, where a lot of UK nurses volunteered, we consider that this is an area that needs to be explored. The UK being a leading nation on healthcare, and contributing to global health, this area warrants consideration. There have been also been a few cases where UK nationals got infected and had to be treated in the UK. This warrants the need to	Thank you for your comment. The 4 year surveillance review did not identify any new evidence relating to this research recommendation. Based on your comment, we will retain this research recommendation.

		ensure that staff are aware of current evidence based guidance. Further, when we work and advise other nations, we would be in a more pragmatic position to influence if we can understand and have evidence base advice and guidance for simple things like hand hygiene where there is a shortage of water.	
South Eastern HSC Trust	Agree	None	Thank you for your comment.
UK Clinical Pharmacy Association (UKCPA)	None	None	Thank you for your comment.
Royal College of UKCPA Paediatrics and Child Health	Agree	Unlikely scenario that clean water will not be available.	Thank you for your comment.
NHS England	Agree	None	Thank you for your comment.
Astellas Ltd.	Agree	None	Thank you for your comment.
PHE	Disagree	The reason given for removing this research question is that there are currently no new evidence relevant to the research recommendation was found and no ongoing studies were identified. Rather than remove this, it seems reasonable to keep such a recommendation given that there is no research activity in this area.	Thank you for your comment. The 4 year surveillance review did not identify any new evidence relating to this research recommendation. Based on your comment, we will retain this research recommendation.
Royal College of General Practitioners	None	None	Thank you for your comment.

Do you agree with the proposal to remove the research recommendation:

When recatheterising patients who have a long-term indwelling urinary catheter, what is the clinical and cost effectiveness of single-dose antibiotic prophylaxis in reducing symptomatic urinary tract infections in patients with a history of urinary tract infections associated with catheter change?

Stakeholder	Overall response	Comments	NICE response
3M	Agree	None	Thank you for your comment.

British Infection Association	Disagree	This is an important question which it would be useful to address.	Thank you for your comment. The 4 year surveillance review did not identify any new evidence relating to this research recommendation. Based on your comment, we will retain this research recommendation.
Royal College of Nursing	Disagree	See comments above in section 1	Thank you for your comment, please see our response to your previous comment.
South Eastern HSC Trust	Agree	None	Thank you for your comment.
UK Clinical Pharmacy Association (UKCPA)	None	None	Thank you for your comment.
Royal College of Paediatrics and Child Health	Agree	Not relevant in the paediatric population	Thank you for your comment.
NHS England	Agree	None	Thank you for your comment.
Astellas Ltd.	Agree	None	Thank you for your comment.
PHE	Disagree	As above	Thank you for your comment, please see our response to your previous comment.
Royal College of General Practitioners	None	None	Thank you for your comment.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
3M	No	None	Thank you for your comment.
British Infection Association	No	None	Thank you for your comment.
Royal College of Nursing	No	None	Thank you for your comment.

South Eastern HSC Trust	No	None	Thank you for your comment.
UK Clinical Pharmacy Association (UKCPA)	No	None	Thank you for your comment.
Royal College of Paediatrics and Child Health	No	Although as a general point we think NICE should always be encouraged to represent the evidence base in paediatrics (where it exists) apart from in adults.	Thank you for your comment.
NHS England	No	None	Thank you for your comment.
Astellas Ltd.	No	None	Thank you for your comment.
PHE	No	None	Thank you for your comment.
Royal College of General Practitioners	None	Why the recommendations for research RR02 (alternatives to running water) and RR05 (prophylaxis for catheter change) have been removed from the guidance. The rationale NICE gives is that there is no research they can find in progress that will be published in the next five years. Surely this is a reason to leave these recommendations in place?	Thank you for your comment. The 4 year surveillance review did not identify any new evidence relating to these research recommendations. Based on your comment, we will retain these research recommendations.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
3M	No	None	Thank you for your comment.
British Infection Association	No	None	Thank you for your comment.
Royal College of Nursing	No	None	Thank you for your comment.
South Eastern HSC Trust	No	None	Thank you for your comment.
UK Clinical Pharmacy Association (UKCPA)	No	None	Thank you for your comment.

Royal College of Paediatrics and Child Health	No	Although as a general point we think NICE should always be encouraged to represent the evidence base in paediatrics (where it exists) apart from in adults.	Thank you for your comment.
NHS England	No	None	Thank you for your comment.
Astellas Ltd.	No	None	Thank you for your comment.
PHE	No	None	Thank you for your comment.
Royal College of General Practitioners	None	Why the recommendations for research RR02 (alternatives to running water) and RR05 (prophylaxis for catheter change) have been removed from the guidance. The rationale NICE gives is that there is no research they can find in progress that will be published in the next five years. Surely this is a reason to leave these recommendations in place?	Thank you for your comment. The 4 year surveillance review did not identify any new evidence relating to these research recommendations. Based on your comment, we will retain these research recommendations.

Other

Members of The British Society for Antimicrobial Chemotherapy (BSAC) have no comments for the NICE Guideline: **CG139 Healthcare-associated infections consultation. –** Thank you for your comment.