National Institute for Health and Clinical Excellence

Infection Control Update
Guideline Consultation Comments Table
13/07/11 - 07/09/11

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Great Western Hospitals NHS Foundation Trust	1.00	Full	4.2.1.210	40	Reads as if it's encouraging staff to use gel after glove removal rather than soap and water. Would always advocate soap and water over gel when practically possible at the end of a procedure. Gel however is suited to intra procedure glove changes.	Thank you for your comment. After careful consideration we have decided not to change this recommendation. The GDG acknowledged that the preferred option is to use soap and water, but felt it important to reflect in a recommendation that in the community this is not always possible.
SH	Great Western Hospitals NHS Foundation Trust	1.01	Full	4.2.1.421	42	It is going to be very difficult to **assess** all users in the correct use and disposal of sharps**, and provide the evidence** to prove they have been assessed, when may staff working in the community setting work alone. Easy to assess when a skill is competency based, such as venepuncture or cannulation, but very difficult to achieve for those staff who are employed and qualified give sub-cut and intra muscular injections without further assessment.	Thank you for your comment. The GDG considered that, as stated in the linking evidence section for this recommendation, this could be included as part of ongoing staff training programmes and that the implementation of this recommendation should not be associated with any additional cost. Training should be considered for new staff and when new devices are implemented for all users. The GDG believes this is a local implementation issue. NICE will be publishing implementation tools shortly after the publication of this Guideline and we will pass your comments to the implementation team to provide information for their consideration about useful tools to support implementation of the relevant

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							recommendation.
SH	Great Western Hospitals NHS Foundation Trust	1.02	Full	4.2.4.422	48	There is no recommendation for skin prep for patients allergic to chlorhexidine. There is no reference to when the skin prep is selected it is 'licensed for use prior to an invasive procedure'. There are many chlorhexidine gluconate 70% alcohol preparations on the market but only one with the said licence. Some guidance on the need for a sterile product over a non sterile would have been useful.	Thank you for your comment. We agree and additional text has been added to the other considerations of linking evidence section of the recommendation (12.4.1.4 of the full guideline): 'The GDG discussed what to use if the patient is allergic to chlorhexidine and thought that alternatives, including iodine, could be discussed with the patient taking into account patient history'. The GDG did not think it was necessary to add 'licensed for use'. The recommendation was about what agent should be used, rather than a specific product.
SH	NHS East of England	2.00	Full – IPC Partial Update draft for consultation	General	General	This document provides robust evidence based guidance for clinical practice in the community. The methodology is sound and the inclusion of evidence of cost-effectiveness, and the discussions that surround and support the recommendations are excellent.	Thank you for your comment.
SH	NHS East of England	2.01	Full	4.2.2.3	36.	We would like 'mental capacity/understanding' to be included in the best approach to catheterisation assessment as a persons' capacity to understand and consent to treatment may change over time.	Thank you for your comment. The recommendation you are referring to was not prioritised within the scope of this partial update. The NICE guideline contains a section on patient-centred care which details the general principles that should be applied against the issues you raise.
SH	NHS East of England	2.02	Full	General	General	The vast majority of these recommendations will apply equally to secondary care given the need for joint approaches for care	Thank you for your comment. The remit for this guideline and the partial update is specifically for primary and community care.

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						pathways i.e. in patients with long term urinary catheters and/or enteral feeding tubes, would it not be possible to apply these recommendations to all NHS commissioned care settings as appropriate?	This area falls outside the scope of the guideline and therefore we are unable to provide a more specific response. We will ensure that the detail of your comment regarding secondary care is passed to NICE who have recently consulted on a core library of topics for NICE guideline/quality standard development.
SH	NHS East of England	2.03	Full	General	General	Has the group considered the keeping of a catheter diary as best practice for people with LTUCs.	Thank you for your comment. After careful consideration we came to the conclusion that this does not need to be amended as it is covered by the following recommendation: 'Catheter insertion, changes and care should be documented'.
SH	The Association of safe Aseptic practice	3.00	NICE Version	General General		This document has made some very welcome progress in clarifying aseptic technique. The acknowledgement of ANTT (Aseptic Non Touch Technique) is especially welcome as it is used widely in practice across the NHS (Rowley & Clare 2009) and is given as a similar best practice example in Epic2 (2007) and the RCN Infusion Guidelines (2010) – and incidentally, by the NHMRC (2010) - and this synergy will help further improve standards of aseptic technique through standardisation to the benefit of patients. Overall, in terms of referring to aseptic technique unambiguously and in a way that is most likely to promote safe practice, this document is a big step forward. If a few	Thank you for your comment. We agree that mixed terminology is confusing and have aimed to clearly define what we mean by aseptic technique in the glossary. We have amended our recommendation regarding PEGs to 'aseptic technique'. Aseptic technique has now been used throughout the guideline, with the exception of one recommendation in the urinary catheters chapter, where no evidence was identified and the GDG felt that the wording did not need to change from the 2003 recommendation. The recommendation stating: 'Preferably, a single lumen catheter should be used to

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				General 11.4.2.3. 11.4.2.3. And General	P157 P157	remaining ambiguities were removed as outlined, this document would set the standard. The remaining ambiguities relate to the historical problem of using mixed terminology for the term aseptic technique. (When often the mixed terminology is confusing, variably defined and interpreted differently). p157 does acknowledge the confusion caused by different terms. But the document then uses three different terms for aseptic technique throughout, (non- touch technique, clean technique and aseptic technique). These terms are not well enough defined (in this document or in other key guidance) or universally standardised enough to be helpful. In practice, these terms are used interchangeably and cause significant confusion. In effect, used in this document, they effectively suggest, if not endorse, a non-defined hierarchical approach to aseptic practice by NICE! Because this hierarchy of terms has no reference to a defined and comprehensive Practice Framework for Aseptic Technique, it will naturally and problematically be interpreted subjectively and variably by health care workers. Whilst we agree with the sentiments on p157 that these terms allude to the same	administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for total parenteral nutrition, and all lumens must be handled with the same meticulous attention to aseptic technique. [2003]', was not updated as part of this partial update.

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				General		meaning, we can only stress from our extensive work across the UK across the last decade that using different terms for essentially the same thing introduces ambiguity, and, that ambiguity in terminology historically, has contributed to the variable poor standards of aseptic technique evident today. We therefore recommend that this document takes a very clear and helpful lead by using only the generic term 'aseptic technique' throughout. It is of course important that an example or examples of a Practice Framework for delivering safe aseptic technique is provided. The GDG/NICE team have done this by including reference to the comprehensive Practice Framework for aseptic technique called ANTT. ANTT is surprisingly the only comprehensive practice framework for aseptic technique – that clearly defines and actually explains, by providing logical risk assessment, how to do aseptic technique. (As ANTT has become the de-facto standard aseptic technique in the UK (Rowley & Clare 2009), many healthcare workers and healthcare organisations will welcome its inclusion.	
				General	P203		
				Glossary		The term 'clean technique' in particular causes much confusion in practice. It implies, and is commonly interpreted, that 'clean' clinical procedure do not need to be	

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						aseptic. This is of course not true and is misleading. The aim of clean technique is still asepsis – i.e. the aim is still not to introduce pathogenic organisms. To this end, the definition of clean technique on p203 provides great potential for ambiguity and poor practice. *"A technique that is designed to prevent the microorganisms, but in recognition that the s bacteria it is not aseptic. Non sterile gloves n* The above definition inadvertently implies that where a site is already contaminated, 'non aseptic' techniques are acceptable. The site may be infected but the aim is always 'aseptic technique' - as one doesn't want any new microorganisms to be introduced. (This may go some way in explaining why chronic wounds remain chronic for so long). We therefore recommend the use of non touch technique is removed throughout the document as per p46 and p156 for enteral feeding – and the same for p135 and intermittent catheterisation and replaced with the term aseptic technique. The use of the adjective 'meticulous' aseptic technique for parental nutrition on p48 – inadvertently suggests other procedures don't require meticulous asepsis. It would	
				4.2.3.3 11.4.1 10.7.7.1 4.2.4.4	P46 156 P 135 P48		

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						help raise standards and prevent ambiguity if NICE sends a strong unambiguous message that all aseptic techniques (no matter how simple or complex) should always be meticulous. We appreciate that the inclusion of the adjective meticulous was not intended to cause confusion. But from our extensive and unique level of site work and experience in this field, we strongly advise that historical and current practice shows that healthcare workers will interpret such subjective terms highly variably. Worse, some healthcare workers will make subsequent assumptions that practice not requiring meticulous care, can be performed with shortcuts. This puts asepsis at risk. To avoid introducing unnecessary ambiguity we again recommend the single term aseptic technique throughout.	
SH	The Association of safe Aseptic practice	3.01		General		To summarise the above, using the singular generic term of 'aseptic technique' throughout the document will provide clarity rather than the ambiguity caused by mixed terms. Supporting this with a best practice example(s) of a comprehensive aseptic technique practice framework (as the document already does by referring to the ANTT Practice Framework) provides	Thank you for your comment. We agree and have amended this where appropriate.

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						readers with reference on how to actually deliver safe aseptic technique. We advise that this simple and consistent approach would set the standard for how aseptic technique is best referred to in national guidance.	
SH	The Association of safe Aseptic practice	3.02		12.8.6	P194	P194 – The document says there was no satisfactory evidence regards IV hub cleaning technique. Kaler and Chin (2007) seems to be widely accepted as reasonable evidence of technique. It demonstrated the need for time and friction. These attributes have been widely adopted in practice nationally and internationally though campaigns like '*Scrub the Hub'*. We recommend this document provides such information for technique as recommending solutions alone would seem a backward step. **References mentioned in the above comments** Rowley S, Clare S (2009) Improving standards of aseptic practice through an ANTT trust-wide implementation process: a matter of prioritisation and care. *British Journal of Infection Prevention* **10**(1): S18-S23 NHMRC (2010) Australian Commission on Safety and Quality in Healthcare: Australian	Thank you for your comment. We did conduct a systematic review of the evidence, but no evidence was identified that met our inclusion criteria. Kaler and Chin (2007) is an in vitro study, and therefore excluded from review. Laboratory studies were excluded because the populations (volunteers, animals or *in vitro*) and settings used are artificial and not comparable to the population we are making recommendations for. These studies would undoubtedly be of very low quality as assessed by GRADE and therefore RCTs, cohort studies or GDG consensus opinion was considered preferable. The rationale was explained in section 3.1.3.4 of the full guideline.

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						Guidelines for the Prevention and Control of Infection in Healthcare. *Commonwealth of Australia*. Available: http://www.nhmrc.gov.au/publications/synopses/cd33syn.htm. Accessed 24 May 2011 Epic2….Pratt RJ, Pellowe CM, Wilson JA, Loveday HP, Harper PJ, Jones SRLJ, McDougall C, Wilcox MH (2007) Epic2: National evidence based guidelines for Preventing Healthcare-Associated Infections in NHS hospitals in England. *Journal of Hospital Infection* **65**: S1-S64 Kaler W, Chinn R (2007) A Matter of time and friction. JAVA **12**(3): 140-142	
NICE	PPIP	4.00	NICE	General		Thank you for the chance to comment on this draft guideline. Overall we found it clear and easy to read.	Thank you for your comment.
NICE	PPIP	4.01	NICE	KPI	9/45	We have been advised that it is important to include with the 2nd bullet under long-term urinary catheters, the recommendation 'do not offer multiple use catheters for use in children or young people of 16 years or under'. Including this statement in the KPIs will highlight the 'all-ages' coverage of this guideline, and ensure that this KPI is not used inappropriately in children/young people aged under 16.	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for

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							intermittent self catheterisation.
NICE	PPIP	4.02	NICE	1.1.1.1	12/45	Should this read 'everyone involved in providing *health*care…'? We are not sure if a NICE guideline can make a recommendation to 'everyone' who provides any type of care?	Thank you for your comment. After careful consideration the GDG decided that this should not be changed. The GDG considered that this recommendation also covers carers and family members who should be educated and trained about standard principles.
NICE	PPIP	4.03	NICE	1.1.4.4	17/45	1st bullet: we see why sharps disposal must be out of reach of children, but is it also important to mention 'others who might come to harm' or some such phrase? I am thinking of people with dementia or learning disabilities, for instance, in their own homes.	Thank you for your comment. We do not wish to be so prescriptive and consider that this level of detail is appropriate in this guidance. The full version of this guideline does discuss waste disposal further in the linking evidence to recommendations section and the Department of Health's guidance on 'Safe management of healthcare waste' is also referenced.
NICE	PPIP	4.04	NICE	1.2.3.3	19/45	1st bullet: We suggest some explanatory text be added after 'age', reflecting the example given in the full version: Age – The length and gauge of the catheter should be appropriate for the patient. For example, the size should be appropriate for the age or size of the child.	Thank you for your comment. After careful consideration the GDG came to the conclusion that they did not agree. This was not meant to be an exhaustive list but a starting point on which to base an assessment. We do not wish to be so prescriptive and we think that it would be up to the healthcare professional to decide according to patient needs and preferences. As stated each bullet point is explained in the linking evidence section in the full guideline and the GDG thought that inclusion in the recommendation would be lengthy and confusing.
NICE	PPIP	4.05	NICE	1.2.3.4	20/45	We feel this recommendation as drafted does not fully reflect some of	Thank you for your comment. We acknowledge your concerns regarding

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						the patient-centred points raised in the full guideline text. The introduction to section 10 of the full guideline includes the following text (p. 114), which does not appear to be reflected in this recommendation: 'Infection is a major problem in LTC although there are other non-31 infectious complications associated with LTC, including physiological/structural damage,[268] urological 32 cancer[62] and psycho-social problems.[207] In selecting particular strategies to manage urinary 33 problems, healthcare practitioners must take account of all of these complications. These guidelines 34 focus on preventing infection. However, because infection has a complex inter-relationship with 35 encrustation and blockage, these aspects of catheter management are also addressed. ' We think it is important to acknowledge in the recommendations the other issues also mentioned, such as psycho-social aspects, physiology etc. Some specific concerns include: **Choice:** The recommendation as drafted appears not to allow for	patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that

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						patient choice in circumstances unique to the patient. Yet such circumstances are specifically highlighted in the text, for instance, in the full text page 130: 'The GDG considered that there may be situations in which it is difficult for patients to wash, dry and store multiple-use non-coated catheters, for example patients with communal washing facilities. On this basis, the GDG agreed that there are situations in which it is not appropriate for patients to use multiple-use non-coated catheters.' On page 132: 'The GDG felt it important to consider privacy and dignity issues when recommending a type of intermittent catheter. In addition to the situations outlined above, they felt there may be other circumstances (such as shared toilets in work places or other public spaces) in which patients may not feel comfortable washing and drying non-coated catheters. In these cases, a coated catheter should be recommended.' We think it is important to review this recommendation, to ensure it is an enabling one, which recommends both cost-effective interventions where they are appropriate, and allows patient choice where there are circumstances for the individual which, for a variety of reasons, mean that non-coated	further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. **Choice:** The text in the LETR has also been amended to read: The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review and that recommendation 36 is worded the to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when selecting an intermittent catheter. **Patient-defined outcomes:** Unfortunately we were unable to conduct a

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						multiple use intermittent catheters may not be (or have been found not to be) appropriate. **Patient-defined outcomes:** It is not clear what balance there was in considering outcomes for people who use intermittent catheters: the focus of this guideline is clearly infection prevention and control; we think it is important that links are made in considering this recommendation, with the ongoing NICE guideline on incontinence in people with neurological conditions, which may have a clearer focus on patient-defined outcomes for catheter use, and also may have a clearer indication of the views of people who use such catheters. It would be helpful to know what input there was to this recommendation from people who use intermittent catheters in a range of situations, for instance at work, in active family life, and other circumstances. **Equalities:** We are not clear the extent to which equalities issues have been considered in arriving at this draft recommendation. For instance, there appears to be a bias in favour of men in the populations considered in the RCTs and in the economic modelling, whereas we have been advised that women may make up a significant proportion of people who use intermittent catheters. Older women may be a specific risk group for infection.	qualitative review of the literature. Due to limited resources we were only able to address a limited number of clinical questions. At the start of the guideline development process the GDG listed their priority questions. However, we have sought advice on this recommendation from our GDG, (which includes 2 patient members) a consultant urology nurse and a consultant urological surgeon (who is the chair of the neurological incontinence guideline currently in development). **Equalities:** The GDG recognise that there are many types of abilities/disabilities and many factors which may influence availability. The GDG considered it impossible to explicitly outline every possible situation which could conceivably arise for every single individual using ISC. Therefore, it was decided to recommend that the clinician should take into account a patient's individual needs and circumstances when prescribing a catheter .Additional text has been added to the linking evidence section to clarify this: The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. *Other equality issues such as cognitive and*

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						We suggest it is also important to consider the impact of the recommendation as worded on disabled people, in terms of equalities legislation, which requires that steps are taken not only to avoid discrimination against disabled people, but also to promote equality for them, and their ability to participate in mainstream society. **Numbers of catheters used per day:** The recommendation appears not to take any account of the numbers of times a person uses an intermittent catheter per day, yet the text clearly states: (p. 128) 'However, multiple use non-coated catheters cease to be the most cost-effective choice when patients use *an average* of more than two catheters per day. Compliance and behaviour are therefore important factors for healthcare workers to consider when prescribing an ISC regime' We think this needs to be made clear in any recommendation about when to offer non-coated multiple use catheters. **Interpretation and limitations (pp. 127-128)**: We are concerned by the discussion in this section, which appears to deny	*visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation, see recommendation 36 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003].* We agree that while the populations of the clinical trials included in the review were predominantly male, the GDG did not think that the relative effectiveness of each type of catheters would not be expected to vary in different subgroups. Two economic models were developed: one in which baseline infection rates and utilities were obtained from patients with SCI and one in which they were obtained from patients without SCI. The extreme upper and lower confidence intervals of each parameter was explored and no effect was found on the outcome of the model. **Numbers of catheters used per day:** The GDG discussed the threshold analysis preformed on the economic model and considered including this result in the recommendation. As outlined in the LETR, they decided that:

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						patient choice, even where there may be clear reasons for patient preference of one type of catheter over another. We think there are issues which might warrant further consideration around the assumptions behind the QALY and the use of EQ-5D which may not adequately reflect the wide range of experiences and needs of people who use intermittent catheterisation. We would welcome clarification of this section (and particularly the last para), which states: 'Healthcare workers must also consider other patient-specific situations when deciding which 8 catheter to prescribe. Under the current decision rule, the recommended treatment is identified as 9 that with the highest ICER that falls below the cost-effectiveness threshold. Preferences are 10 incorporated into the cost-utility analysis through the values that are attached to each health state; 11 these values represent the average weight attached to each health state by the general population 12 and are assumed to be independent of factors related to the health care process…. 'Of the five RCTs included in our review of clinical efficacy, three included a	*No evidence was reviewed regarding the frequency of change for noncoated catheters. The GDG did not feel it was appropriate to make a recommendation regarding the frequency of change of multiple use catheters as this was likely to be influenced by other factors such as comfort or efficacy which would be routinely discussed as part of the normal patient-clinician interaction.* **Interpretation and limitations (pp. 127-128)**: The paragraph you refer to was added in order to explicitly take into account patient preference when selecting an intermittent catheter. Technically, the results of the model show that hydrophilic catheters are not cost-effective. Therefore, where a patient cannot use multiple use catheters, gel reservoir should be prescribed. However, we recognise that some patients may have a preference for hydrophilic catheters. Although they are less effective they are also less expensive, therefore, under the stated reasoning and cited references, they should be permitted to choose hydrophilic catheters if they prefer them.

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						measure of patient 19 preference and comfort; none found any difference between catheter types. Nevertheless, it is still 20 possible that patients may find one type of catheter more comfortable or easier to use than another 21 and therefore derive a benefit from the catheter that is not captured in the model[76]. When deciding 22 between gel reservoir and hydrophilic catheters for patients who cannot use multiple non-coated 23 catheters, the GDG did not wish to force the consumption of more costly gel reservoir catheters. If a 24 patient has a strong preference for hydrophilic catheters then the GDG agreed that they should be 25 able to choose this less costly option. 26 'It is important to note that under this rule patients should not be given a choice of therapies that are 27 more expensive and more costly than the most cost-effective treatment[77]. In other words, this line of 28 reasoning *cannot* be extended to patients who are able to use clean multiple use non-coated 29 catheters but prefer not to, nor to patients who prefer single use non-coated catheters to single use 30 gel reservoir or hydrophilic catheters.'	
NICE	PPIP	4.06	NICE	1.2.3.5	20/45	A question arises from this	Thank you for your comment. The GDG

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						recommendation: what happens when a person reaches age 17, when many of the issues raised in the text such as privacy, schooling etc will continue to be the case. In addition, we are concerned as to whether a young person who has been using one type of catheter will be expected to change, just because they have attained the age of 17?	considered that this would be discussed with the patient as part of their assessment and have added the following bullet point into the recommendation: 'this is considered clinically appropriate following clinical assessment (see recommendation 1.2.3.1)', which includes patient preference. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
NICE	PPIP	4.07	NICE	.12.5.4	12/45	Footnote 21: we would like to see this footnote removed from the final draft. The PPIP offered advice and opinion to the developers about 'instructions' to carers, but we do not have legal qualifications, and we suggest that any confirmation of the approach in this revised recommendation should be given by legal opinion, if that is needed.	Thank you for your comment. This footnote has been removed.
NICE	PPIP	4.08	NICE	4.1	29/45	We note the use of the word 'compliance' here. Elsewhere we refer to 'adherence', for	Thank you for your comment. After careful consideration, we came to the conclusion

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						instance in use of medication. Might 'adherence' be more appropriate?	that we do not agree that this should be changed. We think that this wording is appropriate because we have referred to hand decontamination compliance in chapter 6 of the full guideline and this also reflects the terminology found in the evidence review.
NICE	Technical Team	5.00	Full including appendix J	General	General	The document is overall of high quality.	Thank you for your comment.
NICE	Technical Team	5.01	Full	3.1.3.6	27	Para 1, line 22. It has been agreed with the GRADE working group that NICE can now state that we use GRADE and don't need to say that we use an adaptation of GRADE	Thank you for your comment. This has been updated.
NICE	Technical Team	5.02	Full	3.1.3.6	27	Para 3 line 32. The percentages across studies should not really be reported as you are effectively comparing treatment groups from one trial with control groups in other trials – non-randomised comparison. It can also lead to Simpson's paradox where the crude % from adding up will give an opposite result to the RR from meta-analysis. It is useful to give an idea of the total number of participants and total number of events, but not to present them as a %. This applies to several findings tables in the guideline.	Thank you for your comment. The percentages across studies is part of the GRADEpro output, but we are not making decisions on this basis (but on the risk ratio and the absolute risk difference across studies). We have added further detail about this in the methods section: For binary outcomes such as number of patients with an adverse event, the event rates (n/N: total number of patients with events divided by total number of patients across studies) are shown with percentages (note: this percentage is an output of GRADEpro software. It is not the results of the meta-analysis and is not used in decision making).
NICE	Technical Team	5.03	Full	3.1.5	34	Please add some details about the methods	Thank you for your comment. Consensus

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						of formal consensus that were used in developing recommendations	methods have been detailed further in the methods section including voting in the GDG and anonymous voting via email.
NICE	Technical Team	5.04	Full	5.3.1	52	Recommendations 1 and 2 -there was no review question for adding the extra information – this is discussed in evidence to recommendations sections but might be helpful to also state this in an opening paragraph	Thank you for your comment. We agree and have added further explanatory text to the introduction of this section.
NICE	Technical Team	5.05	Full	5.3.2.2	54	Line 14. Please include the overall numbers of studies etc – this comment applies where relevant throughout the document	Thank you for your comment. We agree and the number of included studies has been added to the relevant section.
NICE	Technical Team	5.06	Full	5.3.2.4	59	No evidence statements are presented for this review - is that because of the nature of the evidence reviewed?	Thank you for your comment. Evidence statements in the style of those presented for intervention reviews were not considered appropriate in this section as it is a qualitative review. The evidence is summarised in Table 6, with the full findings detailed in the appendix.
NICE	Technical Team	5.07	Full	6.2	62	Para 2. It is not clear how the studies described in this section fit in to the subsequent evidence review. Have they been included or are they background information? Please clarify.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update. Section 6.2 forms part of the narrative and evidence review for the 2003 recommendations and remains an important part of the guideline. The two guidelines referred to have contributed to those recommendations made in 2003.
NICE	Technical Team	5.08	Full	6.3.1.1	63	It would be useful to have a description of whether and how these interventions from WHO etc differ.	Thank you for your comment. We agree and have added more detail to this section.
NICE	Technical Team	5.09	Full	6.3.1.4	75	Recommendation 5, bullet point 2. This is mentioned in the evidence to recommendations section as being decided	Thank you for your comment. We agree and have added more detail to this description: The exceptions in the bullet points for when

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						by consensus but more information on the rationale for this decision is needed	to perform hand washing are based on GDG informal consensus, based on discussions at the GDG meeting, as no RCT evidence was identified, but are also consistent with WHO guidance. The GDG considered that during outbreaks such as diarrhoeal illness (which is outside the scope of this guideline), alcohol is ineffective at killing spores such as *Clostridium difficile*. Mechanical friction from washing hands with soap and water was considered more appropriate for physically removing spores from the surface of contaminated hands. The GDG also sought advice from the microbiologist co-optee before considering its final recommendation.
NICE	Technical Team	5.10	Full	7.3.2.1	85	This is an updated recommendation but there was no review question. Please clarify how the studies described in the evidence to recommendations were identified and reviewed. Are they from the previous guideline?	Thank you for your comments. The GDG felt that this recommendation is very important and as such wanted it to sit at the top of the beginning of the glove section. As such, the other consideration section of the recommendation states that: 'This recommendation has been moved to the beginning of the gloves section as the GDG considered it to be very important. The evidence behind the recommendation was searched for under the type of glove material in question (section 7.4).'
NICE	Technical Team	5.11	Full	10.5.1.1	117	Please state that study was an RCT.	Thank you for your comment. We have added this to the relevant section of the guideline.
NICE	Technical Team	5.12	full	10.2.3.5	130	Recommendation. The wording of the recommendation needs to be very precise about the situation in which the	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel

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						recommendation applies - self catheterisation e.g. at home by patient/family carer and with the support of healthcare professionals. It may be necessary to reword the recommendation to specifically state this	(GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
NICE	Technical Team	5.13	full	10.10.1 .1.	146	Table 73. What is the control in this study – no antibiotic prophylaxis? Was this a study of single dose or short-course antibiotics? What was route of administration (oral)? I	Thank you for your comment. We agree and the table has been updated to state that the intervention was meropenem and the control was no treatment. The footnote has

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						wonder if route of administration needs to be mentioned in the evidence to recommendations or is this standard?	also been updated to state that 1g was given IV, 30 minutes prior to catheterisation.
NICE	Technical Team	5.14	Full	General	general	For areas where no economic studies were identified, it might help to refer to national statistics about the cost of hospital infections to the NHS. I believe that there has been work done on estimating the cost to the NHS. This would help justify the statement that the added activity would be offset by reductions in infections.	Thank you for your comment. There has been some work done to estimate the cost of healthcare acquired infections to the NHS (e.g. Plowman et al 1999). However, these apply only to patients in hospital settings and are quite out of date. Before each question was presented to the GDG for discussion, they were asked if it they would find it useful to have estimates of costs to inform their decision making. For questions where no costs are presented they indicated that they would not.
NICE	Technical Team	5.15	Appendix J	J.2.3.2	366	"..., it is preferable to work on the log scale and derive a confidence interval for the log rate, then antilog this to give a confidence interval for a rate." I don't think antilog is the correct term, I think exponent is probably correct.	Thank you for your comment. We agree. We have amended the wording accordingly.
NICE	Technical Team	5.16	Appendix J	J.2.3.2	367	"This is consistent with other epidemiological and observational studies in the literature." This would be better if the results of the observational study could be quoted here to provide context.	Thank you for your comment. We agree. We have added more detail to this description.
NICE	Technical Team	5.17	Appendix J	J.2.3.4	369	Under the subheading for bacteraemia could some reasoning be added for choosing the paper by Saint et al 2000.	Thank you for your comment. We have added more detail to this description.
NICE	Technical Team	5.18	Appendix J	J.2.3.7	374	The steps between the costing explanation and the final values are not clear for multidrug resistant infections and bacteraemia. In particular details for the number of bed days are not quoted and also	Thank you for your comment. We have added more detail to this description and amended the table to reflect the (correct) values which are reported in the model.

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						the split between LA04D with complications and without is not mentioned. In addition there appears to be slight differences to the final values quoted in the model and those reported in table 29.	
NICE	Technical Team	5.19	Appendix J	J.3.1	383	After running the model probabilistically I consistently get a different answer for the gel reservoir catheter. I get total costs of £41,826 and QALYs of 12.446 and an incremental ICER of £52,000 per QALY. This may be due to the slightly different values used in the model. However, this has little change on the interpretation.	Thank you for your comment. We are not sure why this is. The results of the write-up have now changed due to the comments made by stakeholders regarding prescription charges. Please see the updated report for the correct cost and QALY figures (note that the conclusion is similarly unchanged).
NICE	Technical Team	5.20	Appendix J	J.3.3	387	I'm very happy to see value of information analysis included in the guideline. Was this used to inform research recommendations?	Thank you for your comment. The research recommendations were made before the value of information analysis had been finalised. However, the value of information analysis was useful in supporting the GDG's decision.
PR	NETSCC, HTA ref 1	6.00	Full	general	general	**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** I believe that this is a comprehensive review of the available literature and think that this work fulfills the scope.	Thank you for your comments.
PR	NETSCC, HTA ref 1	6.01	Full	general	general	**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at**	Thank you for your comments.

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						http://www.nice.org.uk/page.aspx?o=guidelinesmanual). I believe that the methods used are the current standard methods for such a review.	
PR	NETSCC, HTA ref 1	6.02	Full	general	general	I concur with the quality levels assigned each of the review –LOW or VERY LOW in all cases. Even in the few cases which are listed as MODERATE the strength of the evidence is not great.	Thank you for your comments.
PR	NETSCC, HTA ref 1	6.03	Full	general	general	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The statistical methods used are clear and appropriate. A fairly standard approach has been taken in all aspects of the meta analysis and this is the approach that I would have adopted if I was doing a Cochrane review. I am not always sure that using the total event rate in the control arm is always valid if there is significant heterogeneity in the event rates in the different studies.	Thank you for your comment. We have detailed our approach to heterogeneity in section 3.1.3.9.
PR	NETSCC, HTA ref 1	6.04	Full	general	general	Having read the report combining the event rates is not really an issue in this work. Very few of the analyses involve a meta-analysis as frequently there is only one study. Also from the evidence presented I did not see any evidence of major heterogeneity but it would be difficult to find any as the studies are generally very small.	Thank you for your comment.

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PR	NETSCC, HTA ref 1	6.05	Full	3.1.3	25	The meta analysis search strategy is of high quality.	Thank you for your comment.
PR	NETSCC, HTA ref 1	6.06	Full	general	general	I am not sufficiently qualified to comment on the health economic model.	Thank you for your comment.
PR	NETSCC, HTA ref 1	6.07	Full	6.4.1.1	71	**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** Four studies are mentioned as contributing to the evidence. Five studies are listed in the evidence (Table G.2.2, Appendix G) Only 4 studies are mentioned in the Forest Plots in Figure 8, Appendix I but only 3 of the four are the same as the four studies mentioned in this section. Winnefeld et al., 2000 is mentioned in the report but it is Lucet, 2002 which is in the meta analysis. From the information presented in Table G.2.2, Appendix G it looks as if all 5 studies could be included.	Thank you for your comment. We agree and have amended the text. Five studies were included in the review in section 6.4.1.1. and we have added in the 5th study Larson et al. Only 4 studies appear in the forest plots as one of the studies (Winnefeld et al) only reported one outcome that was presented in the GRADE table, but as it did not report the standard deviation could not be entered into a forest plot.
PR	NETSCC, HTA ref 1	6.08	Full	6.4.1.1	72	Table 12 – has an absolute effect whereas it is an effect size and not in log (CFU) units. The effect size for log10(CFU) comes from the meta analysis on page 338 of the appendix Figure 8 and when you look at that the 2 studies that contribute have such a	Thank you for your comment. We agree and have separated the studies.

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						huge difference in effect. From the Zaragossa study log CFU of 75 is not sensible and when you go back to P248 of the appendix where details of the Zaragossa study are presented you find that it is in fact CFU and not log CFU. This suggests to me that although the description of the statistical methods is valid the high standard has not been carried out in practice in this instance. The quality of the evidence is not very high for this outcome so my quibbles do not have any bearing on the conclusions of the report.	
PR	NETSCC, HTA ref 1	6.09	Full	general	general	I looked at all the meta analyses and the above was the only one that I puzzled over.	Thank you for your comment. We agree and have separated the studies in this instance.
PR	NETSCC, HTA ref 1	6.10	Full	general	general	There were a number (like the above) where the number of studies identified was greater than the ones included in the meta analysis. From looking at details in the Appendix F it is probably the case that the omitted papers did not provide sufficient information to be included but it would have been helpful if the report stated why information from a study was not included.	Thank you for your comment. All papers detailed under study characteristics were considered by the GDG when making recommendations. Some outcomes were reported in GRADE tables that did consist of incomplete data, which could not be put into forest plots and therefore not meta analysed.
PR	NETSCC, HTA ref 1	6.11	Full	12.4	165	An example of what I mean is in Vascular Access Devices where 3	Thank you for your comment. We have looked at this and have found that there are 3 RCTs mentioned and listed in the tables.

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						randomised studies are listed but only 2 used.	All the randomised trials listed were evaluated and presented.
PR	NETSCC, HTA ref 1	6.12	Full	4.2	general	**3.2 Are any important limitations of the evidence clearly described and discussed?** It is clear from reading this report that the quality of evidence from randomized trials is LOW and this is made clear in the tables summarizing the evidence. If one just read the recommendations in section 4.2 you would not be immediately aware that much of the recommendations are based upon low quality information as judged by the review panel.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree. We think that this is adequately covered in the GRADE tables, evidence statements and under the quality of evidence section in the linking evidence to recommendation section. It is the combination of these issues that inform GDG decision making and their discussions are clearly reflected in this section.
PR	NETSCC, HTA ref 1	6.13	Full	general	general	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** I found it easy to see where the recommendations came from and to link this to the evidence. It means switching between 3 places in the documents – main text to two appendices –Once this arrangement has been studied in detail for one of the outcomes it is easy to follow the others.	Thank you for your comment.
PR	NETSCC, HTA ref 1	6.14	Full	general	general	**4.2 Please comment on whether the**	Thank you for your comment.

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						research recommendations, if included, are clear and justified. I think that the research recommendations in each of the sections are clear and address some of the shortcomings in the evidence.	
PR	NETSCC, HTA ref 1	6.15	Full	4.3	general	The key research recommendations in section 4.3 are only a subset of the full list and to my mind it is not clear from 4.3 that there are many more research recommendations.	Thank you for your comment. We agree. We have added an additional sentence to the relevant section of the guideline, stating that these are prioritised recommendations and that further research recommendations are detailed in the chapters.
PR	NETSCC, HTA ref 1	6.16	Full	general	general	**Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.** I found the report easy to read and link from the report to the appendices.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.00	Full	general	general	**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** I see no important ways in which this work deviates from the intentions of the Nice guideline.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.01				**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at**	Thank you for your comment.

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						http://www.nice.org.uk/page.aspx?o=guidelinesmanual). Search strategy used in the review process was carefully constructed and carried out. Research questions were developed by key stakeholders and advisors. Strategies in use rather than hypothetical studies were preferred.	
PR	NETSCC, HTA ref 2	7.02		6.3.2.1	65-78	Although a catholic approach to valid research designs was taken it seems from the reporting of evidence that RCTs would have been preferred.	Thank you for your comment. Our protocols did specify that we were looking for RCTs and systematic reviews, but in the absence of evidence, non-randomised studies were included as appropriate following agreed quality assessment in accordance with the NICE guidelines manual, 2009.
PR	NETSCC, HTA ref 2	7.03		3.3.3.8	29	The limitations of RCTS are set out in table 4. However the difficulties of using RCTs to assess the finely graded alternatives reviewed do not seem to have been fully recognized.	Thank you for your comment. We have stated in our protocol that we have searched for RCTs in the first instance, but have used non randomised studies if no RCTs are found. Non-randomised studies have been quality assessed in accordance with the NICE guidelines manual, 2009.
PR	NETSCC, HTA ref 2	7.04		3.3.3.8	29	The logistical difficulties are great. To locate large enough samples to assess the differences amongst the alternatives in different contexts would be considerable and costly. Biases caused by confounders may occur.	Thank you for your comment. We have listed the main study limitations of RCTs in Table 4 of the full guideline. Non randomised studies have been used where RCT evidence has not been identified, as stated in the review protocols in Appendix E. Non-randomised studies have been quality assessed in accordance with the NICE guidelines manual, 2009.
PR	NETSCC, HTA ref 2	7.05		3.3.3.8	29	Activities are sometimes carried out by a number of people over time. Whilst	Thank you for your comment. We have listed the main study limitations of RCTs in

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						the review of each specific approach or procedure might indicate the dominance of one rather than another the impact on total care may well be affected by earlier or later failures in the delivery of care.	Table 4 of the full guideline. Non randomised studies have been used where RCT evidence has not been identified, as stated in the review protocols in Appendix E. Non-randomised studies have been quality assessed in accordance with the NICE guidelines manual, 2009.
PR	NETSCC, HTA ref 2	7.06		3.3.3.8	29	In some areas of infectious disease management tools have evolved such as 'care bundles' which identify the procedures to be used at the various stages and identifies the person responsible. This ensures best practice approaches are adopted throughout the care package. It appears to improve patient care, allocates responsibility and can be used for surveillance purposes.	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that the guideline should be amended to reflect this issue. Care bundles are discussed in the full guideline under vascular access devices. The Department of Health 'saving lives, care bundle for urinary catheter care and enteral feeding' both reference the 2003 version of this guideline, and therefore we did not want to create circular references.
PR	NETSCC, HTA ref 2	7.07		3.3.3.8	29	Surveillance should be an important feature of control of infectious disease in the community just as it has been in hospitals. Surveillance will be especially useful given the increasing location of many procedures in the community and in checking for emerging infections in these settings.	Thank you for your comment. This area falls outside the scope of the guideline, but we agree that surveillance is important and we will pass these suggestions to the implementation team at NICE who will support best practice in implementing the guideline recommendations. In response, we have also added additional text to the introduction of the guideline: The GDG recognise the important contribution surveillance makes to monitoring infection, but it is not within the scope of this guideline to make specific recommendations.
PR	NETSCC, HTA ref 2	7.08				**2.2 Please comment on the health**	Thank you for your comment.

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						economics and/or statistical issues depending on your area of expertise. Search for articles was comprehensive and they were appropriately reviewed. Criteria were set out for inclusion/exclusion. An assessment was made of each article and each was evaluated.	
PR	NETSCC, HTA ref 2	7.09	Appendices	Appendix H	319	Unfortunately few articles were found that included reliable economic assessments. Good use of economic data was found in chapter 10 on urinary catheters.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.10	Appendices	Appendix J	359-	Cost Utility modeling of intermittent catheterization A very interesting Markov chain model was developed. A static model was chosen because of the uncertainty surrounding resistance. The model was developed using best available data on catheter use and costs of various components of care.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.11	Appendices	Appendix J	359-	It was constructed to be sensitive to contextual matters and patient choice. It provided mean annual costs of a number of different catheters and management costs associate with their use and estimated the cost of treating infections that might arise in their	Thank you for your comment. The models were developed to be sensitive to patient context and did include both the cost of catheters and catheter-associated infections and their associated impact on quality of life. However, we would like to point out that the model did not include 'no catheter' as an

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						absence.	option. Therefore we did not consider the 'cost of infections that might arise in their absence'. The aim of this model was to determine the most cost effective type of intermittent catheter, assuming that intermittent catheterisation is the most appropriate type of catheterisation following assessment.
PR	NETSCC, HTA ref 2	7.12	Appendices	Appendix J	359-	This model is very good and could be useful to managers; it should be highlighted or be made available in some way; at present it is tucked away in Appendix J.	Thank you for your comment. It is standard practice for complete descriptions of our models to be presented in an Appendix. We will consider submitting this model for publication in a peer review journal so that is more widely available to NHS managers, clinicians, and researchers.
PR	NETSCC, HTA ref 2	7.13	Full	3.1.3	30/1	Statistics used explained well.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.14	Appendices	Appendix I	334	Forest plots useful.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.15	Full	5/6	general	**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** The recommendations are justified as far as possible and neither over or understate the case.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.16	Full	5.3	50-59	Recommendations were made that were supported by the literature and expert opinion. For example, use of	Thank you for your comments.

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						education was recommended supported by general thematic convergence from a number of studies and opinions.	
PR	NETSCC, HTA ref 2	7.17	Full	6.2/3	60-9	On hand washing two clinically based trials, two descriptive studies were found that indicated a hand washing programme had reduced infection considerably and these along with expert opinion formed the basis of the hand washing guideline.Hand cleaning techniques were reviewed largely by studies using observational methods. Strong recommendations about hand washing based on the evidence were made. A good example of the use of research was on Long term urinary catheters, in Chapter 10. Research is reviewed and critically assessed as evidence for the guidelines.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.18	Full	general	general	**3.2 Are any important limitations of the evidence clearly described and discussed?** Yes, there is an awareness of the limitations in the evidence and these are taken into account in making recommendations e.g. Table 4	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.19	Full	10	114-152	The review indicates areas which require further research. Expectations were possibly too great	Thank you for your comment.

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						about the practicality and value of doing more studies in some areas. A caution was made about undertaking more studies when dominance of one procedure was clear from a plethora of other work.	
PR	NETSCC, HTA ref 2	7.20	Full	10	114-152	More evidence might be useful on the impact of hand washing in those who experienced some discomfort for it may be that these persons might not comply as well as they might.	Thank you for your comment. The GDG agree that hand decontamination is an important part of catheter management, please see chapter 6 of the full guideline for further details. We have added a sentence to the introduction of the urinary catheter chapter (Section 10.1 of the full guideline) to highlight this.
PR	NETSCC, HTA ref 2	7.21	Full	10	114-152	Future studies should perhaps monitor any changes in funding of infection control in community care practice or procurement as the need for good quality items, gloves for example, have been shown to be important as evidence indicates that deviations might lead to less effective care.	Thank you for your comment. We have stated that the clinical and cost effectiveness are in all the research recommendations made, and as such feel that this is adequately addressed.
PR	NETSCC, HTA ref 2	7.22	Full	7.5	92	The review was comprehensive and thorough; it may not be complete – I recall one study that showed that bedding was infected and handling of it may have implications for washing uniforms or apron use but it seems not to have been included – possibly it did not pass the selection process.	Thank you for your comment. Section 2.5 states that decontamination or cleaning of the healthcare environment and equipment is outside the scope of this partial update.

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PR	NETSCC, HTA ref 2	7.23	Full	7.5.1.4	93	VRE seems to be particularly prone to persist in spite of protective clothing and this should be monitored with the view of introducing additional protection barriers lest VRE should spread in the community.	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree. Although the studies identified are about VRE, advice on the diagnosis, treatment or management and surveillance of specific infections, are outside of the scope of this update.
PR	NETSCC, HTA ref 2	7.24	Full	general	general	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Well presented, accessible and clear. Minor typos and editing issues. Relationship between recommendations and evidence, and its limitations, was clear.	Thank you for your comment. We will address the typo issues through a systematic editorial process before publication.
PR	NETSCC, HTA ref 2	7.25	Full	3.2.3.1 /2	25	Lines 3-10. English language ref repetition	Thank you for your comment. The repetition is intentional, as it is not always possible to restrict searches to English language only, so some non-English papers will be sifted, but still not reviewed.
PR	NETSCC, HTA ref 2	7.26	Full	1.1	14	Lines 1-5. A little ambiguous - would 'non-NHS settings' be better than 'other settings, such as private settings'? Also p17 line 38.	Thank you for your comments. After careful consideration we came to the conclusion that we do not agree. The GDG consider that this wording is appropriate because is clearly states which healthcare settings are covered by this guideline, as stated in the scope of the guideline.
PR	NETSCC, HTA ref 2	7.27	Full	1.1	13	Check references 178 appears to be ref to HAI study but ref is to UTI	Thank you for your comment. Reference 178 is the correct source for this data (National Audit Office. Reducing healthcare

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							associated infections in hospitals in England. 2009).
PR	NETSCC, HTA ref 2	7.28	Full	1.1	14	Lines 19-15 'must' in spite of this proviso there seems to be inconsistencies of usage in text	Thank you for your comments. After careful consideration we came to the conclusion that we do not agree The text in the introduction states that recommendations with 'must' either have a footnote detailing the applicable legislation or if not footnote is present, the GDG deemed to be related to patient safety and if not implemented have a high risk of adverse events to patients.
PR	NETSCC, HTA ref 2	7.29	Full	general	general	**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** These are clearly summarized. The guidelines make an important contribution to improving infectious disease control.	Thank you for your comment.
PR	NETSCC, HTA ref 2	7.30	Full	general	general	To contribute to long term improvement some surveillance should be introduced.	Thank you for your comment. This area falls outside the scope of the guideline, but we agree that surveillance is important will pass these suggestions to the implementation team at NICE. Additional text has also been added to the introduction of the guideline: 'The GDG recognise the important contribution surveillance makes to monitoring infection, but it is not within the scope of this guideline to make specific recommendations.'
PR	NETSCC, HTA ref 2	7.31	Full	1.1	13	**Please make any additional comments you want the NICE**	Thank you for your comment. This area falls outside the scope of the guideline, but we

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						Guideline Development Group to see, feel free to use as much or as little space as you wish. Increased work is undertaken in community – is some surveillance needed to monitor the impact of this and any new infections originating in the community? I think it is.	agree that surveillance is important will pass these suggestions to the implementation team at NICE. Additional text has also been added to the introduction of the guideline: 'The GDG recognise the important contribution surveillance makes to monitoring infection, but it is not within the scope of this guideline to make specific recommendations.'
SH	Department of Health	8.00	Appendix A	A4.3.2(d)	5	We are concerned at the decision to leave out of scope "decontamination or cleaning of the healthcare environment and equipment, other than the clinical devices listed in 4.3.1" CQC registration against requirements relating to cleanliness and infection control was extended to adult social care providers of regulated activities in October 2010 and to providers of primary dental care in April 2011. Final arrangements to extend CQC registration to providers of primary medical care have yet to be agreed. **Recommend**: that cleaning and the management of the physical environment is included in scope, for the following reasons: 1. to be consistent with the previous NICE consultation on Infection Control for Secondary Care (i.e. Quality Statement 10 'Trust estate management' and QS 11'Cleanliness') on the basis that these issues are of equal importance in primary and community care settings,	Thank you for your comment. We agree that decontamination or cleaning of the healthcare environment and equipment is an interesting clinical area but it is outside of the scope of this update. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update. Where appropriate the full guideline details the links between the guidance recommendations and the NHS constitution and the Health and Social Care Act 2008 Code of Practice on the prevention and control of infection and related guidance.

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						2. to be in accordance with the NHS Constitution pledge: "to ensure that services are provided in clean and safe environment that is fit for purpose, based on national best practice" (see below) 3. In line with Secretary of State's duties in Health and Social Care Bill (subject to parliamentary improvement) for "improvement of quality of services and continuous improvement in (a) the prevention, diagnosis or treatment of illness, or (b) the protection or improvement in public health (Part 1, clause 2, 1A (1) and (2)) 4. to be in accordance with the Health and Social Care Act 2008: *Code of Practice on the prevention and control of infection and related guidance*, criterion 2 (see below)	
SH	Department of Health	8.01	Full	1.1	13	The NHS Constitution is referenced as important yet the full meaning and requirements are not carried through into the standards. For example, "Quality of Care and the Environment" is a NHS Constitution right "You have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality." (Section 2a of the NHS Constitution) The NHS Constitution also pledges "*to*	Thank you for your comment. We agree that decontamination or cleaning of the healthcare environment and equipment is an interesting clinical area but it is outside of the scope of this update. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update. Where appropriate the full guideline details the links between the guidance recommendations and the NHS constitution

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						ensure that services are provided in a clean and safe environment that is fit for purpose, based on national best practice (pledge) ➢ This is a holistic concept across the physical environments for care and not limited to certain facets such as PPE, 'safe use and disposal of sharps', or 'Waste disposal' **Recommend**: that the GDG further develop the clinical guidelines to include the physical environment aspects of patient experience and how it enables the NHS Constitution pledge, as described above, to be delivered and hence prevent and control healthcare associated infections in primary and community care settings.	and the Health and Social Care Act 2008 Code of Practice on the prevention and control of infection and related guidance.
SH	Department of Health	8.02	Full	Footnotes to 4.1.1 4.2.1.1. 4.2.1.3 5.3.1.1 (2) 7.2.1.1 7.3.2.1 7.4.1.4 7.6.1.1	37 39 41 53 84 85 88 95	Whilst there are many footnote references to the Health and Social Care Act 2008: *Code of Practice on the prevention and control of infection and related guidance*, it is limited to the context of equipment and supplies. The Health and Social Care Act 2008: *Code of Practice on the prevention and control of infection and related guidance*, sets out ten criteria against which a registered provider will be judged on how it complies with the registration requirement for cleanliness and infection control. Number 2 in the list of criterion is: "*Provide and maintain a clean and appropriate environment in managed*	Thank you for your comment. We agree that decontamination or cleaning of the healthcare environment and equipment is an interesting clinical area but it is outside of the scope of this update. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update. Where appropriate the full guideline details the links between the guidance recommendations and the Health and Social Care Act 2008 Code of Practice on the prevention and control of infection and related guidance and appendix B for

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						premises that facilities the prevention and control of infections." Guidance within the Code for compliance with criterion 2 states (para 2.1): "*all parts of the premises from which it provides care are suitable for the purpose, kept clean and maintained in good physical repair and condition.*" Health and Social Care Act: Code of Practice, Appendix A puts the criterion in context of scale of the care environment, for example, a small care unit would not be expected to adopt the same rigour as an acute hospital. Health and Social Care Act: Code of Practice, Appendix B for Primary Dental Care is explicit and puts it into clinical patient health context by referencing DH guidance that there "*should be a policy for preventing contamination of dental unit water lines*…" And risk assessment for *legionella*. **Recommend**: that GDG further develop the guidelines to include the physical environment aspects of managing the prevention and control of infections in line with the Health and Social Care Act 2008 Code of Practice criterion, and also 'Policies on the environment' (para 2.3), and 'Decontamination' (para 2.5); Appendices A & B.	Primary Dental Care.
SH	Department of Health	8.03	Full	Recom	86	"Gloves that have been used for direct	Thank you for your comment. We agree and

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				mendation 14		patient care or exposed to body fluids must be disposed of as clinical waste in accordance with current national legislation or local policies. (see chapter 9) [new 2012] Gloves are not automatically clinical waste because they have been exposed to body fluids. They could be classed as Offensive waste. The classification of waste is subject to risk assessment. There is a legal definition of clinical waste. **Recommend:** that use wording consistent with Recommendation 18 (page 94) i.e. "ensure they are disposed of correctly"	have amended the recommendation.
SH	Department of Health	8.04	Full	9.1.1.3 Recommendation 27	111	To clarify the colour-coding system is not mandatory and is not specified in regulations. However, each container must be labelled in accordance with the details of the legal requirements for transport and packaging. The colour coding facilitates segregation of the waste categories set out as a minimum requirement arising from the legal prohibition of mixing. **Recommend:** that wording be refined as follows: *"Healthcare waste must be segregated immediately by the person generating the waste into appropriate compliant colour-coded storage/waste disposal bags or containers, as defined by current national legislation and local policies"* [new 2012]	Thank you for your comment. We agree that this recommendation needs clarification and have amended it to state: 'Healthcare waste must be segregated immediately by the person generating the waste into appropriate colour-coded storage or waste disposal bags or containers defined as compliant with current national legislation and local policies [new 2012].'
SH	Department of Health	8.05	Full	Term	203	Note: Definition for clinical waste is still	Thank you for your comment. We are

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				Clinical Waste		extant. However, Defra are reviewing the Controlled Waste Regulations 1992 from which this definition arose and the revised 'Controlled Waste Regulations 2011 are likely to be laid before parliament before the end of the year in which case the definition of clinical waste will change.	unable to amend the definitions contained within the guideline until they are confirmed by parliament.
SH	Department of Health	8.06	NICE	General		The Department welcomes this revised guidance and thinks this revised guidance reads well.	Thank you for your comment.
SH	Department of Health	8.07	NICE	1.1.2.2	13	Please amend the term 'alcohol resistance' – this is a term which could be confused with antimicrobial resistance. Suggest amending the text to say that 'alcohol hand rub should not be used when caring for patients with diarrhoeal illness as it is ineffective. Hands should be cleaned with liquid soap and water'.	Thank you for your comment. After careful consideration the GDG decided that this should not be changed, but have amended the examples in brackets for clarity.
SH	Department of Health	8.08	NICE	1.1.2.3	13	The guidance uses the phrase 'bare below the elbow'. This phrase was not used in, but has become the unofficial title of, DH's 2007 guidance on uniforms and workwear. If the phrase is to be used in the guideline, it is recommended that it be highlighted in some way (perhaps in italics or in quotes) so that the link to the definition provided is more obviously apparent	Thank you for your comment. After careful consideration, we came to the conclusion that we do not feel that this should be amended. It was felt that the definition of bare below the elbow given in the related footnote was adequate and indicated the GDG position rather than provide an explicit link to a Department of Health document.
SH	Department of Health	8.09	NICE	1.1.4.2 second bullet	16	We think the bullet would be better if it was stated 'appropriate safety devices should be used if they will provide a safer system of working'.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate

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						The word appropriate is not descriptive enough	because this is part of a risk assessment.
SH	Department of Health	8.10	NICE	1.2.3.4	20	Please provide the rationale for this statement.	Thank you for your comment. The full rationale for this recommendation is found in the full version of the guideline in section 10.5.2.5 and Appendix J.
SH	Department of Health	8.11	NICE	1.4.2.2	25	Please remove the reference to 'Aseptic Non Touch Technique (ANTT) ' this term has been trademarked by an individual.	Thank you for your comment. The term 'ANTT' has been used as an example of one available aseptic technique. The linking evidence to recommendations in section 12.3.1.3 states that: 'ANTT™ (www.antt.org.uk) was also added to this recommendation as a possible aseptic technique for VAD maintenance. It was the opinion of the GDG that standardisation of aseptic techniques would reduce confusion among healthcare workers and lead to better training about the principles of asepsis. The GDG considered that ANTT™ is widely used in acute and community settings and represents a possible framework for establishing aseptic guidance.' We have added the trademark logo to the term ANTT™.
SH	Department of Health	8.12	NICE	1.4.3.1	25	We note from the full guidance that the GDG had extensive comments on the evidence concerning the strength of chlorhexidine to be used for skin disinfection. Whilst the evidence is limited, the GDG group did comment that 'there is a statistically and clinically important reduction in catheter tip reduction among patients	Thank you for your comments. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that

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						receiving 2% CHG in 70% IPA compared to 70% IPA'. Could the GDG consider giving a concentration of chlorhexidine to be used?	there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is true that there is was statistically significant and potentially clinically important difference in the number of catheter tip colonisation between patients who had 2% chlorhexidine gluconate in 70% IPA compared to those who had only 70% IPA. However, the GDG had considered catheter tip colonisation as a surrogate marker of infections. The study did not show there was a difference in infection related mortality, bacteraemia and VAD related local infection. Moreover, the evidence is of low quality for the purpose of the guideline because of the limitations of the study, and the participants were patients undergoing elective cardiac surgery. More importantly, this study still did not help to answer the question about which chlorhexidine concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to

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							insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A high priority research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. While considering this recommendation, the GDG did take into account the current practice and recommendations from other key guidelines. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf).
NICE	Editor	9.00	NICE	Title	1		We are unable to respond.
			NICE	Introduction	4–5	At the editorial meeting to discuss the UNG and pathway, the GDG members felt that residential care (e.g. care homes) should be specifically mentioned in the UNG as an example of community care. Would it be helpful to also mention residential care specifically in the introduction to the NICE guideline?	Thank you for your comment. We agree. We have amended the text accordingly: Healthcare settings covered by this guideline are: 'Community care settings, such as residential/nursing homes, the patient's own home, schools and prisons, where NHS healthcare is provided or commissioned.'
NICE	Editor	9.01	NICE	1.1.1		I suggest changing the subheading from 'General recommendations' to 'General advice' – this would work better in the	Thank you for your comment. We agree. We have amended the subheading accordingly.

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						pathway.	
NICE	Editor	9.02	NICE	1.1.3.6		At the editorial meeting it was noted that an alternative to latex gloves should be available if family members of a patient have latex sensitivity, even if that family member isn't closely involved in the patient's care. That isn't clear from the recommendation wording at present.	Thank you for your comment. The GDG considered that the wording of the recommendation is appropriate, but that the following additional text should be added to the linking evidence to recommendation section: 'The GDG thought that the latex sensitivity of anyone living with the person should be taken into consideration when deciding which glove type to use.'
NICE	Editor	9.03	NICE	1.2.3.3		I suggest moving this recommendation (about type of indwelling catheter)) to after the recs about intermittent catheters (1.2.3.4 and 1.2.3.5). Rec 1.2.3.2 states that an intermittent catheter should be used preferentially, so it makes sense for the details about intermittent catheters to follow on directly from that rec.	Thank you for your comment. We agree and have moved this recommendation down.
NICE	Editor	9.04	NICE	1.2.3.5		Is '16 years or under' correct, or should it be 'under 16 years'?	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for

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							intermittent self catheterisation.
NICE	Editor	9.05	NICE	1.3.2.7		At the editorial meeting, it was queried whether this recommendation is consistent with current manufacturers' instructions.	Thank you for your comment. No evidence could be identified regarding storing feeds for 24 hours and no manufacturer's instructions were identified that contradicted this. The GDG therefore felt that this recommendation remained valid.
NICE	Editor	9.06	NICE	1.3.4.2		First bullet: suggest changing to 'freshly drawn tap water…'	Thank you for your comment. We agree. We have amended the wording accordingly.
NICE	Editor	9.07	NICE	1.4.1		At the editorial meeting, it was questioned whether a recommendation should be added about teaching patients and carers about how to spot infections.	Thank you for your comment. The GDG considered that this is covered by recommendation 1.4.1.1. The GDG thought that this should be tailored to the patient rather than developing a prescriptive list. This will vary by patient need.
NICE	Editor	9.08	NICE	1.4.4		This subsection is about VADs, not just catheters. I suggest changing the subheading to 'General principles for management of vascular access devices'.	Thank you for your comment. We agree and have amended the subheading accordingly.
SH	Dyson Ltd	10.00	NICE	1.1.1.2	8	When considering the availability of appropriate hand decontamination materials, Dyson suggests that high speed hand dryers that meet the necessary hygiene requirements should be included in the list of appropriate devices. Historically the accepted hygienic method of hand drying has been paper towels. Innovative technology has now improved the capability of hand dryers to stop the spread of infection significantly – now equalling the hygiene credentials of paper towels.	Thank you for your comment. No RCT evidence was identified for Dyson hand dryers for our hand hygiene clinical questions and as such the GDG are unable to make a specific recommendation regarding the use of such equipment.

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						The Airblade is fitted with a HEPA filter that treats contaminated hospital air before use, removing 99 per cent of bacteria and helping to prevent the spread of infection. It also uses anti-microbial coating kills a broad spectrum of bacteria, including MRSA, MSSA and E.coli. It is touch-free and uses cold air, again reducing the spread of infection. And above all, it works; hands are dried in ten seconds, limiting the transferral of bacteria through damp hands. The Airblade has been certified by the NSF protocol P335 and endorsed by the Royal Society of Public Health. It has also been piloted by NHS Supply Chain, having passed the research and evaluation stages. Further research undertaken by the Bradford Infection Group at the University of Bradford has also endorsed the Airblade as a hygienic hand drying option (full report available on request). Dyson suggests that guidelines endorsing only the use of paper towels as a hygienic hand drying option should be reconsidered in light of the technological advances in the sector and potential cost savings to the NHS.	
SH	Dyson Ltd	10.01	NICE	1.1.1.1	8	Dyson suggests that use of high speed hand dryers be included in hand decontamination education and training.	Thank you for your comment. No RCT evidence was identified for Dyson hand dryers for our hand hygiene clinical

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						Historically the vast majority of staff have used paper towels to clean their hands. There is less familiarity with high speed hand dryers. Hand decontamination training should emphasise that the Dyson Airblade HEPA filter removes 99 per cent of bacteria, which helps prevent the spread of disease. It should also outline note that anti-microbial coatings such as those on the Airblade kill a broad spectrum of bacteria, including MRSA, MSSA and E. Coli. Staff should be trained more broadly about technological advances in hand decontamination technology.	questions and as such the GDG are unable to make a specific recommendation regarding the use of such equipment.
SH	Dyson Ltd	10.02	NICE	1.1.1.3	8	As per the above point, Dyson suggests that the use of high speed hand dryers be included in hand hygiene education for patients and carers. When educating patients and carers about the correct techniques for hand decontamination, hygienic high speed hand dryers should be included as an appropriate technique.	Thank you for your comment. No RCT evidence was identified for Dyson hand dryers for our hand hygiene clinical questions and as such the GDG are unable to make a specific recommendation regarding the use of such equipment.
SH	Tameside Acute NHS Trust	11.00	full	4.1.3	38	There is not enough evidence provided to support this recommendation. The only long term study referenced which actually re-used non-coated catheters concluded that hydrophilic coated catheters were more beneficial (262). There are no examples of	Thank you for your comment. The study by Vapnek 2003 compared hydrophilic intermittent catheters to reused non coated catheters over one year. The only relevant outcome measured by this

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						comparative studies looking at prevelance of urethral strictures which can be a long term complication of intermittent catheterisation.	study was mean monthly urinary tract infections. This study found that there was no difference in infections between the two types of catheters (mean difference = -0.01; 95% CI, -0.11 – 0.09). In total, the systematic literature review identified six randomised controlled trials with outcomes relevant to our clinical review. This was one of the areas with the greatest number of studies identified for any question included in the update of this guideline. However, the GDG acknowledge that the overall evidence base is low quality and have amended the stem of the recommendation from 'offer' to 'consider'. The limitations of RCTs have been discussed in the methodology section, 3.1.3.8. and the papers were quality assessed in accordance with the NICE guidelines manual, 2009. We agree that there are no comparative clinical studies of urethral strictures resulting from ISC. Therefore, in the base case of the economic model we assumed that there was no difference (RR =1) and in the sensitivity analysis we explored the extremes of this assumption by assuming that hydrophilic and gel reservoir catheters are 100% effective (RR = 0) at preventing urethral strictures compared to noncoated catheters. The conclusions of the model

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							were unchanged by this sensitivity analysis. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the

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							amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Tameside Acute NHS Trust	11.01	Full	4.1.3 line 26	38	Patients who need to self catheterise more than once a day would have extreme difficulty washing and drying catheters in public lavatories either at work or on social outings. Therefore hydrophilic coated catheters are easier to use, less messy than gel coated or non coated catheters and contribute greatly to an improved quality of life. Also, most patients are taught self catherisation in a hospital or clinic setting. It is impossible to assess the patients hygiene standards without a home visit. All people have different ideas about what is 'clean'	Thank you for your comment. We agree. The linking evidence section states that: *The GDG considered that there may be situations in which it is difficult for patients to wash, dry and store multiple-use non-coated catheters, for example patients with communal washing facilities. On this basis, the GDG agreed that there are situations in which it is not appropriate for patients to use multiple-use non-coated catheters.* We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed

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							their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	B Braun Medical Ltd	12.00	Full	general general 10.9.1.4 10.5.2.5	general general 145 130	B Braun would like to request an extension to the deadline of 7th September for the following reasons: - consultation being during the holiday period therefore many people being absent from work - to put into place a model to demonstrate the extra costs to patient quality of life and to the NHS of the guidance - to carry out detailed cost analysis and show that under health economics grounds this proposal is not justified or needed and acts against QIPP.	Thank you for your comment. NICE set the stakeholder consultation for this update as from the 13/07/11 to the 07/09/11 and unfortunately this cannot be extended.
SH	B Braun Medical Ltd	12.01	Full	10	137-145	To minimize the risk of blockages, encrustations and catheter-associated	Thank you for your comment. We conducted a systematic review of the literature as

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						infections for patients with a long-term indwelling urinary catheter": – do not use bladder instillations or washouts" The draft document reflects on the poor quality of the evidence referred to within the document. (page 145 – 10.8.1.4), This recommendation was therefore based on GDG consensus rather than evidence. Our view is the literature review could have been more robust as there is considerably more evidence available. The remit of this consultation is primarily concerned with Infection prevention and control and the GDG group proposing this recommendation are made up of mainly infection control specialists. For an informed consensus decision to be reached there should be a greater proportion of continence specialist nurse practitioners as part of the GDG making decisions that will ultimately affect their own catheter care practice Our findings also demonstrate that many members of stakeholder groups, notably continence and Urology nurse specialists, are still not aware of the consultation or implications for their patients.	described in Appendix F, which was based on the review protocol in Appendix E. We acknowledge that the evidence base is limited, which is why we explain in section 10.9.1.4. that this recommendation is based on GDG consensus. The GDG consisted of four community nurses, two general practitioners, two patient representatives, a paediatrician, a paramedic, and a microbiologist. All GDG members were selected for their experience administering care in community settings and their interest in infection prevention and control. A continence nurse specialist (Daphne Colpman) was co-opted to join the GDG and contributed to the interpretation of evidence and drafting of all recommendations related to long term urinary catheters. Stakeholder consultation is coordinated by NICE. All registered stakeholders were contacted during the consultation. A list of registered stakeholders can be found at: http://guidance.nice.org.uk/CG/WaveR/85/SHRegistration. Following the stakeholder consultation, the GDG have decided to revert to the original 2003 recommendation: Bladder instillations or washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: 'The GDG considered that the use of

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							bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.'
SH	B Braun Medical Ltd	12.02	Full	10.9.1.4	145-146	Planned catheter change is good practice and we fully support this with many patients changing every 6-8 weeks. However 50% or so of patients are "blockers" **and this is not an UTI**. They usually manage their catheter maintenance by themselves or a carer at home. A persistent blocker may block every few days without bladder washouts (catheter maintenance) use, causing increased nursing resource use, costs and considerable distress to the patient. Any guidance/policy that excludes the use of these products will have significant implications for patients and nurses including financial and socio economics. - Increased admissions to A&E because of blocked catheters - Increased indwelling catheter costs/ lubricant gel costs as number of changes increase - Increased District Nursing time for	Thank you for your comment. Following the stakeholder consultation, the GDG have decided to revert to the original 2003 recommendation due to the poor quality and quantity of evidence: Bladder instillations or washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: 'The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.'

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						planned catheter/unplanned catheter changes because of blocked catheters We estimate this additional cost **per patient** to be around between £1300pa if patients block every 2 weeks up to £7,100pa if patients block every 2/3 days. This is mainly in extra nursing cost and excludes possible increase in hospital admissions due to blocked catheter when nurses are not available.	
SH	B Braun Medical Ltd	12.03	Full	10.9.1.4	145-146	A policy not to use these products will have a negative impact on patients' quality of life: - To prolong the life of their catheter many patients have been taught to administer their own instillations or have a carer who administers it for them, and this allows them to be more self caring. To have this product option removed will disempower the patient from their own care. - Patient's increased worry about unpredictable catheter blockage may lead to impact on their activities. e.g reluctance to go out of the home for fear of blockage or embarrassing leakage in public. A persistent blocker	Thank you for your comment. The clinical review revealed there to be an absence of evidence regarding the efficacy of instillations and washouts for preventing encrustations and blockages. It is uncertain whether there is any difference in the number of catheter replacements, mean time to first catheter change or number of catheter replacements per 100 days of catheterisation. There is also an absence of evidence with respect to the incidence of symptomatic UTI and the use of instillations/washouts compared to no instillation/washouts. The GDG came to a consensus decision that there is a known risk of infection associated with breaking a closed system. The GDG considered the use of bladder

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						will never be able to go on holiday for more than 2/3 days. - Vulnerable patient groups are more prone to blockage e.g MS sufferers, other neurological patients, immobile patients. Frequent re-catheterisation can be a traumatic, invasive, and a very personal procedure. - There is no evidence that links use of Catheter maintenance solutions to an increased risk of UTI - In summary we conclude that the proposed change to the guidelines is in direct contrast to QIPP principles. We believe there is a reduced quality in patient outcomes, quality of life, there is reduced choice, there is less productivity for nurses, A & E referrals are likely to rise dramatically and there is no evidence of prevention/reduction of UTI's.	instillations and washouts to be inferior to the other catheter management strategies mentioned in the recommendation. However, following the stakeholder consultation, the GDG have decided to revert to the original 2003 recommendation due to the poor quality and quantity of evidence: Bladder instillations or washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: 'The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.'
SH	B Braun Medical Ltd	12.04	Full	10.5.2.5	130	Offer non-coated intermittent catheters for multiple use to patients	Thank you for your comment. We acknowledge your concerns regarding

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						B Braun would like to request further clarification to the above statement - how do you clean a catheter? - what type of gel is recommended – single use or otherwise? - what is the procedure for gelling the catheter – gloves etc? - is there an infection risk if the gel dispenser comes into contact with the catheter? - how often do you recommend that patients change their multi-use catheter or how many times should it be used before discarding? - how do you clean and use a catheter at work or in a public convenience?	this recommendation. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders.

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							Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The cleaning of intermittent catheters was outside the scope of this update. Recommendation 59 from the 2003 guideline states: Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. However, following the updated catheter recommendation detailed above the recommendation regarding cleaning reusable catheters has been removed to avoid confusion. The optimal type of lubricant for use with noncoated catheters was outside the scope of this guideline. The economic model used to inform this recommendation assumed that patients would use single use sachets (and that 5% of patients would use lidocaine lubricant as opposed to water-based). The procedure for lubricating a catheter was

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							outside the scope of this guideline update. For the purposes of the economic model it was assumed to be a clean technique (without gloves), as the GDG agreed that intermittent self catheterisation is not an aseptic procedure. The RCTs included in the clinical review did not provide details as to the method of application and as such the GDG have not specified the technique of application in their recommendations. The optimal number of uses for a noncoated catheter was also outside the scope of this update. In the economic model, the number of noncoated catheters used per patient was varied in the sensitivity analysis. Noncoated catheters were found to be the most cost effective option when patients use between one per month and four per week. If patients use more than an average of four noncoated cathters per week, single use coated catheters are the most cost effective option. The GDG considered including this in the linking evidence section but thought this was an issue better left to the patient and clinician to decide. The following text was added to the linking evidence section: *No evidence was reviewed regarding the frequency of change for non-coated catheters. GDG did not feel it was appropriate to make a recommendation*

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							regarding the frequency of change of multiple use catheters as this was likely to be influenced by other factors such as comfort or efficacy which would be routinely discussed as part of the normal patient-clinician interaction. As per the recommendation in question, if facilities for washing and reusing a non coated catheter are not available, single use catheters would be prescribed.
SH	MRSA Action UK	13.00	Full & NICE	General		MRSA Action UK welcomes an update to the guidance particularly in relation to educating patients and carers on the benefits of hand hygiene and its importance in breaking the chain of infection. We are concerned however that the draft revision does not fully represent outcomes that are important to patients and service users, particularly those of us who have been affected through contracting avoidable infections, we believe there are a range of measures that could be included in this guidance that have been omitted. **Higher proportions of MRSA and C.diff in Primary Care** Primary care, care in the home, by healthcare professionals, informal carers, patients and service users is an opportunity to provide the cornerstone to keeping infection risk at bay. MRSA and Clostridium	Thank you for your comment. Advice on the diagnosis, treatment or management of specific infections is not included in the scope of this guideline (see appendix A). Decontamination or cleaning of the healthcare environment (including laundry) is also not covered in the scope of this partial update within. Thank you for your comment on communication. We agree that these suggestions are a good idea and will pass these suggestions to the implementation team at NICE who will support best practice in implementing the guideline recommendations. We are unable to make any recommendations regarding MRSA screening as it is outside of the scope of this partial update.

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						difficile figures reported by the Health Protection Agency show there are more cases reported in the Primary Care setting than in hospital. There needs to be more education for people involved in giving and receiving care in the community setting and at home, it doesn't stop at hand hygiene, and we feel the guidance should also incorporate more about hygiene in the home. There is no guidance given for the treatment of patients screened positive for MRSA and how to cope with pathogens such as Clostridium difficile in the home environment. **Inter-healthcare communication** Sharing information between the Acute and Primary Care providers is essential for the effective treatment of infections. The DoH Clean Safe Care website has examples of transfer forms and guidance which we believe should be incorporated into the NICE guidance http://hcai.dh.gov.uk/files/2011/03/Document_Patient_Transfer_form_FINAL_100825.pdf http://hcai.dh.gov.uk/files/2011/03/Document_Patient_Transfer_form_advice_sheet_FINAL_100831.pdf **Improving communication between patient and healthcare worker**	

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						For patients use of pictorial pathways for communication in terms of what is needed for the safe treatment or suppression of MRSA can help ease anxiety, we recommended the Lincolnshire pictorial guide for the treatment of MRSA http://mrsaactionuk.net/pdfs/MRSA_pictorial_pathway.pdf **Laundry** Domiciliary care may involve assistance with laundry, whether carried out by the patient, informal carer or domiciliary carer, guidance should, in our opinion be included. We receive contact from organisations and staff who help with personal care in clients homes and frequently are ask for guidance on laundry where clients have an infection. MRSA and C.diff spores and soiling can spread from dirty clothes and bedding. When doing laundry, some simple precautions can lessen the risk of contaminating the environment and spreading infection, if preparing for surgery or if the patient has been discharged with MRSA colonisation, or if they have C.diff, then we advise: • Changing towels and bedding and clothing daily. • Have a separate, solid plastic container for the patients' washing, NOT one with ventilation holes or made of canvas or	

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						wicker • Handle laundry that comes in contact with the infection separately from other household laundry • When collecting dirty laundry, hold it away from your body to prevent getting bacteria on your clothes, preferably in a plastic bag or container, the use of disposable plastic aprons is strongly recommended • Wear disposable gloves to handle laundry that is soiled with body fluids, like drainage from a sore, urine, or faeces • Put the laundry in the washer immediately, or store it in a plastic bag until it can be washed • Wash with hot water and detergent and use disinfectant when possible • Dry on the hot setting, and make sure clothes are completely dry • Wash hands after handling dirty laundry and before handling clean laundry, even if you have been wearing gloves • Throw gloves away after taking them off, and do not reuse them Telford and Wrekin NHS Trust has some excellent policies for dealing with laundry and infection control in the community http://www.telford.nhs.uk/Documents/docs_common/Publications%20and%20Policies/Policies%20and%20Procedures/Clinical/Infection%20Control/IPC%2018%20Linen%20Handling%20and%20Laundry%20Policy.pd	

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						f **OPAT** We receive enquiries from organisations, such as sheltered housing providers, care homes and staff who provide personal and domiciliary care regarding patients receiving ongoing care and treatment for infections through OPAT programmes outside of the hospital setting. We believe NICE would benefit from close liaison with the British Society for Antimicrobial Chemotherapy (BSAC) on guidelines for OPAT programmes, and these guidelines should be incorporated into the NICE guidance.	
SH	MRSA Action UK	13.01	Full	5.3.2.4	59	As previously stated we welcome the education of patients and carers on the benefits of hand hygiene. Since the guidance is for use by informal carers and patients we would like to see supplementary information in formats that are clear for all. It is well documented that alcohol hand rub is ineffective on C.diff spores and bacteria that cause other gastrointestinal illness. The NHS East Midlands 'Right time Right Place' initiative gives a good pictorial guide for the appropriate use of alcohol hand rubs and soaps. It is important that the public and patients understand the distinction between the multimodal models of hand hygiene and this poster campaign is easy to understand	Thank you for your comment. We agree that patient guidance is important and NICE are developing a patient version of this guideline (Understanding NICE guidance). We agree that poster campaigns are a good idea and will pass these suggestions to the implementation team at NICE who will support best practice in implementing the guideline recommendations. We are unable to make any recommendations regarding MRSA screening as it is outside of the scope of this partial update. The GDG considered making a separate recommendation for wheel chair users

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						and one that we have adopted as a patient group. This simple pictorial approach gives a clear message that all can understand regardless of literacy or language barriers. Not sharing personal items such as wash cloths, towels, combs, razors and soaps is an important consideration in the home setting for infection prevention and control. If a member of the household has an infection, is colonised or has continuing care of lines, catheters then we believe this advice is very important. We believe liquid soap is a better option than bar soap, as shared bar soaps may harbour bacteria and cause cross infection where patients are immune compromised. This applies to hand hygiene and full body washing. If a person has been screened positive for MRSA we would expect that they would follow appropriate guidance and wash with antibacterial/chlorhexidine soap. NICE guidance should incorporate advice on screening and suppression. **Manual Wheelchair Users** We note no guidance is given for manual wheelchair users on hand hygiene and we would hope to see the consultation take account of service users views on this important aspect of infection control, particularly as there is evidence to show that wheelchairs have been shown to be	regarding hand hygiene, but did not feel it was necessary. They considered that the recommendations already apply to wheelchair users and that no further specific detail was required.

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						vectors for infection in the hospital environment, and patients who are self-caring will need to manipulate their wheelchair whilst carrying out clinical procedures such as catheterisation.	
SH	MRSA Action UK	13.02	NICE		7	Written information is not accessible to all. Replace wording with "Information is in a suitable format and accessible to all".	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate because it states that: 'Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.'
SH	MRSA Action UK	13.03	NICE Full	4.1 4.2.2. 10.4.1	9 37 43 116	**Long term urinary catheters-general** MRSA Action UK supports the views of the Urology User Groups Coalition and note that you make no distinction between indwelling urethral catheters and supra pubic catheterisation (SPC). It is generally thought that SPC is better long term in reducing incidence of UTI. Many patients have combined bladder and bowel dysfunction and there is reduced likelihood of faecal contamination with SPC We also see in the full version evidence to support the use of suprapubic catheters over indwelling urethral ones. Many people find suprapubic catheters easier to manage and	Thank you for your comment. This guideline does include suprapubic catheterisation, which is detailed in section 10.4.1 of the full guideline (how to select the right system) and that indwelling catheters include both urethral and suprapubic catheters. However, in the review looking at types of indwelling catheters only evidence regarding urethral catheters was identified. A research question has been made in this area and additional text has been added to be more explicit that indwelling includes both urethral and suprapubic catheters.

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						have a more spontaneous sex live. This is an equality issue, helping a disabled person participate more easily in society by promoting innovative devices that are designed for the user, and tailoring services to take their needs into consideration. Indwelling urethral catheters tend to inhibit and lead to the likelihood of increased infections if tried as many will remove them and reinsert in less than ideal conditions.	
SH	MRSA Action UK	13.04	NICE Full	4..1.3 4.2.2.3 10.5.1.4	9 38 43 119-	MRSA Action UK supports the views of the Urology User Groups Coalition and whilst we agree that patient preference and choice is needed for indwelling urinary catheters we believe it is vital that all these criteria listed for catheter selection are also applied to intermittent catheters, including type, gauge and length, intermittent self catheterisation users normally frequently need to carry out catheterisation in life style settings which are very different to a clinical or teaching situation or even home. The same initial factors to indwelling catheters influence selection including allergy, size, length, patient preference and choice, and factors needed to overcome an impairment, such as dexterity. We believe failure to recognise these factors for intermittent catheter users is against your key priorities for implementation, including patient choice and equality.	Thank you for your comment. Due to an absence of evidence, the recommendation for the type of indwelling catheter was based on GDG consensus. For a detailed explanation of the evidence and reasoning underpinning the recommendation related to ISC, please refer to section 10.5.2 and Appendix J of the full guideline. Additional text has also been added to the linking evidence section addressing patient preference: We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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							that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The amended linking evidence section of the full version states that: In drafting the revised recommendation, the GDG noted the following issues of importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment,

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							the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]).The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review and that recommendation 36 is worded the to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when selecting an intermittent catheter.
SH	MRSA Action UK	13.05	NICE Full	 4.1 10.5,2 10.5.2.5	9 37 120	We believe offering "non-coated intermittent catheters for multiple use" has the potential for a huge negative impact on outcomes that are important to patients including "nothing about me without me". It does not recognise individual patient clinical and lifestyle need, care having least impact on reducing quality of life, ability not to spend 24/7 focusing on bladder function by having to wash catheters, worry over long term urethral trauma and UTIs which will affect their ability to self manage all their long term condition(s) ability to live with dignity without constant fear of embarrassment, ability to partake in family and public life, ability to be in employment and have a social life etc This recommendation fails to	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for

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						promote patient choice, equality, and may hinder patients ability to reach critical points in the care pathway quickly, as many will fail to cope with Intermittent self catheterisation(ISC) and need long term indwelling catheters, much more expensive in terms of NHS staff resources and likelihood of infections including cost in hospital admissions for the latter. It has also failed totally to look on service delivery. Who is to teach patients in the use of different catheters and reuse? Whilst we recognise reuse of some catheters is an option for a few people who have time and ability to comply with reuse (including a few women who are happy to use silver or stainless steel rigid catheters which are designed for long term reuse) It should not be a main recommendation aimed at preventing catheter related infections or pretending it meets NICE's key criteria Patients have the right to choice. We are in agreement that children should not have to reuse. This should also be applied to adults many of whom have multiple impairments to cope with including preventing deteriorating kidney function. Renal failure used to be a major cause of death of people with spinal cord injury. Many people with neurological and spinal conditions including those with complications of diabetes have incomplete bladder emptying	intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The amended linking evidence section of the

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						and or high pressure in the bladder which means there is a risk of infected urine refluxing up the urethra to the kidneys. The argument to not reuse in children holds for many adults.	full version states that: In drafting the revised recommendation, the GDG noted the following issues of importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]).The GDG acknowledged that patient preference is an important issue

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							and this was clearly highlighted as an important outcome in the evidence review and that recommendation 36 is worded the to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when selecting an intermittent catheter.
SH	MRSA Action UK	13.06	Full	4.2.2.2 10.2.1.1	43 115	Many patients are taught Intermittent catheterisation or have an indwelling urethral catheter inserted for the first time in the community. The best place to teach ISC is in the patient's home. Being taught in the home environment will highlight specific difficulties such as unsuitable water supply for hydrophilic catheters without sterile solution. Hand decontamination needs to take account of disability, for example healthcare staff need to consider manual wheelchair users and the difficulties faced to give appropriate practical advice to reduce infection risk. The need for catheter use should be regularly reviewed and or a note about indications for a more temporary use that need to be checked so that the catheter will be removed when no longer clinically needed. The scope does not cover short term catheter use. You offer no advice on care of the area around the site of a	Thank you for your comments. With regard to reviewing the need for catheterisation, recommendation 34 states: *The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible.* We agree that short term catheter use was not included in the scope. Therefore, we did not search for this evidence and cannot make recommendations related to it. The GDG discussed the need for separate guidance for people with disabilities, including wheelchair users, but considered that separate guidance was not needed and that the needs of this group would be identified as part of their assessment and appropriate catheter choices made with the patient following that assessment. As part of the linking evidence section, they noted:

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						suprapubic catheter, in many people this continually oozes and we believe this guidance is needed.	*The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.* *The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003])* We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the

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							recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. Care of suprapubic catheters was not included in the scope of this partial update. Guidelines are reviewed for update at regular intervals (currently every three years) and we would advise the stakeholder to submit this comment as part of any consultation on future scopes for update.
SH	MRSA Action UK	13.07	Full	4.2.2.5 2.5	44-45 18	Line 18 states the guideline does not cover urinary catheter insertion but 4.2.2.5 page 44 refers to catheter maintenance. Page 18 should state initial suprapubic catheter insertion which the NPSA states should only take place in secondary care All indwelling/suprapubic catheter insertions by the patient or their carer should be advised to carry it out by an aseptic non-touch technique.	Thank you for your comment. We agree that initial insertion of suprapubic catheters should only take place in secondary care setting. However, the scope of this guideline does not cover advice on the procedures of insertion of urinary catheters (although it does cover catheter maintenance) and therefore this has been amended on page 18.
SH	Royal College of Paediatrics and Child Health	14.00	Full	Introduction	13	Line 10 – could add the sentence: "Nevertheless, HCAIs can occur in otherwise healthy individuals" in order to emphasise the point that the patient may have no identifiable risk factors.	Thank you for your comment. We agree and have amended the text to read: HCAI occur in otherwise healthy individuals, especially if invasive procedures or devices are used.
SH	Royal College of Paediatrics and Child Health	14.01	Full	Introduction	14	Lines 19-21 - It is implied that some measures are more likely to prevent death than others. Under the definition of "utility" on page 213, the number "1" is assigned to	Thank you for your comments. The use of must in the recommendations is in line with the NICE guidelines manual, 2009, and are not graded in anyway. The guidelines

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						perfect health, "0" to death and a negative number to something worse than death. It might be helpful to (arbitrarily) assign such a scoring system to the measures appraised in the document. In other words, what measures will help to prevent something unpleasant but not fatal as opposed to measures that could well prevent death.	manual details this concept of the 'strength' of a recommendation that should be reflected in the consistent wording of recommendations within and across clinical guidelines. There are three levels of certainty: • recommendations for interventions that must (or must not) be used • recommendations for interventions that should (or should not) be used • recommendations for interventions that could be used.
SH	Royal College of Nursing	15.00	General	General		We are pleased this guideline is being revised and welcome the new document.	Thank you for your comment.
SH	Royal College of Nursing	15.01	NICE	General	4	The term 'avoidable infections', whilst this is frequently referred to in practice the inclusion of this term in the NICE guidance should be accompanied by a clear definition.	Thank you for your comment. We agree and have added the term 'avoidable infections' to our glossary: infections which could be prevented by taking appropriate measures to reduce the risk.
SH	Royal College of Nursing	15.02	NICE	General	8	Could you please replace hand decontamination with hand hygiene? Both terms are used interchangeably and consistency is required	Thank you for your comment. We agree that the current use of both terms could cause confusion. As hand decontamination was more frequently used throughout the 2003 version of the guideline the GDG decided for consistency to use this terminology.
SH	Royal College of Nursing	15.03	NICE	General	9	Standard principles for hand hygiene – the document should state that these are indications for hand hygiene and do not represent all occasions. It should be emphasised that HCW's should	Thank you for your comment. After careful consideration we do not agree. The GDG felt that the recommendation: "Hands must be decontaminated in all of the following circumstances: • immediately before every episode of

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						undertake a risk assessment for hand hygiene	direct patient contact or care including aseptic tasks. • immediately after every episode of direct patient contact or care, • immediately after any exposure to body fluids • immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated • immediately after removal of gloves" adequately covers all occasions on which hands MUST be decontaminated. The GDG also noted that whilst NICE guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills. The GDG felt that appropriate HCW training would include risk assessment: "Everyone involved in providing care should be: • educated about the standard principles of infection prevention and control and • trained in hand decontamination, the use of personal protective equipment
SH	Royal College of Nursing	15.04	NICE	General	10	Supra-pubic catheters are not mentioned - these are frequently changed in the community by nursing staff and can be a cause of UTI and sepsis – guidance should be included on changing and management of these.	Thank you for your comment. This guideline does include suprapubic catheterisation, which is detailed in section 10.4.1 of the full guideline (how to select the right system) and that indwelling catheters include both urethral and suprapubic catheters. However in the review looking at types of indwelling

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							catheters, only evidence regarding urethral catheters was identified. A research question has been made in this area. Catheter maintenance was not included in the scope of the partial update of this guideline.
SH	Royal College of Nursing	15.05	NICE	General	11	The use of term hand decontamination – see above	Thank you for your comment. We agree that the current use of both terms could cause confusion. As hand decontamination was more frequently used throughout the 2003 version of the guideline the GDG decided for consistency to use this terminology.
SH	Royal College of Nursing	15.06	NICE	General	13	Indications for hand hygiene - as above	Thank you for your comment. After careful consideration we do not agree. The GDG felt that the recommendation: "Hands must be decontaminated in all of the following circumstances: • immediately before every episode of direct patient contact or care including aseptic tasks. • immediately after every episode of direct patient contact or care, • immediately after any exposure to body fluids • immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated • immediately after removal of gloves" adequately covers all occasions on which hands MUST be decontaminated. The GDG also noted that whilst NICE guidelines assist the practice of healthcare professionals, they do not replace their knowledge and

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							skills.
SH	Royal College of Nursing	15.07	NICE	General	13	The need to include skin care for HCW's to ensure intact skin for hand hygiene	Thank you for your comment. Skin care is covered in recommendation 1.1.2.6: "An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted."
SH	Royal College of Nursing	15.08	NICE	1.1.3.5	15	Disposal of gloves and use of term 'clinical waste' – this should be amended in light of the revised HTM 07-01. The term 'healthcare waste' is preferred and should be managed in line with local policies. Gloves may be disposed of as municipal, offensive or infectious waste.	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree. The terms 'clinical waste' and 'healthcare waste' are both defined in the glossary of the full version of the guideline. The full version of this guideline does discuss waste disposal further in the linking evidence to recommendations section and the Department of Health's guidance on 'Safe management of healthcare waste' is also referenced.
SH	Royal College of Nursing	15.09	NICE	1.1.3.6	15	The need to reference HSE guidance on the use of latex which should be limited to circumstances where suitable substitutes are not available. At present there is not a total ban on the use of latex gloves but there is a need to justify use based on risk assessment	Thank you for your comment. We agree and have added a reference to the HSE and latex gloves in the linking evidence section of the full version of the guideline.
SH	Royal College of Nursing	15.10	NICE	1.4.2.2	25	Re-use of ANTT – there is no evidence supporting the effectiveness of ANTT	Thank you for your comment. After careful consideration, we came to the conclusion

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						and this process has not formally been evaluated. I have concerns regarding the inclusion of this term as although asepsis has an evidence base ANTT does not. Inclusion of the term in EPIC does not justify inclusion in this NICE document	that we do not agree that this should be changed. We think that this wording is appropriate because we have conducted a systematic review regarding aseptic techniques, detailed in section 12.3 in the full guideline. No clinical evidence was identified and the recommendation was based on GDG consensus. The recommendation states that an aseptic technique must be used and states ANTT™ as an example, not as the only aseptic method available.
SH	Royal College of Nursing	15.11	Full	7.3.21	85	Could there be a suggestion about removing gloves in the clinical area and not wearing them between areas and opening doors with gloved hands?	Thank you for your comment. The following recommendation was made as part of the 2003 guidance, but was outside of the scope of the update guideline: Gloves must be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient [2003]. The GDG are unable to make more specific recommendation in the areas you describe.
SH	Royal College of Nursing	15.12	Full	8.2.11		Should there be a mention of Post Exposure Prophylaxis after a needle stick injury? See DH guidance	Thank you for your comment. We agree and have added the following text to the sharps chapter: The GDG acknowledge that there is existing guidance on HIV post-exposure prophylaxis from the Department of Health.
SH	Royal College of Nursing	15.13	Full	general		General comment on disposal could there be a mention about disposing	Thank you for your comment. We do not wish to be so prescriptive and consider that this level of detail is not appropriate in this

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						urine after urine testing and the requirement not to use a sink?	guidance.
SH	Royal College of Nursing	15.14	Full	10.9.1.4	145	In examining the new proposed guidelines the previous (2003) guideline states *'bladder instillations or washouts must not be used to prevent catheter associated infection'.* The new proposal replaces that with just 'do not use bladder instillations or washouts'. The repercussions of recommending 'no use' at all has severe implications for patients and nursing resource. The majority of patients have constant problems with their long term catheters. With the use of catheter maintenance solutions nurses can manage their catheters and prolong the catheter life, minimising the number of re-catheterisations. Should we not be able to implement use based on a robust risk assessment? The financial impact on nursing time and resources, and the patient's quality of life could be severely compromised. The group would have benefited by having more continence specialist input on it.	Thank you for your comment. After careful consideration we came to the conclusion that the recommendation should revert to the original 2003 recommendation due to the poor quality and quantity of evidence: Bladder instillations or washouts must not be used to prevent catheter-associated infections. The group did have continence specialist input from Daphne Colpman, cooptee (nurse consultant, incontinence specialist). Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations
SH	Royal College of Nursing	15.15	NICE	1.2.3.	20	Offer non-coated catheters for multiple	Thank you for your comment.

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				4		uses - This could have a significant impact on patients in terms of Quality of life and potential UTI rates. Cochrane advised a big study to try to determine this. This has not been done.	We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that

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							further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Royal College of Nursing	15.16	NICE	1.2.3.4	20	Patient compliance and acceptance of ISC is a big problem, patients also can experience discomfort on ISC and coated slippery catheters are more comfortable to use. Also Glycerine coated catheters are not mentioned? Patients struggle with acceptance and compliance with ISC, how will people tolerate washing out their catheters, especially in shared facilities (at work)? People who are busy working or out and about trying to lead a normal life will not tolerate rinsing catheters in communal wash basins.	Thank you for your comment. None of the studies identified in our review reported compliance. The GDG did consider that compliance is an important factor and have added the following text into the linking evidence section in the full guideline: *Patient compliance was also identified as important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options.* We have chosen to refer to glycerine coated catheters as 'gel reservoir' catheters. We have amended this term in the glossary to state that they are also known as glycerine coated catheters.

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							The GDG did consider privacy and dignity issues as discussed in section 10.5.2.5 of the full version: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces.
SH	Royal College of Nursing	15.17	NICE	1.2.3.4	20	There are no guidelines on how long a catheter should be used. Patients may experience practical problems in complying with best practice guidance. Men especially may have trouble looking after their catheters properly when working and the reusable type do not bend and cannot be stored bent.	Thank you for your comment. As stated in the full version of the guideline, in section 10.5.2.5: *The GDG did not feel it was appropriate to make a recommendation regarding the frequency of change of multiple use catheters as this was likely to be influenced by other factors such as comfort or efficacy which would be routinely discussed as part of the normal patient-clinician interaction. Furthermore no evidence was reviewed in this area.* In the economic model, the base case assumed that patients using multiple use non coated catheters use average of one per week. This was explored in sensitivity analysis; a threshold analysis was run on the number of non coated multiple use catheters and the results indicate that clean ISC ceases to be the most cost-effective option when an average of 208 non-coated catheters are used per year; this equivalent

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							to approximately 4 catheters per week. Therefore, if on average patients use more than four non-coated catheters per week, gel reservoir catheters are the most cost-effective option for ISC. This has been added to the linking evidence section.
SH	Royal College of Nursing	15.18	NICE	1.2.3.4	20	Patients may be referred to specialist centres with problems associated with ISC, recurrent UTIs, discomfort, poor compliance, poor dexterity or bad technique. If a specialist centre recommends a single use ready to use catheter there is a danger such a product will be changed. This should not happen. Specialist procedures are carried out such as continent diversions where ISC is needed, and re usable catheters should not be used. If a patient stops doing ISC because they find using a reusable catheter unacceptable we are uncertain what the impact would be?	Thank you for your comment. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Royal College of Nursing	15.19	NICE	1.2.3.4	20	From experience, we are aware that the most important aspect is patient choice to help with acceptance of this very difficult therapy. Choice should not be taken away from the patient.	Thank you for your comment. The GDG have taken into account patient choice and preferences, which were also outcomes used in the clinical and cost effectiveness review. Additional text has been added the to the linking evidence section in the full guideline:

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							The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review. The GDG worded the recommendation to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when selecting an intermittent catheter. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Royal College of Nursing	15.20	NICE	1.2.3.4	20	Patients already on single use may not wish to change and through patient groups and continence support, new patients may express a preference for the same choice.	Thank you for your comment. The GDG have taken into account patient choice and preferences, which were also outcomes used in the clinical and cost effectiveness review. Additional text has been added to the

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							following text to the linking evidence section in the full guideline: *The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review. The GDG worded the recommendation to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances.* We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Royal College of Nursing	15.21	NICE	1.2.3.4	20	Has the impact of this on patients with disability been considered? Some of these patients often need to catheterise on beds or chairs and need catheters with drainage bags. This would present	Thank you for your comment. The GDG did consider disability when making this recommendation. They discussed whether there was a need for separate guidance for people with disabilities, including wheelchair

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						great difficulties.	users, but considered that separate guidance was not needed and that this would form part of their assessment. Additional text has been added to the linking evidence section of the full guideline to clarify this: *The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.* *The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]).* We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments

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							and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Royal College of Nursing	15.22	NICE	1.2.3.4	20	We feel strongly that there should have been a Urologist or Urology Nurse on the group who understands the challenges of ISC on a day to day basis for the patient	Thank you for your comment. At the beginning of the guideline development process, Daphne Colpman, an incontinence specialist, was co-opted to help the GDG interpret the clinical evidence, inform the economic model, and draft the recommendations. The evidence and recommendation was also discussed with a consultant urologist (chair of the NICE guideline on Incontinence in Neurologic Disease currently in development) who supported our approach.
SH	Royal College of Nursing	15.23	NICE	1.2.3.4	20	There is greater awareness and a call for more research and focus on the psychological impact of ISC on the patient. This can only reveal a need for individual assessment and patient choice. We are concerned with the proposed recommendation.	Thank you for your comment. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG

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							has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. Additional text has been added to the linking evidence section of the full guideline to clarify this: *The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]).*
SH	Royal College of Nursing	15.24	NICE	1.2.3.4	20	We feel that suggested changes will have a significant impact on patients. There is no evidence whatsoever to indicate that switching to re usable catheters will not impact on infection rates. The cost of UTI to the NHS could exceed the cost of catheters.	Thank you for your comment. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use

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							non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the

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							evidence behind the amended recommendation may be revisited.
SH	Royal College of Nursing	15.25	NICE	1.2.5.10	22	The recommendation stating 'do not use bladder instillations or washouts' requires clarification as bladder instillations or washouts are clinically regarded as 'active' treatment pathways (e.g. intra-vesicle instillation of oxybutinin/bladder irrigation initiated in secondary care for specific urological conditions/procedures) within local practice. Catheter maintenance solutions may be what this element of the guideline refers to?	Thank you for your comment. This recommendation is for primary and community settings and does not cover secondary care. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections.
SH	Royal College of Nursing	15.26	NICE	1.2.5.10	22	If reference is being made to catheter maintenance solutions (e.g. citric acid solution/saline) a blanket recommendation not to use them seems rather reductive – although interrupting the closed drainage system of an indwelling catheter should occur as infrequently as possible there are some individuals who benefit from this type of catheter maintenance.	Thank you for your comment. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections.
SH	Royal College of Nursing	15.27	NICE	1.2.5.	22	Good quality clinical evidence does	Thank you for your comment.

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				10		appear to be limited regarding this aspect of catheter care – perhaps further research would be a useful recommendation as repeated re-insertion of urethral catheters also has significant risks inherent in the procedure too.	The systematic literature review identified six randomised controlled trials with outcomes relevant to our clinical review. This was one of the areas with the greatest number of studies identified for any question included in the update of this guideline. The limitations of RCTs have been discussed in the methodology section, 3.1.3.8. and the papers were quality assessed in accordance with the NICE guidelines manual, 2009. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to

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							implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.00	Fu11	5.2		Does not seem to exist in the contents page	Thank you for your comment. We agree. We have amended the table of contents.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.01		general	general	I think that there is some lack of clarity in the document about when indwelling catheters/ization is being referred to and when intermittent catheterization is being referred to. Examples of this are included in my comments.	Thank you for your comment. We agree and have clarified this in the section headings and have reviewed the order of recommendations to reflect this.

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SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.02	Full	4.1.3	38	The title of this section does not make it clear that it refers to both indwelling and intermittent urinary catheterization. Does it only refer to long term indwelling catheters (i.e. up to 12 weeks) or all indwelling catheters – possibly change to 'indwelling and intermittent urinary catheters'	Thank you for your comment. This section details the key priorities for implementation and as such has the chapter heading as the title. The GDG did not feel that it was necessary to change this.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.03	Full	4.2.2	43	Again I think that the reference to 'long-term urinary catheters' is ambiguous/misleading given the content of the section and suggest amending to 'indwelling and intermittent urinary catheters' or the like	Thank you for your comment. We agree that this section is confusing and have reordered the recommendations to keep intermittent catheters and indwelling catheters separate. We have defined what we mean in the glossary and in the introduction to the chapter and that the whole chapter refers to long term catheterisation, defined as: the use of a catheter (indwelling or intermittent) for a period greater than 28 days.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.04	Full	4.2.2.1	43	Does point 32 refer to both indwelling and intermittent catheterization	Thank you for your comment. Yes this does refer to all long term urinary catheterisation. Long term is defined in the glossary and in the introduction to the chapter as: the use of a catheter (indwelling or intermittent) for a period greater than 28 days.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.05				Does it made to be made clearer that the length of time the catheter will be in situ needs to be considered when selecting a suitable catheter (although this could be considered to be include din the 'reason for catheterization'	Thank you for your comment. The recommendation that specifically relates to the selection of indwelling catheters for long term catheterisation is supported by a definition of that period. We have defined long term as longer than 28 days.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.06		4.1.3	38	Why doesn't the point re children and young people under 16 not receiving reusable intermittent catheters (which appears in section 4.2.3 as point 40) appear in section	Thank you for your comment. The GDG considered that the recommendation regarding children not using reusable intermittent catheters was very important

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						4.1.3	and would have more emphasis as a standalone recommendation however this was not prioritised for inclusion as a key priority for implementation which are detailed in section 4.1.3. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.07		4.1.3	44	It may be worth making it clearer that the mfr instructions must be followed wrt the volume and type of fluid used to inflate the balloon of an indwelling catheter (point 41)	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be included. We do not wish to be so prescriptive and think that our statement that requires users to follow manufacturers' guidelines adequately covers this.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.08	Full	10.1	114	As for earlier comments possibly change title to 'Long term use of indwelling and intermittent urinary catheters'	Thank you for your comment. We agree that this section is confusing and have reordered the recommendations to keep intermittent catheters and indwelling catheters separate. We have defined what we mean in the glossary and in the introduction to the chapter and that the whole chapter refers to

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							long term catheterisation, defined as: the use of a catheter (indwelling or intermittent) for a period greater than 28 days.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.09	full	10.3.2.5	131	Comments relating to 'Other considerations' section. This section needs to be revised – some of the information appears to be inaccurate or incorrect or confusing. The point that is being made is not clear to me and this section seems to suggest that the reuse of single use non-coated catheters is acceptable which is not the case. Comments (not necessarily exhaustive): 1) A definition of single-use is '**Do not reuse.** A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.' Would this be preferable to what currently appears. 2) the information in the 4th bullet point is confusing – particularly in relation to the previous 3 bullets. If what is stated is the case then the device will not be designated as a single use device, if never the less it is designated single use then this would be inconsistent and probably non compliant with the regulations and should to be reported to the MHRA	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to

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						3) Bullet point 5 could be construed as it being acceptable for single use catheters to be reused – it should be clear that this is not acceptable. The potential consequences of doing so are made clear in MDA/2010/001. 4) Users should follow the manufacturer's instructions with respect to number of reuses of reusable catheters rather than what appears in the Drug Tariff. Please provide details of where this information appears in the Drug Tariff as it needs to be reviewed. 5) There is no distinction in the definition of single-use between the community and healthcare settings. Single use is single use in whatever setting the device is used. If users reuse a single-use device they may become legally liable for the safe performance of the device (again see MDA/2010/001). 6) In the last para of page 131 if devices are washed and reused this should be within the mfrs intended purpose (and this needs to be made clear in the guidance) and reprocessing instructions	recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders, particularly the MHRA. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. Reprocessing instructions are supplied with devices from several manufacturers. Several stakeholders have mentioned that to infer intent for reuse from instructions for cleaning & reuse is erroneous as by doing so manufacturers are simply complying with Department of Health directives. It is outside of the scope of our guideline to determine true intent or resolve differences between manufacturers' interests, department of health requirements, and MHRA designations. RE: washing and reprocessing, the original 2003 recommendation already states: *Reusable*

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						should be supplied with the device by the mfr. 7) In the 3rd line, second para of page 132 'could' should be changed to 'should'. 8) In the following para again users should follow mfr instructions regarding the frequency of change of multiple use catheters.	*intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. [2003].* To minimise confusion that this 2003 recommendation may cause further to the GDG deliberations and stakeholder feedback in this area, we have removed this recommendation from the final version of the guideline pending further evidence becoming available that will resolve this issue. The section regarding manufacturers' instructions has been removed from the updated LETR.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.10		10.7.1.1	1346 pt 54	Consider amending to '… and should be changed as indicated in the mfrs instructions'	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.11		10.10.5	150	Consider amending this para to '… Reusable single patient use intermittent catheters need to be cleaned dried and stored after use according to the mfrs instructions in conditions which are least likely …'	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.

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							After careful consideration the GDG decided that this 2003 recommendation about how to clean reusable catheters should be removed from the guideline to avoid confusion.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.12		10.10.5	150	Consider amending to 'Reusable single patient use intermittent catheters need to be cleaned dried and stored after use according to the mfrs instructions'.	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. After careful consideration the GDG decided that this 2003 recommendation about how to clean reusable catheters should be removed from the guideline to avoid confusion.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.13		Glossary	212	For all safety devices consider changing 'prevents sharps injuries' to 'reduces the risk of sharps injuries'	Thank you for your comment. We agree and have amended the glossary term to read 'reduces the risk of sharps infection'.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.14	Full	General	General	There are many references to Health and Safety Regulations, PPE Regulations and COSH Regulations, however I did not notice any	Thank you for your comment. We agree and have incorporated Medical Devices Regulations into the device chapter

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						mention of the Medical Devices Regulations - which of course apply to many of the healthcare products this guideline document focuses on, such as : venous catheters, urinary catheters, needles, medical gloves etc. A few sentences throughout stating that all medical devices should comply with the Medical Device Regulations (MDR) should be considered.	introductions.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.15	Full	General	General	Please consider a reminder to report adverse incidents with medical devices to the MHRA.	Thank you for your comment. We agree and have incorporated Medical Devices Regulations into the device chapter introductions. We are unable to make a recommendation regarding reporting of adverse incidents as we have not reviewed the evidence in this area.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.16	Full	4.2.1.3 & 7.3.2.1	Page 41 & Page 85	Page 41; Para 11; Lines 6 & 7 plus Page 85, Recommendation 11 The current "h" reference at the word "standards" on line 7 is incorrect and should be replaced with a slightly amended sentence currently referenced "z" at the bottom of page 85:- "z At the time of consultation on the guideline (July 2011) : BS EN 455 Parts 1 - 4 Medical gloves for single use". Please note it is not mandatory to demonstrate conformity with the European Standards in order to conform to the Medical Device Regulations.	Thank you for your comment. We agree and have amended the footnote to state: BS EN 455 Parts 1 - 4 Medical gloves for single use. The GDG considered the wording of the recommendation and have amended it to read: Gloves used for direct patient care: • must conform to current EU legislation (CE marked as medical gloves for single use) and • should be appropriate for the task.

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						I suggest rewording the sentence 4.2.1.3 11 to be more accurate as follows: "Gloves used for direct patient care must(j) be CE marked to show they conform to the Medical Devices Regulations (MDR) and should be appropriate for the task."	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.17	Full	7.3.2	84	Page 84; line 28- 30 Suggest combining and rewording the last 2 sentences of the paragraph to the following:- "Revised European standards relating to the manufacture of medical gloves for single use give performance requirements for gloves according to the constituent material. 28-30 "	Thank you for your comment. This section is text from the 2003 guideline and was not prioritised for update and therefore cannot be altered.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.18	Full	14	215	CE is not the abbreviation for European Community. It should be EC. MDA does not exist anymore and should be replaced with MHRA MDR should be included to refer to the Medical Device Regulations	Thank you for your comment. We agree and have amended MDA to MHRA and included reference to Medical Device Regulations where appropriate. The recommendation relating to glove CE marking has also been amended to state: Gloves used for direct patient care: • must conform to current EU legislation (CE marked as medical gloves for single use) and • should be appropriate for the task.
SH	Medicines and Healthcare Products Regulatory	16.19	Full	15	218	the references 28 – 31 are incorrect and should be worded as follows:-	Thank you for your comment. We agree. We have amended the references accordingly.

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	Agency (MHRA)					28. BSi. BS EN 455-1 2000 Medical gloves for single use Part 1: Requirements and testing for freedom from holes 29. BSi. BS EN 455-2 2009 Medical gloves for single use Part 2: Requirements and testing for physical properties 30. BSi. BS EN 455-3 2006 Medical gloves for single use Part 3: Requirements and testing for biological evaluation 31. BSi. BS EN 455-4 2009 Medical gloves for single use Part 4: Requirements and testing for shelf life determination	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.20	FULL	11.4.1 line 25	156	Amend: The Medicines and Healthcare products Regulatory Agency (formerly known as the Medical Devices Agency) Amend reference to 'items' – replace with 'medical devices'	Thank you for your comment. We agree. We have removed the term 'items' and replaced with 'medical devices'.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16.21	FULL	11.4.1 line 26	156	Reference 166 – this Alert has been withdrawn. Recommend referencing: Medicines and Healthcare products Regulatory Agency DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse.	Thank you for your comment. We agree. We have amended the reference accordingly.
SH	3M Health Care Limited	17.00	Full	12.3.1.3	164	No.79 – Use of ANTT and lack of supporting clinical evidence. We support the consolidation of technique using ANTT as a teachable, well principled version of the broader term "aseptic technique" which	Thank you for your comment.

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						has been open to several interpretations and is may be taught differently.	
SH	3M Health Care Limited	17.01		12.5.1.5	178	No. 81 – Fully supportive of this recommendation to protect the site with a waterproof TSM dressing and also to provide better secural of the catheter.	Thank you for your comment.
SH	3M Health Care Limited	17.02		12.5.1.5	179	No. 82 – Fully support recommendation that has been recommended practice in US for many years. Also available are TSM dressings with an integral absorbent pad that will function well in this patient group.	Thank you for your comment.
SH	3M Health Care Limited	17.03		12.6.1.4	181	No. 83 – Fully supportive of this recommendation. However re-phrasing will make it clearer to readers what the intent of the recommendation is: "Change the transparent semipermeable membrane dressing covering a central venous access device insertion site every 7 days, or sooner if the dressing adherence is no longer intact or moisture collects under it. [2012]"	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree that the recommendation should be changed. When a dressing is considered "intact", it is not just referring to the fact that is adhering or "sticking" well to the skin. It also means there are no breaks or any perforations to the dressing which can compromise the protection it appears. Furthermore, there are other definitions of term 'adherence' in the healthcare context.
SH	3M Health Care Limited	17.04		12.6.1.4	181	No.84 – fully support this recommendation	Thank you for your comment.
SH	3M Health Care Limited	17.05		12.6.1.4	181	No. 85 – Change this recommendation to read " For infection prevention purposes, dressings used on tunnelled or implanted central venous catheter sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner." Patients often	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree. Recommendations were made in accordance with the NICE guidelines manual, 2009 which states that the reason justifying the recommendation should not be included in the

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						strongly presser to have a TSM in place post healing to provide confidence re secrurement of the long term CVC.	recommendation itself (section 9.3.2).
SH	3M Health Care Limited	17.06	Full	12.7.1.3	191	No. 86 – Fully support this recommendation. 0.5% CHG in alcohol may well be as effective as 2% CHG in alcohol. A key parameter was not discussed. What is the volume of chlorhexidine gluconate in alcohol required for skin decontamination for peripheral and CVC access sites, and for insertion and maintenance. Most VAD related guidelines published across the globe, recommend a skin preparation but none state the volume to be used for insertion or regular decontamination of the site. A 3mL 2% chlorhexidine gluconate in alcohol applicator may well be the optimum ratio of cost and effectiveness for CVC insertion procedures but a 1mL 2% Chlorhexidine gluconate in alcohol may well be better suited for line maintenance.	Thank you for your comment. The GDG did not prioritise a clinical question regarding the volume of chlorhexidine gluconate in alcohol, but have noted in the linking evidence section that technique and volume of product is important. However, in the absence of evidence we have not been able to be more specific about the volume. We also wish to point out that the current guideline is not covering the insertion of CVC, which is usually not conducted in the primary care setting.
SH	3M Health Care Limited	17.07		12.9.5	199	No. 103. Fully support this critical way to avoid cross contamination of IV fluids.	Thank you for your comment.
SH	3M Health Care Limited	17.08		12.11	200	An additional research recommendation should be included. To compare the clinical and cost effectiveness of 1ml and 3ml doses of 2% Chlorhexidine gluconate in alcohol for maintenance of VAD access sites	Thank you for your comment. The GDG did not consider this to be an area to be prioritised for research recommendation.
SH	3M Health Care Limited	17.09		12.11	200	An additional research recommendation should be included. To compare the clinical and cost effectiveness of TSM with integral 2% Chlorhexidine gluconate patch with	Thank you for your comment. The GDG did not consider this to be an area to be prioritised for research recommendation.

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						separate Chlorhexidine gluconate patch and covering TSM. Outcomes: exit site infection, BSI, overall costs	
SH	Association for Continence Advice	18.00	Full	10.3.2.5	130	While the association acknowledges the caveats NICE has made to the recommended use of reusable rather than single use ISC catheters it is concerned that urethral damage and stricture formation have not been considered as a risk that is associated with poorly lubricated, multiuse catheters .Neither does the additional cost of lubrication appear part of the financial equation and that patient choice and QOL have been marginalised in favour of cost cutting.	Thank you for your comment. There is no comparative clinical evidence of the incidence of urethral damage and stricture associated with different types of intermittent catheters. Nevertheless, the potential for one type of catheter to reduce urethral damage & stricture formation was explicitly incorporated into the economic model: in the base case we assumed that there was no difference (RR =1; due to a lack of comparative clinical evidence) and in the sensitivity analysis we explored the extremes of this assumption by assuming that hydrophilic and gel reservoir catheters are 100% effective (RR = 0) at preventing urethral strictures compared to noncoated catheters. The conclusions of the model were unchanged by this sensitivity analysis. The cost of lubricant was factored into the cost of noncoated catheters. We assumed that patients would use between 4 and 6 sterile sachets of lubricant per day, and that 5% of patients use lidocaine lubricant while the rest use water-based lubricant. Please refer to Appendix J for a full breakdown of the evidence, assumptions and costs included in the economic model. Taking into account all of the stakeholder

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							consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the

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							inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Infection Prevention Society	19.00	NICE version	General	Title	Should this also relate to care in social care settings as healthcare is provided in own homes by carers or family members?	Thank you for your comment. The title has been set as part of the initial scoping phase and has undergone public consultation.
SH	Infection Prevention Society	20.00		Introduction	4	Only reflects a narrow range of topics and not all the principles of standard precautions – what about PEG/NG care, asepsis, decontamination of equipment, immunisation of staff, linen/laundry and wound care etc. How does this fit in with other documentation and strategies for prevention of HCAI and programmes work for safety express, 1000 lives, code of practice and national strategy? What about standards for CCQ? It should also be fit for purpose for all UK countries.	Thank you for your comment. Due to limited resources we were only able to address a limited number of clinical questions. The scope of this partial update was formally consulted on prior to development and is detailed in Appendix A. Key clinical issues covered include standard infection control precautions (hand hygiene, personal protective equipment and the safe use and disposal of sharps), long-term urinary catheters, percutaneous gastrostomy feeding, vascular access devices and asepsis. Decontamination of equipment, immunisation and laundry were not prioritised for inclusion in the scope for this partial update. The GDG acknowledge that there are national strategies for prevention of HCAI, like MRSA and C. Diff., which makes community infection control and prevention

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							an important guideline to develop and be disseminated. Advice on the diagnosis, treatment or management of specific infections, are outside of the scope of this update. We think that the issue related to other documentation and strategies is adequately covered in the introduction of the guideline 'preventing healthcare associated infections remains a key priority in the patient safety agenda', and the GDG considered national priorities and relevance to the NHS when prioritising research recommendations. The GDG consider that the guideline is fit for purpose within NICE's remit of England and Wales.
SH	Infection Prevention Society	20.01			5	This should state children and young people	Thank you for your comment. Our scope states that the population covered for this population is all adults and children receiving healthcare where standard infection control precautions apply in primary and community care. This is also clearly identified in the introduction section of the NICE guideline under 'audience'.
SH	Infection Prevention Society	20.02			5 Line 8 bullet point 2	Should read "Health care workers" and those providing care. This then covers carers and volunteers	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree. We think that this is adequately covered in the introduction of the guideline which states 'Much care is also delivered by informal carers and family members, and this guideline is equally applicable to them.

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SH	Infection Prevention Society	20.03		Drugs	6	Why are 'off label' drugs recommended?	Thank you for your comment. In accordance with the NICE guidelines manual it is appropriate for guideline developers to recommend 'off label' drugs for use in the NHS if there is evidence to support it. Antibiotics are reviewed in the long term urinary catheter chapter and are reviewed and discussed in detail in chapter 10.
SH	Infection Prevention Society	20.04			8 Last bullet point	Timing of hand hygiene. There should be a reference to the first bullet on page 9	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendations as they stand because their current wording is clear. The full version of the guideline details the references used in the clinical review and section 6.3.1.4. explains how the GDG considered the evidence.
SH	Infection Prevention Society	20.05		Hand Hygiene	9	Not all NPSA 5 moments included in list	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks".
SH	Infection Prevention Society	20.06		Long-term catheter	9	A definition of long-term catheters would be useful	Thank you for your comment. We have defined long term catheterisation in the glossary of the full version of the guideline as the use of a catheter (indwelling or intermittent) for a period greater than 28 days.
SH	Infection Prevention	20.07		Long-	9	Why are multiple use intermittent	Thank you for your comment. Please refer to

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	Society			term catheter		catheters recommended?	section 10.5.1 and Appendix J of the full guideline for a detailed explanation of the evidence. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.

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SH	Infection Prevention Society	20.08		Long-term catheter	9	No statement included on avoidance where possible	Thank you for your comment. Recommendation 34 (2003) states: 'Indwelling urinary catheters should be used only after alternative methods of management have been considered'.
SH	Infection Prevention Society	20.09		Key priorities	8-10	Repetition here with 1.2 re hand hygiene etc Vascular devices – the recommendation for chlorhexidine/70% does not reflect CDC recommendation for PVC insertion There are no references in the document to documentation and care bundles??	Thank you for your comments. This section (key priorities for implementation) highlights the recommendations which had been identified as key priorities for implementation. Therefore, these recommendations appear twice in the guideline. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access.

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							A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf). Care bundles are referred to whenever appropriate in the full guideline, for example in the "Linking Evidence to Recommendation" section 12.6.1.4 of the vascular access devices section. In that section, it was stated that the GDG took into account that the Department of Health Saving Lives: reducing infection, delivering clean and safe care, peripheral intravenous cannula care bundle had also recommended that cannulae should be replaced in a new site after 72 to 96 hours or earlier if clinically indicated. The GDG had noted that many care bundles reference the 2003 version of this guideline. Therefore, we were careful about referencing care bundles to avoid creating circular references.
SH	Infection Prevention	20.10		Vascu	10	The sentence relating to aseptic	Thank you for your comment. This

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	Society			lar access devices		principles does not make sense. This should read, "carried out using aseptic technique principles"	recommendation was not updated from the original guidance and the GDG considered the recommendation accurate.
SH	Infection Prevention Society	20.11			10	Should read **2%** chlorhexidine gluconate in 70% alcohol	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the

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							percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf).
SH	Infection Prevention Society	20.12			10	No mention of ongoing care management documentation which should be based on care bundles.	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that the guideline should be amended to reflect this issue. Care bundles are discussed in the full guideline under vascular access devices. The Department of Health 'saving lives, care bundle for urinary catheter care and enteral feeding' both reference the 2003 version of this guideline, and therefore we did not want to create circular references.
SH	Infection Prevention Society	20.13			10	There is no concentration for Chlorhexidine (should state 2%) only alcohol concentration (repeated throughout the document)	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct

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							comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf) .
SH	Infection Prevention Society	20.14		Terms	11	Hand decontamination – hand rub should not be in a definition which	Thank you for your comment. We agree. We have amended the wording accordingly.

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						relates to the PHYSICAL removal of organic matter	
SH	Infection Prevention Society	20.15		1 Handrub	11	Alcohol handrub preferable as in 1.1.2.5	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate as we have stated in section 6.4.1.4 of the full guideline that 'The GDG noted that although there was no evidence available for non-alcohol handrubs they did not want to prevent such products being used if they meet European and British Standards. Therefore, the recommendation specifies a 'handrub conforming to current European and British Standards', rather than an 'alcohol' handrub. BS EN 1500 is the British Standard test for determining the bactericidal efficacy of hygienic hand disinfection (handrubs). To meet the standard the hands of 12-15 volunteers are artificially contaminated with Escherichia coli and treated in a crossover design with the test or reference product (60 second application of 60% 2-propanol). The tested handrub should not be significantly less effective than the reference alcohol.
SH	Infection Prevention Society	20.16		1.1.1.2	12	Materials for hand decontamination should be listed	Thank you for your comment. We do not wish to be so prescriptive and we think that it would be up to the individual to decide according to their/ the patient's needs and preferences.

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SH	Infection Prevention Society	20.17		Section 1.1.2.1	13	The circumstances where it indicates where hands must be decontaminated differ from the WHO Guidelines on Hand Hygiene in Healthcare 2009 – '5 Moments'. There is no mention of clean/aseptic procedures and the addition of 'immediately after removal of gloves' comes under the 'body fluid exposure risk' in the WHO guidelines.	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks". The GDG considered it was important to emphasise "after the removal of gloves" as a separate point.
SH	Infection Prevention Society	20.18		1.1.2.2	13	What is the rational for using handrub over soap and water when this is available?	Thank you for your comment. A systematic review has been conducted and presented in section 6.4 of the full guideline. The rationale behind the relevant recommendation is detailed in section 6.4.1.4. The evidence shows that alcohol handrubs are as effective, if not more effective, at reducing Colony Forming Units on hands compared to hand washing. Alcohol handrub has also been linked to increased hand decontamination compliance, which is also found in the multi model hand decontamination interventions included in the 'when to wash your hands' review question, see section 6.3.1.4.
SH	Infection Prevention Society	20.19		1.1.2.2	13	Recommending hand rub too prescriptive. Repeated use of hand rub leads to build up and loss of effectiveness. Use of hand rub should be recommended only up to	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as it stands because it is based on a systematic review of the

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						manufacturers recommendations and use of hand washing should be encouraged and given equal importance. Use of hand washing or hand rub should be recommended here (unless central vascular device in which case both).	evidence found in section 6.4, and the consensus of the GDG. The reasoning behind this recommendation can be found in section 6.4.1.4 of the full guideline.
SH	Infection Prevention Society	20.20		1.1.2.2	13	I do not agree with the assertion that hand rub is preferable to hand washing. Does the evidence support this in community settings? In many community settings such as special schools, learning disability day centres, care homes hand washing is accessible and socially acceptable. I don't think the impression that hand washing is inferior to using hand rubs should be given.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as it stands because it is based on a systematic review of the evidence found in section 6.4 and the consensus of the GDG. The evidence discussed was related to all hospital settings as none was identified in the community. The reasoning behind this recommendation can be found in section 6.4.1.4 of the full guideline.
SH	Infection Prevention Society	20.21		1.1.2.3	13	Should include forearm jewellery	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that the recommendation wording is appropriate because the terms 'bare below the elbow' and 'removal of wrist...jewellery' adequately covers removing forearm jewellery.
SH	Infection Prevention Society	20.22		1.1.2.3	13	Consider inserting a bullet point concerning 'no false nails' Also where wrist supports are worn these should be of a impermeable and wipeable material which is capable of being	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as it stands because the

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						decontaminated and removed easily for hand washing.	footnote to the recommendation clarifies the GDG's understanding of the term 'bare below the elbow' and states that "For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand decontamination.". The GDG have not reviewed the evidence for wrist supports and are therefore unable to make a specific recommendation.
SH	Infection Prevention Society	20.23		1.1.2.3	13	We should keep this as must. There may not be legislation but there is evidence, and this makes it more robust and easier to ask for compliance with.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate because, in line with the NICE guidelines manual 2009, 'must' can only be used in recommendations where there is legislation or the consequences of not implementing them means that the risk of adverse events (including death) is so severe that the use of 'must' is appropriate (NICE Guidelines Manual [2009]). In this case, the GDG do not feel the use of the word 'must' is appropriate.
SH	Infection Prevention Society	20.24		1.1.2.3	13	It is good to see "bare below the elbow" in the guidance – no mention is made of the wearing of one plain metal ring. The guidance should clearly state whether this is acceptable practice or not as it	Thank you for your comment. The GDG did not specifically review the evidence for wearing a plain band. The GDG acknowledged this in the other considerations section (6.5.1.4) for this recommendation in the full guideline

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						will be used as a reference point for local policy and guidance.	'The GDG recognise that healthcare workers are either reluctant or cannot remove wedding rings and are aware that some local dress code policies consider that one plain band is acceptable'. In the absence of a specific evidence review, the GDG do not feel able to make a recommendation about single plain wedding rings and have detailed that in the guideline as above.
SH	Infection Prevention Society	20.25		1.1.2.4	14	Paper towels may not be available in the patient home.	Thank you for your comment. We are aware that hand decontamination equipment may not be available in the patient home and have recommended that: Wherever care is delivered, healthcare workers must have available appropriate supplies of: • materials for hand decontamination • sharps containers • personal protective equipment (recommendation 1.1.1.2).
SH	Infection Prevention Society	20.26		1.1.2.4	14	Stress antimicrobial preparations should only be used for surgical hand decontamination	Thank you for your comment. This is a 2003 recommendation. Only essential changes to these recommendations can be made, for example, if a recommended drug/intervention is no longer available or terminology is now incorrect. The GDG considered that as the recommendation gives a choice of liquid soap or an antimicrobial preparation no change to this recommendation was required and thus the 2003 remains extant.
SH	Infection Prevention Society	20.27		1.1.2.4	14	No mention of removal of jewellery, for example watches and washing of the	Thank you for your comment. After careful consideration, we came to the conclusion

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						wrists as part of the hand hygiene technique	that we do not agree that this should be changed. Recommendation 1.1.2.3. covers this by ensuring healthcare workers are bare below the elbow and have removed wrist and hand jewellery. The footnote to the recommendation clarifies the GDG's understanding of the term 'bare below the elbow' and states that "For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand decontamination.". A systematic review was conducted to identify if wrists should be washed, but no evidence was identified. The GDG decided that in the absence of evidence they did not wish to make a recommendation in this area. Section 6.5 of the full guideline details the clinical question for decontaminating wrists. The linking evidence to recommendation section states that: No RCT or cohort studies comparing decontaminating the wrists against not decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists.
SH	Infection Prevention Society	20.28		1.1.2.4	14	Wrists should be added to the hand washing procedure.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be

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							changed. A systematic review was conducted to identify if wrists should be washed, but no evidence was identified. The GDG decided that in the absence of evidence they did not wish to make a recommendation in this area. Section 6.5 of the full guideline details the clinical question for decontaminating wrists. The linking evidence to recommendation section states that: No RCT or cohort studies comparing decontaminating the wrists versus not decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists.
SH	Infection Prevention Society	20.29		1.1.2.4	14	The handwash solution must come into contact with all surfaces of the hand **and wrist**	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. A systematic review was conducted to identify if wrists should be washed, but no evidence was identified. The GDG decided that in the absence of evidence they did not wish to make a recommendation in this area. Section 6.5 of the full guideline details the clinical question for decontaminating wrists. The linking evidence to recommendation section states that: No RCT or cohort studies comparing decontaminating the wrists against not decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists.
SH	Infection Prevention	20.30		1.1.2.	14	The hands **and wrists** must be	Thank you for your comment. After careful

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	Society			5		rubbed….	consideration, we came to the conclusion that we do not agree that this should be changed. A systematic review was conducted to identify if wrists should be washed, but no evidence was identified. The GDG decided that in the absence of evidence they did not wish to make a recommendation in this area. Section 6.5 of the full guideline details the clinical question for decontaminating wrists. The linking evidence to recommendation section states that: No RCT or cohort studies comparing decontaminating the wrists against not decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists.
SH	Infection Prevention Society	20.31		1.1.2.5	14	No mention of removal of jewellery, for example watches and washing of the wrists as part of the hand hygiene technique	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. Recommendation 1.1.2.3. covers this by ensuring healthcare workers are bare below the elbow and have removed wrist and hand jewellery. We are satisfied with the recommendation as it stands because the footnote to the recommendation clarifies the GDG's understanding of the term 'bare below the elbow' and states that "For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when

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							delivering direct patient care and performing hand decontamination.". A systematic review was conducted to identify if wrists should be washed, but no evidence was identified. The GDG decided that in the absence of evidence they did not wish to make a recommendation in this area. Section 6.5 of the full guideline details the clinical question for decontaminating wrists. The linking evidence to recommendation section states that: No RCT or cohort studies comparing decontaminating the wrists against not decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists.
SH	Infection Prevention Society	20.32		1.1.3.1	14	Consider the following: "Selection of protective equipment must be based on an assessment of both the risk of transmission **and the mode of transmission** of microorganisms to the patient…"	Thank you for your comment. This is a 2003 recommendation. Only essential changes to these recommendations can be made, for example, if a recommended drug/intervention is no longer available or terminology is now incorrect.
SH	Infection Prevention Society	20.33		1.1.3.2	15	A recommendation on types of gloves to be worn would be useful ie vinyl/ latex/ nitrile	Thank you for your comment. Section 7.4 in the full version of the guidelines contains the review question: which types of gloves provide the best protection against healthcare-associated infections? Only one paper was identified comparing nitrile to latex gloves. The GDG made a recommendation stating that gloves should

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							conform to current European Community standards as all single use gloves meeting these standards are required to meet the same resistance to punctures or holes, irrespective of glove material. This seems to be the most appropriate recommendation based on the review of the available evidence.
SH	Infection Prevention Society	20.34		1.1.3.5	15	PPE is listed as ok for tiger stripe bags which are (if non-infectious) not classified as clinical waste	Thank you for your comment. We do not wish to be so prescriptive and consider that this level of detail is not appropriate in this guidance. The full version of this guideline does discuss waste disposal further in the linking evidence to recommendations section and the Department of Health's guidance on 'Safe management of healthcare waste' is also referenced.
SH	Infection Prevention Society	20.35		1.1.3.5	15	Glove choice not included	Thank you for your comment. Section 7.4 in the full version of the guidelines contains the review question: which types of gloves provide the best protection against healthcare-associated infections? Only one paper was identified comparing nitrile to latex gloves. The GDG made a recommendation stating that gloves should conform to current European Community standards as all single use gloves meeting these standards are required to meet the same resistance to punctures or holes, irrespective of glove material. This seems to be the most appropriate recommendation based on the review of the available evidence.

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							Further recommendations are also made stating that alternatives must be available to those sensitive to natural rubber latex and that polythene gloves are not appropriate for clinical interventions.
SH	Infection Prevention Society	20.36		1.1.3.5	15	What about EU waste codes? The waste stream and colour coding for orange/tiger stripe e.g. are not reflected here by stating clinical waste, what about coding for sharps boxes? What about transport of clinical waste e.g. community nurses	Thank you for your comment. We do not wish to be so prescriptive and consider that this level of detail is not appropriate in this guidance. The full version of this guideline does discuss waste disposal further in the linking evidence to recommendations section and the Department of Health's guidance on 'Safe management of healthcare waste' is also referenced.
SH	Infection Prevention Society	20.37		1.1.3.6	15	No mention of glove powder or extractable protein levels.	Thank you for your comment.. The full version of the guideline discusses powdered gloves in section 7.4.1.4. and the statement that says 'powdered gloves should not be used' has been removed from this recommendation. The recommendation in the previous guideline referred to latex powdered gloves that are associated with latex allergy. Corn starch used in powdered latex gloves is thought to be a source of latex sensitisation, because the natural rubber latex easily binds to it, transporting it through the skin and into the circulation. However, alternative powdered gloves are now available that are non-latex and thus avoid this problem.
SH	Infection Prevention Society	20.38		1.1.3.7	15	While it states polythene should not be used its should also say vinyl should not be used with blood or body fluids	Thank you for your comment. No evidence was identified regarding vinyl gloves and the GDG chose not to make a consensus recommendation regarding their use.

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							Additional text has been added to the linking evidence section stating that: No evidence was identified for vinyl gloves, but the GDG considered that if they met the relevant CE standards they could be used in clinical settings.
SH	Infection Prevention Society	20.39		1.1.3.8	16	Do ambulance men wear plastic aprons?? Long sleeve gowns may be required for certain infections where direct skin to skin contact is likely	Thank you for your comment. The GDG agree that further clarification is needed and additional text has been added to the linking evidence section for this recommendation in the full guideline: The GDG acknowledged that ambulance staff wear aprons when required, but it is unusual to wear full gowns in the community. Full gowns are generally only available in exceptional circumstances, such as high risk transfers and/or previously known risks or scenarios, which are rare. The GDG considered that the recommendation is appropriate for the majority of healthcare workers in the community.
SH	Infection Prevention Society	20.40		1.1.4 Safe use and disposal of sharps	Pg 16	Has the June 2010 publication of EU Council Directive 2010/32 /EU, on the prevention of sharps injuries in the hospital and healthcare sector been reviewed with regards the wording used……changing from "must" to "should" ?	Thank you for your comment. Section 8.2.1.1. of the full guideline states: 'Unavoidable situations for recapping, bending or breaking needles were brought to the attention of the GDG by dental colleagues during the stakeholder workshop. The GDG noted DH advice that some syringes used in dentistry are not disposable and needles should be re-sheathed using

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							the needle guards provided.' We agree however and have amended the recommendation to state that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Infection Prevention Society	20.41		1.1.4.2	16	EU directive states that there must be no re-sheathing of any needle. What about injury?	Thank you for your comment. The EU directive states that 'the practice of recapping shall be banned with immediate effect'. However, as stated in section 8.2.1.1. of the full guideline: 'Unavoidable situations for recapping, bending or breaking needles were brought to the attention of the GDG by dental colleagues during the stakeholder workshop. The GDG noted DH advice that some syringes used in dentistry are not disposable and needles should be re-sheathed using the needle guards provided. ' Therefore, we have amended the recommendation to state that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Infection Prevention Society	20.42		1.1.4.2	16	Recapping of needles in any circumstances is not in line with EU Directive on sharps	Thank you for your comment. Section 8.2.1.1. of the full guideline states: 'Unavoidable situations for recapping, bending or breaking needles were brought to the attention of the GDG by dental

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							colleagues during the stakeholder workshop. The GDG noted DH advice that some syringes used in dentistry are not disposable and needles should be re-sheathed using the needle guards provided.' We agree however and have amended the recommendation to state that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Infection Prevention Society	20.43		1.1.4.2	16	We should keep this as must. Sharps incidents are largely preventable. This is not something which should be negotiated. If there are issues re recapping this should be broken onto two statements as no needles should be bent or broken.	Thank you for your comment. Section 8.2.1.1. of the full guideline states: 'Unavoidable situations for recapping, bending or breaking needles were brought to the attention of the GDG by dental colleagues during the stakeholder workshop. The GDG noted DH advice that some syringes used in dentistry are not disposable and needles should be re-sheathed using the needle guards provided.' We agree however and have amended the recommendation to state that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Infection Prevention Society	20.44		1.1.4.4	17	What is the rationale for advising 3 months as the time limit for saharps containers to be left open?	Thank you for your comment. As stated in the linking evidence section for this recommendation in the full guideline: The

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							GDG noted that any amendments to the original recommendation should conform to the Safe Management of Healthcare Waste guidelines. This says that: Sharps containers should be collected when filled to the fill line and should never exceed the permissible marked mass. If the sharps container is seldom used, it should be collected after a maximum of three months, regardless of the filled capacity.
SH	Infection Prevention Society	20.45		1.2.2	18	Catheterisation miss-spelling	Thank you for your comment. We agree. We have amended the text accordingly.
SH	Infection Prevention Society	20.46		1.2.3.3	19	Why is age mentioned?	Thank you for your comment. Age is mentioned in the recommendation as stated in the full version of the guideline in section 10.5.1.4: 'The length and gauge of the catheter should be appropriate for the patient. For example, the size should be appropriate for the age or size of the child. '
SH	Infection Prevention Society	20.47		1.2.3.4	20	Why is multiple use intermittent catheters recommended	Thank you for your comment. Please refer to section 10.5.1 and Appendix J of the full guideline for a detailed explanation of the evidence. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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							that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Infection Prevention Society	20.48		1.2.3.5	20	Can a reason be given for the multiple-use catheters in children – an explanation can help to increase compliance.	Thank you for your comment. Multi-use intermittent catheters are not recommended for use in children: *'Consider non-coated intermittent catheters for multiple use only if all of the following conditions are met:.....* • *the patient is aged 16 years or over and. ....'*

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							The reasons for this are discussed in the full version of the guideline in section 10.5.1.5. The GDG recognised that symptomatic UTI in childhood carries the risk of serious kidney damage. In light of the absence of evidence related to the use of single- vs. multiple- use non-coated catheters in children, and the uncertainty surrounding the real lifetime risk of established renal failure as a result of childhood UTI, the GDG decided to adopt a precautionary approach when making this recommendation.' Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent

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							catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Infection Prevention Society	20.49		1.2.5.3	21	Is there a case for requesting sterile gloves when changing the 5-7 day leg bags as high up the link system?	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.50		1.2.5.5	21	Add a needleless sampling port system should be used	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.51		1.2.5.8	22	Consider updating the advice on the frequency of the drainage bag changes to every 5 to 7 days or as per manufacturer's recommendation.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.52		1.2.5.8	22	? empty when 2/3s full	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.53		1.2.5.10	22	2nd bullet point does not include specific reasons when bladder instillations can be given ie post urology surgery/ visible encrustation. Bladder instillations need to be prescribed.	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree that this should be amended. The full version of the guideline (section 10.9.1.4) does acknowledge 'that therapeutic intervention, such as instillations for patients undergoing chemotherapy, was an area beyond the scope of the guideline.' In addition the scope of this guideline is for long term (over 28 days) catheters, which does not cover post urology surgery.

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							The GDG have decided to revert to the original 2003 recommendation: Bladder instillations or washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.
SH	Infection Prevention Society	20.54		1.2.5.10	22	What about documentation/care bundles?	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that the guideline should be amended to reflect this issue. Care bundles are discussed in the full guideline under vascular access devices. The Department of Health 'saving lives, care bundle for urinary catheter care and enteral feeding' both reference the 2003 version of this guideline, and therefore we did not want to create circular references.
SH	Infection Prevention Society	20.55		1.2.5.10	22	Catheter positioning should be included to reduce trauma and back flow	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be amended. The GDG felt that this is already covered in the following recommendations from the guideline:

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							Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor. [2003] The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated. [2003]
SH	Infection Prevention Society	20.56		1.2.5.13	22	Why are multiple use intermittent catheters recommended. Could single use be introduced for new clients	Thank you for your comment. Please refer to section 10.5.1 and Appendix J of the full guideline for a detailed explanation of the evidence. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent

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							catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Infection Prevention Society	20.57		1.2.5.12	22	Should patients considered to be at high risk of bacteraemia also be included?	Thank you for your comment. The GDG considered that this did not need amending, as they felt that the bullet points included were the most important points when considering antibiotic prophylaxis. However, additional text has been added to the linking evidence section: 'The GDG discussed patients with a high risk of bacteraemia, such as immunosuppressed patients, and that they could also be considered for antibiotic prophylaxis.'
SH	Infection Prevention Society	20.58		1.3.2.5	23	"No touch technique" I know what you mean but would a carer? Needs defined/explained further perhaps in the glossary	Thank you for your comment. We agree. We have removed 'no touch' and replaced with 'aseptic'. The term 'aseptic technique' has been defined further in the glossary.
SH	Infection Prevention Society	20.59		1.3.3.3	24	Extensions sets have been omitted from the guidance as they were in 2003. I have raised this issue with Carol Pellowe in the past and I am concerned that it has been omitted again. Some manufacturers recommend extension	Thank you for your comment. This area falls outside the scope of the guideline update. Therefore we could not provide a response. Details of your comment are held on file and may be considered as part of the scope of further updates of this guideline.

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						sets can be rinsed and reused for 2 weeks. This is not consistent with the administration set being used for only 24 hours. I feel this issue has to be recognised in the guidance as it puts HCW in a very difficult position. A recommendation for further research should be made if there is a lack of evidence.	
SH	Infection Prevention Society	20.60		1.3.4.1	24	Need more info re stoma – PEG/Jej/gastrostomy	Thank you for your comment. This area falls outside the scope of the guideline update. Therefore we could not provide a response.
SH	Infection Prevention Society	20.61		1.4.2.1	25	Include need for gloves too	Thank you for your comment. After careful consideration we have decided that we do not agree. We think this is adequately covered in the Personal Protective Equipment chapter, 1.1.3.3. in the NICE version.
SH	Infection Prevention Society	20.62		1.4.2.2	25	We use sterile (aseptic) technique for site care/dressing change	Thank you for your comment. The current recommendation does state that an aseptic technique must be used, and ANTT™ was given as an example. However we are aware that other aseptic techniques are acceptable. For this guideline the GDG had defined "aseptic technique" as: "An aseptic technique ensures that only uncontaminated equipment and fluids come into contact with susceptible body sites. It should be used during any clinical procedure that bypasses the body's natural defences. Using the

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							principles of asepsis minimises the spread of organisms from one person to another".
SH	Infection Prevention Society	20.63		1.4.3.1	25	In 2003 2% CHX was recommended, has the evidence changed that much that the concentration of CHX can no longer be recommended? I am concerned that managers will put pressure on HCW to use cheaper products with less CHX in if the guidance is not specific. Is there evidence to suggest that products with less than 2% are as safe or effective?	Thank you for your comments. The recommendation in the previous guideline, published in year 2003, did not specify the concentration of chlorhexidine gluconate - it only specified than an alcoholic CHG solution should be used. Therefore, there is no change to the updated recommendation in this respect. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. One study comparing 2% chlorhexidine gluconate in aqueous vs. 0.5% chlorhexidine gluconate in alcohol did not provide any conclusive evidence on whether there were any difference in catheter tip colonisation, septicaemia and bacteraemia cases. There were slightly more cases for patients using 2% chlorhexidine gluconate in aqueous compared to 0.5% chlorhexidine gluconate in alcohol but this was not statistically significant and there was uncertainty as to

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							whether the effect size was potentially clinically significant. Given the lack of comparative clinical evidence the GDG did not wish to prescribe one concentration over another; nor did they wish to be prescriptive about the details of local implementation.
SH	Infection Prevention Society	20.64		1.4.3.2	25	Transparent semipermeable membrane dressing **unless allergy**	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree that the recommendation should be changed. The GDG considered did not wish to be so prescriptive and we think that it should be up to the healthcare professional to decide according to patient needs and preferences.
SH	Infection Prevention Society	20.65		1.4.3.9	27	Products should be licensed for use	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.66		1.4.4.5	27	Is practice of alternating duel lumen weekly for TPN acceptable? For long term use at home, no other drugs given except saline flushes to unused lumen.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.67		1.4.4.6	27	Is there evidence that Hepsal should not be used with implanted ports?	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.68		1.4.4.11	28	Access port decontaminated with alcohol and chlorhexidine solution not alcohol only	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention Society	20.69		1.4.4.12	28	CDC suggest up to 96hrs for giving sets.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Infection Prevention	20.70		1.4.4.	28	Right information but maybe in wrong	Thank you for your comment. After careful

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	Society			15		place	consideration, we came to the conclusion that this is the most appropriate place for this recommendation. This recommendation is from a new question developed in this update and the GDG felt that this was the best place in the guideline.
SH	Infection Prevention Society	20.71		1.4.3.1-1.4.4.15	25 - 28	PICC's may be managed in the community but are placed in acute setting as a CVC where full barrier asepsis is required and following of care bundle. As previous there is conflict with CDC guidance on chlorhexidine use for PVC's here for insertion and maintenance. The evidence base for ANTT is weak	Thank you for your comment. The scope of the guideline is the prevention of infections in the community setting. The GDG agreed that the placement of central lines do not occur in the community and had outlined this in the introduction section (Section 12.4 in the full guideline). Therefore, the procedures for placement of central lines are not included within the scope**.** The recommendation is not in conflict with the CDC guidance. The GDG were aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf). We agree that the ANTT^{TM} evidence base is limited and have only recommended it as an example of an aseptic technique.
SH	Infection Prevention Society	20.72		General comments		Key documents do not seem evident – EPIC2, CDC, EU directives on waste, sharps, NPSA/ WHO on hand hygiene?	Thank you for your comment. The full version of the guideline does refer to these documents. The hand hygiene chapter reviews both CDC and WHO hand hygiene

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							guidance. The chapters on sharps, personal protective equipment and waste disposal detail EU directives on waste and sharps.EPIC2 is referenced when under personal protective equipment. It is not in line with the NICE editorial style guide to reference documents in the NICE version of the guideline
SH	Infection Prevention Society	20.73				What about key drivers and Strategies for infection reduction	Thank you for your comment. The GDG acknowledge that there are national directives on reduction of HCAI, like MRSA and C. Diff., which makes this community infection control and prevention guideline an important one to update and be disseminated.. We think these issues are adequately covered in the introduction of the guideline 'preventing healthcare associated infections remains a key priority in the patient safety agenda', and the GDG considered national priorities and relevance to the NHS when prioritising research recommendations.
SH	Infection Prevention Society	20.74				Training is a principle but not detailed	Thank you for your comment. We think that this is adequately covered in recommendation 1: Everyone involved in providing care should be: educated about the standard principles of infection prevention and control and trained in hand decontamination, the use of personal protective equipment and the safe use and disposal of sharps. [2012]
SH	Infection Prevention Society	20.75				OCCH for staff	Thank you for your comment. This area falls outside the scope of this partial update and therefore we are unable to provide a more

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							specific response. We cannot be prescriptive about the details of local implementation, although we agree that occupational health is an important area.
SH	Infection Prevention Society	20.76				Cleanliness and decontamination of care equipment is not detailed and it also refers to dental practice	Thank you for your comment. This area falls outside the scope of this partial update. It is clearly stated in chapter 2: section 2.5 that decontamination or cleaning of the healthcare environment and equipment (other than the clinical devices listed in 2.4). The dental practice setting is within the remit of the scope of the update.
SH	Infection Prevention Society	20.77				Focus is mainly how to decontaminate hands, IV and urinary catheter care. Was this the intention?	Thank you for your comment. The scope of this partial update is detailed in Appendix A and this document clearly details the focus on decontamination as you describe. Key clinical issues covered include standard infection control precautions (hand hygiene, personal protective equipment and the safe use and disposal of sharps), long-term urinary catheters, percutaneous gastrostomy feeding, vascular access devices and asepsis.
SH	Infection Prevention Society	20.78				The document is sort of procedural but doesn't address all areas	Thank you for your comment. Due to limited resources we were only able to address a limited number of clinical questions. At the start of the guideline development process the GDG listed their priority questions. The scope of this partial update was formally consulted on prior to development and is detailed in Appendix A. Key clinical issues covered include standard infection control precautions (hand hygiene, personal protective equipment and the safe use and

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							disposal of sharps), long-term urinary catheters, percutaneous gastrostomy feeding, vascular access devices and asepsis.
SH	Infection Prevention Society	20.79				Nice to see some of the amendments. I think this makes things much clearer and will be easier for staff to follow	Thank you for your comment.
SH	Infection Prevention Society	20.80	Appendix C	Section 1.1.2.2	13	'in clinical situations where there is potential for the spread of alcohol resistant organisms' – where it mentions Norovirus and organisms that cause diarrhoeal illness as being alcohol resistant, this is not quite correct. Viruses are susceptible to alcohol hand gels, but it does depend on the alcohol content of the formulation. This is discussed in the WHO guidelines- Section 11 'Review of preparations used for hand hygiene' and table I.11.5 – Virucidal activity of antiseptic agents. Rotavirus, a non enveloped virus which has greater resistance to antiseptic agents, is a cause of diarrhoeal illness and is indicated as being susceptible to 60% ethanol. As many alcohol gels have proven efficacy against enveloped and non enveloped viruses, such as those mentioned here, it would be more appropriate to indicate that alcohol	Thank you for your comment. We agree and have removed 'norovirus' from the recommendation. This now reads: Decontaminate hands preferably with a handrub (conforming to current British standards), except in the following circumstances, when liquid soap and water must be used: • when hands are visibly soiled or potentially contaminated with body fluids or • in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as *Clostridium difficile*, or organisms that cause diarrhoeal illness).

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						based handrubs with proven virucidal efficacy can be used against viruses that cause diarrhoeal illnesses.	
SH	Infection Prevention Society	20.81			42	As above, as the appendix is a summary of the changes.	Thank you for your comment. We agree and have removed 'norovirus' from the recommendation.
SH	Infection Prevention Society	20.82	Full	Audience Heading	5	I thought the follow statement was curious '*for which standard infection-control precautions apply in primary and community care.* Surely SICP applies across the board with every patient?	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree. We think it is important to state that the population covered in this guideline is all adults and children receiving healthcare for which standard infection-control precautions apply in primary and community care, and that this level of detail avoids ambiguity.
SH	Infection Prevention Society	20.83	Full	1.1.2.2	13	I would question the statement that Norovirus is an alcohol resistant organism but	Thank you for your comment. We agree and this has been removed from the recommendation.
SH	Infection Prevention Society	20.84	Full	General		I think the review has made positive changes and clarified meaning. It is easy to read and I feel is an improvement	Thank you for your comments.
SH	Infection Prevention Society	20.85	Full	General		Under PPE the wording refers to a "full body" fluid repellent gown-this is not universally used descriptor. The more common one is a long sleeved fluid repellent gown. I would suggest it is also specific about it being a single use disposable gown since there are re-useable washable gowns?	Thank you for your comment. We agree. We have amended the recommendation to include 'long sleeved'. The GDG considered that 'single use' was not necessary and that 'disposable' adequately covered this.
SH	Nottinghamshire Healthcare NHS Trust	21.00	Draft NICE		10/20	The word should requires changing to **MUST** Any catheterisations carried out by	Thank you for your comment

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						healthcare staff must only be carried out using an ANTT. Stated in Evidence based EPIC Guidelines and Essential Steps (DH 2007) etc, and has been evident cause of RCA investigations where a lack of asepsis has been identified as the route cause of the bacteraemia relating to catheters	We think that this wording is appropriate because 'must' can only be used in recommendations where there is legislation or the consequences of not implementing them means that the risk of adverse events (including death) is so severe that the use of must is appropriate (NICE Guidelines Manual [2009]).
SH	Nottinghamshire Healthcare NHS Trust	21.01	Draft NICE	1.1.2	13	Hand Hygiene section does not state that hands require decontamination prior to an aseptic technique as stated in the WHO 5 MOMENTS OF CARE and endorsed by the National Patient Safety Agency	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks".
SH	Nottinghamshire Healthcare NHS Trust	21.02	Draft Nice	1.1.2.3	13	Confusing as this section states that all healthcare workers should be bare below the elbows this means removing all stoned rings and wrist watches which effectively is bare below the elbows. No mention of wedding rings, implies that all rings should be removed however this DH initiative did not actually state this, needs more definition.	Thank you for your comment. Due to limited resources we were only able to address a limited number of clinical questions. At the start of the guideline development process the GDG listed their priority questions, and as such did not review any specific evidence for wearing a plain band. The GDG acknowledged this in the other considerations section (6.5.1.4) for this recommendation in the full guideline: 'The GDG recognise that healthcare workers are either reluctant or cannot remove wedding rings and are aware that some local dress code policies consider that one plain band is acceptable'. The GDG are not able to make a more specific statement in the absence of an evidence review in this

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							area.
SH	Nottinghamshire Healthcare NHS Trust	21.03	Draft	1.1.4	16	The word **MUST** needs to be re inserted there is no negotiation in relation that risks are decreased when staff do not pass sharps from hand to hand. This practice has been outlawed for many years by all NHS trusts and this advice has been advocated by the Health and Safety executive and the RCN and EU legislation. Need to review Safety devices should be used as EU legislation has now been passed RCN to comment in November. We are signed into this legislation and all healthcare Trusts have until 2013 to ensure that Safety engineered devices are available and used by all staff this will not be negotiable. NICE need to review EU legislation .	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We have reviewed the EU Directive (2010/32/EU) introduced in the UK in May 2010 entitled: prevention of sharps injuries in hospitals and the healthcare sector. We have referred to this in the guideline. This Directive does state that the practice of recapping shall be banned with immediate effect, but does not specifically state that passing sharps from hand to hand is a 'must' not, and therefore without legislation we are unable to have this as a 'must'.
SH	Nottinghamshire Healthcare NHS Trust	21.04		1.2.5.5	21	Urine samples must be obtained Would be more appropriate to state ANTT.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as no new evidence was identified since the 2003 guideline. The GDG chose to leave the recommendation as it stands – see section 10.6.
SH	Nottinghamshire Healthcare NHS Trust	21.05	Full		241. 3.3	The administration of feeds section states minimal handling and no-touch technique to connect the administration system to the enteral feeding tube however the Essential Steps to safe clean care (DH 2007) clearly states an aseptic non touch technique this requires clarity thus not to confuse health care professionals.	Thank you for your comment. We agree. We have removed 'no touch' and replaced with 'aseptic'. The term 'aseptic technique' has been defined further in the glossary.

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SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.00	Full	4.1.1	38	Some patients may not feel able to challenge practice. This will depend on the individual and how assertive/confident they feel in challenging healthcare workers.	Thank you for your comment. We agree and have added details regarding the GDG's discussion on this issue to the text on linking evidence to recommendations in this section: The GDG were aware that not all patients may be comfortable in asking health care workers to wash their hands and that they will need encouragement to do so along with education. The review looked at factors which encouraged patients to do so and be more involved in hand decontamination of healthcare workers.
SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.01	Full	4.2.1.2	40	Point 4: is there a particular method of hand decontamination recommended by NICE following removal of gloves? Should this method be stated? The Trust recommends soap and water to remove latex proteins/chemicals is there an update for this?	Thank you for your comment. The GDG have drafted 3 new recommendations regarding hand decontamination. After careful consideration of your comment we have decided not to amend these recommendations. The GDG acknowledged that the preferred option is to use soap and water, but felt it important to reflect in a recommendation that in the community this is not always possible. The GDG feel that the recommendations provide sufficient guidance for hand decontamination.
SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.02	Full	4.2.1.2	40	On point 6 how is the "duration" of clinical work defined? Is this by procedure or shift for example?	Thank you for your comment. The GDG intended this to cover any instance when clinical work was being delivered and have clarified this in the linking evidence section of the full guideline to include a shift as an example of this.
SH	Rotherham, Doncaster and South Humber	22.03	Full	4.2.1.3	41	Is there any guidance recommending the use of vinyl gloves for clinical practice?	Thank you for your comment. No evidence was identified regarding vinyl gloves and the

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	NHS Foundation Trust					Some vinyl gloves are CE marked but previous guidelines have not recommended this type of glove as they are not suitable for use when dealing with blood and body fluids.	GDG chose not to make a consensus recommendation regarding their use. Additional text has been added to the linking evidence section stating that: No evidence was identified for vinyl gloves, but the GDG considered that if they met the relevant CE standards they could be used in clinical settings.
SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.04	Full	4.2.1.4	42	Preference for "must" to be continued as a clear directive and not an option.	Thank you for your comment. We agree and have amended the recommendation to state that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.05	Full	4.2.2.3	44	Informed by Trust Continence Team that all catheters supplied for self intermittent use are disposable and are never re-used.	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness

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							evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Rotherham, Doncaster and South Humber NHS Foundation Trust	22.06	Full	4.2.3.4	47	Point 74: What are the recommendations for patients with jejunostomy tubes for flushing? Since the protective mechanisms of the stomach are bypassed should sterile/cooled bottled water be used?	Thank you for your comment. This area falls outside the scope of the guideline update. Therefore we could not provide a response. Details of your comment are held on file and may be considered as part of the scope of further updates of this guideline.
SH	Royal College of Physicians London	23.00	Full	General	general	The RCP is grateful for the opportunity to comment on this guideline consultation. We would like to make the following comments.	Thank you for your comment.
SH	Royal College of Physicians London	23.01	Full	General	general	These guidelines deal with an important subject given the increasing complexity of interventions in primary care. The primary care environment has its own characteristics which justify a different approach when compared to secondary care. For example, the intimacy of the consultation is important for appropriate management of a wide range of problems (often dealing with patients who would be unwilling to be managed in a secondary care environment). Sometimes patients	Thank you for your comment. The GDG did take equality and diversity into consideration when making recommendations, but felt that separate recommendations were not necessary for patients with cognitive impairment. Decontamination or cleaning of the healthcare environment and equipment is an interesting clinical area, but it is outside of the scope of this update. The scope of this partial update is listed in

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						may have mental problems and familiarity with the staff and environment is a key aspect of healthcare delivery. We feel that this important aspect of primary care is not covered within the guidelines, as stands. The guidelines deal almost exclusively with hand hygiene, handling of sharps, urinary catheters and vascular access devices. The guidance in these areas is well presented and, in the main, irrefutable. However these are not the areas that staff in primary care need assistance with. Our experts would prefer to see some guidance on the suitability of carpets in primary care as well as advice on decontamination (Should stethoscopes be decontaminated? How should a GP deal with decontamination of instruments used for minor surgery?). It would also be helpful to know whether curtains should be changed and, if so, how often. What about disposable curtains? What about soft toys for children. If soft toys are not safe and hard toys are required, how should they be decontaminated? As stands, the guidance covers areas where best practice is very clear but fails to address the more contentious subjects.	appendix A. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update. Your other comments are noted and the detail will be held on file for future reference in relation to any subsequent updates.
SH	Royal College of Physicians London	23.02	Full	8.2.22	97	*'Appropriate safety devices should be used'*. We would suggest changing the	Thank you for your comment. We agree and have amended the recommendation to state

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						word *'should'* to *'must'*. This would bring it into line with the principles of the EU Directive 2010/32/EU. Recapping of needles is banned in all other areas of healthcare except dentistry. There are clinical reasons for continuing this practice within dentistry but in order to protect the healthcare worker and other patients this procedure must only be permissible when a safety device is used - either a safety syringe device or a needle guard. The single handed scoop technique is open to mis-use.	that needles must not be recapped (in dentistry if recapping or disassembly is unavoidable a risk assessment must be undertaken and appropriate safety devices should be used).
SH	Royal College of Physicians London	23.03	Full	8.4.26	108	*'Train and assess all users in the correct use and disposal of sharps'*. We would suggest changing this to; '*Train and assess all users in the correct use and disposal of sharps and sharps safety devices'*. In many instances there are two basic designs of a sharp, the conventional form and the redesigned sharp safe version. In addition, safety devices may not be integrated within the design of the sharp and are therefore not disposed with the sharp. Healthcare workers would therefore require different training in sharps disposal for these fundamentally different designs. Furthermore, concern has been raised in the Guidelines regarding the lack of training in the use of new safety devices. We believe that the suggested change in wording would put due attention on the need to specifically train staff in the use of these devices.	Thank you for your comment. We agree and have amended the recommendation.

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SH	HCAI SURF(service Users in Research Forum)	24.00	NICE	General 1.1.1.1 1.1.1.2 1.1.1.3 1.1.2.1 1.1.2.3	8, 9	In general HCAI SURF welcomes an update to the guidance particularly in relation to educating patients and carers on the benefits of hand hygiene and its importance in breaking the chain of infection. We particularly welcome your use of qualitative data where it is relevant to the recommendation. However data is often from the acute setting or is not always relevant to patients self managing at home and completely lacking for some recommendations. SURF are concerned however that the draft revision does not fully represent outcomes that are important to patients and service users, particularly those of us who have been affected through contracting avoidable infections, we believe there are a range of measures that could be included in this guidance that have been omitted.	Thank you for your comment. Your individual comments have been addressed in your further comments 24.01 to 24.11.
SH	HCAI SURF(service Users in Research Forum)	24.01	Appendix G		215	The hand hygiene recommendation although it contained some qualitative data seeking the views of users it mostly appears to have been from secondary care including those from Burnett, Davies, Duncan, Dunanson. How transferable this is to the community setting is unclear especially in patients' homes or to vulnerable people in care homes. The mother and child study though interesting doesn't focus on patients and or their family	Thank you for your comments. Limited evidence was found in community settings in our systematic review, therefore we looked at other indirect evidence. The protocol for this question outlined that if direct evidence from community settings was not identified, we would look at other settings (for example: acute care, developing countries).The target population outlined in the review protocol included anyone who received/will receive care in community settings. This includes

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			Full			carers/ PA's coping with what could be described as clinical procedures being carried out in the home for example care connected to a catheter or feeding tube. We would welcome a recommendation for further qualitative research to look at how patients, carers and healthcare workers carry out hand hygiene in the patient's home or care home. What are the actual barriers, and how can they be over come?	mothers who care for babies at home (in reference to the mother and child study) and patients who are being discharged from hospital or visitors to hospitals (in response to including studies form acute care settings) (See Appendix E, Section E.1). In response to the applicability and transferability of the findings derived from acute care settings to community settings, we have been explicit in our review by stating that this is an issue and there may be limited applicability. The limitations section of the review summary also lists this (See Table 6, Section 5.2.2.2 of the full guideline). Thank you for your comment regarding future research. We agree that the barriers to hand decontamination is an interesting research question and have made it one of our top 5 Research Recommendations see section 4.1 (also see further details in appendix M (Section M.1.1): "What are the barriers to compliance with standard precautions of infection prevention and control that patients and carers experience in their own homes?"
SH	HCAI SURF(service Users in Research Forum)	24.02	Full		40	We note from the full guidance that the GDG looked at equality issues, including how disabled people with different face difficulties to hand hygiene. The specific issues facing manual wheelchair users need to be addressed both under hand hygiene and urinary catheterisation	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. The GDG felt that recommendation "Educate patients and carers about: • the benefits of effective hand

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			NICE		21	including ISC, both at and away from home. Every time wheelchairs are propelled the user's hands are contaminated. It is important that these equality factors on hand hygiene appear in a recommendation so they appear in the NICE Version. This is particularly important in regards to norovirus, Clostridium difficile, or organisms that cause diarrhoeal illness as normal alcohol hand rubs that many wheelchair users rely on would be ineffective. There is therefore the requirement for research to look at how hand hygiene can effectively carried out by wheelchair users to overcome contamination by bacteria and viruses resistant to alcohol and how difficulties with hand hygiene influence CAUTIS.	decontamination • the correct techniques and timing of hand decontamination • when it is appropriate to use liquid soap and water or handrub • the availability of hand decontamination facilities • their role in maintaining standards of healthcare workers' hand decontamination." adequately covered that patients should be educated in the appropriate technique for their situation and they felt that there were too many variables to this to stipulate individual situations. The GDG believe that the principles outlined in this recommendation were applicable across a broad range of patient experiences.
SH	HCAI SURF(service Users in Research Forum)	24.03	Full	6.8	82	Whilst we recognise the importance of this recommendation for some community settings. There is a clear need for a research question about the best why of carrying out hand hygiene in patients' homes where facilities may differ from excellent to no nearby wash basin, no hot water and no access to a clean towel or very dirty facilities. The recommendation on hand hygiene may be unrealistic in part in practice outside a clinical environment. Experience of patients and the public suggests that liquid soap is a better option than bar soap, as shared bar soaps may harbour bacteria and cause cross infection	Thank you for your comment. Research recommendation 2 does focus on how to clean hands in the absence of running water. In addition the guidance does recommend using liquid soap in section 6.4.1.4. The GDG acknowledge that screening is an important issue, but this is outside the scope of the partial update of this guideline.

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						where patients are immune compromised. This applies to hand hygiene and full body washing. If a person has been screened positive for MRSA we would expect that they would follow appropriate guidance and wash with antibacterial/chlorhexidine soap. NICE guidance should incorporate existing evidence based DH advice on screening and suppression.	
SH	HCAI SURF(service Users in Research Forum)	24.04	Full Appendix G	4,2,1.3	41 251	There seems to be little qualitative evidence on the use of gloves especially related to care homes to see if in practice the recommendation of "*Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient"* actually happens. We would welcome a research recommendation in this area. Observations suggest that in patients' homes often a community nurse will bring in a pair of gloves to use rather than a box .It is vital that any recommendation should be easily transferable to the home setting if that is where care is given. Some service users have also expressed concern that the gloves are aimed purely at protecting the health care worker, not protecting the patient from transferable infections and this should be further explored.	Thank you for your comment. The recommendation you are referring to relates to the 2003 guideline and was not prioritised for update. We agree that a qualitative review of glove use and patient views is an interesting research question but it is outside of the scope of this guideline update.
SH	HCAI SURF(service Users in Research Forum)	24.05	Full		112	RE 29. *Educate patients and carers about the correct handling, storage and disposal of healthcare waste. [new 2012]* There is no mention of how this applies either to waste	Thank you for your comment. We do not wish to be so prescriptive about local implementation and we think that it would be up to the healthcare professional

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						generated by healthcare staff in the patients home, or by patients and or carers self managing their condition. Anecdotal evidence based on patient experience and feedback from around the country has indicated that most waste other than sharps is left for the patient to dispose of. HCW do not take it away, and no advice is usually given	to decide according to patients/carers type and level of waste generated in accordance with local policy.
SH	HCAI SURF(service Users in Research Forum)	24.06	Full	10.1	114	SURF agrees that the burden on patients in dealing with urinary catheters is high. It is vital that this is reflected in all your recommendations related to catheter users. If the burden is too high corners are likely to be cut which may lead to an increase in CAUTIS. There is a need for further qualitative research looking at compliance and incidence of UTI	Thank you for your comment. The GDG did take into consideration patient preference, comfort and quality of life when making recommendations in this section, which are detailed in the linking evidence sections. The GDG have also prioritised research recommendations for types of indwelling catheters and antibiotic prophylaxis for this chapter.
SH	HCAI SURF(service Users in Research Forum)	24.07	Full	10.2	115	SURF agrees everyone involved in catheter management should be educated about infection prevention. It must be consistent. Many people, including children, will manage their own catheters whether indwelling, supra pubic or intermittent & change from one mode of catheterisation to another to cope with travel or change in health: they must be confident and proficient in procedures, aware of the signs and symptoms of urinary tract infection, including those whose symptoms may differ from the usual due to loss of, or heightened sensation related to neurological damage. Research is required to identify and develop the best way of providing education which is	Thank you for your comment. The first three recommendations in the long term urinary catheter chapter are about education of patients, carers and healthcare workers and the GDG acknowledge that this is an important area. Qualitative research regarding intermittent catheters was not prioritised by the GDG as an area of further research. The scope of the guideline with regards to education and training on infection control practices covered a wide range of patient groups receiving care in the community, which includes patient receiving urinary catheters, among others. Due to limited resources we were only able to address a limited number

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						consistent between different modes of catheterisation and empowers the patient..	of clinical questions. At the start of the guideline development process the GDG discussed which areas should be prioritised and listed their priority questions. A qualitative question was asked regarding barriers to hand hygiene, which the GDG considered to be a particularly important area that they required updating and hand hygiene, which is a key element of infection control would benefit all patients in the cared in the community setting. Patient views on urinary catheters were also considered important and a possible area, but it was considered of lower priority as there were already a lot of information for patients in this area.
SH	HCAI SURF(service Users in Research Forum)	24.08	Full	10.6.2	116	Catheter removal is the ideal situation in those who only need catheters for short term use(outside scope) it is vital that HCW distinguish between those where this is possible and people with long term conditions that rely on suprapubic catheters for often lifelong management of bladder dysfunction. Mode of catheterisation however should be reassessed on a regular basis to see if the catheter user may wish to consider ISC or if applicable urinary sheaths for men if incomplete bladder emptying is not an issue. Many HCW think it is easier for the patient not to have to catheterise up to 6 times a day due to their preconceived ideas. Research is needed to explore how decisions are made by both professionals and patients. It appears many	Thank you for your comment. The GDG agree that catheterisation however should be reassessed on a regular basis and have recommended that: The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible. [2003] We also agree that education is vital and as such recommend: Community and primary healthcare workers must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance. [2003] This guideline does include suprapubic catheterisation, which is detailed in section 10.4.1 of the full guideline (how to select the

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						community nurses have not been taught how to teach ISC It is of concern that there is no recommendation encouraging **suprapubic catheterisation** over indwelling urethral catheterisation in those people who are likely to need catheterisation long term to reduce CAUTIS especially as many people have both bladder and bowel dysfunction together. Research is needed to the barriers to SPC for example the need for it to be put in initially by secondary care experts. The guidance omits that ISC can be taught concurrently with an SPC in situ unlike an indwelling urethral catheter, allowing the patient to learn ISC at their own pace. Research is needed to obtain qualitative evidence of how potential ISC users find this approach. Anecdotal and qualitative evidence suggests many people taught ISC feel burdened by the pressure to immediately master ISC after one brief teaching session with a catheter they find difficult to use and in woman failure to find the urethral opening. ISC is simple in theory but not always in practise(Logan K. , Shaw C., Webber C. , Samuel S. & Broom L. (2008) Patients' experiences of learning clean intermittent self-catheterization: a qualitative study.Journal of Advanced Nursing 62(1), 32–40.	right system) and that indwelling catheters include both urethral and suprapubic catheters. However in the review looking at types of indwelling catheters only evidence regarding urethral catheters was identified. A research question has been made in this area. The GDG were unable to make a research recommendation for a qualitative study as a review question for this topic was not prioritised in the guideline.. As stated in the NICE guideline manual 2009: Research recommendations can cover questions about any aspect of the guidance and are designed to address uncertainties that have been identified. As no search was conducted we are unable to state whether this research currently exists or not and are therefore unable to make a research recommendation in this area
SH	HCAI SURF(service Users in Research Forum)	24.09	Full	10.5.14	119	We welcome the recommendation to *" Select the type and gauge of an indwelling urinary catheter based on an assessment of*	Thank you for your comment. The indwelling urinary catheter recommendation was based on GDG consensus as there was insufficient

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						the patient's individual characteristics, including: age any allergy or sensitivity to catheter materials gender history of symptomatic urinary tract infection patient preference and comfort previous catheter history reason for catheterisation. [new 2012]" However we are very concerned that this is not considered equally or more important in ISC, where catheter innovation has increased the range of catheters designed to meet users needs, not clinicians, in non clinical settings and may reduce burden on the patient user. Research is needed to find which design features make catheterisation easier and safer, for example, enabling a simple no touch technique, when used in the home or a public toilet.	evidence to recommend one type of catheter over another. The recommendation regarding intermittent catheters was based on a systematic review of the clinical evidence and an economic model as more evidence was available. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG

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							interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The GDG did not decide to prioritise a research recommendation on design features of catheterisation.
SH	HCAI SURF(service Users in Research Forum)	24.10	NICE Full Appendix J	 10.5.2 10.5.2.5 4.1	9 120 121 44 359-392	We are shocked that there was no apparent qualitative evidence of patients who use ISC when making the recommendation for the multiple uses of non-coated catheters with separate lubricant. The evidence used does not seem to be relevant to the wide range of ISC users with different underlying aetiologies or reflect current UK practice. The number of uncoated catheters on the	Thank you for your comment. The protocol for this clinical question is detailed in appendix E. Due to limited resources we were only able to address a limited number of clinical questions. At the start of the guideline development process the GDG listed their priority questions. Exploration of evidence about specific consideration of patients with faecal leakage

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						Drug Tariff is only 10 % of those for ISC, with the majority of the other 44 catheters being hydrophilic. These are not generic. This guidance previously acknowledges the burden that catheterisation puts on patients yet does not focus on patient preference, ease of use and comfort which , as demonstrated by ISC users' feedback, is likely to affect men and women in different ways and where choice is vital . The guidance does not acknowledge that impairments may play an important part in learning the technique nor the problems faced at home and lifestyle situations. This is required under NICE's Equality Duty. It is known that many ISC users have multiple co-morbidities. Exploration of issues around why people fail to cope with ISC and what might influence infection rates are not reviewed in the development of the guidance, despite the focus being infection control. Data for infection rates in people, subdivided in to men and women who have regular faecal leakage is also not reviewed. The closeness of the female urethra to the source of leakage places them at very high risk. Also not considered is evidence that menopausal/post menopausal woman with thinning urethral tissue can be a high risk group to get UTI. Appendix J notes that trials had serious	was outside the scope of this guideline update. The GDG did consider that compliance is an important factor and have added the following text into the linking evidence section: *'Patient compliance was also identified as important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options.'* With respect to the details of the clinical trials included in the economic model, please refer to Appendix G for detailed clinical evidence tables. The GDG have taken into account patient preferences and additional text has been added the to the linking evidence section: The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review and that recommendation 36 is worded the to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and

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						limitations but major assumptions appear to have been made from them. The tables do not include, patient sex, age or underlying condition or length of time since learning ISC or patient's usual catheter. From the appendix it appears nearly all were males with SCI who only make up small numbers of the total ISC population in the UK the guidance notes the majority of the studies were low quality. Accurate data is required for the number of prescription dispensing fees as the current data is not consistent with monthly repeat prescriptions that most users get. Most people using single use catheters would only generate 12 prescriptions per year for catheters not one for each box of 20-30 catheters, however reuse would normally generate 2 per month (one for catheters and one for lubricant) A far reaching main recommendation appears to have been made based on poor quality cost utility data. The later is fundamentally flawed for using the standard method of calculating the QALY of £50000 for a single use catheter using the 5D-EQ which values the normal well lives of those who cannot walk, need help with personal care such as washing and dressing and have some pain to a negative value(most people with SCI). Any change in value is not likely to change with ISC or UTI as the	cost effectiveness should all be considered when selecting an intermittent catheter. With respect to the calculation of prescription charges, we agree and have updated the model to reflect this. Instead of one prescription charge for each box of catheters and lubricant, the model now includes two charges per month for patients using non coated catheters and one charge per month for patients using coated catheters. As explained in detail in Appendix K, the EQ-5D was *not* used to calculate utility values for people with UTI and UTI-associated infections. In the base case analysis, patient-level SF-12 data from people with spinal cord injuries was mapped to preference-based values using published algorithms and probabilistic calculation methods. Other sources of utility values were explored in sensitivity analysis, including a version of the Short Form questionnaire specifically modified to take into account issues specific to the SCI population. The GDG did consider disability when making this recommendation and intended the first bullet point of to address this (if the patient is unable to wash and dry catheters). Additional text has been added to the linking evidence section of the full guideline to

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						5D-EQ or other HRQoF used do not consider continence. Issues relating to this were raised at a NICE Citizen's Council meeting in Jul 2008. A speaker stated "***none (HRQoL) can capture the full complexity of individual lives. Because they're subjective, QoL scores can change without the person being assessed having experienced any alteration in his or her actual circumstances."*** Research is needed using qualitative data from UK ISC users from a wide range of underlying conditions and impairments to assess patient reported QoL if QALYs are to be calculated Disability related equality issues should also have been considered given NICE's duty to actively promote equality of opportunity, i.e. facilitate participation of disabled people in society. The recommendation fails to acknowledge or look for the underlying risk factors for UTI in men and woman who use ISC. SCI is not the main use in the UK or truly consider the implications and practicalities of reuse and how it could increase UTI in some ISC users. Whilst the recommendation acknowledges there are situations were reuse would be difficult it does not spell this out in the main recommendation. Even this would increase	clarify this: The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]). The implication of the single use symbol is an issue which was raised with our commissioners from the beginning of the guideline development process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). Taking into account all of the stakeholder

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						ISC user burden and NHS resources as most people would need to be taught to use 2 different catheters and to reuse. There is no thought to what happens to teenagers over the age of 16 and adults who have reflux or high pressure bladders or abnormal urinary tracts, or what happens when teenagers turn 17. Are they suddenly expected to reuse? There must be catheter choice both at and away from home for all ISC users. The focus needs to be on facilitating long term self-management and preventing any UTI. SURF members recognise the crossed 2 symbol for single use only of medical devices and are aware of MHRA guidance on this. Experience suggests that patients are likely be totally confused if told to ignore it as the key recommendation suggests. There is no good quality evidence to show that reuse of ISC catheters is safe. The only catheters designed for reuse are metal catheters for woman. Their rigid nature makes then unsuitable for many women and the cost utility model does not consider their use. We would urge reconsideration for this main recommendation which appears to conflict with current evidence based principles of infection prevention.	consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the

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							inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	HCAI SURF(service Users in Research Forum)	24.11	NICE	4.1 General	29	SURF welcomes the vital research question ***Standard principles of infection prevention and control*** ***What are the barriers to compliance with the standard principles of infection prevention and control that patients and carers experience in their own homes?*** SURF would urge you to add and lifestyle situations. There is no guidance given in the draft for the treatment of patients screened positive for MRSA and how to cope with pathogens such as Clostridium difficile in the home environment. Although we are aware that the draft guidance does not cover specific infections we would have expected general recommendations in this area using qualitative data from users. Currently SURF members are aware of many difficulties patients and their carers face in coping in their own home. Feedback from patients and their carers highlights that advice is	Thank you for your comment. Lifestyle situations were not prioritised in the review. Due to limited resources we were only able to address a limited number of clinical questions. At the start of the guideline development process the GDG listed their priority questions. Advice on the diagnosis, treatment or management of specific infections is not included in the scope of this guideline (see appendix A). The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update. As such we are not able to make detailed recommendation in the areas you suggest.

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						often given by healthcare professionals with little thought to the practicalities and capabilities faced particularly in areas such as changing bed linen and laundry. Advice is needed on not sharing personal items such as wash cloths, towels, combs, razors and soaps is an important consideration in the home setting for infection prevention and control. If a member of the household has an infection, is colonised or has continuing care of lines and catheters then we believe this advice is very important.	
SH	Faculty of General Dental Practice & Royal College of Surgeons of England	25.00	Full	8.2.1.1	98	The document states that: "*Used sharps must be discarded immediately into a sharps container conforming to current standards by the person generating the sharps waste*." It would be helpful to identify the person generating the sharps waste in a dental setting as the clinician (i.e. dentist, dental therapist or hygienist), as most sharps injuries in dental surgeries are sustained by dental nurses. (Shah, SM, Merchant, AT and Dosman JA. Percutaneous injuries among dental personnel in Washington State. BMC Public Health, 2006;6:269)	Thank you for your comment. Additional text has been added in the linking evidence section to reflect this.
SH	Faculty of General Dental	25.01					Thank you for your comments.

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	Practice & Royal College of Surgeons of England		Full	General		The sections devoted to hand hygiene and personal protective equipment provide excellent evidence-based advice. The advice within the rest of the document in relation to dental practice is appropriate.	
NICE	Implementation	26.00	NICE	general	general	Implementation support have no comments to make. The guideline is very clear and logical which should help lead to effective implementation.	Thank you for your comment.
SH	Bard Limited	27.00	Infection Control	10.9	General	It is widely acknowledged that there is no impact on either reducing the risk of or treating infections which is all that is mentioned in the title, but the section includes blocking and encrustation which presents a very different problem. This is the incidence of unblocking and dissolving encrustation to avoid the critical issue in avoiding acute retention of urine in a bladder. The recommendations conclude that the healthcare worker should record blockages and plan the catheter change to prior to this event thus avoiding crisis management. What this document fails to include is the patient experience. The issue is confused then by the next statement 10.9.2 changing catheters which states their search identified a higher rate of infection associated with frequent catheter changes.	Thank you for your comment. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient

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						Increasing fluids is not always an option as a lot of patients who require catheters will be frail, fragile and perhaps elderly and what about the medication / mobility that affects calcium deposits etc. While we appreciate that they have to have research based studies etc and they have identified this as an area of further investigation it does not leave the professional within a community setting a lot of options whilst dealing with blocked catheters. It does not take the patients perspective- would you like to have a catheter changed every few / weeks days as it is a most embarrassing / distressing and intimate procedure – doing so more frequently must be considered in the response.	evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.
SH	Johnson & Johnson Medical	28.00	NICE & FULL	1.4.3.2 & General	25 & General	Johnson and Johnson Medical Ltd (J&J) believe the guideline currently overlooks the significant impact Chlorhexidine Impregnated Sponge Dressings (CHG) could have on the reduction of CRBSI's acquired in the community. Moreover, in its current form the proposed guidelines on CVC care represent a missed opportunity to incentivise an internationally recognised standard of care which could considerably improve patient outcomes and reduce the cost burden associated with CRBSI's to the NHS. Contrary to the GDG's view the role and benefits associated with a CHG Impregnated Sponge	Thank you for your comment. Impregnated dressings were included in the protocol, but no evidence was identified in community settings. Studies were identified in intensive care or high dependency units, which the GDG deemed not applicable to the population of this guideline. The paper you identify, Ho et al, reviews studies from intensive care or high dependency units and therefore did not meet our inclusion criteria.

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						dressing are well documented and a significant volume of peer reviewed studies exist which describe the enhanced outcomes which can be provided by this treatment modality versus traditional standards of care, including the methods proposed within the draft. This impact is best described by the meta-analysis conducted by Ho et al[1] which concludes**: *"the current evidence strongly suggests that a chlorhexidine-impregnated dressing is effective in preventing catheter-related bloodstream infections for both plain and antiseptic- or antibiotic-impregnated vascular catheters. A chlorhexidine-impregnated dressing should be routinely used with vascular catheters in adult patients unless it is contraindicated"*** J&J would argue that the methodology applied to the development of the CVC recommendation in this guideline is flawed and the decision to exclude from review studies which have been conducted outside the community setting has led to an inappropriate conclusion. While the body of evidence which exists to support the use of CHG dressings has primarily been captured in the acute setting, to exclude this data from review is perverse given the origin of the majority of causative pathogens related to CRBSI reside. We describe this rationale further below: *A central question important to the pathogenesis and prevention of vascular catheter infections is where do the micro-organisms that cause CRBSI's originate? It has been found that 71% of bacteria found on the tip of (remove 'short-term' if you can) central venous catheters*	

[1] Ho et al. Use of chlorhexidineimpregnated dressing to prevent vascular and epidural catheter colonization and infection: a meta-analysis. Journal of Antimicrobial Chemotherapy Advance Access published 2010

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						genetically match the bacteria found on the insertion device. Thus, these micro-organisms come from the patient's own skin.[2] Without continual suppression, bacteria on the skin surface can repopulate and migrate into the bloodstream, elevating the risk of CRBSI. *There are a number of opportunities for bacterial colonisation, only the first opportunity for such contact is during insertion of the catheter, as it passes through the layers of normally colonised skin. Both transient and resident micro-organisms exist on the surface of the skin. About 80% of resident micro-organisms inhabit the first 5 cell layers of the stratum corneum. The remaining 20% survive in biofilms (colonies of encapsulated bacteria) within the underlying epidermal layers, sebaceous glands, and hair follicles.[3] Any or all of these bacteria may cause an infection at exit sites and coming from the patient's own skin, this can just as likely occur in the community as another setting.* *Biofilms allow the micro-organisms to adhere to any surface, living or nonliving. Microbial biofilms, which often are formed by antimicrobial-resistant organisms, are responsible for 65% of infections treated in the developed world.[4]* *Medical devices known to be associated with biofilm development include central venous catheters, arterial lines, haemodialysis catheters, peritoneal dialysis catheters and enteral feeding tubes.[5] Patients live with all of these at home today.*	

[2] Skin: The First Battlefield Anaesth Analg 2003; 97:933-5 Prielipp, R, Shereretz,R
[3] Catheter-Related Infections: It's All About Biofilm Topics in Advanced Practice Nursing eJournal. 2005;5(3) Marcia A. Ryder, PhD, MS, RN
[4] Bacterial biofilms: a common cause of persistent infections. Science 1999;284:1318-1322. Abstract Costerton JW, Stewart PS, Greenberg EP
5 Catheter-Related Infections: It's All About Biofilm Topics in Advanced Practice Nursing eJournal. 2005;5(3) Marcia A. Ryder, PhD, MS, RN

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						According to the Nosocomial Infection National Surveillance Service, "almost two thirds of bacteraemias of known source were associated with an intravascular device or with device-related infections." Of these, "central IV catheters were the commonest source" with 40% of the isolates were staphylococci[6] *In the community, one-third of the normal population is colonized with the same deadly staphylococci, a leading cause of CRBSI.*[7] *Whilst infection rates have not been studied extensively in the community, pre 48-hour cases make up 42% of the total national MRSA cases.*[8] *The addition of invasive devices in primary care puts the patient at increased risk. Nationally, pre 48 hour MRSA bacteraemia cases make up 43% of the total national MRSA bacteraemia cases and this appears to be increasing.* ***The patients' own skin is a major source of pathogens****, with 60% of Catheter related blood stream infections caused by microflora originating from the patient's own skin*[9]*.* ***Therefore despite the patient setting, maximum precautions must be taken in preventing infection.*** By accepting the principals described above it is logical to accept the setting in which the patient finds themselves becomes less relevant when taking into account that 60% of Bactria is found on the patient's own skin. Any environment, especially those not monitored by HCPs (ie a	

[6] Nosocomial Infection National Surveillance Service. "Surveillance of Hospital-Acquired Bacteraemia" 2002
7 Mayo Clinic
8 Department of Health. Clean Safe Care. "Pre 48hr MRSA Bacteraemia Project – Reducing the Risk"
[9] Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. *Intensive Care Med.* 2004;30:62-67

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						patient in the home), is a dirty setting. As such, J&J firmly believe that evidence gathered outside of the community setting has a highly relevant role to play when assessing the potential impact a CHG impregnated sponge dressing could have on the reduction of CRBSI's in the primary and community setting. If the GDG were to consider the complete body of evidence which exists for CHG impregnated sponge dressings we firmly believe a more appropriate conclusion would be drawn on their effectiveness. In fact this was the case during the development of guidelines by the Centre for Disease Control & Preventions. This globally recognised organisation recommends the use of CHG impregnated sponge dressings as a clinically and cost effective method to reduce CRBSI and document a 1B[10] recommendation for the use of a CHG impregnated sponge dressing as a standard of care. The case for cost effectiveness of CHG is also compelling when all data sources are considered, even when allowance is made for the fact only 60% of pathogens are associated to the patient's own skin. We describe this impact further below: *While the evidence base for CHG has primarily been developed in the hospital setting a number of important conclusions can be drawn on clinical and cost effectiveness in the community. Having a line is a major risk for any type of catheter-related blood stream infection (CRBSI) irrelevant of where the care is provided. It is commonly accepted th****e patients' own skin is a major source of pathogens, with 60% of catheter related blood stream infections***	

[10] Strongly recommended for implementation

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						caused by microflora originating from the patient's own skin[11] rather than the setting in which they find themselves. *Using this pretext, financial analysis can be undertaken using a multiplier effect in terms of further complications including septic thrombosis, infective endocartidis and most significantly, death. Cost effectiveness can be assessed using the current evidence base and aggregated against the 60% of pathogens found on the patient's own skin and, as described in this consultation response, is as likely to occur in the community as in secondary care.* *Decision analytical modelling can provide an insight into the financial benefits of this dressing compared to the current standard therapy in the NHS in terms of costs saved and the number of CRBSI's avoided. According to published literature there is a 76% reduction in the number of CRBSI's due to CHG[12].* *The costs associated with managing a CRBSI is £4300[13].* *Therefore based on modelling results with 200,000 CVC inserted annually, there are a total of 2500 CRBSI's to manage. Applying the 60% multiplier described above, this equates to 1500 unnecessary CRBSI's occurring. This number could be avoidable and analysis shows this figure could be reduced to 360 with CHG Impregnated Sponge Dressings. The costs associated with standard dressing based on these figures would be £14,406,630.00, whereas with CHG Impregnated Sponge Dressings this is*	

[11] Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. *Intensive Care Med.* 2004;30:62-

[12] Timsit J.F., Schwehel C., Bouadma L., Geffroy A., Garrouste-Orgeas M., Pease S. et al., (2009), Chlorhexidine-Impregnated Sponges and Less Frequent dressing Changes for Prevention of Catheter- Related Infections in Critically Ill Adults. American Medical Association, Vol 301, No. 12; pp 1231- 1241.

[13] Morse A. (2009) "Reducing healthcare associated infections in hospitals in England" National Audit office.

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						reduced to, £3,455,355.60 including the costs of CHG and the related complications and infections. *This indicates there is a potential saving of* ***£10,951,274.40*** *which could be allocated to other healthcare facilities benefitting not only the patients but also the healthcare provider.* *(The detailed analysis and decision tree models are available upon request.)* *These figures suggest that unequivocal benefits are provided by the application of a CHG impregnated sponge dressing. It suggests cost-effectiveness in comparison to the current standard therapy adopted by the NHS; and, if utilised on a day-to-day basis can significantly reduce the burden placed on the NHS due to nosocomial infections.* Based on these findings J&J strongly suggest that CHG dressings should form a key part of the guidance given on the management of Vascular Access Devices. In conclusion we would encourage statement 1.4.3.2 to be amended to read: **"Use a sterile transparent semipermeable membrane dressing and Chlorhexidine Impregnated Sponge dressing to cover the vascular access device insertion site."**	
SH	Ophthalmic pharmacy group	29.00	NICE	1.1	General	Due to reduction of beds in secondary care more serious eye infection are being managed in primary care. Patients with these problems are more prone to infections as the integrity of the eye is compromised.	Thank you for your comment which is noted.

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SH	Ophthalmic pharmacy group	29.01	NICE	1.1	General	Ophthalmic pharmacy group fully support the role of NICE in educating and enforcing good hand hygiene of Health care assistants/carers and patients family	Thank you for your comment.
SH	Ophthalmic pharmacy group	29.02	NICE	1.1.	General	Important to ensure HCW or other carers are trained to have a good technique so the tip of eye drop bottle does not become contaminated during instillation. To prevent contamination of eye drops it is important to have single patient use in primary care clinic sessions. Also to store the eye drops correctly and ensure in-use discard dates provided by the manufacturers are adhered to.	Thank you for your comment. This area falls outside the scope of the guideline and therefore we are unable to provide a more specific response.
SH	Ophthalmic pharmacy group	29.03	NICE	1.1.	General	The guidance on in-use expiry dates of eye drops is very old and the evidence base for these recommendations was for devices no longer in use (e.g. amber open top eye drop bottles with separate dropper). Therefore the ophthalmic pharmacy group in partnership with the Royal Pharmaceutical Society are setting up a working party to look at evidence for microbial	Thank you for your comment. This area falls outside the scope of the guideline.

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						contamination of both preserved and preservative free eye drops and medical devices for optical instillation in different clinical settings and developing appropriate evidence based in-use expiry dates	
SH	British Dental Association	30.00	Full	General	General	Infection control requirements for primary care dental settings are now covered by the Code of Practice on the prevention and control of infections, and HTM 01-05 'Decontamination in primary care dental practices'. Reference to HTM 01-05 should be made as it contains detailed guidance for the dental profession on hand hygiene. It discusses 3 levels of hand hygiene (social, hygienic and surgical) which are not explained in the guideline.	Thank you for your comment. We agree. We have added this to the relevant section of the guideline (Section 6.1 of the full guideline): 'The GDG were made aware that current guidance on hand decontamination for the dental profession is detailed in the Department of Health's 'Health Technical Memorandum 01-05: Decontamination in primary care dental practices'(guideline ref id DOH2009A).'
SH	British Dental Association	30.01	Full	8.2	92	Line 2 gives the transmission odds for BBVs and 1 in 319 for positive source of HIV and relates to need for PEP. Reference to the odds of transmission from undetectable viral load source patients should be provided if known. Also, recent EAGA advice on PEP is that this is no longer recommended following an inoculation injury where the source patient has an undetectable HIV load.	Thank you for your comment. This refers to text from the 2003 guideline which cannot be changed unless it is incorrect. Additional text regarding DH guidance on post exposure prophylaxis has been added.
SH	The Urology Trade Association	31.00	Full	10	114-151	The recommendation that patients use non-coated intermittent catheters for multiple-use is a significant change to current practice in the UK and the Urology Trade	Thank you for your comment. We agree that patient lifestyle, clinical need and comfort are important for practitioners to consider when prescribing a catheter for ISC. Stakeholder consultation is coordinated by

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						Association (UTA) is concerned about the implications of this decision especially as infection control is not the only factor on which choice of catheters are prescribed; lifestyle, clinical need and comfort are all factors that should be considered. Because the remit of the consultation is primarily infection prevention and control, the sections on catheters for intermittent use and catheter maintenance solutions may not have been given sufficient prominence to many members of some relevant stakeholder groups, notably continence advisors and urology nurse specialists, and they may therefore not yet be aware of the full extent of the consultation or of its far reaching implications for their patients.	NICE. All registered stakeholders were contacted during the consultation. A list of registered stakeholders can be found at: http://guidance.nice.org.uk/CG/WaveR/85/SHRegistration We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to

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							recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The Urology Trade Association	31.01	Full	10	114-151	There are very few studies available that provide meaningful data about the rate of urinary tract infections (UTIs) arising from the use of different catheters. The current research base is very weak and extracting meaningful data from these is flawed. This is especially related to the fact that trials tend to exaggerate the hygiene aspects associated with preparing catheters for re-use. Trial subjects are taught very thoroughly how to look after themselves and prepare their catheters. However, users will normally frequently need to carry out	Thank you for your comment. The systematic literature review identified six randomised controlled trials with outcomes relevant to our clinical review. This was one of the areas with the greatest number of studies identified for any question included in the update of this guideline. However, the GDG acknowledge that the overall evidence base is low quality and have amended the stem of the recommendation from 'offer' to 'consider'. The limitations of RCTs have been discussed in the methodology section, 3.1.3.8. and the papers were quality assessed in accordance with the NICE

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						catheterisation in life style settings which are very different to a clinical or teaching situation. Outside of this controlled environment, these techniques are at times impossible for users who self-catheterise to reproduce, whether in the home or workplace. There are vastly different approaches to hygiene within the community; conditions in people's homes may not be conducive for the re-use of catheters even if nominally there are adequate facilities to wash and dry multiple-use catheters. These aspects need to be taken into consideration and acknowledged in the guidance.	guidelines manual, 2009. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	The Urology Trade Association	31.02	Full	10	114-151	We are aware of clinical studies on intermittent catheterisation which conclude that use of gel or hydrophilic catheters do reduce instances of urinary tract infection but these do not seem to be referenced in the draft guidelines. We would draw NICE's attention to the following study: *Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention*, Neurourol	Thank you for your comment. The first paper you identify (Chartier-Kastler and Denys, 2011) is a non systematic review and includes a mix of RCTs and observational studies (conference posters and abstracts). Therefore, this paper was excluded from our review. The second paper you identify (Cardenas et al, 2011) was published after the cut off date for our literature search (18th April 2011.). In order to be consistent and systematic in our inclusion criteria we will not consider papers after this date.

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						Urodyn. 2011 Jan;30(1):21-31. doi: 10.1002/nau.20929. Epub 2010 Oct 6. It is also important to note the conclusions of this study on 224 spinal injured patients, *Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicenter trial* PM R. 2011 May;3(5):408-17. This research found that hydrophilic catheters are associated with a delay in the onset of the first antibiotic-treated symptomatic UTI and with a reduction in the incidence of symptomatic UTI in patients with acute SCI during the acute inpatient rehabilitation. The study also found that use of hydrophilic catheters is associated with high levels of patient satisfaction because they are comfortable to use.	It is also not eligible for inclusion in this guideline as it is a study of short term intermittent cathetersiation (less than 28 days of intermittent catheterisation). Even if had been published before the cut-off date, it would have been excluded based on the criteria outlined in the review protocol in appendix E.
SH	The Urology Trade Association	31.03	Full	10	114-151	The UTA would highlight the decision taken by the USA Government to change its policy on mandatory re-use of catheters from 1st April 2008 to allow for reimbursement of 200 sterile single use	Thank you for your comment. The GDG would like to highlight that that the healthcare system in the USA operates very differently from that in the UK. The cost of doctor visits, medications and catheter-associated UTIs in the USA is not applicable to the UK. The economic model presented in

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						catheters per month. In 2007, the Veterans Administration (VA) issued the following recommendations: • Clinicians should follow the manufacturer's instructions for catheter use, which recommend single-use devices should not be re-used in any setting. • Patients should be provided with an adequate number of catheters to allow the use of a sterile catheter for each catheterization. • Clinicians should inform patients, family members, and caregivers that catheters are for single-use only (*Department of Veterans Affairs, 2007; Newman, 2008*). Information from a variety of sources about this decision all points to the conclusion that the costs of doctor visits, medications and catheter-associated UTIs were much more	Appendix J was designed to fully account for the UK-specific costs associated with treating catheter-associated UTIs, quality of life in people with UTI, and the cost associated with the catheters themselves. We also wish to highlight that the decision taken by the VA in 2007 (and subsequently by Medicare and Medicaid in 2008) was not evidence based. As such it did not meet the criteria for inclusion within this guideline. With respect to the single use symbol, this is a query which was raised with our commissioners from the beginning of the guideline development process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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						than the cost of reimbursing for single-use of up to 200 devices per month. The decision was taken due to the rising costs to the Medicare programme from higher risks of UTI. Even though this change has increased costs on the supply side, the overall costs to Medicare are lower with this new structure. Also supporting this, the Food and Drug Administration **(**FDA) has never approved intermittent catheters for reuse, but instead they are approved as single-use-devices, therefore the act of patients using only 4 per month was not an FDA approved practice. The UTA would draw attention to the similar MHRA guidance on re-use of products marked as single use devices according to *Device Bulletin 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse.*	that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The Urology Trade Association	31.04	Full	10	114-151	Whilst the studies in ISC attempt to relate the incidence of UTI to individual products, each individual catheter type is no more likely than another to push bacteria into the bladder. It is the technique and preventative measures employed to reduce the opportunity for contamination that have a material and substantial effect upon the rate of UTIs that are observed. Only single use catheters with the facility for pre-lubrication prior to exposing the catheter for use can ensure consistent, repeatable catheter presentation for the patient. After that it is the patient's technique and personal hygiene that can make a difference to UTI rates. Providing a uniform standard of hygiene control demands a single use product that is independent of additional resources for lubrication.	Thank you for your comment. The question that the GDG asked was designed to determine the most clinically and cost effective type of intermittent catheter for ISC. Based on a systematic review of the evidence, economic modelling, and consideration of the many other factors which are relevant to this question, we have come to the conclusion that what is most likely to be the most effective, cost-effective and appropriate type of intermittent catheter will differ between different people. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.

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SH	The Urology Trade Association	31.05	Full	10.5.2.1	120-129	None of the studies mentioned within the guidance appear to report on the use of pre-gelled catheters. There would seem to be no particular reason for singling out this type of catheter presentation as any better or worse than any other single use product with built in lubrication.	Thank you for your comment. We have chosen to refer to 'pre-gelled' catheters as 'gel reservoir' catheters. The study by Giannantoni et al 2001 included gel reservoir catheters as a comparator (and referred to them as 'prelubricated' within their study). We have amended this term in the glossary to state that it is also known as 'pre-gelled'.
SH	The Urology Trade Association	31.06	Full	10.5.2.3	128	The UTA agrees that compliance and behaviour are important factors for healthcare workers to consider when prescribing an ISC regime. However we do not believe that the studies looking at re-use comment on patient technique of use, or compliance to it, which clearly affects infection control and prevention. Records from our membership show that in practice, a very high percentage of patients give up on self-catheterisation or fail to comply with instructions as to how many times to catheterise when using the product. Compliance is thought to be closely related to ease of use of the product and having to wash and re-use a catheter many times is clearly not as convenient as having a	Thank you for your comment. The GDG thought that a patient's individual needs, circumstances and compliance would be considered by the clinician both at the initial assessment and during routine follow-up. The following section has been added the following text into the linking evidence section: *Patient compliance was also identified as important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options.* Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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						device that is ready and simple to use. Time spent on catheterisation should not lead to it taking over someone's life, nor cause them embarrassment. Having to wash, dry and re-use catheters along with needing to use separate, and often ineffective, lubricant can mean the difference between someone coping with ISC or giving up. The alternative is an indwelling catheter, which is not the optimal treatment option, is proven to increase infection risk and has implications for long term dependence on NHS staff resources. The development and design of urology products which are easy to use and which understand a patient's lifestyle needs, e.g. pre-lubricated or hydrophilic coated single-use catheters, has been a significant advance in product innovation that improves users' quality of life, makes products easier to use and improves compliance.	that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next

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							scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The Urology Trade Association	31.07	Full	10.5.2.5	130	In practice, the recommendation that patients are offered non-coated intermittent catheters would require extremely good and close clinical management and nurse attention. The impact on nursing resources does not appear to have been factored into the cost analysis of this recommendation.	Thank you for your comment. After careful consideration we came to the conclusion that we disagree. The GDG thought that the level of clinical management and nurse attention was determined by individual need and not catheter type. They did not think that patients using non coated catheters would require more nursing attention than patients using coated single use catheters. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	The Urology Trade Association	31.08	Full	10.5.2.5	130	As well as considering the cost implications of multiple-use versus single-use devices, NICE should also give full consideration to the implications of its recommendations on the lives of people who use them.	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline

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						The UTA welcomes the acknowledgement in the draft guidance that there are situations in which it is not appropriate for patients to use multiple-use catheters. However, it would appear that these situations focus primarily on a user's domestic setting rather than recognising that the majority of people who depend on these products lead independent working and social lives which will inevitably lead them to use communal or public facilities on a daily basis which cannot meet the same hygiene levels. The UTA feels that it should be made much clearer within the guidelines that inevitably it will not only be domestic facilities that make it difficult for patients to wash and dry catheters. Often patients will not be able to have access to these facilities and will require single-use devices. This should be taken into account. The draft guidelines should therefore make it clear that a user's lifestyle in terms of their working and social life, and the different requirements users have in each setting, should be given equal consideration by clinicians.	Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. Additional text has been added into the linking evidence section to state that: In drafting the revised recommendation, the GDG noted the following issues of importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.

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						Using inappropriate or less than optimal medical devices for a user's lifestyle and clinical needs has the potential to prevent these patients from self caring and leading independent lives. Single use catheters allow users flexibility to overcome physical or clinical impairments that might prevent full participation in society, employment or education.	
SH	The Urology Trade Association	31.09	Full	10.5.2.5	130	The UTA is unsure whether the mobility and dexterity impairments of the vast majority of users are fully considered in these guidelines. Due to the nature of the conditions which require long term urinary continence management, many users have dexterity and mobility issues. These factors need to be taken into account when considering an ISC regime. Some patients will simply not be able to re-use catheters, wash and dry them, because of their physical impairments. For example, for manual wheelchair users, their hands would become contaminated as	Thank you for your comment. The GDG did take into account mobility and dexterity impairments when making this recommendation. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.

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						soon as they move the chair away from a washbasin. It may not be practicable for some patients to safely and effectively clean catheters for re-use due to these impairments which would have an impact on how they can use products. Many single-use intermittent catheters have been developed over recent years to incorporate features that facilitate a no touch technique to overcome these problems; or they come in/with sterile solution to negate the lack of hand washing facilities in public bathrooms or supply of drinking quality water. Equally, modifications have been brought to market to compensate for the particular needs or impairments of users. These modifications are not simply about infection control but also quality of life and clinical need; the latter we feel have not been properly addressed in this guidance even though the recommendations made would have a significant impact on users' lives. The UTA is concerned that the Government's policy principles, as advocated in the Health White Paper, of "no	Additional text has been added into the linking evidence section to state that: The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003])

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						decision without me" is not given due emphasis in the draft guidelines given that its recommendations are to considerably limit choice of catheters for patients.	
SH	The Urology Trade Association	31.10	Full	10.5.2.5	130	The vast majority of patients who use ISC in the UK use single-use catheters. Given that the recommendations made in the draft guidance would in practice be a considerable change in UK policy, it would affect a significant number of people who already use single-use devices and above all have been taught how to use these safely and effectively to, for example, avoid increasing their chances of contracting an infection. The UTA is concerned about service delivery and what care pathway and products existing ISC patients can expect in the future and whether they would need to be clinically re-evaluated in order to switch products. Clearly this clinical re-evaluation would also entail costs and it is not clear whether this would have been considered in the analysis.	Thank you for your comment. The cost impact of the guideline recommendations are considered separately to cost-effectiveness considerations and have not been included in the analysis. NICE will be publishing implementation tools shortly after the publication of this guideline to support best practice in implementing the guideline recommendations. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments

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							received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	The Urology Trade Association	31.11	Full	10.5.2.5	130	The UTA is concerned that the Government's policy principles, as advocated in the Health White Paper, of "no decision without me" is not given due emphasis in the draft guidelines given that its recommendations are to considerably limit choice of catheters for patients. The recommendation to restrict prescription of single-use catheters will have a significant impact on patient choice. In the urology market, out of 55 approved intermittent catheters, the Drug Tariff only lists 11 types of PVC/latex uncoated catheters, and the majority of these are marked for single-use and carry the MHRA single use only symbol. The UTA feels strongly are inappropriate for multiple-use	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent

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						and would not recommend that patients re-use these products. This is a significant reduction in patient choice on the basis of only one factor, infection control, even though a number of other factors affect catheter selection.	catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The Urology Trade Association	31.12	Full	10.5.2.5	130	We agree with the recommendation that multiple catheters should not be offered for use in children or young people of 16 years or under.	Thank you for your comment.
SH	The Urology Trade Association	31.13	Full	10.5.2.5	131	The UTA is concerned by this section which would seem to advocate that patients should be encouraged to disregard product	Thank you for your comment. With respect to the single use symbol, this is a query which was raised with our commissioners at the beginning of the guideline development

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						safety information such as the "not for re-use" symbol. This would contradict what many patients are taught about product information and packaging which is to recognise the "not for re-use" symbol and would have implications for product safety. It is the UTA's understanding that under the MHRA guidelines *DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse*, the re-use of single-use devices has legal implication for the clinician who administers the device or the clinician who prescribes the device. The UTA understands that a number of PCT prescription formularies clearly note that clinicians assume a legal liability if they prescribe a device marked as single-use with the intention that it is re-used. The UTA does not feel that the legal implications of reusing a single-use device on patients or on prescribing clinicians have been fully considered and we would urge NICE to look again at the implications of this recommendation. The guidelines claim that because manufacturers provide instructions for	process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). They considered that for patients performing intermittent *self* catheterisation in the community, washing and reusing intermittent catheters represents a viable option, providing the other conditions outlined in the recommendation and that the act of recommending the reuse of the single use device to the patient is carried out by a clinician exercising his or her judgement (informed by the guideline). We acknowledge your concerns regarding single use logos. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this

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						cleaning non-coated catheters, this can be taken to imply that manufacturers intend for these products to be used more than once and therefore that the MHRA guidance on re-use of single-use devices do not apply. The UTA would like to make clear that manufacturers include these instructions on the insistence of the Department of Health for listing in the Drug Tariff; to argue that this is because manufacturers intend products to be reused is incorrect. The UTA has sought guidance from the MHRA and been advised that their response to this consultation is under consideration.	recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.

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SH	The Urology Trade Association	31.14	Full	10.5.2.5	131	The UTA would also ask for clarification on the statement in the NICE guidelines on p.131, "*The NHS Drug Tariff states that non-coated catheters can be re-used for up to one week*". The UTA understands that this has been inferred from the statement in Part IX of the Drug Tariff on intermittent catheters, which notes, "*4. 5-units of plastic catheters, for example, represents on average one month's supply for patients practising intermittent catheterisation"*. This does not take into consideration that a product may be marked for single-use as per manufacturers' advice, as explained above. The UTA feels that NICE should revisit this statement in view of this. This statement does also not reflect current prescribing practice.	Thank you for your comment. The statement '*The NHS Drug Tariff states that non-coated catheters can be re-used for up to one week'* is inferred from the statement in Part IX of the Drug Tariff on intermittent catheters, which notes, "*4. 5-units of plastic catheters, for example, represents on average one month's supply for patients practising intermittent catheterisation".* The implication of the single use symbol is an issue which was raised with the NICE legal team from the beginning of the guideline development process. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice. They considered that for patients performing intermittent *self* catheterisation in the community, washing and reusing intermittent catheters represents a viable option, providing the other conditions outlined in the recommendation are met. The cost impact of the guideline recommendations are considered separately to cost-effectiveness considerations and have not been included in the analysis. NICE will be publishing implementation tools shortly after the publication of this guideline to support best practice in implementing the guideline recommendations.

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							Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	The Urology Trade Association	31.15	Full	10.5.3	133	Product innovation is extremely important in the urology sector given the impact that advances in product design specification and technology have on improving quality of life, a user's potential to self-care, facilitate mobility and an independent working or social life. In recent years a number of advances in catheter design have taken the user's needs and how they use the catheters into consideration. This has been significant innovation in product design which differs from the majority of uncoated catheter designs,	Thank you for your comment. We agree that quality of life, independence and ability to self care are important for people performing ISC. The GDG had intended that consideration of a patient's physical condition and abilities should be taken into account during clinical assessment. We do not agree that this recommendation will discourage manufacturers from investing in catheter R & D. The superior efficacy of different catheter's performance needs to be underpinned with high quality comparative clinical evidence and cost-utility analysis. Currently, there is no comparative clinical evidence to suggest that hydrophilic or gel reservoir catheters reduce the incidence of urethral damage or stricture. Please note

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						which are based on Nelaton catheters designed for use only by healthcare professionals. As an example, hydrophilic catheters were developed to reduce urethral friction, thereby minimising trauma and sticking, and making them more acceptable to the patient, and easier and safer to use. The UTA is concerned that a recommendation to limit patient choice in such a way would ignore significant advances in product design, restrict innovation and discourage manufacturers from investing in new technology and products. It is clear that the diffusion of new technology and innovative products in the NHS is a priority for the Government and the Department of Health is presently taking forward a review of uptake and diffusion of innovative medical devices and technology. The UTA is concerned that recommendations such as those included in the draft guidance will prejudice future product development which would aim to improve quality of life and ease of use	that in the absence of evidence, the theoretical possibility of this effect was incorporated into the sensitivity analysis of the economic model and found to have no effect on the result. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of

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						products for patients, especially when infection control is not the only factor as to why a particular catheter or urology product is chosen. Few users will go back to using an uncoated catheter if they have been using single use pre-lubricated or hydrophilic coated catheters, especially if it is these products which match the demands of, and enable, their current quality of life.	the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The Urology Trade Association	31.16	Full	10.8.1.1	136	We agree that the recommendation that patients managing their own catheters, and their carers, must be educated about the need for hand decontamination before and after manipulation of the catheter is sensible and should be included. However, it should be made clear that these techniques should be taught in all lifestyle settings, not simply a clinical or teaching setting.	Thank you for your comment. After careful consideration we came to the conclusion that this does not need to be amended and that the current detail is adequate. We do not wish to be prescriptive about local implementation.
SH	The Urology Trade Association	31.17	Full	10.9.1.4	145	The recommendation that bladder washouts should not be conducted does not leave	Thank you for your comment. After careful consideration we came to the conclusion that the recommendation should revert to

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						health professionals in a community setting many options for dealing with blocked catheters. After infection has occurred and blockages are occurring, acidic bladder washouts can be an important part of an effective management scheme. Regular bladder washouts prevent emergency callouts of community staff and regular anti-biotic use.	the original 2003 recommendation due to the poor quality and quantity of evidence: Bladder instillations or washouts must not be used to prevent catheter-associated infections.
SH	The Urology Trade Association	31.18	Full	10.9.2	146	Increasing fluids is not always an option as a lot of patients who require catheters will be frail, fragile and perhaps elderly. Medication and a patient's mobility, which affect calcium deposits, must also be taken into account.	Thank you for your comment. After careful consideration the GDG decided that this should not be amended. This list is not an extensive list of choices and increasing fluids is given as an example of one option and the GDG considered that it would depend on patient assessment as highlighted in the first bullet point.
SH	The Urology Trade Association	31.19	Appendix J	Appendix J	359-391	The UTA is unsure about the accuracy of NICE's assumptions about prescriptions for catheters. Appendix J contains more than one dispensing fee per month for coated, single-use catheters. However, this does not reflect actual clinical and prescription practice. The majority of users will get a prescription that covers multiple boxes that last for a period of longer than a month. Only one	Thank you for your comment. We agree and have updated the model to reflect this. Instead of one prescription charge for each box of catheters and lubricant, the model now includes two charges per month for patients using noncoated catheters and one charge per month for patients using coated catheters.

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						dispensing fee should have been included. For users using non-coated catheters, with separate lubricant, there would be two prescription charges per month.	
SH	The Urology Trade Association	31.20	Appendix J	Appendix J	359-391	It is not clear from the studies into intermittent catheterisation with plain catheters what type of gel was being used and how it was presented. There is a difference, for example, between a sterile gel presented for single use only and a tube with many applications of gel and therefore the potential to be contaminated accidentally after the first use. The latter is far more easily contaminated and would entail added prescription costs to the NHS and patients if needed to be re-prescribed due to poor presentation and compliance. Full knowledge of the recommended procedure and an extension in the time for response would allow for proper consideration and, if appropriate, the development of a model to better inform the Group about patient quality of life outcomes and the potential for any significant additional costs to the NHS resulting from	Thank you for your comment. The economic model used to inform this recommendation assumed that patients use single use sachets (and that 5% of patients would use lidocaine lubricant as opposed to water-based). Please refer to Appendix J for a full description of the evidence and assumptions used to inform the model.

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						the recommendations.	
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.00	Full	General	General	This is a comprehensive report on prevention of HCAI but sadly continues to be based on very limited evidence throughout, with majority of recommendations based on expert opinion and/or legislation. There is a severe lack of evidence re cost-effectiveness and clinically significant procedures. Recommendations for future research are made and the findings from these will become more critical as healthcare interventions make the transition from secondary to primary care	Thank you for your comment. We agree that the evidence base for this guideline is limited and have, as you state, made detailed research recommendations in areas where evidence is lacking.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.01	Full/NICE	General	General	Algorithm for hand washing that could be laminated and kept in consultation and treatment rooms, patients houses and with healthcare worker would be useful as a simple prompt. Could also incorporate when and how to use gloves.	Thank you for your comment. We agree that these suggestions are a good idea and will pass these suggestions to the implementation team at NICE who will support best practice in implementing the guideline recommendations.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.02	Full/NICE	General	General	Simple single-sided A4 chart explaining waste (including sharp) disposal that could be laminated and kept in consultation and treatment rooms, patients houses and with healthcare worker would be useful as a simple prompt	Thank you for your comment. We agree that these suggestions are a good idea and will pass these suggestions to the implementation team at NICE who will support best practice in implementing the guideline recommendations.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.03	Full	Guideline Development Group Co-optees (2012)	11	Typo in name – should read Professor Mark Wilcox	Thank you for your comment. We agree and this has been amended.

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SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.04	Full	1.1	13 line 9	Could be misleading. Catheters are the most common cause of Healthcare-associated UTI and not all UTI	Thank you for your comment. We agree. We have amended the text accordingly.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.05	Full	1.1	13 line 20	These cost-related data are seriously out-of date, yet keep being churned out	Thank you for your comment. This refers to the National Office of Statistics, 2009 report reducing healthcare associated infections in hospitals in England, which is the latest version of the report.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.06	Full	1.1	14 line ¾	Is it not that the guideline should apply to services commissioned by the NHS rather than the guideline being commissioned for the NHS?	Thank you for your comment. We agree and have amended the text accordingly.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.07	Full	2.5	18 line 18	Why did the group not look at urinary catheter and IV line insertion? These devices are often inserted in primary care settings and are increasingly likely to	Thank you for your comment. We acknowledge that this partial update does include infection prevention guidance on the insertion of intermittent and long term urinary catheters, and peripheral vascular devices, which are conducted in the community, but not the actual instructions for how to do the procedures which is not the focus of this guidance. The GDG also noted that central lines are not inserted in the community.
SH	Department of Health Advisory Committee on	32.08	Full/NICE	4.1	General	Strongly support the principle of 10 priorities for implementation. This will help to focus	Thank you for your comment.

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	Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)					on the key issues	
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.09	Full/NICE	4.1.2	38 line 5-11	This does not fit with the '5 moments' and the step where hand decontamination prior to performing an aseptic task is missing	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks".
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.10	Full	4.1.3	38 line 13-	Should a periodic review for the requirement for continued catheterisation be included?	Thank you for your comment. Periodic review of the need for catheterisation is included under recommendation 34 (from the 2003 guideline): *The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible.*
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.11	Full/NICE	4.1.4	39 line 11	2% Chlorhexidine should be specified for consistency with 'saving lives' and other guidance (accept that the evidence is limited, however mixed messages are not helpful)	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol.

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							It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. While considering these recommendations, the GDG did take into account the current practice and recommendations from other key guidelines. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf) In addition, saving lives references the

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							previous version of this guideline and the GDG did not wish to create circular references.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.12	Full/NICE	4.2.1.2	40 line 4	This does not fit with the '5 moments' and the step where hand decontamination prior to performing an aseptic task is missing	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks".
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.13	Full/NICE	4.2.1.2	40 line 22	No acrylic or bonded nails needs to be added	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as it stands because the GDG considered that 'making sure that fingernails are short, clean and free of nail polish' adequately covers this and the footnote to the recommendation clearly states that "For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand decontamination.".
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection	32.14	Full	4.2.2.3	43 S. 38	Periodic review of the requirement for continued catheterisation	Thank you for your comment. Recommendation 34 from the 2003 guideline states: The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed

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	(ARHAI)						as soon as possible.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.15	Full	4.2.2.5	43 S. 56	When is a catheter bag change clinically indicated? What does this statement mean? Should it not be in line with manufacturers instructions or when leaking, damaged, when catheter changed etc?	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.16	Full/NICE	4.2.2.5	45 S. 58	Antibiotics chosen for prophylaxis should reflect local policies and be based on local sensitivity data	Thank you for your comment. We agree and have stated in the linking evidence section for this recommendation that: The choice of antibiotics has not been specified because resistance patterns could vary based on locality and over time. It is assumed that clinicians will follow local guidance and prescribe an effective antibiotic with the lowest acquisition cost unless otherwise indicated.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.17	Full/NICE	4.2.3.3	46 S. 70	Hand hygiene before breaking the link in a system?	Thank you for your comment. We agree that hand decontamination is an important part of procedures in enteral feeding and have added a sentence to the introduction of the enteral feeding chapter (Section 11.1 of the full guideline). We also agree that the term 'no touch technique' in the recommendation "Use minimal handling and an aseptic no-touch technique to connect the administration system to the enteral feeding tube" may cause some confusion regarding hand decontamination. We have removed 'no touch' and replaced with 'aseptic'. The term 'aseptic technique' has been defined further in the glossary.
SH	Department of Health Advisory Committee on	32.18	Full/NICE	4.2.4.2	47 S. 79	The term ANTT is trademarked (see also p. 164-5,	Thank you for your comment. We acknowledge that ANTT™ is trademarked.

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	Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)						We have only used it as an example of an aseptic technique, not recommended it as the only technique to use. We have added a trademark logo to wherever ANTT™ is mentioned.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.19	Full/NICE	4.2.4.3	47 S. 80	2% Chlorhexidine should be specified for consistency with 'saving lives' and other guidance	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the

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							percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. While considering these recommendations, the GDG did take into account the current practice and recommendations from other key guidelines. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf) In addition, saving lives references the previous version of this guideline and the GDG did not wish to create circular references.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.20	Full/NICE		48 S. 87	2% Chlorhexidine should be specified for consistency with 'saving lives' and other guidance	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol.

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							It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. While considering this recommendations, the GDG did take into account the current practice and recommendations from other key guidelines. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf) In addition, saving lives references the

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							previous version of this guideline and the GDG did not wish to create circular references.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.21	Full/NICE	4.2.4.3	48 S. 89	2% Chlorhexidine should be specified for consistency with 'saving lives' and other guidance	Thank you for your comments. It was the intention of the GDG not to specify the concentration of chlorhexidine gluconate. After careful consideration of stakeholder comments, we came to the conclusion that the recommendation should remain unchanged. The GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine gluconate in alcohol. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. Therefore, the GDG decided not to make a specific recommendation about the percentage of chlorhexidine gluconate in alcohol for the purpose of skin decontamination prior to insertion of peripheral vascular access devices, during dressing changes and decontamination of ports and hubs prior to access. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been

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							made; see section 12.11 of the full guideline. While considering this recommendations, the GDG did take into account the current practice and recommendations from other key guidelines. The GDG were also aware that the latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion (website: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf) In addition, saving lives references the previous version of this guideline and the GDG did not wish to create circular references.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.22	Full/NICE	4.2.4.3	49 S. 103	Agree, but DH did sanction multi-dose vials during the flu pandemic so this needs to be clarified	Thank you for your comment. Outbreak situations such as the flu pandemic are outside the scope of this guidance. Within the scope of this guideline, the GDG considered that for routine use in the community multidose vials are not appropriate. In addition, this recommendation is for vascular access devices, not for subcutaneous or intramuscular administration.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare	32.23	Full/NICE	3.3	58	"intention is an important factor in actually asking hand washing" – what does this mean? (ref 153)	Thank you for your comment. We agree and have amended this to read: Intention to ask healthcare workers about

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	Associated Infection (ARHAI)						handwashing is an important factor in actually asking about hand washing (covariance 0.36, p<0.001)(guideline ref id LUSZCZYNSKA2007)
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.24	Full	3.3	58	First statement doesn't make sense the way the point is structured because of the other points mentioned underneath – either need to take out initial statement or change initial statement to "patients would be more willing…" then bullet points as currently	Thank you for your comment. We agree and this has been amended to read: • Patients would be more willing to ask healthcare workers whether they have washed their hands if they were less anxious about asking hospital staff and had prior hospital admissions[UK](guideline ref id DUNCAN2007A) or had a history of MRSA infection [UK](guideline ref id DUNCAN2007A) ▪ There is a possible relationship between knowledge and asking about hand washing (covariance 0.06) [UK](guideline ref id LUSZCZYNSKA2007) ▪ 57% asked after reading a patient education brochure on hand washing [USA](guideline ref id MCGUCKIN1999)
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.25	Full	5.4	60 Lines 9-11	Statement "majority of HCAI attributable to areas other than acute health provision. Currently no evidence from UK exists in this area…" – so where does initial statement come from? (no ref)	Thank you for your comment. We agree and have amended this to read: Currently, no evidence of surveillance of HCAI in the community from the UK exists.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare	32.26	Full	5.4	60 Lines 12-17	Highlighting need for research very important	Thank you for your comment.

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	Associated Infection (ARHAI)						
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.27	Full	6.3.1.4	69 S 4	This does not fit with the '5 moments' and the step where hand decontamination prior to performing an aseptic task is missing. The guideline should discriminate between bullet 1 and performing an aseptic task and make mention specifically of this	Thank you for your comment. We agree. We intended for the first bullet point "immediately before every episode of direct patient contact or care" to include aseptic tasks. We have amended the text to make the recommendation more explicit, the bullet point now reads "immediately before every episode of direct patient contact or care, including aseptic tasks".
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.28	Full	6.5.5.1	75 line 16	Acrylic/bonded nails should be included	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We are satisfied with the recommendation as it stands because the GDG considered that 'making sure that fingernails are short, clean and free of nail polish' adequately covers this and the footnote to the recommendation clearly states that "For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand decontamination.".
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.29	Full/NICE	6.8	82	No identification of whether hand washes to be prescribed for patients/carers or bought – if to be prescribed could add statement about selected from local formulary	Thank you for your comment. Unfortunately this is outside the scope of this partial update and as such no specific recommendations in this area can be made.

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SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.30	Full	6.8	82	Would an ATP test be useful for hand gel, where organisms are killed and not necessarily removed? A high ATP score could mean little if everything is dead	Thank you for your comment. The GDG do consider this to be a valid outcome, but have also added CFU measurement by swabbing on agar plates as a secondary outcome into the appendices for this research recommendation.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.31	Full	6.8	82	Detergent, disinfectant, antiseptic (soap) – terms not explained in glossary and also could cause confusion as detergent and disinfectant appear only once. Need clarification of what these terms mean.	Thank you for your comment. We agree and have changed the wording of the research recommendation to: "A randomised controlled trial is required to compare hand wipes (**alcohol or antiseptic)**, hand gels and other hand decontamination products that can be used without running water, to determine the most effective way to remove physical dirt in the absence of running water, in order to make a recommendation for their use in real situations."
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.32	Full/NICE	8.2.1.1	99 S. 24	No statement about procedure for waste disposal when waste in patient's home (e.g. sharps containers, clinical waste) – how will this actually be collected for disposal and how frequently?	Thank you for your comment. We do not wish to be so prescriptive about local implementation and we think that it would be up to the healthcare professional to decide according to local policy.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.33	Full		113	What is "non-clinical offensive waste"?	Thank you for your comment. We agree that this does not read clearly and have amended this as follows: 'Most of the waste in the community setting is non-clinical waste, such as packaging, and offensive waste. '
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare	32.34	Full	10.10.4	148 S. 58	Antibiotics chosen for prophylaxis should be included in local policies and be based on local sensitivity data	Thank you for your comment. We agree and have stated in the linking evidence section for this recommendation that: The choice of antibiotics has not been specified because

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	Associated Infection (ARHAI)						resistance patterns could vary based on locality and over time. It is assumed that clinicians will follow local guidance and prescribe an effective antibiotic with the lowest acquisition cost unless otherwise indicated.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.35	Full	10.10.4	148	No advice is provided on the use of maintenance courses of long-term antimicrobial prophylaxis that are in widespread use. Should the guideline development group have considered this?	Thank you for your comment. Use of long-term antimicrobial prophylaxis is outside the scope of this partial update. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.36	Appendix B	B.1	General	The interests of the co-optees have not been included and they were involved in the development of parts of the guideline. They should be included for consistency and transparency	Thank you for your comment. We agree and have added the declarations of interest of the co-optees to the appendix B.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.37	Full/NICE	General	General	"Educate" and "Training" for healthcare workers and family/patient mentioned – who provides this? how frequently? How is learning to be assessed (and should competence be measured). How frequently should updates be given?	Thank you for your comment. The GDG believes this is a local implementation issue. The GDG do not wish to be so prescriptive and think that it would be up to the healthcare professional to decide according to patient needs and preferences regarding education for family/patients.
SH	Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)	32.38	Full/NICE	General	General	What about routine phlebotomy? – is there any evidence for best practice concerning this e.g. glove wearing, using chlorhexidine before puncturing skin?	Thank you for your comment. This area falls outside the scope of the guideline and therefore we are unable to provide a more specific response. We have made specific recommendations on personal protective equipment and sharps, which are discussed in chapters 7 and 8.
SH	Department of Health Advisory Committee on	32.39	Full/NICE	General	General	Is there any issue (e.g. insurance/indemnity) re driving with	Thank you for your comment. This area falls outside the scope of the guideline. Therefore

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	Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)					sharps/clinical waste in car for healthcare worker? (e.g. if accident)  Infection control guideline_covering let	we are unable to provide a more specific response.
SH	Urology User Group Coalition	33.00	Full & NICE	General	General	The Urology User Group Coalition is grateful for the chance to respond to this draft version of the updated NICE guidance on infection control in primary and community care, particularly the recommendations relating to the use of intermittent catheters. Whilst broadly welcoming an update of the 2003 guidance, we are concerned about the impact of the recommendations. In particular we are concerned that the recommendations on intermittent catheters will not prevent infections or reduce variation in care and outcomes. Supporting patient choice in this area will lead to a more efficient use of NHS resources and promote equalities. Inappropriate provision of products can mean that patients reach critical points in the care pathway more quickly, and this guidance is moving in the wrong direction. Due to the potential impact of these proposals on users, the guidance also does not fully comply with NICE's legal duties under the Equality Act and NICE's own	Thank you for your comment. We agree with your first point and have included an additional sensitivity analysis to consider a higher baseline rate of UTI and urethral trauma in non-SCI individuals. The GDG did not think that there was any clinical reason to suspect that the relative efficacy of each type of catheter would differ between different patient groups; please refer to Appendix J for a full description of the evidence and assumptions used to inform the model. The GDG agreed that issues such as high bladder pressure, reflux, or any other condition which increases the risk of UTI would be taken into consideration by the clinician at the assessment stage. The GDG indicated that in most cases indwelling catheters would most likely be selected for this patient group. There is very little data in the literature directly relevant to each of the many conditions and ages ranges of ISC users. Where data was available, the economic model accounted for different baseline rates

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						Equality policy, which includes a duty to promote/advance equality of opportunity between people who share a protected characteristic and those who do not. This is especially important to those covered by Disability Equality legislation. For example, disabled people should be supported to participate more easily in society by promoting innovative devices that are designed for the "patient" user rather than a healthcare professional. This may allow them to no longer be housebound, and allow them to carry out necessary care safely and independently according to standard principles in infection control both at, and away from, home allowing fuller participation in society, employment and education. Patients' impairments and the needs they present must be considered at all stages. It is clear from the document that equality issues were discussed by the GDG in relation to hand hygiene but even these do not recognise difficulties faced by manual wheelchair users. It is vital that the NICE guidance highlights these issues. **Manual Wheelchair Users** We note no guidance is given for manual wheelchair users on hand hygiene and we would hope to see the consultation take account of service users views on this important	of infections and utilities among many different types of non-SCI ISC users in sensitivity analysis (see Appendix J). The gender balance of the model included in the sensitivity analysis (for 'non-SCI populations') was designed to account for this. As the evidence base does subgroup the relative risk of symptomatic UTI by sex, the only input into the model that is affected by gender is all cause mortality. Implementation of recommendations is considered separately from per-patient cost-effectiveness analysis. NICE will be publishing implementation tools shortly after the publication of this guideline to support best practice in implementing the guideline recommendations. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.

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						aspect of infection control, particularly as there is evidence to show that wheelchairs have been shown to be vectors for infection in the hospital environment, and users who are self-caring will need to manipulate their wheelchair whilst carrying out clinical procedures such as catheterisation.	The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Urology User Group Coalition	33.01	NICE & Full	General	General	The UUGC is concerned that no distinction is made between indwelling urethral catheters and suprapubic catheterisation	Thank you for your comment. This guideline does include suprapubic catheterisation, which is detailed in section 10.4.1 of the full

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						(SPC). It is generally thought that SPC is more effective at reducing the incidence of UTIs over the long term. Additionally, many people have combined bladder and bowel dysfunction and there is reduced likelihood of faecal contamination with SPC. The full version of the guidance contains evidence to support the use of SPC over indwelling urethral catheterisation. Many people find suprapubic catheters easier to manage. Indwelling urethral catheters tend to inhibit and lead to the likelihood of increased infections as many people will remove them and reinsert in less than ideal conditions.	guideline (how to select the right system) and that indwelling catheters include both urethral and suprapubic catheters. However in the review looking at types of indwelling catheters, only evidence regarding urethral catheters was identified. A research question has been made in this area.
SH	Urology User Group Coalition	33.02	NICE		9	It should be noted that written information to support communication between healthcare professionals and patients is not accessible to all – therefore it should be specified that information should be provided in other suitable formats where appropriate.	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate because it states that: Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.
SH	Urology User Group Coalition	33.03	NICE		7	We strongly agree that patient preference and choice is needed for indwelling urinary catheters. However, it is vital that that all the criteria listed for catheter selection on	Thank you for your comment. Due to an absence of evidence, the recommendation for the type of indwelling catheter was based on GDG consensus.

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						page 9 are also applied to intermittent catheters including type, gauge and length. Intermittent self catheterisation (ISC) users frequently need to carry out catheterisation in lifestyle settings which are very different to a clinical or teaching situation, including situations out of the home where public toilets may have to be used. The same initial factors as for indwelling catheters influence selection including allergy, size, length, patient preference and choice and factors needed to overcome impairment. Referring to selection of a long-term indwelling catheter, the document states that "*the GDG considered the trade off in time involved in selecting an appropriate catheter and the benefit of increased patient satisfaction. The GDG also considered the risk of infection of choosing an inappropriate catheter balanced against the need for patient comfort and choice. The GDG discussed the clinical and economic evidence, but felt that there was not sufficient evidence to recommend one type of catheter over another. The GDG discussions centred around the key factors that would influence choice of catheter in practice and chose to make a recommendation based on a consensus agreement of these factors, which are discussed under other considerations".*	For a detailed explanation of the evidence and reasoning underpinning the recommendation related to ISC, please refer to section 10.5.2 and Appendix J of the full guideline. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the

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						We are unclear why this applies to indwelling catheters but not intermittent catheters. Patient choice is still vitally important for people who use intermittent catheters, in order to enable them to lead an independent life and remain free from infection, something which has been recognised by the Government as part of the Health and Social Care Bill and the subsequent Future Forum response. Failure to recognise these factors for intermittent catheters is against NICE's key priorities for implementation, including patient choice and equality.	guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Urology User Group Coalition	33.04	Full	2.5	18	Page 18 states the guideline does not cover urinary catheter insertion but page 44 includes it. We suspect page 18 should state initial suprapubic catheter insertion which the NPSA states should only take place in secondary care. However, surely all indwelling/suprapubic catheter insertions by the patient or their carer should also be advised to carry it out by an aseptic technique?	Thank you for your comment. We agree that initial insertion of suprapubic catheters should only take place in secondary care setting. However, the scope of this guideline does not cover advice on the procedures of insertion of urinary catheters (although it does cover catheter maintenance) and therefore this has been amended on page 18.
SH	Urology User Group Coalition	33.05	Full	4.2.2.2	43	Line 30 is outdated. Many people are taught ISC or have an indwelling urethral catheter inserted for the first time in the community, rather than the hospital. The best place to teach ISC is in the patient's home, as this	Thank you for your comment. The GDG did consider individual clinical need and have added an additional bullet point to the recommendation to reflect this:

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						will highlight difficulties such as unsuitable water supply for hydrophilic catheters without sterile solution. Hand decontamination must take account of disability, for example healthcare staff need to consider manual wheelchair users and the difficulties this poses, before they can give appropriate practical advice to reduce infection risk. The sentence in line 34 on removing the catheter as soon as possible is inappropriate to many long term catheter users who have been told they need them for life. It would be more appropriate to just state that the need for catheter use should be regularly reviewed, or to include a note about indications for a more temporary use that need to be checked regularly so that the catheter will be removed when it is no longer clinically needed. The scope unfortunately does not cover short term catheter use.	this is considered clinically appropriate after assessment (see recommendation 1.2.3.1). Additional text has been added to the linking evidence section: The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36: 'Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected' [2003]).The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review and that recommendation 36 is worded the to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when selecting an intermittent catheter.

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							Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders.

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							Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Urology User Group Coalition	33.06	Full	4.2.2.3 Line 39	44	Line 39: As indicated, the UUGC is extremely concerned at the recommendation that patient should be offered non-coated intermittent catheters for multiple use. This would have a huge negative impact on outcomes that are important to people. The individual needs of patients need to be taken into account, along with the potential impact on their ability to lead an independent life. Patients forced into using re-usable catheters will fail to reach critical points in the care pathway more quickly as many will fail to cope with Intermittent self catheterisation (ISC) and need a long term indwelling catheter, which is much more expensive in terms of NHS staff resources and presents an increased likelihood of infection. Single-use intermittent catheters allow individuals to live independently; by	Thank you for your comment. The GDG agrees that individual needs should be taken into account when prescribing a catheter for ISC. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness

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						allowing them to live free from worry about how to wash catheters and allowing them to self manage their condition. Many users have neurological or spinal conditions along with dexterity and mobility difficulties and other co-morbidities such as diabetes or poor vision. Choice of catheter can make the difference between being housebound and leading a fulfilling relatively independent normal life style free of infection. Intermittent catheterisation takes longer than normal micturition. Time spent on catheterisation should not lead to it taking over someone's life, nor cause them pain, loss of dignity or embarrassment. Re-use may increase all of these factors and lead to preventable infection. Having to wash dry and reuse may not seem like much to a non disabled person. However, the fact that patients would have to use separate, messy and sometimes ineffective lubricant to carry out this procedure around 2000 times a year can mean the difference between someone coping with ISC or giving up and ending up with an indwelling catheter. Indwelling catheters have an increased infection risk, and also increase long term dependence on NHS staff resources. The recommendation fails to uphold a number of key principles, including promoting patient choice and promoting	evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The amended linking evidence section now states: In drafting the revised recommendation, the GDG noted the following issues of

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						equalities.	importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36).
SH	Urology User Group Coalition	33.07	Full	4.2.2.3 Line 39	44	Catheter choice is based on many factors not simply prevention of infection. Firstly a patient must be able to use it to actually carry out ISC. It does not matter how cost effective it is, it will be useless in managing bladder dysfunction if either the patient can't use it or it causes urethral trauma, strictures or false passages or vulvodynia. We do not feel that the draft guidance fully	Thank you for your comment. We agree that each patient's ability to self catheterise must be taken into account when prescribing intermittent catheters and have added additional text to the linking evidence section: In drafting the revised recommendation, the GDG noted the following issues of importance:

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						appreciates the impact on the many thousands of people who rely on ISC for life. The greater the friction between the catheter and the urinary tract, the greater the risk that catheterisation will cause injury and bleeding. Several studies show that injuries usually become visible only after some years of, usually, uncoated catheter use. As users often lack a sense of feeling, pain cannot always be relied upon to serve as a warning system for damage or injury or infection. For some others nerve damage leads to being hypersensitive to urethral and bladder pain. Hydrophilic catheters are not generic and coating varies between brands finding the best one to meet individual need takes time. Some people cope better with softer less rigid catheters, others the reverse. Your evidence does not consider these issues which can affect trauma and compliance which in turn affects infection risk. Whilst we recognise re-use of some catheters is an option for a few people who have time and ability to comply with re-use (including a few women who are happy to use silver or stainless steel rigid catheters which are designed for long term re-use), it should not be a main recommendation aimed at preventing catheter related infections or pretending it meets NICE's key criteria. Patients have the right to choice.	The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36). Currently, there is no comparative clinical evidence regarding the incidence of urethral trauma, strictures, false passages or vulvodynia as a result of ISC. Therefore, it is not possible to determine whether one type of intermittent catheter results in fewer complications than another. The potential for different catheters to prevent these types of adverse events was explored in the cost-

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							utility analysis as a sensitivity analysis. This is reported in Appendix J. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.

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							The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Urology User Group Coalition	33.08	Full	4.2.2.3 Line 39	44	It is also worth acknowledging that it is against MHRA policy to reuse devices marked with a single use only mark – most non-coated intermittent catheters carry this symbol (MHRA DB 2006(04). Patients are taught to recognise this symbol on the products they use. Our understanding is that NICE has chosen to ignore this due to the fact that products are supplied into primary care with instructions for cleaning. However, this is a requirement from the Department of Health for inclusion on the Drug Tariff. It does not suggest that catheters should generally be used in this way, and it could undermine the usefulness of this mark if people are taught to ignore this. We have sought further clarification on this	Thank you for your comment. This is a query which was raised with our commissioners from the beginning of the guideline development process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed

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						issue from the MHRA, and expect that they will also be responding to this consultation.	their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Urology User Group Coalition	33.09	Full	4.2.2.3 Line 39	44	As the recommendations acknowledge that reusable catheters will not be suitable for every situation, it is important that alternatives do remain available for those who need them. The recommendation could threaten the	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the

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						viability of up to 80% of intermittent catheters from the UK market for routine use, including some niche products that some people totally rely on to meet their needs and hence allow them to live independently. The guidance does not consider any qualitative evidence from a range of ISC users – only quantitative evidence that is insensitive to individual conditions and infections.	outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed.

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							The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. A qualitative review question was not prioritised by the GDG. Due to limited resources we were only able to address a limited number of clinical questions. However, patient preference and comfort were highlighted by the GDG as key outcomes in our review. The GDG also added additional text regarding patient preference to the linking evidence section and made several changes to the recommendation including adding in a bullet point about assessment, which includes patient preference as a factor.
SH	Urology User Group Coalition	33.10	Full	4.2.2.3 Line 39	44	Other issues which need to be considered when choosing the correct catheter include: • The even higher incidence of UTI in menopausal and post menopausal women who have thinning urethral tissue which is more easily subject to trauma by catheters or the difficulties faced by women coping with menstruation as well as catherisation. • ISC users over the age of 16 who have an abnormal urinary tract,	Thank you for your comment. We agree with your first point and have included an additional sensitivity analysis to consider a higher baseline rate of UTI and urethral trauma in non-SCI individuals. The GDG did not think that there was any clinical reason to suspect that the relative efficacy of each type of catheter would differ between different patient groups; please refer to Appendix J for a full description of the evidence and assumptions used to inform the model.

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						have a high pressure bladder and/or have reflux which increases the risk of any UTI causing kidney damage. • The impairments that people who carry out ISC are likely to have or effect on the ability to catheterise with catheters that are non-coated and have to be reused, e.g. people who fail to master ISC and end up with indwelling catheters. • In the UK women are likely to be the biggest users of ISC as urinary sheaths are not an option as they are for men. • The wide range of conditions and ages of ISC users have not been addressed adequately in the cost analysis. Simply using general UTI data is likely to be making false assumptions. • You have not issued guidance on general UTI in the community Issues of service delivery also need to be considered. Will existing ISC users who are used to single-use catheters now be offered multiple use catheters? This will require increased NHS resources to teach them how to use reusable catheters.	The GDG agreed that issues such as high bladder pressure, reflux, or any other condition which increases the risk of UTI would be taken into consideration by the clinician at the assessment stage. The GDG indicated that in most cases indwelling catheters would most likely be selected for this patient group. There is very little data in the literature directly relevant to each of the many conditions and ages ranges of ISC users. Where data was available, the economic model accounted for different baseline rates of infections and utilities among many different types of non-SCI ISC users in sensitivity analysis (see Appendix J). The gender balance of the model included in the sensitivity analysis (for 'non-SCI populations') was designed to account for this. As the evidence base does subgroup the relative risk of symptomatic UTI by sex, the only input into the model that is affected by gender is all cause mortality. Implementation of recommendations is considered separately from per-patient cost-effectiveness analysis. NICE will be publishing implementation tools shortly after the publication of this guideline to support best practice in implementing the guideline recommendations.

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							Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Urology User Group Coalition	33.11	Full	4.2.2.3 Line 39	44	There is no conclusive evidence available that states reuse is safe (see rates of bacteriuria page 116) or studies which compare this to a no touch technique of catheterisation using hydrophilic catheters that come in or with sterile solution or pre lubricated with gel/glycerine Current evidence on intermittent catheterisation: sterile single-use catheters or clean reused and incidence of UTI Getliffe K et al 2007 J wound Ostomy Continence Nursing 34(3): 289-96). Any intermittent catheter is likely to become immediately contaminated if a user touches the part that enters the urethra. Many of the studies looking at re-use do not comment on patient technique of use or compliance to it. Those that require tap water are easily contaminated. Many adapted bathrooms	Thank you for your comment. The GDG did not consider aseptic or no touch techniques to be relevant for intermittent self catheterisation in a community setting. The study by Getcliffe et al 2007 is a review article and is therefore not included in our review of RCTs. The systematic literature search reported in Section 10.5.2 of this guideline represents the most up to date systematic review and meta-analysis of the effectiveness of different types of intermittent catheters. It is interesting to note that both our review and the article by Getcliffe et al have reached the same conclusion: that although the overall evidence base is of low quality,

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						and most public/business premises are fed from a tank which is not drinking quality water. This is one reason which has led to product development and the fact that at least 18 types of catheter now come "ready to use".	there is no difference in the incidence of UTIs between clean ISC and sterile ISC. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Urology User Group Coalition	33.12	Full	4.2.2.3 Line 39	44	We are aware of clinical studies on intermittent catheterisation which conclude that use of gel, hydrophilic catheters do reduce infections and which do not seem to be referenced in the NICE guidance. We would draw NICE's attention to the following study: *Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention*, Neurourol Urodyn. 2011 Jan;30(1):21-31. doi: 10.1002/nau.20929. Epub 2010 Oct 6. It is also important to note the conclusions of this study on 224 spinal injured patients,	Thank you for your comment. The first paper you identify (Chartier-Kastler and Denys, 2011) is a non systematic review and includes a mix of RCTs and observational studies (conference posters and abstracts). Therefore, this paper was excluded from our review. The second paper you identify (Cardenas et al, 2011) was published after the cut off date for our literature search (18th April 2011.). In order to be consistent and systematic in our inclusion criteria we will not consider papers after this date. It is also not eligible for inclusion in this

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						Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicenter trial PM R. 2011 May;3(5):408-17. This research found that hydrophilic catheters are associated with a delay in the onset of the first antibiotic-treated symptomatic UTI and with a reduction in the incidence of symptomatic UTI in patients with acute SCI during the acute inpatient rehabilitation. The study also found that use of hydrophilic catheters is associated with high levels of patient satisfaction because they are comfortable to use.	guideline as it is a study of short term intermittent catheterisation (less than 28 days of intermittent catheterisation). Even if had been published before the cut-off date, it would have been excluded based on the criteria outlined in the review protocol in appendix E.
SH	Urology User Group Coalition	33.13	Full	4.2.2.3 Line 39	44	The recommendation to use uncoated intermittent catheters is a significant change to current practice in the UK. In recent years most UK patients have been taught using hydrophilic catheters (Patients' experiences of learning clean intermittent self-catheterization: a qualitative study. Logan K et al 2008 Journal of Advanced Nursing 62(1), 32–:40). The note in the Drug Tariff re the use of intermittent catheters, which suggests that 5 units should last for a month, has been virtually unchanged for over a decade and is ignored by most prescribers, due to the fact that it is not suitable for allowing most	Thank you for your comment. The GDG agree that coated catheters are currently the most commonly used type of intermittent catheter in the UK. The purpose of NICE clinical guidelines is to review evidence to inform best practice which does not always reflect current practice. The review question set by the GDG sought to answer the question as to which intermittent catheter was most effective and cost-effective. NICE will be publishing implementation tools shortly after the publication of this Guideline to support best practice in implementing the guideline recommendations. The decision taken by the Veterans

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						users to live independently. In the USA re-use was common until 2008 when Medicare altered its policy "*The Medicare policy for intermittent catheterization recognizes catheters as single-use devices, meaning doctors can prescribe catheters for single use, and users are reimbursed for each covered catheterization. The policy changes will likely reduce UTI (Urinary Tract Infection) risk and make more choices available to people living with incontinence or who have permanent conditions requiring bladder care and management programs. Now clinicians can focus on prescribing the best quality/performing product for their patient, rather than having clinical care decisions impaired by insurance requirements. and users can live better with access to more product choices, fewer hospital or urgent care visits and less exposure to bacteria"*	Administration in 2007 (and later by Medicare and Medicaid in 2008) in the USA was not based on evidence of comparative efficacy. As such, it does not meet the criteria for inclusion within this guideline. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Urology User Group Coalition	33.14	Full	4.2.2.3 Line 40	44	We are in agreement that children should not have to reuse catheters. This should also be applied to adults many of whom have multiple impairments to cope with including preventing deteriorating kidney function. Renal failure used to be a major cause of death of people with spinal cord injury. Many people with neurological and spinal conditions including those with complications of diabetes have incomplete bladder emptying and or high pressure in the bladder which means there is a risk of	Thank you for your comment. The GDG agreed that issues such as high bladder pressure, reflux, or any other condition which increases the risk of UTI would be taken into consideration by the clinician at the assessment stage. The GDG indicated that in most cases indwelling catheters would most likely be selected for this patient group. If patients with these conditions are

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						infected urine refluxing up the ureters to the kidneys. The argument to not reuse catheters in children is valid for many adults. Teenagers do not suddenly stop having a reflux issue but are more likely to rebel against treatment and be non-compliant.	considered suitable for ISC, clinicians should take into account patients' individual clinical situations. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Urology User Group Coalition	33.15	Appendices	Appendix J		We have some real concerns about the costing model used to come up with a QALY of over £50,000 for single use catheters. This is partly due to the way which QALY is usually calculated, which can lead to people with spinal injuries, for example, receiving a negative score for quality of life. The minutes of the July 2008 NICE Citizens council meeting discuss this issue and the flaws in interpretation of quality of life data. Having one or several UTIs is unlikely to change any of the other HRQOL scoring systems used in the studies as they are insensitive to infection or combined bladder	Thank you for your comment. In cost-utility analysis, the primary measure of effectiveness is the incremental difference in quality adjusted life years (QALYs) between treatment arms. Therefore, it is the relative difference in quality of life associated with different health states(rather than the absolute utility value) that is of consequence, This is true as long as the health state utilities are elicited using consistent methods and patient groups. The data sources and methods used to calculate quality of life in people with spinal cord injuries and UTI are explained in detail

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						and bowel dysfunction present in SCI hence the value of quality of life in QALY is unlikely to significantly change. Any change in these studies was likely to be due to other factors in the person's life. There are also other issues to consider in calculating costs. For example, people are also likely to waste more uncoated catheters as they are easy to drop whilst preparing with lubricant. In addition, the studies NICE has included are all on males with spinal cord injuries who seem to have acquired them before adulthood; this does not therefore represent the likely impacts on the full range of users of these products – for example women have a much higher incidence of UTI due to their anatomy.	in Appendix K of the full guideline. As this section shows, the best available evidence was used to calculate utilities associated with UTI and different sources were used to inform sensitivity analysis, including a modified Short Form questionnaire in which the stair climbing question was changed to reflect the mobility limitations of people with SCI. Please note that none of the health state descriptions produce negative utility values. Variability in the number of noncoated catheters used was accounted for in the probabilistic analysis and in sensitivity analysis. The GDG acknowledge that the majority of studies included in the clinical review consist primarily of males with spinal cord injuries. They agree that the mean baseline likelihood of UTI may be different in different patient groups and this is accounted for by the wide confidence interval surrounding the baseline probability of UTI, as well as in sensitivity analysis. However, they see no clinical reason why the relative likelihood of infection associated with the use of different *types* of intermittent catheters per se would differ between patient groups.
SH	Urology User Group Coalition	33.16	Full	4.2.2.5 Line 41	44	It should be clear this applies to Indwelling/suprapubic catheters. This is slightly out of date as some catheters (but not all) come with a glycerine solution.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.

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SH	Urology User Group Coalition	33.17	Full	4.2.2.5 Line 44	44	Whilst we welcome the recommendation for the need for lubricant in reducing urethral trauma in non-coated intermittent catheters, it should be noted that this is messy and less effective than single use pre-lubricated or hydrophilic intermittent catheters.	Thank you for your comment. The recommendation you refer to was originally made in 2003 and as such has been outside of the scope of this update. Please refer to sections 10.5.2 ,Appendix J, and forest plots in Appendix I (section 1.4.1.2) of the full guideline for detailed data regarding the relative efficacy of non coated, gel reservoir and hydrophilic intermittent catheters.
SH	Urology User Group Coalition	33.18	Full	4.2.2.5 Line 45	44	There is no evidence that additional cleaning is needed over and above normal daily washing for people carrying out ISC. In women over cleaning can reduce the body's natural defence against infection and lead to soreness. It should be clear it refers only to indwelling urethral catheterisation.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Urology User Group Coalition	33.19	Full	4.2.2.5 Line 48	44	Bags should be changed when clinically indicated and/or in line with manufacturers' instructions.	Thank you for your comment. This comment relates to the 2003 guideline and it is outside of the scope of this update.
SH	Urology User Group Coalition	33.20	Full	4.2.2.5 Line 50 Line 56	45	In addition, you offer no advice on care of the area around the site of a suprapubic catheter. Specific advice needs to be given to wheelchair users on hand hygiene. We have concerns with the blanket recommendation "do not use bladder instillations or washouts". Some catheter users would rather use catheter instillations before early	Thank you for your comment. The comment about cleaning around the site of the suprapubic catheter relates to the 2003 guideline and it is outside of the scope of this update. The GDG considered wheelchair users and hand hygiene and came to the conclusion that separate advice does not need to be made. Following the stakeholder consultation, the GDG have decided to revert to the original

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						replacement of a catheter, and many self manage. We agree that it may not be cost effective if it fails, but patient choice and ability to self mange comes first if not clinically contraindicated, in line with the principle of 'no decision about me without me'. In addition, people with augmented or neo bladders often require bladder washouts to remove mucus and prevent bladder stone formation and associated infections. We would appreciate clarification on whether you are stating that the latter should no longer be done, and what the evidence there is to support this change of practice. **Case study**: One individual the UUGC spoke in preparation for drafting this response used a condom/leg bag system for bladder drainage for 30 years before failure of the bladder sphincter function led to a urethral catheter being installed. This worked well for three years with routine 12 week catheter changes. Then a period of 6 months with very poor care standards followed, with both very poor hygiene and physical handling standards. Urethral bleeding, urine and general infections and catheter blockages became	2003 recommendation due to the poor quality and quantity of evidence: Bladder instillations or washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.

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						very problematic. This ended in a 12 hour blockage which severely damaged the individual's urology systems. Very good care was then re-established, but is has taken 2 years to re-establish the catheter change routine at 12 weeks. A vital part of this recovery has been the use of acetic acid (solution g) bladder washouts on a regular basis (currently 2 weekly). The washout removes mucus and bladder debris and reinforces the acidic environment vital to prevent the excessive multiplication of Proteus Mirabilis bacteria. The individual drinks at least 3 litres (6 pints) of acidified drinks every day to create an acidic bladder environment, but this needs assistance to be effective. The original 30 year period of good health did not need and, indeed, could have been threatened by unnecessary bladder washouts. However, after infection has occurred and blockages are occurring, acidic bladder washouts can be an important part of an effective management scheme. Regular bladder washouts prevent emergency callouts of community staff and regular anti-biotic use.	
SH	Urology User Group Coalition	33.21	Full	4.2.2.5 Line 59	45	There is no evidence that washing intermittent catheters with water is adequate or safe. There are real difficulties with drying the inside of PVC or latex	Thank you for your comment. Unfortunately, cleaning of intermittent catheters was outside the scope of the partial update of this guideline.

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						catheters, and if the inside of a reused catheter remains damp, this can be a breeding ground for bacteria if contaminated. Given the prevalence of the "no re-use" symbol, prescribers or a willing user who has been fully informed of all risks and benefits and choice of alternative single use catheters need to take on the risk if uncoated catheters are used for multiple use.	
SH	Urology User Group Coalition	33.22				**Case Studies of ISC users** <u>Sarah(wheelchair user)</u> Sarah has a spinal condition and been on ISC for 19 years. Her initial ISC teaching was on uncoated catheters which she had been instructed to wash and reuse. She struggled to learn as her mobility and dexterity difficulties limited hand function and positions that she could use. Catheterisation was painful when the catheters went in and were removed. Reuse was difficult and not endorsed by the manufacturer. During her attempts of catheterisation the catheters often became blocked meaning she had to take another one as changing position, mirror, and jug to catch the urine was not a realistic option. Trying to spread lubricant was messy and ineffective and	Thank you for your comment and the case studies that you have submitted which we read with interest. We have stated in our protocols in appendix E that we only included RCTs for this review question and looked for cohort studies if no evidence was identified. Case studies were not considered as evidence of effectiveness of one type of intermittent catheter compared to another. Patient preference and comfort was a primary outcome for this review. In no instance did we compare the use of ISC to not using ISC.

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						she frequently dropped catheters. UTIs also UTIs resulted from contaminated water from a tank that fed her bathroom taps. This led to depression due to the amount of time spent dealing with the ISC and UTIs, leaving her virtually housebound. Limited mobility and dexterity caused other problems such as being unable to drain directly into a toilet. Attaching a leg drainage bag with a short tube partly overcame this however there were other problems with leakage. Once new hydrophilic catheters in sterile solution became prescribable. This helped overcome the problems and eventually she was able to be prescribed these for use both in out of the home, leading to a transformation in her life, with more independence, less time spent on ISC and fewer UTIs. <u>Ruth (MS sufferer)</u> Ruth was diagnosed with MS 10 years ago. In the past 2 years she has been aware of bladder difficulties with a feeling that her bladder nearly always full and some leakage. A scan showed she was not empting her bladder fully on normal urination.	

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						Her local continence nurse has just taught her ISC using a new product designed for easy use by women, which needs virtually no preparation, and is discreet to carry around. She is very concerns about the draft NICE guidance, particularly as uncoated catheters she have "no reuse" symbols on them. Although she regularly got cystitis before starting ISC she hadn't had an attack for 12months since she started on ISC.	
SH	Coloplast Limted	34.00	Full		10	We are surprised that a consultant urological surgeon is not present on the 2012 panel compared with the 2003 panel in respect of section 10.	Thank you for your comment. We have taken advice from a consultant urological surgeon (chair of the NICE incontinence in neurological disease guideline) during the stakeholder consultation and have added this to the acknowledgements of the full guideline.
SH	Coloplast Limted	34.01	Full	10	114–152	The recommendation for uncoated catheters for multiple use will be a major change to current clinical practice in the UK. Coloplast is concerned about the implications of this recommendation as infection control is not the only factor determining which catheters are prescribed; quality of life (QoL) factors, such as lifestyle – both work and social – clinical need and comfort should all be considered. Also, patients have been trained in the use of disposable catheters and associated hygiene.	Thank you for your comment. The systematic literature review identified six randomised controlled trials with outcomes relevant to our clinical review. This was one of the areas with the greatest number of studies identified for any question included in the update of this guideline. However, the GDG acknowledge that the overall evidence base is low quality and have amended the stem of the recommendation from 'offer' to 'consider'. The limitations of RCTs have been discussed in the methodology section,

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						Only a small number of studies are available that provide meaningful or insightful data about the rate of urinary tract infections (UTIs) arising from the use of different types of catheters. The research base is very limited and extracting meaningful data from clinical studies is difficult, as they often have relatively small numbers of trial subjects. In addition, clinical trials tend to emphasise the hygiene aspects associated with preparing catheters for reuse. Trial subjects are thoroughly schooled in how to look after their own cleanliness and prepare their catheters, and are taught aseptic techniques. Patients, however, will normally frequently need to carry out catheterisation in life style settings, which are very different to a clinical or teaching setting. Outside of this controlled environment, these techniques are often impossible for users who self-catheterise to reproduce, whether in the home or workplace. Examples of this may be an itinerant manual worker with very limited or no washing and other hygiene facilities, or a wheelchair user having to use standard facilities rather than those designed for the disabled acquiring post-washing contamination from the wheels	3.1.3.8. and the papers were quality assessed in accordance with the NICE guidelines manual, 2009. It is recognised in clinical research that there is a distinction between efficacy and effectiveness; this is a limitation to which all clinical studies are subject to and does not in itself limit the applicability or usefulness of this evidence base for the purposes of evidence-based decision making. The uncertainty inherent in trials with small sample sizes was incorporated into the cost-utility analysis using a Bayesian framework and explored through robust sensitivity analysis. We agree that quality of life is an important outcome to any clinical and economic question. As per recommendation 30, the GDG expect that all patients performing ISC would be well trained in the preparation and use of their catheter. None of the trials included in the clinical review used aseptic techniques; we agree that this is not appropriate for patients using ISC in a community setting. The study by Kovindha 2004 is not relevant to this question due to the study design (*not* an RCT) and intervention (not a comparative study and participants in the trial had used the *same* intermittent catheter for an

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						while moving the chair. Approaches to hygiene within the community and workplace show a wide variation; the real environment within people's homes may not be conducive or allow for the reuse of catheters even if nominally there are adequate facilities to wash, dry and adequately store multiple-use catheters. Workplace facilities will vary, but washrooms in public places may impact on hygiene for catheter users. This all needs to be taken into consideration and acknowledged in the guidance. Kovindha *et al* showed that in their study of reusable catheters there was a higher rate of infection compared to the use of disposables in other studies. (Kovindha A, Na Chiang Mai W, Madersbacher H. Reused silicone catheter for clean intermittent catheterization (CIC): is it safe for spinal cord-injured (SCI) men? *Spinal Cord* 2004; **42:** 638—642.)	average of three years). We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.

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							The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Coloplast Limted	34.02	Full	10	114–152	Intermittent catheterisation is becoming the gold standard for the management of bladder-emptying dysfunctions and following surgical interventions. Certain advantages to intermittent catheterisation, including the lower risks of catheter-associated UTI (CAUTI) and associated complications, make it a more desirable and safer option than indwelling catheterisation. Practicing intermittent catheterisation, however, may be difficult for patients with limited dexterity, mobility and vision, although, in these cases, family members and caregivers can be taught the procedure. (Robinson J. Urinary catheterization: Assessing the best options for patients. *Nursing Standard* 2009; **23***:* 40–45.)	Thank you for your comment. The GDG are aware that coated single use catheters are the most commonly prescribed intermittent catheters in the UK. The purpose of NICE clinical guidelines is to review evidence to inform best practice which does not always reflect current practice. The current recommendation was based on a systematic review and cost-effectiveness analysis based on best available comparative clinical evidence. The decision taken by the Veterans Administration in 2007 (and later by Medicare and Medicaid in 2008) in the USA was not based on evidence of comparative efficacy. As such, it does not meet the criteria for inclusion within this guideline.

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						Hydrophilic-coated single-use catheters are currently the first choice for healthcare professionals teaching patients intermittent self-catheterisation (ISC) and patients themselves. This clinical choice has been the main management option within Europe over the past 15–20 years. (European Association of Urology. *Guidelines on Urinary Incontinence.* www.uroweb.org/gls/pdf/16_Urinary_Incontinence%202010.pdf [last accessed 2 September 2011]) Up until five years ago the US operated a multiple-use catheter policy where patients were only reimbursed for one catheter per month. In the past four years, following pressure from patient lobby groups, this practice has been overturned and patients are now reimbursed for up to 200 catheters per month. (NHIC Corp Medicare Services. www.medicarenhic.com/ [last accessed 2 September 2011] Saint S, Meddings J A, Calfee D, Kowalski CP, Krein S L. Catheter-Associated Urinary Tract Infection and the Medicare Rule Changes. Ann Intern Med 2009; **150**: 877–884.)	We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that

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							further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Coloplast Limted	34.03	Full	10	114–152	While the studies in ISC attempt to relate the incidence of UTI to specific products, each individual catheter type is no more likely than any other to mechanically introduce bacteria into the bladder. It is the insertion technique and preventative measures employed that reduce the opportunity for contamination, which has a major effect on the rate of UTIs observed. Only single-use pre-sterilised catheters with pre-lubrication prior to use can ensure consistent and repeatable catheter presentation to the patient. From then on it is the patient's insertion technique and personal hygiene training that can make a notable difference to UTI rates.	Thank you for your comment. This question was designed to determine the most clinically and cost effective type of intermittent catheter for ISC. Based on a systematic review of the evidence, economic modelling, and consideration of the many other factors which are relevant to this question, we came to the conclusion about what is most likely to be the most effective, cost-effective and appropriate type of intermittent catheter will differ between different people. The evidence base indicates that 'uniformly' prescribing single use catheters for all people is not a cost effective use of NHS resources. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their

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						A uniform and consistent standard of hygiene control is only fully satisfied by a single-use catheter that is independent of additional resources for lubrication.	recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	Coloplast Limted	34.04	Full	10.5.2.1	120–129	Compliance is thought to be closely related to the ease of use of the product and any discomfort experienced. (Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med* 2005; **4:** 487–497.) Having to wash and reuse a catheter multiple times is simply not as convenient as having a catheter that is ready and simple to use. Hydrophilic-coated catheters improve health outcomes. Ease of use is, therefore, an important factor that can impact not only on clinical success, but also on personal QoL. Compliance with a regular IC schedule is essential in minimising the risk of urinary tract complications. Maintaining a catheterisation volume of less than 400 ml is associated with reduced risk of bacteriuria.	Thank you for your comment. We agree that quality of life, independence and ability to self care are important for people performing ISC. Additional text has been added to the linking evidence section regarding compliance: Patient compliance was also identified as an important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options. The systematic review undertaken as part of this question did not find any difference in patient satisfaction between different types of intermittent catheters. The study you have cited by Hedlund et al 2001 is not a randomised controlled trial and therefore did not meet the inclusion criteria of the review. The papers by Cardenas et al 2009 and de

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						(Bakke A, Vollset SE. Risk factors for bacteriuria and clinical urinary tract infection in patients treated with clean intermittent catheterization. *J Urol* 1993; **149:** 527–531. Stenballe J, Looms D, Nielsen PN, Tvede M. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: A prospective randomised, participant-blinded, crossover study of three different types of catheters. *Eur Urol* 2005; **48**: 978–983.) Compared with uncoated PVC catheters, traditional hydrophilic-coated catheters provide better patient satisfaction, with patients exhibiting a preference for this type of catheter over the uncoated ones. (Hedlund H, Hjelmås K, Jonsson O, Klarskov P, Talja M. Hydrophilic versus non-coated catheters for intermittent catheterization. *Scand J Urol Nephrol* 2001; **35**: 49–53.) Time spent on the catheterisation procedure should not mean that it takes over someone's life, nor cause them embarrassment. Having to wash, dry, store and reuse catheters along with needing to use separate, and what is quite often ineffective, lubricant can make the difference between a patient coping with	Ridder et al 2005 were included as part of the systematic clinical review and therefore formed part of the evidence base informing this recommendation. Please refer to section 10.5.1, Appendix I, and Appendix J of the full guideline. Neither haematuria nor bacteraemia were considered relevant clinical outcomes by the GDG for this question. The abstract/conference poster by Cardenas et al has now been published (Cardenas et al 2011). However, it was published after the cut off date for our literature search (18th April 2011.). In order to be consistent and systematic in our inclusion criteria we will not consider papers after this date. It is also not eligible for inclusion in this guideline as it is a study of short term intermittent cathetersiation (less than 28 days of intermittent catheterisation). Therefore, even if had been published before the cut-off date, it would have been excluded based on the criteria outlined in the review protocol in appendix E. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given

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						ISC or becoming non-compliant. The alternative is an indwelling catheter, which is not the optimal treatment. Hydrophilic-coated catheters perform better than uncoated catheters with regard to haematuria and preference. (Stenballe J, Looms D, Nielsen PN, Tvede M. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: A prospective randomised, participant-blinded, crossover study of three different types of catheters. *Eur Urol* 2005; **48**: 978–983.) Hydrophilic catheter use was associated with reduced numbers of treated UTIs compared with standard non-hydrophilic catheters. (Cardenas DD, Hoffman JM. Hydrophilic catheters versus non-coated catheters for reducing the incidence of urinary tract infections: A randomized controlled trial. *Arch Phys Med Rehabil* 2009; **90:** 1668–1671.) The use of SpeediCath, a ready-to-use hydrophilic-coated intermittent catheter delays the onset of the first UTI. It reduces the number of UTIs compared with the uncoated catheter. Using ready-to-use hydrophilic-coated catheters could minimise	the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed.

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						UTI-related complications, treatment costs and rehabilitation delays in acutely injured spinal cord injury patients. (Cardenas D, Moore K, Dannels-McClure A *et al.* Intermittent catheterization with hydrophilic-coated catheters delays the onset of urinary tract infection in patients with acute spinal cord injury: an international, multicenter, randomized control trial. ICS-IUAG Annual Meeting. Toronto, 2010.) The use of a hydrophilic-coated catheter is associated with a beneficial effect on the incidence of symptomatic UTIs. Significantly fewer patients using the SpeediCath ready-to-use hydrophilic-coated catheter experienced UTIs compared with those using uncoated polyvinyl chloride (PVC) catheters. Overall, twice as many patients using the SpeediCath ready-to-use hydrophilic-coated catheter were free of UTIs compared with uncoated catheters during the one-year study period. (De Ridder DJ, Everaet K, Fernandez LG *et al*. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol 2005*; **48:** 991–995.)	The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.

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						Using hydrophilic-coated catheters for clean intermittent catheterisation (CIC) may result in lower rates of bacteriuria, although there was a lack of prospective, randomised, long-term multicentre studies to fully support this at the time. (Hedlund H, Hjelmås K, Jonsson O, Klarskov P, Talja M. Hydrophilic versus non-coated catheters for intermittent catheterization. *Scand J Urol Nephrol* 2001; **35**: 49–53.)	
SH	Coloplast Limted	34.05	Full	10.5.2.5	130	The recommendations begin with a focus on the patient having no manual dexterity to wash the reusable catheters. This is eminently sensible and they should be allowed a single-use, disposable catheter. It goes on to recommend a single-use catheter if there are no facilities available for the patient to wash, dry and store multiple-use catheters. It does not mention that some patients will be unable to access existing washing facilities, because of mobility problems, for example. The recommendation of single-use catheters if administered by a healthcare professional or close family member as opposed to the patient is laudable. It should also be noted that many patients will have a life outside of the home, notably	Thank you for your comment. It was not the intention of the GDG that the word 'ability' should be restricted to physical ability, nor was the 'availability' of facilities intended to be limited to the physical presence of facilities in a patient's environment. The GDG recognise that there are many types of abilities/disabilities and many factors which may influence availability. The GDG considered it impossible to explicitly outline every possible situation which could conceivably arise for every single individual using ISC. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group

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						for work or some form of socialisation. This will require patients to self-catheterise in washroom facilities frequented by other members of the public. Under these conditions it is questionable whether the level of hygiene that can be attained will match that of the domestic environment. Wheelchair users will also contaminate their hands after washing when manoeuvring their chair in some limited facilities. A single-use catheter would be desirable under such conditions, rather than a reusable catheter. The Scottish Intercollegiate Guidelines Network (2004) sections 2.1 and 2.1.1 stress how important the quality of life is for ISC patients. Adverse effects are: social isolation, loneliness and sadness, psychological effects such as depression, embarrassment with acts of daily living, stigmatisation, effects on sexual relations and disturbed sleep. (Scottish Intercollegiate Guidelines Network. *Management of urinary incontinence in primary care. A national clinical guideline.* www.sign.ac.uk/pdf/sign79.pdf [last accessed 2 September 2011]) Logan *et al* have shown that in conjunction with a nurse's skills for teaching clean intermittent self-catheterisation (CISC), a	(GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the

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						friendly and relaxed atmosphere alleviated embarrassment and anxiety, thus facilitating information exchange and retention of information. Anecdotal evidence from discussion with continence advisors suggests that people experience practical and technical difficulties, such as positioning themselves to perform CISC, travelling and using public toilets. To date, the user perspective on learning and performing CISC has not been studied. (Logan K, Shaw C, Webber I, Samuel S, Broome L. Patients' experiences of learning clean intermittent self-catheterization: a qualitative study. *J Adv Nurse* 2008; **62;** 32–40.) We feel that QoL issues as described above should have a higher prominence in the guidelines, together with their significance for patients and methods for addressing them. There are strong arguments that intermittent catheterisation is a safe and efficacious method to treat neurogenic bladder dysfunction due to a spinal cord lesion. Complications can occur, of which UTI is the most frequent and significant. Factors that help to prevent UTIs included the use of aseptic techniques, patient education and complete emptying of the bladder to avoid residual urine. The use of	re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The guideline already makes recommendations about the training and education of patients and healthcare workers regarding insertion of catheters (see recommendations 30, 31 and 32) which the GDG feel sufficient to address the comments you make regarding teaching ISC.

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						hydrophilic-coated catheters is also thought to lower the rate of complications. (Wyndaele JJ. Complications of intermittent catheterisation: their prevention and treatment. *Spinal Cord* 2002; **40**: 536–541.)	
SH	Coloplast Limted	34.06	Full	10.5.2.5	130	Coloplast urges NICE to consider the overall physical condition of patients who have to use intermittent catheterisation. They are usually physically impaired and many may have manual dexterity problems. This perhaps needs to be further examined and considered. The vast majority of patients who carry out ISC in the UK do so with single-use catheters. Given that the recommendations made in the draft guidance would, in practice, be a considerable change in UK policy, it would affect a significant number of people who already use single-use catheters. They have been specifically trained in their safe and effective use to, for example, avoid increasing their chances of contracting an infection. Also, patients with multiple sclerosis, spina bifida, spinal cord injury and hydrocephalus patients, all high risk, may also suffer memory loss incidents. As such, they should not be switched to multiple-use catheters, which require relatively complex procedures to clean and prepare. (Jensen MP, Kuehn CM, Amtmann D,	Thank you for your comment. Thank you for your comment. We acknowledge your concerns regarding and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of

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						Cardenas DD. Symptom burden in persons with spinal cord injury. *Arch Phys Med Rehab* 2007; **88:** 638–645. National Institute of Neurological Disorders and Stroke. *Hydrocephalus Fact Sheet.* www.ninds.nih.gov/disorders/hydrocephalus/detail_hydrocephalus.htm [last accessed 2 September 2011]) Spinal cord injury patients present a variety of challenges dependent on where the lesion is along the cord. It is possible that if such a patient develops a UTI they could go on to develop autonomic dysreflexure because of the pain. This is a serious condition related to a significant rise in blood pressure causing a hypertensive emergency, which may lead to cardiovascular damage. The use of catheters that have been shown to reduce the frequency of UTIs will be beneficial in such patients. (Vallès M, Benito J, Portell E, Vidal J. Cerebral hemorrhage due to autonomic dysreflexia in a spinal cord injury patient. *Spinal Cord* 2005; **43:** 738–740.)	non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. The GDG did not consider whether it was more effective to catheterise or not to catheterise a patient in whom catheterisation was indicated. We are therefore uncertain as to the meaning of your comment and the relevance of the paper by Valles 2005. The paper by Vapneck 2003 was included as part of the systematic clinical review and therefore formed part of the evidence base informing this recommendation. Please refer to section 10.5.1 and Appendix J of the full

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						Use of the hydrophilic catheter by ISC patients is associated with less haematuria and a significant decrease in the incidence of UTI. (Vapnek JM, Maynard FM, Kim J. A prospective randomized trial of the Lofric hydrophilic-coated catheter versus conventional plastic catheter for clean intermittent catheterisation. *J Urol* 2003; **169:** 994–998.) The recent government white paper *Equity and excellence: Liberating the NHS* advocates putting patients at the heart of the NHS and focusing on those things that really matter to patients, the outcome of their healthcare. 'No decision about me without me' can be found on page 13. It is felt that not enough emphasis has been given in this guidance regarding discussing the merits and demerits of the recommended changes with the patients themselves and the implications of any changes to their overall QoL. (Department of Health. *Equity and excellence: Liberating the NHS.* www.dh.gov.uk/prod_consum_dh/groups/dh	guideline.

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						_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf [last accessed 2 September 2011])	
SH	Coloplast Limted	34.07	Full	10.5.2.5	131	Coloplast notes with confidence that the Medicines and Healthcare products Regulatory Agency (MHRA) interpretation of the single-use symbol is adhered to in all healthcare settings or where care is given by healthcare professionals. With respect to manufacturers including washing/cleaning instructions with certain non-coated types of catheter, we wish to point out that this information is supplied at the behest of the Department of Health/Drug Tariff. Therefore, to argue that manufacturers intend the product to be reused is erroneous.	Thank you for your comment. The implication of the single use symbol is an issue which was raised with our commissioners from the beginning of the guideline development process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). They considered that for patients performing intermittent *self* catheterisation in the community, washing and reusing intermittent catheters represents a viable option, providing the other conditions outlined in the recommendation are met and clinicians are exercising their judgement (informed by the recommendation). Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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							that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Coloplast Limted	34.08	Full	10.5.2.5	131	"The NHS Drug Tariff states that non-coated catheters can be reused for up to one week." Is this stated explicitly or is it inferred? The Drug Tariff does state whether a specific catheter is reusable, for example, silver female reusable catheter. The MHRA states: A device designated for 'single use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient. The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk. The reuse of single-use devices has legal implications. (Medicines and Healthcare products Regulatory Agency. *DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse* www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2024995 [last	Thank you for your comment. The statement '*The NHS Drug Tariff states that non-coated catheters can be re-used for up to one week'* is inferred from the statement in Part IX of the Drug Tariff on intermittent catheters, which notes, "*4. 5-units of plastic catheters, for example, represents on average one month's supply for patients practising intermittent catheterisation".* For patients reusing non coated catheters for themselves, the GDG disagree that this would negatively affect safety, performance or effectiveness. Please refer to section 10.5.1 and Appendix J of the full guideline for a detailed explanation of the clinical evidence and reasoning behind this recommendation. The implication of the single use symbol is an issue which was raised with our commissioners from the beginning of the guideline development process who sought advice from their legal team. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used

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						accessed 2 September 2011]) Coloplast urges NICE to fully explore any legal implications in recommending a single-use product for reuse with the MHRA. Eucomed has stated that France, Spain, Portugal and Italy have banned the reuse of single-use devices. Mention is made of the MHRA warning against the reuse of single-use medical devices. (Eucomed. *Eucomed White Paper on the reuse of single use devices.* www.eucomed.org/uploads/Press%20Releases/Eucomed%20White%20Paper%20on%20the%20reuse%20of%20single-use%20devices.pdf [last accessed 2 September 2011] Eucomed Medical Technology. *Reuse of single-use devices.* www.eucomed.org/key-themes/patients-safety/reuse-of-single-use-devices [last accessed 2 September 2011])	in the appropriate clinical setting by a clinician exercising his or her judgement (informed by the guideline). They considered that for patients performing intermittent *self* catheterisation in the community, washing and reusing intermittent catheters represents a viable option, providing the other conditions outlined in the recommendation are met and clinicians are exercising their judgement (informed by this guideline). Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent

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							catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	Coloplast Limted	34.09	Full	10.5.2.5	132	Coloplast agrees with the recommendation not to offer multiple-use catheters for use in children or young people of 16 years or under. However, the implication in the text is that although there is only a single clinical trial, UTIs in childhood may cause kidney malfunction, with consequences in later life. It is implied that single-use catheters,	Thank you for your comment. Please refer to the results of the systematic clinical review in section 10.5.1 and forest plots in Appendix I of the full guideline for a full description of the relative risk of infection associated with each type of intermittent catheter. Please also see Appendix J for a full explanation of the evidence, assumptions and Bayesian methods used to inform this recommendation.

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						therefore, reduce the likelihood of UTIs. If this is the case for children, then surely it is true for adults, in that a single-use catheter will result in a reduced incidence of UTIs? As point 7 explains, many adults using self-catheterisation have spinal cord injury, spina bifida or multiple sclerosis, or have had hydrocephalus. Therefore, they should surely be using single-use catheters, as a UTI can, as described in point 7, cause complications, with mortality as a result.	In summary, gel reservoir and hydrophilic catheters have been found to result in non-significantly reduced incidence of UTIs. In adults, many different data sources were identified and used to inform the cost of UTIs, risk of more UTI-associated infections and death, and quality of life in UTI. These data were incorportated into a model. Compared to non coated multiple use catheters, the results of the model show that we are 99.6% confident that single use catheters do not represent a cost effective option for ISC. In children, similar data about the risks, quality of life and costs of UTI do not exist. Therefore, it was not possible to evaluate the cost-effectiveness of these catheters in this population. The GDG decided to employ a precautionary principle when recommending these catheters. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation

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							to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	Coloplast Limted	34.10	Full	10.5.3	133	The concern here is that a limitation on the type of catheter a patient can choose to use will adversely affect their QoL. Once again this takes us back to the government white paper *Equality and excellence: Liberating the NHS*, which advocates putting patients at the heart of the NHS and focusing on those things that really matter to patients, the outcome of their healthcare. Modern catheters are sophisticated and innovative devices. We feel that recommendations as to which catheter to recommend should feature a greater patient involvement in the final choice and should	Thank you for your comment. We agree that quality of life, independence and ability to self care are important for people performing ISC. The GDG had intended that consideration of a patient's needs, circumstances and abilities should be taken into account during clinical assessment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group (GDG) has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided

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						also factor in the NHS quality, innovation, productivity and prevention (QIPP) agenda, involving the topics of innovation, quality and prevention. As several papers cited above show, hydrophilic-coated catheters reduce the number of UTIs experienced by patients compared with uncoated multiple-use catheters.	that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	UK Clinical Pharmacy Association (UKCPA)	35.00				UKCPA have no comments to make on this consultation.	Thank you.
SH	CareFusion	36.00	Full	12.4	165	**Quality of evidence:** Three randomized, controlled trials were cited in the evaluation of antiseptic solutions for the insertion of peripheral vascular access devices (VADs). Based on these studies, the guidelines continue to recommend chlorhexidine in alcohol for skin antisepsis prior to peripheral VAD insertion; however, no recommendation regarding the concentration of chlorhexidine is made. Two studies are cited that support the use of chlorhexidine gluconate (CHG) in alcohol. Cobbett & LeBlanc, 1999, found a lower catheter tip colonization rate and decreased symptoms of pain and redness after IV discontinuation in patients prepped with 0.5% CHG swabs, compared to those prepped with povidone-iodine (PI) and isopropyl alcohol (IPA). Small et al, 2008, found that the use of 2% CHG in IPA reduced catheter tip colonization compared to IPA alone. Because no recommendation of chlorhexidine concentration is made, it appears that these studies were viewed by the guideline development committee as being equal. However, the Cobbett & LeBlanc study was published in a non-	Thank you for your comments. The evidence review was conducted as detailed in section 3.13 in the full guideline. Relevant studies found in our search process would be included in the review. The Cobbett and le Blanc study was published in a peer reviewed journal indexed in CINAHL database. The full copy of the article can be obtained from the standard document order of journals from the British Library. For the guideline review process, the quality of evidence was evaluated by outcome, as recommended in the GRADE process. This took into consideration the limitations posed by the study design and conduct, the applicability of the evidence to the recommendation, inconsistency of evidence, risk of publication bias and precision of the estimate of effect. When making the recommendation, the GDG had taken into consideration that there is a lack of evidence and direct comparisons of different concentrations of chlorhexidine

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						indexed, non-peer-reviewed journal and is not readily available to readers of the guideline who might wish to evaluate the evidence first-hand. In fact, the only published report of this study that we were able to obtain was an abstract, which should disqualify it from inclusion in this guideline. The guideline development committee rated the evidence statements derived from the Cobbett study as being of very low quality (p 169). In contrast, the Small study was published in a peer-reviewed journal, results are of higher quality, and the data are readily available to readers. Therefore, we do not think the Cobbett study adequately justifies equal consideration of the 0.5% concentration of CHG with the 2% concentration of CHG.	gluconate in alcohol to make a specific recommendation of the optimal concentration of chlorhexidine gluconate. It is unclear which concentration has the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG recognised that the optimal concentration is a pertinent issue and evidence should be available to guide clinical practice. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and a research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. We wish to reiterate that the evidence review and interpretation was conducted according to standard processes as outlines. The assumptions made about whether the GDG had considered whether studies were equal or not is untrue and not part of the standard review process.
SH	CareFusion	36.01	Full	12.4	165	**2% CHG specified in guidelines:** While there is merit in using strict inclusion criteria to gain the greatest specificity, products for skin disinfection prior to catheter incision generally are not indicated solely for one kind of catheter insertion (peripheral VAD) in only one kind of environment (primary care). Skin-dwelling pathogens commonly associated with both peripheral vascular and central venous access device (CVAD)	Thank you for your comments. The scope of the guideline is for prevention of infection the primary care setting. As such, the GDG had considered which evidence is relevant and can be extrapolated with confidence to the primary care setting carefully. The GDG were aware of the

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						infection are the same, including coagulase-negative staphylococci, *Staphylococcus aureus*, aerobic gram-negative bacilli, and *Candida albicans* (Mermel, 2001). Therefore, broader expert guidelines addressing prevention of catheter-related infection in general provide an important source of research and opinion. A concentration of 2% CHG in 70% IPA has been strongly recommended for skin antisepsis prior to catheter insertion in guidelines for prevention of healthcare-associated and catheter-related infections, notably the epic2 *National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England* (Pratt, 2007) and the Centers for Disease Control *Guidelines for the Prevention of Intravascular Catheter-related Infections*. The epic2 guidelines rate the evidence in support of 2% CHG/70% IPA for cutaneous antisepsis as Category A, the highest rating. Similarly, the CDC guidelines were acknowledged by the NICE guideline committee as "the most authoritative reference guidelines currently available" (p 162). The 2002 CDC guidelines referenced by the NICE committee recommend the use of 2% CHG for cutaneous antisepsis prior to catheter insertion. Since the 2002 version, a new CDC guideline has been published (O'Grady, 2011) that continues to recommend CHG in alcohol in	recommendations made by other key guidelines, such as EPIC2 guideline in the hospital setting, and also the Centers for Disease Control *Guidelines for the Prevention of Intravascular Catheter-related Infection.* Evidence for the community setting is lacking about which concentration of chlorhexidine in alcohol is optimal. There were no direct comparisons of 0.5% chlorhexidine versus 2% identified in our systematic review. The GDG had considered the optimal concentration a pertinent issue, and therefore a research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made, see section 12.11 of the full guideline. The comment referring to page 162 about the CDC guideline was in a non-updated section of the guideline. There is a newer guideline published in 2011 by CDC. The latest guideline from CDC also had not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial insertion. It had not recommended a concentration of >0.5% for all procedures as implied by the stakeholder. In fact, the CDC guideline listed alternative agents for the other processes. The GDG had recognised the limitations of

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						concentrations greater than 0.5%. These updated guidelines cite a study by Humar et al (2000) that found no difference between 0.5% tincture of chlorhexidine and 10% PI in catheter colonization or in catheter-related bloodstream infection (CRBSI). In fact, a review of the literature regarding the efficacy of 0.5% CHG in reducing catheter colonization and infection produces contradictory results, with some studies finding no difference compared to PI (Humar, 2000; Kasuda, 2002) and some finding greater reductions in catheter colonization and infection rates in subpopulations such as paediatric and neonatal patients (Kinirons, 2001; Garland, 1995). There are no data demonstrating superiority of 0.5% CHG over PI. In contrast, clinical studies and meta-analyses consistently demonstrate the superiority of 2% CHG/70% IPA compared to PI for reduction of catheter colonization in adult and paediatric patients treated in a variety of environments (Small, 2008; Maki, 1991; Onder, 2009; Chaiyakunapruk, 1999). Because 0.5% CHG is, at best, equivalent to 10% PI, and 2% CHG is superior to PI, it follows that 2% CHG is superior to 0.5% CHG, based on all of the clinical data currently available. Until more definitive and consistent data are available to support the use of 0.5% CHG for reducing catheter colonization and infection, we request that 2% CHG be specified for skin	the current evidence base for the optimal concentration of chlorhexidine gluconate and a research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline.

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						decontamination prior to insertion of peripheral VADs	
SH	CareFusion	36.02	Full	12.4	165	**Interventions to reduce CRBSI:** In addition to guidelines, another source of important supplementary information that should be considered is "real-world" interventions to reduce catheter-related infections. Young et al (2006) reported a decrease in CRBSIs from 11.3 per 1000 catheter-days with a 10% PI and a small sterile drape protocol to 3.7 per 1000 catheter-days after introduction of a new intervention protocol using 2% CHG/70% IPA and a large sterile drape. Peer-reviewed reports such as this about actual use of antisepsis in healthcare practices can help frame inconclusive or low-quality results from RCTs.	Thank you for your comments. As outlined in section 3.13 about review methodology and the protocol of the review for this clinical question, evidence from RCTs was prioritised for the review. The GDG had considered which evidence is relevant and can be extrapolated with confidence to the primary care setting carefully. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and the importance of identifying the optimal concentration. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. This was felt to be more appropriate rather than making a prescriptive recommendation of concentrations in the absence of evidence.
SH	CareFusion	36.03	Full	General 4.1.4, point 10 4.2.4.3, points 80 and	General 39 47-48 169	**2% CHG as standard of care:** As noted in comments 2 and 3, 2% CHG/70% IPA has been specified in several guidelines for skin antisepsis prior to catheter insertion and has also demonstrated superiority for skin antisepsis prior to surgery (Darouche 2010, Ostrander 2005, Saltzman 2009, Levin 2011); for reducing blood culture contamination (Tepus 2005, Thomas 2011,	Thank you for your comments. An independent systematic review was conducted for this area. As outlined in section 3.13 about review methodology and the protocol of the review for this clinical question, evidence from RCTs was prioritised for the review. The GDG had considered which evidence is relevant and

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				87 12.4.1.3		Dhillon 2009, Madeo 2009, Madeo 2008); and for donor arm disinfection (McDonald 2010). In fact, 2% CHG/70% IPA in a single 1.5-mL applicator was adopted in 2006 by the U.K.'s National Blood Service for all donations, replacing 0.5% CHG/70% IPA wipes (McDonald 2001, McDonald 2010). There is substantial evidence in the medical literature demonstrating the efficacy of 2% CHG/70% IPA for skin antisepsis prior to various types of invasive medical procedures, and several guidelines recommend 2% CHG as a standard of care. Therefore, 2% CHG/70% IPA is the standard against which 0.5% CHG should be measured. As such, we believe that the draft guidelines do not include enough evidence demonstrating equivalence between 0.5% CHG and 2% CHG to justify the lack of a specific recommended concentration in sections 4.1.4 (p 39), 4.2.4.3 (p 47-48), and 12.4.1.3 (p 169).	can be extrapolated with confidence to the primary care setting carefully. The studies suggested met at least one of the exclusion criteria of the review. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and importance of identifying the optimal concentration. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. This was felt to be more appropriate rather than making a prescriptive recommendation of concentrations in the absence of evidence.
SH	CareFusion	36.04	Full	4.1.4, point 10 4.2.4.3, points 80 and 87 12.4.1.3	39 47-48 169	**Non-equivalence of CHG concentrations:** For insertion of PVADs, the draft guidelines compare only 0.5% and 2% CHG concentrations and conclude that there are not enough data to support the recommendation of a specific concentration. We have addressed the lack of support for a 0.5% CHG concentration but also wish to reference data demonstrating that 1% CHG is no more effective than PI for preoperative skin disinfection (Nishihara 2011). A total of 74	Thank you for your comments. An independent systematic review was conducted for this area. As outlined in section 3.13 about review methodology and the protocol of the review for this clinical question, evidence from RCTs was prioritised for the review. The GDG had considered which evidence is relevant and can be extrapolated with confidence to the primary care setting carefully. The studies suggested met at least one of the exclusion

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						healthy adult subjects meeting criteria for minimum baseline bacterial counts on test sites (potentially multiple per subject) were enrolled to evaluate efficacy of the test products on skin of the antecubital fossa, the abdomen, and the inguina at post-treatment time points of 10 minutes for inguina and abdomen, and 30 seconds for antecubital fossae. In addition, persistent effects were evaluated at all sites 6 hours and 24 hours post-treatment. The 1% CHG-ethanol preparation and the PVP-I solution demonstrated statistically equivalent antimicrobial efficacy at the inguinal, abdominal, and antecubital sites immediately, 6 hours, and 24 hours post-treatment. The equivalence shown in this study is in contrast to studies demonstrating the superiority of 2% CHG/70% IPA v PI for reduction of microbial counts.	criteria of the review. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and importance of identifying the optimal concentration. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. This was felt to be more appropriate rather than making a prescriptive recommendation of concentrations in the absence of evidence.
SH	CareFusion	36.05	Full	12.7.1.3	191	**2% CHG for site care:** 2% CHG/70% IPA was not evaluated in section 2.7, decontaminating skin when changing dressings. Several studies evaluating the use of 2% CHG/70% IPA for catheter insertion also evaluated the drug for catheter insertion site care. In one study conducted in Asia, a locally formulated chlorhexidine gluconate formulation was adopted for CVC site care in intensive care units (ICUs) at Siriraj Hospital (Balamongkhon 2007). A total of 312 patients who needed CVC insertions in three ICUs from January to July 2006 were	Thank you for your comments. An independent systematic review was conducted for this area. As outlined in section 3.13 about review methodology and the protocol of the review for this clinical question, evidence from RCTs was prioritised for the review. The GDG had considered which evidence is relevant and can be extrapolated with confidence to the primary care setting carefully. The studies suggested met at least one of the exclusion criteria of the review.

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						included in the study. Of these, 120 patients received 2% chlorhexidine gluconate in 70% alcohol, and 192 patients received 10% povidone-iodine for CVC insertion and site care. The patients were assessed for CVC-related infections and for any adverse effects of 2% chlorhexidine gluconate in 70% alcohol. The incidence of CRBSIs was lower in patients with indwelling CVCs who received 2% chlorhexidine gluconate in 70% alcohol compared to those who received 10% povidone-iodine during the same period, 3.2 versus 5.6 episodes per 1000 CVC days, respectively (P = 0.06; OR, 3.26; 95% CI: 0.97-10.92). No adverse effects related to using 2% chlorhexidine gluconate in 70% alcohol were observed. We believe that 2% CHG in 70% IPA should be considered in the review of antisepsis solutions for skin disinfection during dressing changes.	The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and importance of identifying the optimal concentration. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. This was felt to be more appropriate rather than making a prescriptive recommendation of concentrations in the absence of evidence.
SH	CareFusion	36.06	Full	12.4	165	**Supplementary data:** The efficacy of skin antisepsis products in the presence of organic matter such as blood and their activity against biofilm microorganisms are important considerations. The antimicrobial efficacy of 2% chlorhexidine gluconate (CHG) in 70% v/v isopropyl alcohol was compared to five other antisepsis agents, including 70% v/v IPA, 10% w/v aqueous PI, 0.5% aqueous CHG, 2% aqueous CHG, and 0.5% CHG in 70% IPA using quantitative in vitro time-kill tests against *Staphylococcus epidermidis* RP62A in the	Thank you for your comments. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and importance of identifying the optimal concentration, for example there is no direct comparison of different concentrations of chlorhexidine gluconate in alcohol. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline.

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						presence or absence of protein (Adams, 2005). The study demonstrated that in the presence of biofilm enriched with 10% human serum, 2% CHG/70%IPA produced greater log_{10} reductions than the other antiseptics, including 0.5%CHG/70% IPA. We believe these results provide important supplementary information that clarifies the difference between 0.5% and 2% concentrations of CHG.	This was felt to be more appropriate rather than making a prescriptive recommendation of concentrations in the absence of evidence. The studies which CareFusion had cited in the consultation comments did not meet at least one of the inclusion criteria. For example, Adams, 2005 is a laboratory study. We had stated that laboratory studies were excluded because the populations (volunteers, animals or *in vitro*) and settings used are artificial and not comparable to the population we are making recommendations for. These studies would undoubtedly be of very low quality as assessed by GRADE and therefore RCTs, cohort studies or GDG consensus opinion was considered preferable. The rationale was explained in section 3.1.3.4 of the full guideline.
SH	CareFusion	36.07	Full	12.4.1.4	170	**CHG persistence:** The draft guidelines acknowledges that residual antimicrobial effects (persistence) is greater with higher concentrations of CHG but does not wish to specify a concentration due to the lack of direct comparisons. In a randomized, parallel-group, active-control, open-label clinical study by Hibbard (2002), the immediate and persistent antimicrobial efficacy and safety of 2% CHG/70% IPA was evaluated for preoperative skin preparation, compared to 70% IPA alone and 2% CHG alone. Each antiseptic significantly reduced abdominal and	Thank you for your comments. The GDG had recognised the limitations of the current evidence base for the optimal concentration of chlorhexidine gluconate and importance of identifying the optimal concentration, for example there is no direct comparison of different concentrations of chlorhexidine gluconate in alcohol. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline. This was felt to be more appropriate rather

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						inguinal microbial counts from baseline at 10 minutes, 6 hours, and 24 hours (P =0.0001). 2% CHG/70% IPA provided significantly more persistent antimicrobial activity on abdominal sites than IPA (P =0.003) or CHG (P =0.028) at 24 hours. In the absence of comparison studies using different concentrations of CHG, we believe that RCTs using other comparator products should be considered.	than making a prescriptive recommendation of concentrations in the absence of evidence. The studies which CareFusion had cited in the consultation comments did not meet at least one of the inclusion criteria. For example, Hibbard 2002 was conducted in a patient undergoing an operation. This clearly did not meet the inclusion criteria of our review protocol.
SH	CareFusion	36.08	Full	12.4.1.2	168	**Cost data:** The cost meta-analysis (Chaiyakunapruk, 2003) addressed site care associated with vascular access devices and is therefore relevant to the NICE Primary Care Guidance document. The NICE guideline criteria for study inclusion states that the study must pertain to the guideline population (p 26). Patients with central vascular access catheters make up a valid population as defined in lines 10-11 on page 18 of the draft guidelines. The fact that the meta-analysis included some studies of central catheter infections should not negate its usefulness in providing guidance to healthcare workers. Rather, cost outcomes from the meta-analysis should be included but restricted to the discussion of central catheters as a subset of all VADs. The draft guidelines also state that the meta-analysis includes many studies published in abstracts, therefore excluding it. That is a valid concern and would be more applicable	Thank you for your comment. The cost-effectiveness analysis paper by Chaiyakunapruk 2003 had been identified but excluded by the GDG for the following reasons: • The studies used to inform the effectiveness estimates in this analysis were derived from studies of centrally inserted vascular access devices in hospital settings. The data is therefore not relevant to the population considered by this question. • The costs included in this evaluation are obtained from an American intensive care ward; they are not applicable to a UK community setting. • Because the studies included in the meta-analysis on which the cost - effectiveness analyses was based on had included are unpublished and not available in the public domain. Therefore, it is not possible to reproduce the results of the analysis or determine exactly how the data

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						if the abstract studies were considered as primary references. But the meta-analysis itself was peer reviewed and published in a leading infectious disease journal. While it is not an ideal reference meeting all inclusion criteria, it is credible, applicable, and useful for guidance. We propose that the Chaiyakunapruk meta-analysis be included with pertinent limitations described.	used in the cost-effectiveness analysis has been derived. It is our experience that a journal's reputation is not necessarily an indicator of study quality; we do not exclude studies based on the journal in which they are published and therefore see no reason to use this as a basis for inclusion. • Given that this analysis did not meet any of our inclusion criteria it was excluded. The GDG did not think that it was useful for decision making. The GDG also note that inclusion of this study would not have changed the recommendation.
SH	CareFusion	36.09	Full	12.4.1.2	168	**Product pricing:** The price listing in Table 83 on page 168 is problematic for the following reasons: a. It provides average costs of different products with varying numbers of units within a package, rather than comparing on a per-unit or per patient basis. The 2% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) product comes in a single-use applicator, with one applicator used per procedure. The amount of solution and number of sterile gauze pads or wipes used per procedure is not presented. b. It includes only 10.5-ml applicators of 2% CHG in 70% IPA. In primary care, the product most likely to be used for peripheral venous	Thank you for your comment. We agree that the information in Table 83 could be more clearly presented to represent unit costs. This table has been updated to reflect these suggestions. The GDG indicated that sterile dressing packs (including sterile gauze, gallipots, etc) would typically be used to apply decontamination solution. These would be disposed of after the procedure, not reprocessed.

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						cannulation would be the 0.67ml product (£71.13 for 200); for the care of central lines and PICCS, it would be the 3ml product, (£25.59 for 25). c. For 7% and 10% PI solutions, the average cost table lists "+ sterile gauze," but the cost of gauze is not included. Also not included is the cost of forceps, galley pots, and other equipment needed to apply the solution in a manner to avoid bottle contamination, or the cost of reprocessing, which can be substantial. The product pricing as listed is not a valid comparison. d. The 0.5% / 70% IPA wipes listed in the table are not indicated for skin preparation prior to invasive procedures and therefore should not be included in the table (see comment 3 on this form). We agree with the conclusion reached on page 170 of the guidelines, which states that the cost savings and quality of life gain associated with preventing VAD-related infections outweigh potentially higher per-unit costs for alcoholic chlorhexidine but do not believe Table 83 is helpful in understanding that conclusion. Unless Table 83 can be modified to address these problems, we propose that it be excluded.	
SH	CareFusion	36.10	Full	12.4.1.2	168	**CHG wipes:** Table 83 lists 0.5% CHG in 70% IPA wipes. The Medicines and	Thank you for your comment. We do not think that this should be changed. We have

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						Healthcare products Regulatory Agency states the following: "wipes/swabs containing antiseptics/antimicrobials such as chlorhexidine, iodine, cetrimide and similar will remain as medicinal products and therefore will continue to require a marketing authorisation" (MHRA) We do not believe that the 0.5% CHG wipes referenced in the table carry the necessary marketing authorisation for skin disinfection prior to peripheral vascular access device insertion and therefore should not be included as a comparator.	not recommended a specific percentage of chlorhexidine, but have listed products available for comparison from the NHS supply catalogue (2010), as referenced in the footnote. The GDG agreed that evidence is lacking in this area, and there were no direct comparisons of 0.5% chlorhexidine versus 2%, and as such were unable to make a recommendation on the percentage of chlorhexidine. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made; see section 12.11 of the full guideline.
SH	CareFusion	36.11	Full	12.4.1.2	168	**Indirect costs:** The indirect costs listed in tables 84 and 85 (cost of catheter tip colonization, costs of admission for bloodstream infections, quality of life estimates, etc.) should not be included in the guidelines unless they can be tied to one of the products evaluated. Presumably, an effective skin antisepsis product would reduce the need for catheter tip culture, for example, whereas a less effective product would increase the cost. It is clear that the costs of care associated with infections is substantial; we believe that a more helpful discussion to include in the guideline is a broader review of the literature demonstrating reduced costs associated with specific products (i.e., Chaiyakunapruk 2003). We also note that costs associated	Thank you for your comment. After careful consideration we came to the conclusion that we do not agree. The costs related to vascular catheter-associated infections are included in the guideline to provide context for the outcomes included in the clinical review. More effective decontamination solutions would reduce infection-associated costs. The costs and effects included within the analysis by Chaiyakunapruk 2003 were not included in the guideline because they are not relevant to a UK community-based setting. In the absence of evidence of relevant cost-

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						with infection will vary substantially due to differences in infection control protocols.	effectiveness evidence, it is standard practice to include both the cost of each intervention and cost of the consequences associated with each intervention where available and when the GDG indicates that they may be useful for decision making.
SH	CareFusion	36.12	Full	12.11	200	**RCT comparing costs:** We agree that it would be ideal to have a randomized controlled trial to evaluate costs and clinical outcomes of 0.5% versus 2% CHG but believe that is very unlikely to happen due to costs of conducting studies and the number of patients/procedures necessary to reach statistical power. In the absence of RCT data, we believe it is prudent to rely on the peer-reviewed information that is available now, including the Chaiyakunapruk 2003 meta-analysis and other published opinions describing the cost efficacy of using 2% CHG/70% IPA to reduce risk of infection. Compared to the cost of antibiotic treatment of infection (Madeo 2008), as well as costs associated with blood culture contamination (Thompson 2009), these published results underscore the efficacy and cost effectiveness of 2% CHG/70% IPA. We ask that the guideline committee retain 2% CHG as a standard of care, based on the extensive evidence demonstrating its efficacy and the cost savings associated with reduced infection risk. We are not aware of any similar cost data associated with 0.5% CHG.	Thank you for your comment. After careful consideration we have come to the conclusion that we do not agree. When producing evidence-based guidance, there are two separate decisions which must be made for each clinical question: whether to adopt an intervention and whether to collect further evidence to inform reassessment of the decision in the future. Currently, here is no evidence comparing the effectiveness or cost-effectiveness of 0.5% CHD to 2% CHD. There is weak evidence that 2% CHD is more clinically effective than povidone iodine. The GDG decided to recommend chlorhexidine over povidone iodine, but did not believe there was any basis for recommending 2% over 0.5% chlorhexidine. They noted that an absence of evidence was not the same as absence of effectiveness. They thought that the cost of research would be outweighed by the cost and QALY benefit of ascertaining the best method of skin disinfection for the insertion of peripheral lines.

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SH	Health Protection Agency	37.00	Full	General	General	These guidelines are extremely useful. The detail and the evidence base clearly provide the necessary credibility for the frontline workers.	Thank you for your comment.
SH	Health Protection Agency	37.01	Full	General	General	The detail is excellent, but hopefully the actual guidelines will be a shorter version of the currently circulating document. The evidence base and research recommendations are very useful, however the document would be much easier to read if they were included as appendices. The current length of the document (235 pages at present) would hamper people's inclination to actually read it.	Thank you for your comment. We agree that the information in Table 83 could be more clearly presented to represent unit costs. This table has been updated to reflect these suggestions. The GDG indicated that sterile dressing packs (including sterile gauze, gallipots, etc) would typically be used to apply decontamination solution. These would be disposed of after the procedure, not reprocessed.
SH	Health Protection Agency	37.02	Full	18	2.5	Other topics and areas that need to be addressed or a statement made regarding their exclusion include; 1. The importance of an infection control programme within a healthcare setting, specifically; a. Local policies and manuals for infection prevention and control that include standard and additional precautions and all other aspects essential to infection prevention and control. Examples comprise: aseptic technique, use of single	Thank you for your comment. We do not think that this should be changed. We have not recommended a specific percentage of chlorhexidine, but have listed products available for comparison from the NHS supply catalogue (2010), as referenced in the footnote. The GDG agreed that evidence is lacking in this area, and there were no direct comparisons of 0.5% chlorhexidine versus 2%, and as such were unable to make a recommendation on the percentage of chlorhexidine. A research recommendation regarding the percentage of chlorhexidine before insertion and during dressing changes has been made, see section 12.11 of the full guideline.

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						use devices, reprocessing of instruments and equipment, management of blood/ body fluid exposure, handling of blood and body products etc. b. Surveillance for those organisations with returning patients or inpatients c. Training for staff d. Protection of healthcare workers (e.g. Immunisations, appropriate training) 2. Infection Prevention and Control Precautions - (standard and additional precautions) e.g.; a. Standard precautions b. Respiratory precautions (airborne / droplet) c. Contact precautions d. Enteric precautions The inclusion of infection prevention and control precautions in the guidance is essential so that healthcare settings understand the transmission based precautions that are required for different organisms or outbreaks they may encounter. 3. Environmental management	

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						practices including; appropriate cleaning practices, adequate floor space for beds, adequate and appropriate isolation facilities, measures to prevent fungal spores during renovations (waste management has been addressed). 4. Safe reprocessing of instruments and equipment. It is essential to address the principles behind safe reprocessing of instruments and equipment and how healthcare environments should do this. 5. Single use instruments and equipment – this is briefly addressed in line section 4.2.4.4 (point 103 page 49). However, this needs to be stronger and warrants explanation and detail. 6. Outbreak detection, management, control and reporting. This is particularly important to ensure healthcare settings comply with criterion 9 of the Code of Practice Prudent antimicrobial prescribing and stewardship.	
SH	Health Protection Agency	37.03	Full	Line 39 page 13	1.1	It is essential that NICE makes a statement saying that this guideline does not cover all aspects of infection, prevention and control, outlining the topics which have not been	Thank you for your comments. After careful consideration, we came to the conclusion that we do not agree. The scope in appendix A details the scope of this partial update and

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						addressed (see point 3 above for details of aspects the HPA feel have not been covered by this guidance).	the 'development of the guideline chapter' in the full guideline also details this in chapter 2.
SH	Health Protection Agency	37.04	Full	General	General	The guidelines are mainly focused on infection control operationally, but there is too little on prevention. The main omission is really the absence of any information, appendix or even mention of the need for judicious use of antimicrobials in the community. The guidance must include antimicrobial / antibiotic prescribing guidelines, based on available evidence. There is only coverage of antibiotic usage in the section on catheter care. This is a significant omission in infection **prevention** guidelines.	Thank you for your comment. Antimicrobial/antibiotic prescribing is outside the scope of this partial update. Antibiotic prophylaxis for long term urinary catheters is included in chapter 10. The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update.
SH	Health Protection Agency	37.05	Full	General	General	The guidance must include information on decolonisation procedures for patients who are found to be MRSA positive following a hospital admission. This is another major omission. The guidance refers to skin and hand decontamination and in relation to VADs, parenteral feeding and in relation to catheter management. They need to make sure that information on appropriate processes for decolonisation of those found to be colonised with MRSA are added to these guidelines.	Thank you for your comment. Advice on the diagnosis, treatment or management of specific infections is not included in the scope of this guideline (see appendix A). The scope of the guideline was formally consulted upon with stakeholders before finalising the content of the focussed update.
SH	Health Protection Agency	37.06	Full	Point 103 page 49	4.2.4.4	Single use instruments and equipment – this is briefly addressed in line section 4.2.4.4 (point 103 page 49). However, this needs to be stronger and warrants	Thank you for your comment. The full clinical question regarding the use of multidose vials in section 12.9. Details are provided in the linking evidence section 12.9.5, regarding the recommendation: Avoid the use of multidose

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						explanation and detail.	vials, in order to prevent the contamination of infusates. We are unsure as to what you are referring to in relation to 'single use instruments and equipment' and are therefore unable to provide a more detailed response.
SH	Health Protection Agency	37.07	Full	63	6.3.1.1	It is not clear what conclusion was drawn from these papers or if they were excluded.	Thank you for your comment. This section describes the papers included in the review and the next section provides the results (Tables 7 and 8). The evidence statements are provided in section 6.3.1.3 and conclusions discussed in section 6.3.1.4. A full list of excluded studies can be found in Appendix L of the full guideline.
NICE	Guideline Commissioning	38.00	NICE	1.2.3.4 / 1.2.3.5	20	Given that recommendation 1.2.3.4 is a key priority, it would be helpful to incorporate the footnote (that highlights that the recommendation does not apply to children) directly into 1.2.3.4. There is a risk that readers will miss the fact that the recommendation does not apply to children when viewing the key priority recommendations in isolation, for example in the implementation tools.	Thank you for your comment. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments

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							received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation.
SH	The British Healthcare Trades Association (BHTA)	40.00	Full	10	114-152	The recommendation to use uncoated catheters for multiple-use is a significant change to current practice in the UK and BHTA is concerned about the implications of this decision especially as infection control is not the only factor on which choice of catheters are prescribed; lifestyle, clinical need and comfort are all factors that should be considered. There are very few studies available that provide meaningful data about the rate of urinary tract infections (UTIs) arising from the use of different catheters. The current research base is very weak and extracting meaningful data from these is flawed. This is especially related to the fact that trials tend to exaggerate the hygiene aspects associated with preparing catheters for re-	Thank you for your comment. The systematic literature review identified six randomised controlled trials with outcomes relevant to our clinical review. This was one of the areas with the greatest number of studies identified for any question included in the update of this guideline. The limitations of RCTs have been discussed in the methodology section, 3.1.3.8. and the papers were quality assessed in accordance with the NICE guidelines manual, 2009. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that

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						use. Trial subjects are taught very thoroughly how to look after themselves and prepare their catheters. However, users will normally frequently need to carry out catheterisation in life style settings which are very different to a clinical or teaching situation. Outside of this controlled environment, these techniques are at times impossible for users who self catheterise to reproduce, whether in the home or workplace. There are vastly different approaches to hygiene within the community; conditions in people's homes may not be conducive for the re-use of catheters even if nominally there are adequate facilities to wash and dry multiple-use catheters. These aspects need to be taken into consideration and acknowledged in the guidance.	implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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							evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The British Healthcare Trades Association (BHTA)	40.01	Full	10	114-151	BHTA notes the decision taken by the USA Government to change its policy on mandatory re-use of catheters and from 1st April 2008 allow for reimbursement of 200 sterile single use catheters per month. In 2007, the Veterans Administration (VA) issued the following recommendations: • Clinicians should follow the manufacturer's instructions for catheter use, which recommend single-use devices should not be re-used in any setting. • Patients should be provided with an adequate number of catheters to allow the use of a sterile catheter for each catheterization. • Clinicians should inform patients, family members, and caregivers that catheters are for single-use only	Thank you for your comment. The NCGC would like to highlight that that the healthcare system in the USA operates very differently from that in the UK. The cost of doctor visits, medications and catheter-associated UTIs in the USA is not applicable to the UK. The economic model presented in Appendix J was designed to fully account for the UK-specific costs associated with treating catheter-associated UTIs, quality of life in people with UTI, and the cost associated with the catheters themselves. We also wish to highlight that the decision taken by the VA in 2007 (and subsequently by Medicare and Medicaid) was not evidence based. As such it does not meet the criteria for inclusion within this guideline. With respect to the single use symbol, this is a query which was raised with our legal team from the beginning of the guideline development process. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and do not consider the re-use of catheters bearing a single use symbol for ISC to be unlawful as long as they are used in the appropriate clinical setting.

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						(*Department of Veterans Affairs, 2007; Newman, 2008*). Information from a variety of sources all points to the conclusion that the costs of doctor visits, medications and catheter-associated UTIs were much more than the cost of reimbursing for single-use of up to 200 devices per month. The decision was taken due to the rising costs to the Medicare programme from higher risks of UTI. Even though this change has increased costs on the supply side, the overall costs to Medicare are lower with this new structure. Also supporting this, the Food and Drug Administration **(**FDA) has never approved intermittent catheters for reuse, but instead they are approved as single-use-devices, therefore the act of patients using only 4 per month was not an FDA-approved practice. In the UK, there is similar guidance from MHRA on re-use of products marked as single use devices according to *Device*	Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in

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						Bulletin 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse.	cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited.
SH	The British Healthcare Trades Association (BHTA)	40.02	Full	10	114-151	Whilst the studies in ISC attempt to relate the incidence of UTI to individual products, each individual catheter type is no more likely than another to push bacteria into the bladder. It is the technique and preventative measures employed to reduce the opportunity for contamination that have a material and substantial effect upon the rate of UTIs that are observed. Only single use catheters with the facility for pre-lubrication prior to exposing the catheter for use can ensure consistent, repeatable catheter presentation for the patient. After that it is the patient's technique and personal hygiene that can make a difference to UTI rates.	Thank you for your comment. This question was designed to determine the most clinically and cost effective type of intermittent catheter for ISC. Based on a systematic review of the evidence, economic modelling, and consideration of the many other factors which are relevant to this question, we have come to the conclusion that what is most likely to be the most effective, cost-effective and appropriate type of intermittent catheter will differ between different people. The evidence base indicates that 'uniformly' prescribing single use catheters for all people is not a cost effective use of NHS resources. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding

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						Providing a uniform standard of hygiene control demands a single use product that is independent of additional resources for lubrication.	issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation.
SH	The British Healthcare Trades Association (BHTA)	40.03	Full	10.5.2.3	128	BHTA agrees that compliance and behaviour are important factors for healthcare workers to consider when prescribing an ISC regime. However we do not believe that the studies looking at re-use comment on patient technique of use, or compliance to it, which clearly affects infection control and prevention. Records from our membership show that a very high percentage of patients give up on self-catheterisation or fail to comply with instructions as to how many times to catheterise when using the product in practice. Compliance is thought to be closely related to ease of use of the product and having to wash and re-use a catheter many times is clearly not as convenient as having a device that is ready and simple to use. Time spent on catheterisation should not	Thank you for your comment. None of the studies identified in our review reported compliance. The GDG did consider that compliance is an important factor and have added the following text into the linking evidence section: *Patient compliance was also identified as important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options.* Text added to the linking evidence section also states that: *In drafting the revised recommendation, the GDG noted the following issues of importance:* *The GDG feel it important to consider privacy and dignity issues when*

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						lead to it taking over someone's life, nor cause them embarrassment. Having to wash, dry and re-use catheters along with needing to use separate, and often ineffective, lubricant can mean the difference between someone coping with ISC or giving up. The alternative is an indwelling catheter, which is not the optimal treatment option, proven to increase infection risk and has implications for long term dependence on NHS staff resources. The development and design of urology products which are easy to use and that accommodate a patient's lifestyle needs, eg pre-lubricated or hydrophilic coated single-use catheters, has been a significant advance in product innovation that improves users' quality of life, makes products easier to use and improves compliance.	*recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces.* *The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.* *The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation (see recommendation 36).*
SH	The British Healthcare Trades Association (BHTA)	40.04	Full	10.5.2.1	120-129	None of the studies mentioned within the guidance appear to report on the use of pre-gelled catheters. There would seem to be no particular reason for singling out this type of catheter presentation as any better or worse than any other single-use product with built in lubrication therefore requiring no additional resources.	Thank you for your comment. We have chosen to refer to 'pre-gelled' catheters as 'gel reservoir' catheters. The study by Giannantoni et al 2001 included gel reservoir catheters as a comparator (and referred to them as 'prelubricated' within their study). We have amended this term in the glossary

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						BHTA has identified two studies which show the advantages of hydrophilic catheters: Cardena DD, Moore KN, Dannels-McClure A, Scelza WM, Graves DE, Brooks M, Busch AK (2011) "Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicentre trial". *PM R*. 2011 May;3(5):408-17 Chartier-Kastler E, Denys P (2011) "Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention". *Neurourol Urodyn*. 2011 Jan; 0(1):21-31	to state that it is also known as 'pre-gelled'. The paper by Chartier-Kastler and Denys 2011 is a non systematic review and includes a mix of RCTs and observational studies (conference posters and abstracts). Therefore, this paper was excluded from our review. The paper by Cardenas et al 2011 was published after the cut off date for our literature search (18th April 2011.). In order to be consistent and systematic in our inclusion criteria we will not consider papers after this date. However, it is also not eligible for inclusion in this guideline as it is a study of short term intermittent catheterisation (less than 28 days of intermittent catheterisation), as detailed in the review protocol in appendix E.
SH	The British Healthcare Trades Association (BHTA)	40.05	Full	10.5.2.5	130	As well as considering the cost implications of multiple-use versus single-use devices, NICE should also give full consideration to the implications of its recommendations on the lives of people who use them. BHTA welcomes the acknowledgement in the draft guidance that there are situations in which it is not appropriate for patients to	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that

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						use multiple-use catheters. However, it would appear that these situations focus primarily on a user's domestic setting rather than recognising that the majority of people who depend on these products lead independent, working and social lives, which will inevitably lead them to use communal or public facilities on a daily basis which cannot meet the same hygiene levels. BHTA feels that it should be made much clearer within the guidelines that inevitably it will not only be domestic facilities that make it difficult for patients to wash and dry catheters. Often patients will not be able to have access to these facilities and will require single-use devices. This should be taken into account. The draft guidelines should therefore make it clear that a user's lifestyle in terms of their working and social life, and the different requirements users have in each setting should be given equal consideration by clinicians. Using inappropriate or less than optimal medical devices for a user's lifestyle and clinical needs has the potential to prevent	implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical

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						these patients from self caring and leading independent lives. Single-use catheters allow users flexibility to overcome physical or clinical impairments that might prevent full participation in society, employment, or education.	evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. In drafting the revised recommendation, the GDG noted the following issues of importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36).
SH	The British Healthcare	40.06	Full	10.5.2.5	130	BHTA is unsure whether the mobility and	Thank you for your comment.

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	Trades Association (BHTA)					dexterity impairments of the vast majority of users are fully considered in these guidelines. Due to the nature of the conditions which require long term urinary continence management, many users have dexterity and mobility issues. These factors need to be taken into account when considering an ISC regime. Some patients will simply not be able to re-use catheters, wash and dry them, because of their physical impairments. For example, for manual wheelchair users, their hands would become contaminated as soon as they move the chair away from a washbasin. It may not be practicable for some patients to safely and effectively clean catheters for re-use due to these impairments which would have an impact on how they can use products. Many single-use intermittent catheters have been developed over recent years to incorporate features that facilitate a no touch technique to overcome these problems; or they come in/with sterile solution to negate the lack of hand washing facilities in public bathrooms or supply of	We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that

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						drinking quality water. Equally, modifications have been brought to market to compensate for the particular needs or impairments of users. These modifications are not simply about infection control but also quality of life and clinical need; the latter we feel have not been properly addressed in this guidance even though the recommendations made would have a significant impact on users' lives. BHTA is concerned that the Government's policy principles, as advocated in the Health White Paper, of "no decision without me" are not given due emphasis in the draft guidelines given that its recommendations will considerably limit choice of catheters for patients.	further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. Additional text has been added text to the linking evidence section: In drafting the revised recommendation, the GDG noted the following issues of importance: The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces. The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities. The GDG thought the patient's physical

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							ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36).
SH	The British Healthcare Trades Association (BHTA)	40.07	Full	10.5.2.5	130	The vast majority of patients who use ISC in the UK use single-use catheters. Given that the recommendations made in the draft guidance, would in practice, be a considerable change in UK policy, it would affect a significant number of people who already use single-use devices and above all have been taught how to use these safely and effectively to, for example, avoid increasing their chances of contracting an infection. BHTA is concerned about service delivery and what care pathway and products existing ISC patients can expect in the future and whether they would need to be clinically re-evaluated in order to switch products. Clearly this would entail costs and it is not clear whether this has been considered in the analysis.	Thank you for your comment. We acknowledge your concerns regarding patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost

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							effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. We cannot be prescriptive about the details of local implementation. NICE will be producing implementation tools which and these will include an interactive cost impact spreadsheet to assist trusts in implementing the guideline. These will be published shortly after publication of the guideline.
SH	The British Healthcare Trades Association (BHTA)	40.08	Full	10.5.2.5	130	BHTA is concerned that the Government's policy principles, as advocated in the Health White Paper, of "no decision without me"	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder

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						are not given due emphasis in the draft guidelines given that its recommendations will considerably limit choice of catheters for patients. The recommendation to restrict prescription of single-use catheters will have a significant impact on patient choice. In the urology market, out of 55 approved intermittent catheters, the Drug Tariff only lists 11 types of PVC/latex uncoated catheters, and the majority of these are marked for single-use, which BHTA strongly feels are inappropriate for multiple-use. This is a significant reduction in patient choice on the basis of only one factor, infection control.	consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the

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							inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. Additional text has been added text to the linking evidence section: *In drafting the revised recommendation, the GDG noted the following issues of importance:* *The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces.* *The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.* *The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair*

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							users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 36).
SH	The British Healthcare Trades Association (BHTA)	40.09	Full	10.5.2.5	130	We agree with the recommendation that multiple-use catheters should not be offered for use in children or young people of 16 years or under.	Thank you for your comment.
SH	The British Healthcare Trades Association (BHTA)	40.10	Full	10.5.2.5	131	BHTA is concerned by this section which would seem to advocate that patients should be encouraged to disregard product safety information such as the "not for re-use" symbol. This would contradict what many patients are taught about product information and packaging which is to recognise the "not for re-use" symbol. Additionally, under the MHRA guidelines *DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse*, the re-use of single-use devices has legal implications for a clinician who administers the device or who prescribes the device. BHTA understands that a number of PCT device and prescription formularies clearly note that clinicians assume a legal liability if	Thank you for your comment. We acknowledge your concerns regarding single use logos and patient related issues. Taking into account all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness

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						they prescribe a device marked as single-use for multiple-use. We do not feel that the legal implications of reusing a single-use device on patients or on prescribing clinicians have been fully considered and we would urge NICE to look again at the implications of this recommendation. The guidelines claim that because manufacturers provide instructions for cleaning non-coated catheters, this can be taken to imply that manufacturers intend for these products to be used more than once and therefore that the MHRA guidance on re-use of single-use devices. We would like to make clear that manufacturers include these instructions on the insistence of the Department of Health/Drug Tariff; to argue that this is because manufacturers intend products to be re-used is incorrect. BHTA would also ask for clarification on the statement in the NICE guidelines on p.131, "*The NHS Drug Tariff states that non-coated catheters can be re-used for up to one week*", which we assume has been inferred from the statement in the Drug Tariff notes: "*4. 5-units of plastic catheters,*	evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. This question was designed to compare the clinical and cost-effectiveness of each alternative type of intermittent catheter. According to the literature and clinical experience, clean ISC is widely recognised

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						for example, represents on average one month's supply for patients practising intermittent catheterisation". This does not take into consideration that a product may be marked for single-use as per manufacturers' advice, as explained above. NICE should revisit this statement in view of this.	as an acceptable method of intermittent catheterisation. However, we were also aware that most of these devices have a single use symbol on their packaging. This issue was raised with the NICE legal team at the beginning of the guideline development process in order to determine whether it represents a valid alternative for consideration within the clinical review and economic model. The lawyers considered the MHRA bulletin 'Single-use Medical Devices: Implications and Consequences of Reuse' when giving their advice and decided that it was. The legal team was also consulted once the recommendation had been drafted. They considered that for patients performing intermittent *self* catheterisation in the community, washing and reusing intermittent catheters represents a viable option, providing the other conditions outlined in the recommendation and that the act of recommending the reuse of the single use device to the patient is carried out by a clinician exercising his or her judgement (informed by the guideline).
SH	The British Healthcare Trades Association (BHTA)	40.11	Full	10.5.3	133	Product innovation is extremely important in the urology sector given the impact that advances in product design specification and technology have on improving quality of life, a user's potential to self-care, and facilitation of mobility and an independent	Thank you for your comment. We agree that quality of life, independence and ability to self care are important for people performing ISC. We acknowledge your concerns regarding patient related issues. Taking into account

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						working or social life. In recent years a number of advances in catheter design have taken the user's needs and how they use them into consideration. This is a significant innovation in product design which differs from the majority of uncoated catheter designs, which are based on Nelaton catheters designed for use only by healthcare professionals. BHTA is concerned that a recommendation to limit patient choice in such a way would ignore significant advances in product design, restrict innovation and discourage manufacturers from investing in new technology and products. It is clear that the diffusion of new technology and innovative products in the NHS is a priority for the Government and the Department of Health is presently taking forward a review of uptake of innovative medical devices and technology. Recommendations such as those included in the draft guidance will prejudice future product development which would aim to improve quality of life and ease of use products for patients, especially when	all of the stakeholder consultation comments and NICE guideline review panel (GRP) feedback, the Guideline Development Group has reviewed their recommendation. Given the outstanding issues surrounding the single use logo on catheters, the GDG has decided that implementation of the recommendation regarding multiple-use non-coated catheters would be inappropriate at this time. The GDG have amended this recommendation to state: Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self catheterisation. The amended recommendation reflects the available clinical and cost-effectiveness evidence as well as stakeholder comments received at consultation on the original recommendation in terms of barriers to implementation for non-coated intermittent catheters for multiple use. The guideline continues to reflect the clinical and cost effectiveness evidence for multiple-use of non coated intermittent catheters. The GDG interpretation of this evidence remains in the guideline and the linking evidence to recommendation section provides details of the GDG discussions supporting the amended recommendation. The GDG think that it is very important that further work in this area is undertaken in cooperation with external stakeholders. Evidence-based discussions regarding the

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						infection control is not the only factor as to why a particular catheter or urology product is chosen. Few users will go back to using an uncoated catheter if they have been using single-use pre-lubricated or hydrophilic coated catheters, especially if it is these products which match and enable their current quality of life.	inclusion of a single-use logo on non coated intermittent catheters and clarity regarding NHS Drug Tariff recommendations for the re-use of intermittent caterers are needed. The GDG have prioritised this question for further research. If higher quality clinical evidence is published prior to the next scheduled review for update, then the evidence behind the amended recommendation may be revisited. We do not agree that this recommendation will discourage manufacturers from investing in catheter R & D. The superior efficacy of different catheter's performance needs to be underpinned with high quality comparative clinical evidence and cost-utility analysis. Currently, there is no comparative clinical evidence to suggest that hydrophilic or gel reservoir catheters reduce the incidence of urethral damage or stricture. The theoretical possibility of this effect was incorporated into the sensitivity analysis of the economic model and found to have no effect on the result.
SH	The British Healthcare Trades Association (BHTA)	40.12	Full	10.8.1.1	136	We agree that the recommendation that patients managing their own catheters, and their carers, must be educated about the need for hand decontamination before and after manipulation of the catheter is sensible and should be included. However, it should be made clear that these	Thank you for your comment. After careful consideration, we came to the conclusion that we do not agree that this should be changed. We think that this wording is appropriate because the recommendation refers the user to chapter 6, on hand hygiene, In addition, the GDG did not wish to be so prescriptive and that this is a local

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						techniques should be taught in all lifestyle settings, not simply a clinical or teaching setting.	implementation issue. NICE will be publishing implementation tools shortly after the publication of this Guideline which we hope will help with this matter.
SH	The British Healthcare Trades Association (BHTA)	40.13	Full	10.9	137-145	In relation to the following: "To minimise the risk of blockages, encrustations and catheter-associated infections for patients with a long-term indwelling urinary catheter: – do not use bladder instillations or washouts" Our members' review of evidence shows that encrustation occurs in at least 50% of patients with long term catheters and 'recurrent blockage is known to cost the NHS in time and resources'. Getliffe 1994, 1996, 2003). It has long been recognised as a major cause of catheter blockage, with many studies verifying this and the problems associated with it. (Getliffe, 1994, 1996, 2000, Hesse et al 1989, Cox 1989, Choong 1999, Stickler et al 1998, 2003, Burr 1997 - others available if required). The recognition of patients as "blockers" and "non-blockers" is useful because it allows pro-active care to be planned and the correct treatment administered. There	After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations. With regard to the additional studies referred to, they did not meet the inclusion criteria for this review question as detailed in appendix E of the full guideline. Only randomised controlled trials were included. The studies highlighted are *in vitro* studies or discussion papers.

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						are many causes of catheter blockage and proper identification of the cause results in appropriate treatment. Infection control nurses may believe that blocked catheters are caused by UTIs, rather than by a build up of mucous/blood clots or a process of encrustation that builds up in and around the outside of the catheter. 'For those in whom a pattern can be identified, scheduled catheter changes prior to likely blockage may be an important aspect of their management. For others, in whom there is no clear pattern or for whom frequent catheter changes are traumatic, acidic washouts can be beneficial in reducing catheter encrustation... the effects of catheter associated complications are minimized and the resources available are used most effectively'. (Getliffe, K. 1996) In recent years the evidence has shown that two sequential washouts of smaller amounts of acidic solution has a much more significant effect on the encrustation within a catheter than one instillation of a larger amount of fluid. (Getliffe et al 2000). This smaller volume is more gentle, and the double instillation, without breaking the closed system reduces potential infection	

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						implications whilst having a better effect in encrustation dissolution. This new innovation has resulted in patients having a much better outcome with less instillations required. This, and other more recent research, has been overlooked in this draft document, which only refers to the 100ml volumes. Only four studies were identified to back up this guideline:- 1. Kennedy et al, 1992 2. Waites et al, 2006 3. Moore et al 2009 4. Muncie et al, 1989 The GDG group highlights the poor quality of the research used (page 145 – 10.8.1.4) The Kennedy 1992 trial concluded that (a) long term catheterised patients tend to be crystal formers, and (b) acidic washouts did not have a demonstrable effect in preventing encrustation. However, the second point is questionable as the crystal presence studied were those of uric acid, calcium oxalate and sodium urate. The principle composition of catheter encrustation is struvite and calcium	

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						phosphate, with other crystals seldom, if ever, implicated in catheter blockage. (Hedelin et al, 1984, Cox et al 1987) It is, therefore the effects of washouts on struvite and calcium phosphate which are the most important. The Waites 2006 study had serious limitations, very low sample size and inconclusive results. The Moore 2009 study concluded that the evidence was insufficient as to whether saline or the acidic solution used was more effective in reducing blockage. However, it also concluded that 'no increased risk of UTI was associated with washout regimes'. The Muncie study examined regular saline washouts v no washouts and its effects on infection and obstruction, and predictably concluded no significant difference and therefore regular saline washouts deemed unnecessary as a matter of routine. Anecdotal evidence from the many, many patients and nurses successfully using instillations should also be taken into account.	

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SH	The British Healthcare Trades Association (BHTA)	40.14	Full	10.9.1.4	145-146	**'Trade off between clinical benefits and harms'** This statement of considerations the GDG took does not take into account the research it examined (Moore 2009), proving 'no increased risk of UTI was associated with washout regimes', nor the potential risk of increasing the number of re-catheterisations due to increased blockage problems, and the evidence proving that re-catheterisation **does** increase the infection risk. (White 1995).	Thank you for your comment. The evidence reviewed for this clinical question (including Moore 2009) was taken into consideration by the GDG when making this recommendation. However due to the low quality of the evidence due to study limitations and inconclusive outcomes the GDG made a recommendation based on consensus. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections. White 1995 was not included 2003 version of the guideline and as this question was an update to the 2003 guideline, databases were searched from 2002. We are unable to locate the paper without the full reference.
SH	The British Healthcare Trades Association (BHTA)	40.15	Full	10.9.1.4	145-146	**'Economic considerations'** Whilst considering the cost of administering and instillation, the draft guidelines do not consider the costly consequences of	Thank you for your comment. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and

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						withholding them altogether. It, again, mentions infection risk (see above comment), and although suggests increasing fluid intake, this is not always possible with some patients. (Nurses are very aware of the need for good fluid intake but this is often very hard to monitor, especially in the community.) Planned catheter changes is good practice but if a patient is a persistent blocker they may block every few days without CMS use, causing increased nursing resource use, costs and considerable distress to the patient.	washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections. Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations
SH	The British Healthcare Trades Association (BHTA)	40.16	Full	10.9	137-145	**Implications of 'NO USE' of instillations/catheter maintenance solutions on the NHS & patients** **Financial** Without the use of CMS to help maintain patency, and therefore longevity of the catheter in the long term catheterised patient, the following financial implications would occur in the NHS:- • Increased District Nurse visits for increased, and unplanned, catheter changes and general care of catheter	Thank you for your comments. We acknowledge the detailed issues you raise. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations and have removed this from the recommendation. The original 2003 recommendation has been put back into the guideline: Bladder instillations and washouts must not be used to prevent catheter-associated infections.

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						problems. • District Nurses are already stretched by increasing work load as patients are discharged home earlier all the time. This will cause further strain on District Nurse resources and community budgets. • Less productivity from community staff results in higher costs for primary and secondary care. • Increased 'out of hours' costs as blockages happen anytime and often in the night. • Increased hospital referrals from nursing and residential homes that have patients with catheters – will ring direct to the hospital for any catheter problem rather than manage it themselves. • Increased cost of more indwelling catheters used eg patients that block off every few days, if not using CMS, will require new catheters each time. • Increased potential for infections as patient requires complete re-catheterisation technique each time there is a problem. • Increased call outs for Doctors, or	Additional text has also been added to the linking evidence to recommendation section: The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledge that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.

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						increased A/E attendance for male patients as many nurses still do not do male catheterisation. • Increased Ambulance costs for transporting patients with blocked catheters to A/E in D/N absence or patient emergency with retention problems • Increased attendance in the A/E departments of patients with blocked catheters (this is already a recognised problem in areas suffering with diminished District Nurse numbers, eg Whipps Cross Hospital,) and this will inevitably increase without ability to use CMS. • Increased utilisation of hospital staff attending to catheter blockage problems. • Potential extra hospital admission costs. **Patient safety & quality of life implications** • Patients would be at risk of more frequent blockages and relative complications of retention, bypassing, pain and trauma, bladder damage, etc.	

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						• Many patients block their catheters every few days, if not using CMS, and would, therefore, be subject to much more frequent re-catheterisation and its potential infection risk as well as the trauma of undergoing an invasive, very personal procedure, much more often. • Many patients administer their own instillations or have a carer who administers it for them, and therefore they manage some aspect of their catheter care themselves. Ringing the D/N or the ambulance service for admission to A/E is a last resort. Inability to have the option to use CMS will disempower the patient from their own care. • Patients at risk of unnecessary pain, trauma and retention complications if delays occur eg no D/N available to visit immediately, or delays in A/E admission. • Unnecessary A/E attendance, if admitted with a blocked catheter that could have been addressed in their own home. • Patients who suffer with encrustation	

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						around the catheter tip often require CMS prior to catheter changes to dissolve encrustation and ensure a less painful and traumatic catheter removal. • Patient's increased worry about unpredictable catheter blockage may lead to impact on their activities. eg reluctance to go out of the home for fear of blockage or embarrassing leakage in public. • Terminally ill patients, unable to increase fluid intake, will be unable to have a gentle flush of the catheter for thick, mucoid or debris complicating their catheter. • Patients with Mitrofanoff, or augmentations, which create a lot of mucus, will be unable to remove it. • Nurses attending to 'post - urology surgery' patients, who may still experience blood clots in the catheter, will be unable to remove them simply and gently. • Higher risk for male patients, should they block their catheter, as many community nurses do not perform male catheterisation. The patient may	

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						then be subject to more delays finding someone who can perform the procedure, or may have another hospital attendance, which could have been avoided. • Higher risk for more vulnerable patient groups more prone to blockage eg MS sufferers, other neurological patients, immobile patients etc. • Patients requiring bladder instillations for therapeutic reasons, such as chemotherapy, will be affected, as, although saying it is an area outside the scope of the guideline, it will cause much confusion. The statement merely states not to use them, and does not clarify any further. • Given the above implications on not using bladder instillations, both in cost and patient risk, more clarification is needed and the previous statement used in the 2003 document '**Bladder instillations or washouts must not be used to prevent catheter associated infection'** allowed the appropriate use of instillations for the correct indication.	

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SH	The British Healthcare Trades Association (BHTA)	40.17	FULL	general	general	**Reference list (those not on NICE draft list)** Burr RG, Nuseibeh IM (1997) 'Urinary catheter blockage depends on urine pH, calcium and rate of flow'. *Spinal Cord* **35**(8):521-5 Cardena DD, Moore KN, Dannels-McClure A, Scelza WM, Graves DE, Brooks M, Busch AK (2011) "Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicentre trial". *PM R*. 2011 May;3(5):408-17 Chartier-Kastler E, Denys P (2011) "Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention". *Neurourol Urodyn*. 2011 Jan; 0(1):21-31 Choong S, Hallson P, Whitfield H, Fry C (1999) 'The physiochemical basis of urinary catheter encrustation'. *BJU Int* **83**(7):770-5 Cox AJ, Harries JE, Hukins DWL, Kennedy AP, Sutton TM (1987) ' Calcium phosphate in catheter encrustation' *Br J Urol* **59** : 159-63 Getliffe KA (1994) The use of bladder washouts to reduce urinary catheter encrustation. *Br J of Urol*: 73:696-700	Thank you for providing these references. We have looked through them and found that they do not meet our inclusion criteria as they are non-randomised trials, observational studies, non systematic reviews or are indirect evidence (such as in a different population such as secondary care or intensive care settings). The full protocol for the review questions in this update are in appendix E.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Getliffe KA (1996) Bladder instillations and bladder washouts in the management of catheterized patients. *J Adv Nurs* 23 :548-54 Getliffe KA, Hughes SC, Le Claire M (2000) The dissolution of urinary catheter encrustation. *BJU Int* 85 (1):60-4 Getliffe KA (2003) 'Managing recurrent urinary catheter blockage: problems, promises and practicalities' *J Wound Ostomy Continence Nursing* **30** (3): 146-51 Hesse A, Schreyger F, Tuschewitzki GJ, Classen A, Bach D (1989) Experimental investigations on dissolution of encrustations, including the effects of allopurinol treatmentds. *Br J Urol* 56:250-4 Hedelin H, Bratt CG, Eckerdal G, Lincoln K (1991) 'Relationship between urease producing bacteria, urinary pH and encrustation on indwelling urinary catheters'. *Br J Urol* **67**(5): 527-31 Morris NS, Stickler DJ (1998) 'Encrustation of indwelling urethral catheters by Proteus Mirabilis biofilms growing in human urine'. *J Hosp Infection* **39** (3) :227-34	

These stakeholder organisations were approached but did not respond

Abbott Laboratories Limited
Abbott Laboratories Limited
African Health Policy Network
Alder Hey Children's NHS Foundation Trust
Anglian Community Enterprise
Ark Therapeutics Ltd
Aspen Medical Europe Ltd
Association of British Health-Care Industries
Association of Dance Movement Psychotherapy UK
Association of Paediatric Anaesthetists of Great Britain and Ireland
Astellas Pharma Ltd
Astellas Pharma Ltd
Augustine Biomedical International
Barchester Healthcare
Barnsley Hospital NHS Foundation Trust
Baxter Healthcare Ltd
BD (Beckton, Dickinson and Company)
Berkshire Healthcare NHS Foundation Trust
Birmingham City University
BMJ
Bolton PCT
Brighton and Sussex University Hospitals Trust
British Association of Otolaryngologists Head and Neck Surgeons (ENT UK)
British Association of Social Workers
British Dietetic Association
British Elbow and Shoulder Society (BESS)
British In Vitro Diagnostics Association
British Infection Association (formerly Association of Medical Microbiologists)
British Infection Association (formerly British Infection Society)
British Medical Association (BMA)
British National Formulary (BNF)
British Orthopaedic Association
British Paediatric Allergy, Immunity & Infection Group
British Pain Society
British Psychodrama Association
British Psychological Society, The
British Renal Society

British Renal Society
British Society of Immunology
Cambridge Temperature Concepts Ltd
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Camden and Islington Mental Health and Social Care Trust
Cancer Voices
Care Quality Commission (CQC)
Central & North West London NHS Foundation Trust
CJD Support Network
CLIC Sargent
Cochrane Wounds Group
Colchester Hospital University NHS Foundation Trust
College of Optometrists
Commission for Social Care Inspection DO NOT USE - Replace by CQC
Connecting for Health
ConvaTec
Cook Medical
Cornwall & Isles of Scilly PCT
County Durham PCT
Covidien UK Commercial
Covidien UK Commercial
Craegmoor
Danone UK Limited
Dental Practitioners Association
Department for Communities and Local Government
Department of Health, Social Services & Public Safety, Northern Ireland (DHSSPSNI)
Derbyshire Mental Health Services NHS Trust
Dermal Laboratories Ltd
DH Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection
Diving Diseases Research Centre, The
Dorset PCT
Elective Orthopaedic Centre, The
English Community Care Association (ECCA)
Enturia Ltd
Eusapharma (Europe) Ltd
Faculty of Dental Surgery
Faculty of Intensive Care Medicine
Federation of Ophthalmic & Dispensing Opticians (FODO)

Forest Laboratories UK Limited
Fresenius Medical Care
General Dental Council
George Eilot Hosptal Trust
Gloucestershire Hospitals NHS Trust
Gloucestershire LINk
Greater Manchester West Mental Health NHS Foundation Trust
Greater Manchester West Mental Health NHS Foundation Trust
Greater Manchester West Mental Health NHS Foundation Trust
Guy's and St Thomas NHS Foundation Trust
Haag-Streit UK
Hampshire Partnership NHS Foundation Trust
Hayward Medical Communications
Health Protection Scotland
Healthcare Improvement Scotland
Healthcare Quality Improvement Partnership
Herpes Viruses Association
Hertfordshire Partnership NHS Trust
Homeless Link
Hospital Infection Society
Hull and East Yorkshire Hospitals NHS Trust
Humber NHS Foundation Trust
ICNet International
Insitute of Biomedical Science
Interhealth Canada
Janssen
JBOL Ltd
Karomed Limited
KCI Europe Holding B.V.
KCI Medical Ltd
Kent & Medway NHS and Social Care Partnership Trust
Kettering General Hospital NHS Foundation Trust
King's College London Dental Institute
Lambeth Community Health
Lancashire Care NHS Foundation Trust
Launch Diagnostics Limited
Leeds PCT
Leicestershire Partnership NHS Trust

Letterkenny General Hospital
Leukaemia & Lymphoma Research
Liverpool Community Health
Liverpool PCT
Liverpool PCT Provider Services
London Ambulance Service NHS Trust
Lothian University Hospitals Trust
Luton & Dunstable Hospital NHS Foundation Trust
Maidstone and Tunbridge Wells NHS Trust
Maidstone and Tunbridge Wells NHS Trust
Manchester Community Health
MAST Group
Medihoney (Europe) Ltd
Medway Community Centre
Medway NHS Foundation Trust
Ministry of Defence (MoD)
Monitor - Independent Regulator of NHS Foundation Trusts
Mother and Child Foundation
National Care Forum
National Concern for Healthcare Infections (NCHI)
National Day Nurseries Association
National Electronic Library for Infection
National Infusion & Vascular Access Society
National Patient Safety Agency (NPSA)
National Patient Safety Agency (NPSA)
National Pharmacy Association
National Treatment Agency for Substance Misuse
NCC - Cancer
NCC - Mental Health
NCC - National Clinical Guideline Centre (NCGC)
NCC - Women & Children
Nestor Healthcare Group Ltd
NETSCC, Health Technology Assessment
Newcastle and North Tyneside Community Health
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Direct
NHS Forth Valley
NHS Knowsley

NHS Knowsley
NHS Plus
NHS Sefton
NHS Sheffield
NHS Western Cheshire
NICE - CHTE for info
NICE - CPHE
NICE - CPHE Methodology - Simon for info
NICE - Guidelines - GC, HE, Tech Lead
NICE - Guidelines HE for info
NICE - IMPLEMENTATION CONSULTANTS (ALL)
NICE - IMPLEMENTATION CO-ORDINATION for info
NICE - PPIP
NICE - R&D for info
Nordic Surgical Ltd.
North Essex Partnership NHS Foundation Trust
North Somerset PCT
North Staffordshire Combined Healthcare NHS Trust
North West London Perinatal Network
Northampton Primary Care NHS Trust
Nottingham University Hospitals NHS Trust
Nottinghamshire Acute Trust
Nutricia Ltd (UK)
Nuture Antenatal
Offender Health - Department of Health
Outer North East London Community Services
Owen Mumford Ltd
Oxford Health NHS Foundation Trust
Oxford Health NHS Foundation Trust
Oxford Health NHS Foundation Trust
Oxford Health NHS Foundation Trust
Paediatric Intensive Care Society
Paediatric Intensive Care Society
Patient's Association
Patient's Association
Patients Council
Pennine Healthcare
PERIGON Healthcare Ltd

Pfizer Limited
Pilgrims Hospices in East Kent
PINNT
Plymouth Local Involvement Network
Poole and Bournemouth PCT
Public Health Medicine Environmental Group (PHMEG)
Public Health Wales
Queen Victoria Hospital NHS Trust
Retreat, The
Reusable Healthcare Textiles Association
Richard Wells Research Centre
Robinson Healthcare Ltd
Roche Diagnostics
Rotherham NHS Foundation Trust
Royal Berkshire NHS Foundation Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Pathologists
Royal College of Psychiatrists
Royal College of Radiologists
Royal Free Hospital NHS Trust
Royal Pharmaceutical Society of Great Britain
Royal Society of Medicine
Sanctuary Care
Sandwell PCT
Sanofi-Aventis
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield Children's NHS Foundation Trust
Sheffield Health and Social Care Foundation Trust
Sheffield PCT
Sheffield PCT
Sheffield Teaching Hospitals NHS Foundation Trust
Sickle Cell Society

Smith & Nephew Healthcare
Social Care Institute for Excellence (SCIE)
Social Exclusion Task Force
Society and College of Radiographers
Society for Acute Medicine
Society of British Neurological Surgeons
Society of British Neurological Surgeons
Society of Chiropodists & Podiatrists
Solent Healthcare
South Asian Health Foundation
South East Coast Ambulance Service
South Essex Partnership NHS Foundation Trust
South Staffordshire & Shropshire NHS Foundation Trust
South Staffordshire PCT
South West Yorkshire Partnership NHS Foundation Trust
South Western Ambulance Service NHS Foundation Trust
Southport & Ormskirk Hospital NHS Trust
Spinal Injuries Association
Spinal Injuries Association
Spinal Injuries Association
St Andrew's Healthcare
St Marys Hospital, Manchester
StickSafe
Sue Ryder Care
Surgical Dressing Manufacturers Association (SDMA)
Sussex Partnership NHS Foundation Trust
Synergy Healthcare (UK) Limited
Tees Esk & Wear Valleys NHS Trust
The Society and College of Radiographers
Trafford NHS Provider Services
Turning Point
UNISON
United Kingdom Clinical Pharmacy Association (UKCPA)
United Lincolnshire Hospitals NHS Trust
University Hospitals Birmingham NHS Foundation Trust
University of Southampton
Urgo Medical Ltd
Vifor Pharma UK Ltd

Welsh Government
Welsh Scientific Advisory Committee (WSAC)
West Hertfordshire PCT & East and North Hertfordshire PCT
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire Acute Hospitals NHS Trust
Worcestershire PCT
Wound Care Alliance UK
Xpand Medical Ltd
York Teaching Hospital NHS Foundation Trust