

National Institute for Health and Care Excellence

**Surgical Site Infection
Quality Standard Consultation Comments Table
17th May – 18th June 2013**

ID	Stakeholder	Statement No	Comment on	Comments	Response
1	Public Health England	General	Title of quality standard	It seems counterintuitive to have a quality standard for surgical site infection. Perhaps this should be for 'prevention and management' of SSI.	The title of this quality standard was referred to NICE by the Department of Health. It was originally "Surgical site infection and sepsis" however it has since been agreed that sepsis would be covered by a separate standard.
2	British Society for Antimicrobial Chemotherapy (BSAC)	General	Scope	The Quality Standard covers the key areas for quality improvement. It is suggested that procedures to be included are hip and knee replacements plus groin hernias and varicose veins. For hernias and veins most guidance would suggest that antibiotics are not required therefore some of the standards may not apply. Should focus not be procedures with high risk and high burden of surgical site infection e.g. GI, urology, major vascular.	The scope of the quality standard covers all surgical incisions through the skin.
3	Gloucestershire Hospitals NHS Foundation Trust	General	Scope	Surgical site infection is a type of healthcare-associated infection in which a wound becomes infected after an invasive (surgical) procedure'. Surely it is going to be a surgical procedure by default as they are called Surgical site infections- would it not be an 'invasive site infection' otherwise?	Introductory text changed to: 'Surgical site infection is a type of healthcare-associated infection in which a surgical incision site becomes infected after a surgical procedure'.
4	The British Society of Interventional Radiology in collaboration with The Royal College of Radiologists	General	Scope	<p>Thank you for giving us the opportunity to comment on this. Although this appears to be directed primarily for open surgical procedures. This guidance we believe would also be relevant to interventional radiology (IR), Endoscopy (PEG) and to Cardiology and we feel it should be phrased in a much more generic fashion. We believe specific mention of IR should be incorporated to make it clear to commissioners, providers and Radiologists that this guidance applies to their interventions in the same way it does to all surgeons.</p> <p>I'm sure NICE will interpret arthroscopy and laparoscopy as "surgery", and similarly this should apply to other minimally invasive procedures such as EVAR, PTC/stent etc? It may be that a separate guidance is to be prepared for these other minimally invasive procedures, which will cover these areas.</p>	<p>The quality standard covers surgical incisions through the skin. However, the Topic Expert Group developing this standard felt that some areas of care, in particular those which are preoperative, may apply to other procedures which do not include a visible incision. This is documented in the scope of the QS.</p> <p>A full list of quality standard topics that have been referred to NICE is available on our website: www.nice.org.uk</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
5	Gloucestershire Hospitals NHS Foundation Trust	General	Introduction	'At least 5% of patients who have a surgical procedure develop a surgical site infection' I think that this needs to be qualified as surgery in general as we know that orthopaedics sits around the 0.5%-1% mark whereas colorectal sits around 9%, both of which are different to 5%	Introductory text updated to state that incidence depends on type of procedure.
6	Public Health England	General	Introduction	The statement that at least 5% of patients who have a surgical procedure develop an SSI needs to be supported by citation of an appropriate reference.	Introductory text updated, including addition of relevant reference.
7	Public Health England	General	Introduction	Describing standards as being 'measurable' – It is not known whether these standards are truly measurable as this depends on whether service providers already have systems in place to collect all the data items proposed. It may be very challenging to collect certain data items.	Quality measures are intended to form the basis for audit criteria developed and used locally.
8	British Association of Dermatologists (BAD)	General	Question 1	Yes.	Thank you for your comment.
9	Papworth Hospital	General	Question 1	There are too many, and many of them could be improved by mandatory SSI surveillance in England. Continuous SSI surveillance in our experience informs practice, and reduces rates of SSIs. However, at present England does not have mandatory surveillance.	The final quality standard includes a statement specifically on surveillance (statement 7).
10	Royal College of Nursing	General	Question 1	We agree that the draft quality standard does appear to accurately reflect the key areas for quality improvement However, it seems heavily biased towards infection prevention. It would be good to include more holistic elements that impact on development of infections such as nutrition, hydration, pneumaturia, promoting normal elimination etc.	Thank you for your comment. The topic expert group prioritised the areas they felt were most important for quality improvement, using the accredited guidance available.
11	Royal College of Surgeons of Edinburgh	General	Question 1	The Royal College of Surgeons of Edinburgh (RCSEd) believes that the draft quality standard accurately reflects the key areas for quality improvement. We have, however, some suggested amendments and these are provided below [see statement-specific comments].	Thank you for your comments.
12	Arhai	General	New statement	Section 10 in briefing paper –Patient Information should be one of the 10 Quality Standards proposed, but has been dropped. Informing patients what is being done to protect them not only increases patients understanding of their care, but is a powerful reinforcement to good practice. Patients should be informed about SSI risk and management	Statement 5 in the final quality standard covers information and advice for patients and carers on wound and dressing care, including how to recognise problems with the wound, and who to contact if they are

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				as part of the consent process.	concerned Statement 7 in the final quality standard covers surveillance and provision of feedback to staff and stakeholders, which includes patients.
13	British Association of Dermatologists (BAD)	General	New statement	A very well worked out piece of work, which attempts to cover the breadth of surgical practice. However, a statement from the GDG on community- or hospital/outpatient-based skin surgery would be appropriate. Particularly, focusing on the breadth of skin surgery which is now done in minor procedure rooms rather than operating theatres (see below). Surgical site infection rates in dermatological surgery worldwide are low with most studies quoting 2-5%.	The scope of the quality standard covers all settings including primary and community care, secondary care and tertiary care. The topic expert group prioritised the areas they felt were most important for quality improvement, using the accredited guidance available.
14	British Society for Antimicrobial Chemotherapy (BSAC)	General	New statement	When a patient is being discharged on an antibiotic, could we highlight that the discharge letter to the GP must provide information on the nature, reason and proposed duration of an antibiotic?	NICE quality standard 15 on patient experience in adult NHS services covers coordinated care through the exchange of information.
15	Deltex Medical	General	New statement	We suggest considering the evidence to support the use of oesophageal Doppler for intraoperative fluid management (IOFM) when making any recommendation regarding surgical site infections. Use of oesophageal Doppler for IOFM has been proven to reduce postoperative complications, one of which is wound infections. Pillai et al. [1] reported post-operative wound infections in only 6% of patients who received IOFM guided by oesophageal Doppler, vs. 29% in patients who received standard anaesthetic care (P<0.01). Other randomised controlled trials have also reported (non-significant) reductions in wound infections in patients who receive IOFM using oesophageal Doppler [2-6]. In a Health Technology Assessment conducted by Maeso et al. [7], oesophageal Doppler was deemed to have a favourable effect (RR=0.61, P=0.001) on postoperative complications, which included surgical site infections (“the most common postoperative complications were pneumonia, surgical site infections, wound dehiscence and	Quality statements are developed using existing NICE or NICE-accredited guideline recommendations. NICE clinical guideline 74 does not cover this intervention.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>arrhythmias.”). Furthermore, in the recent Cochrane review by Grocott et al. [8] which included a meta-analysis on the effect of perioperative fluid management, the authors reported “the intervention significantly reduced the rate of wound infections”. Analysis revealed a relative risk of 0.65 (P=0.0013). Dalfino et al. [9] conducted a similar analysis of studies, and concluded “perioperative goal-directed therapy significantly reduced surgical site infections”, OR 0.58; P < 0.0001).</p> <p>The maintenance of adequate circulation and oxygen delivery across the perioperative period reduces postoperative complications; surgical site infections are one of these. Oesophageal Doppler is the only technology proven to consistently improve patient outcome when used intraoperatively to guide fluid management.</p> <p>References</p> <ol style="list-style-type: none"> 1. Pillai, P.M., I.; Gaughan, M.; Snowden, C.; Nesbitt, I.; Durkan, G.; Johnson, M.; Cosgrove, J.; Thorpe, A., <i>A double-blind randomized controlled clinical trial to assess the effect of Doppler optimized intraoperative fluid management on outcome following radical cystectomy</i>. J Urol, 2011. 186(6): p. 2201-6. 2. Brandstrup, B., et al., <i>Which goal for fluid therapy during colorectal surgery is followed by the best outcome: near-maximal stroke volume or zero fluid balance?</i> Br J Anaesth, 2012. 109(2): p. 191-9. 3. Gan, T.J., et al., <i>Goal-directed intraoperative fluid administration reduces length of hospital stay after major surgery</i>. Anesthesiology, 2002. 97(4): p. 820-6. 4. Srinivasa, S., et al., <i>Randomized clinical trial of goal-directed fluid therapy within an enhanced recovery protocol for elective colectomy</i>. Br J Surg, 2013. 100(1): p. 66-74. 5. Venn, R., et al., <i>Randomized controlled trial to investigate influence of the fluid challenge on duration of hospital stay and perioperative morbidity in patients with hip fractures</i>. Br J Anaesth, 2002. 88(1): p. 65-71. 6. Wakeling, H.G., et al., <i>Intraoperative oesophageal Doppler guided fluid management shortens postoperative hospital stay after major bowel surgery</i>. Br J Anaesth, 2005. 95(5): p. 634- 	

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>42.</p> <p>7. Maeso, S., et al., <i>Esophageal Doppler monitoring during colorectal resection offers cost-effective improvement of hemodynamic control</i>. Value Health, 2011. 14(6): p. 818-26.</p> <p>8. Grocott, M.P., et al., <i>Perioperative increase in global blood flow to explicit defined goals and outcomes after surgery: a Cochrane Systematic Review</i>. Br J Anaesth, 2013.</p> <p>9. Dalfino, L., et al., <i>Haemodynamic goal-directed therapy and postoperative infections: earlier is better. A systematic review and meta-analysis</i>. Crit Care, 2011. 15(3): p. R154.</p>	
16	Johnson & Johnson Medical Ltd	General	New statement	<p>Suggested New Statement – “Peri operative practice should aim to minimise risk of acquiring an SSI”.</p> <p>Metrics - Compliance with intra-operative phase recommendations in revised version of CG74. Denominator - Adherence to Recommendations Numerator - Percentage reported compliance based on number of surgical procedures.</p>	NICE quality statements describe specific areas for quality improvement that relate to an identified action or intervention. They do not replace existing guidance, which should still be considered alongside the quality standard.
17	Maquet UK Ltd	General	New statement	<p>We have new open vascular prosthesis’s (Intergard Synergy) that has been developed with a dual antimicrobial agents, which significantly reduces the risk of SSI’s, blending of antimicrobial agents has been shown to be more effective than antibiotics, while at the same time not promoting resistant strains. Therefore people requiring a vascular prosthesis who are judged to have an increased likelihood of developing an SSI should receive this graft instead of a normal vascular graft.</p> <p>The antimicrobial agents of Intergard Synergy, in the concentration present on the graft “out of package” at the time of implantation, are bactericidal and kill all bacteria on the graft including MRSA. There is no contraindication to the use of Intergard Synergy in a contaminated implant site. The graft was designed for routine prophylactic use.</p>	Quality statements are developed using existing NICE or NICE-accredited guideline recommendations. NICE clinical guideline 74 does not cover this intervention.
18	Public Health England	General	New statement	<p>Three areas omitted:</p> <ul style="list-style-type: none"> glucose control for diabetic patients – this should be included in Quality Statement 8 (homeostasis) – the proportion of diabetic patients whose glucose level was maintained pre-operatively, peri-operatively and post-operatively antimicrobial prophylaxis – agent used to cover expected pathogens at operative site <p>antimicrobial prophylaxis – % of patients where timing / frequency of</p>	The topic expert group prioritised the areas they felt were most important for quality improvement, using the accredited guidance available.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				dose is compliant with guidelines	
19	Royal Brompton and Harefield NHS Foundation Trust	General	New statement	Key areas for quality improvement: We would add HbA1C measure for all patients with diabetes. Hba1C or Glycated Hb >7.5% is associated with higher incidence of SSI.	The topic expert group prioritised the areas they felt were most important for quality improvement, using the accredited guidance available.
20	The Independent Healthcare Advisory Services	General	New statement	Training of estate and clinical staff in prevention and control of infection IHAS will absolutely agree with. Additionally IHAS would suggest that somewhere within the document under the post-operative phase that Clinical staff should have training in recognising infection/sepsis as part of caring for the post-operative patient.	The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in surgery, including surgical site infection prevention and treatment, should be sufficiently and appropriately trained and competent to deliver the actions and interventions described in the quality standard.
21	British Association of Dermatologists (BAD)	General	Question 2	Overall yes, although there would be significant workload involved. This may cause problems in different specialties where the staffing levels are already insufficient to meet the daily clinical service demands. Such audit work could be incorporated into a department's rolling audit activities but would probably require additional staffing levels (would be a useful part of a CNS work plan). Some of the audit work could be shared out between different departments (specific specialty/anaesthetics/microbiology/estates).	Thank you for your comments.
22	Chelsea and Westminster Hospital NHS Foundation Trust	General	Question 2	If the necessary resources were in place this data could be gathered. Some of this data is already captured in terms of clinical practice audit, reporting of SSI rates internally and externally, and patient nursing and medical records.	Thank you for your comments.
23	Papworth Hospital	General	Question 2	This would require huge resources to be put in place, particularly for staph screening on all patients. I refer back to my first point the need for mandatory SSI surveillance in all surgical specialities.	Thank you for your comments. The final quality standard does not cover S.aureus screening. Quality statement 7 covers surveillance of surgical site infections.
24	Patients Association	General	Question 2	The Patients Association believes that data collection for the proposed quality measures would be possible although it requires detailed administration and commitment by all healthcare staff. It is essential that data are comparable, meaningful and are readily accessible and assessable. Hence, we would welcome if guidelines on accurate data	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and used locally.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				collection methods would be distributed to all healthcare professionals working in surgeries. The collection of appropriate data and then its analysis would help to improve infection control practices.	
25	Public Health England	General	Question 2	At service provider level – this very much depends on whether data collection is routine.	Thank you for your comment.
26	Royal Brompton and Harefield NHS Foundation Trust	General	Question 2	Yes as a proportion of patients may be reviewed (ie snap shot audits are appropriate). However the standards will require considerable resources /time to gather and there is some concern that data collection efforts will leave little resource remaining to implement change and improvements.	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and prioritised locally.
27	Royal College of Nursing	General	Question 2	Given the many variations in IT provision across the NHS we are not confident that all areas will be able to collect/provide meaningful data for reporting purposes. We suspect that in some areas this may result in paper forms to collect data that could then be inputted separately, a process which is time consuming and increases the margin for error in recording data.	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and used locally.
28	Royal College of Surgeons of Edinburgh	General	Question 2	Firstly, the systems and structures in many areas are simply not available to collect this data. Some standards simply cannot be audited without labour intensive spot checks, such as Standard 2. People having surgery are cared for by staff who follow practices that minimise the risk of surgical site infection. Some standards, for example Standard 3, are easily identified from the WHO checklist. Others for example, Standard 6, regarding information and advice availability of such education material is limited and not universal. In addition, information and advice which is culturally appropriate; accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English is woefully poor.	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and used locally.
29	Royal College of Nursing	General	Measures	We have noticed that all of the draft quality statements except for statement 1 (personal preparations) do not have an outcome measure within the quality measure. Within the Patient Safety Programme in Scotland, outcome measures would be included, for example, each clinical area must demonstrate at least 95% compliance with antibiotic prophylaxis, 95% compliance with screening etc. In our understanding of quality improvement, each process measure should have an outcome measure.	Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					and professional judgement, and therefore desired levels of achievement should be defined locally.
30	British Society for Antimicrobial Chemotherapy (BSAC)	General	Guideline	1.1.4 – “Always inform patients after their operation if they have been given antibiotics”. Does this refer to prophylaxis or subsequent treatment?	This comment relates to NICE clinical guideline 74.
31	The Independent Healthcare Advisory Services	General	Guideline	1.3.3 – The use of the negative “Do not use” does not feel as helpful as a positive statement such as “Always use”	This comment relates to NICE clinical guideline 74.
32	Arhai	General	General	These Quality Standards should be published in consistent, plain English. If this is done, they will be useful to patients and carers and be clear to all clinical team members. The current drafting is a mix of good plain English with some unnecessary clinical terms. Suggested re-drafts as follows [see statement sections].	The quality standard is accompanied by information for the public which provides a plain English version of the statements.
33	British Orthopaedic Association	General	General	We are concerned that the routine collection of data on a huge number of surgical patients will put unacceptable additional burdens on hospital healthcare professionals. Nursing and medical staff are already being stretched to the limits on many mundane paper exercises (read Mid-Staffs enquiry). Careful consideration must be given on the necessity and practicality of collection on yet another set of data. Currently, we are spot auditing SSI for one month of the year and it would be sensible not to create any additional workload.	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and prioritised locally.
34	British Orthopaedic Association	General	General	The British Orthopaedic Association has reviewed the briefing paper on your draft guidance on surgical site infection. We are supportive on most of the proposals and welcome its eventual introduction to standardise surgical wound care. We have, however, some reservations on the following points [see other comments].	Thank you for your comments.
35	Defence Medical Services; MOD	General	General	The document is wordy and repetitive, this repetition does not add value or clarity. Can it be made more succinct?	We will shortly be undertaking a user research project on the quality standards template to determine whether any improvements can be made.
36	Department of	General	General	We welcome this NICE quality standard for surgical site infection (SSI).	Thank you for your comments.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
	Health			The Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection discussed the prevention of SSI when they met in February 2013. It was agreed that improved compliance to the evidence based interventions to reduce SSI was an area where current practice could be improved.	
37	Faculty of Intensive Care Medicine	General	General	I have read the document and am very appreciative of the large amount of work that has gone into it. I cannot see any areas where there are significant omissions, and while there is still a long way to go, this should be an important document in guiding surgeons towards an evidence based approach to reducing surgical infections.	Thank you for your comments.
38	Patients Association	General	General	The Patients Association welcomes the opportunity to give our views on this important topic. In order to improve patient safety in hospitals, we believe it is vital that the comments set out below are considered and included in the NICE Quality Standard for Surgical Site Infection. These recommendations are based on conclusions from numerous surveys with healthcare professionals and patients that the Patients Association conducted in the last decade, on the issue of infection control. For ease of reference I have also attached a copy of our most recent infection control report, 'Rolling the Dice: Could IPC be a victim of its own success?'.	Thank you for your comments.
39	Royal College of Anaesthetists	General	General	Members of the Professional Standards Committee of the Royal College of Anaesthetists have reviewed this standard and are happy with the contents and have no additional comments to offer.	Thank you for your comment.
40	Royal College of Nursing	General	General	The standards reflect key areas for quality improvement. It would provide an audit tool to audit practice.	Thank you for your comment.
41	Royal College of Physicians	General	General	RCP has had sight of and wishes to endorse the comments submitted by the BAD on the QS.	Thank you for your comment.
42	The British Dental Trade Association Ltd	General	General	The BDTA supports in principle the draft quality standard for surgical site infection and the general principles embodied in the standards.	Thank you for your comment.
43	The Independent Healthcare Advisory Services	General	General	General comment on the document. The document is only talking about NHS trusts. IHAS would recommend the use of a more inclusive language such as Healthcare providers/Healthcare organisations. A considerable number of NHS funded operations are carried out in the independent sector and all healthcare organisations providing surgery	Specific references to 'NHS Trusts' have been removed in the final quality standard. The scope of the quality standard covers all settings including primary and community care, secondary care and tertiary care.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				for patients NHS funded or privately funded should be expected to adhere to the Quality Standards programme.	
44	3M Health Care	1	Statement	Add final sentence: "Patients should be advised that where hair removal is required it will take place within the hospital and prior to surgery."	This is covered by recommendation 1.2.3 in NICE clinical guideline 74: surgical site infection.
45	British Association of Dermatologists (BAD)	1	Statement	The advice for patients to shower, wash or not remove hair pre-operatively is not routinely given pre-dermatological or plastic surgical procedures under local anaesthesia. Also, this should not be too prescriptive. Surgical preferences will vary – for example, for split-thickness skin grafts on the lower leg, patients would not normally be allowed to wash the area after 48 hours (usually 1 week). Hair is usually not removed during skin surgery procedures even if located on hair-bearing areas such as the scalp, but if necessary is often achieved by "close trimming" with scissors which minimises any surface trauma.	The Topic Expert Group prioritised pre-operative personal preparation for surgery. The quality statement is developed from recommendations in NICE clinical guideline 74: surgical site infection. The quality standard should be used in the context of professional judgement and individual circumstances.
46	British Society for Antimicrobial Chemotherapy (BSAC)	1	Statement	Consider adding other advice for patients eg non-use of face flannels for post-op washing of wounds; use of chest support or bra for postoperative cardiac patients. Or if such specifics are not possible, a statement about written instructions (preoperative information leaflet) relevant to the surgery should be provided and it would be possible to audit that too.	The Topic Expert Group prioritised preoperative personal preparation for surgery. They also felt it was important to go beyond providing written information. For example, the statement covers active help with washing if the person having surgery is unable to wash themselves.
47	Papworth Hospital	1	Statement	Agree with statement	Thank you for your comment.
48	Patients Association	1	Statement	The advice and help given to patients before and after surgery are significant factors in preventing surgical site infections as well as detecting them in a reasonable time. Early detection ensures more efficient treatment. We believe this information should be given to patients not only verbally but also in a written format. Patients would then be able to prepare adequately for their surgery according to general standards and use the written information for further guidance after the surgery (e.g. recognising a surgical site infection, wound care, contact details for further advice).	Thank you for your comment. Statement 1 covers help with as well as advice on personal preparations for surgery (active help with washing if the person having surgery is unable to wash themselves). Statement 5 of the final quality standard covers information and advice for patients on wound and dressing care, including how to recognise problems with the wound, and who to contact if concerned.
49	Royal Brompton and Harefield NHS Foundation	1	Statement	Agree. We would recommend antimicrobial wash (Tanner <i>et al.</i> Jan 2012 JIP)	Thank you for your comment. Whilst the quality statement does not state which product people should wash with, the quality statement is developed from NICE

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
	Trust				clinical guideline 74, which recommends washing with soap.
50	Royal College of Surgeons of Edinburgh	1	Statement	Agreed unchanged.	Thank you for your comment.
51	The British Dental Trade Association Ltd	1	Statement	The BDTA supports these statements.	Thank you for your comment.
52	Royal College of Nursing	1	Source guidance	The EPIC 3 guidelines are currently under consultation with University West of London – we suggest that this should be considered with respect to the development of this statement so it aligns with the surgery standards - http://www.uwl.ac.uk/school_of_nursing_midwifery_and_healthcare/epic3_guidelines.jsp	At the time of development of the quality standard, the epic 3 guidelines were not published or accredited and therefore could not be used as a development source for the quality standard.
53	3M Health Care	1	Measures	The QS1 indicates that where hair removal takes place it should be undertaken with a surgical clipper with single use head. Razors should not be used. This is an important aspect of patient preparation which if ignored significantly raises the risk of surgical site infection. A Quality Measure should be associated with this practice so clinical audit can confirm/deny that this standard is being applied to surgical preparation of the patient.	The final quality statement includes measures on advising people having surgery not to remove hair from the surgical site, which was the quality improvement area prioritised by the Topic Expert Group. The rationale section of statement 1 states that the use of razors for hair removal can increase the risk of infection and that if hair needs to be removed, this should be done by healthcare staff using electric clippers with a single-use head on the day of surgery.
54	British Society for Antimicrobial Chemotherapy (BSAC)	1	Measures	Will be difficult to measure	Measures for advising not to remove hair and advising to have (or help to have) a shower, bath or bed bath have been separated in the final quality standard. Quality measures are intended to form the basis for audit criteria developed and used locally.
55	Public Health England	1	Measures	As advice not to remove hair may not apply to all situations, the quality measure and description followed by the final definition discussing hair removal appear contradictory. It is difficult to see if this indicator in its	Measures for advising not to remove hair and advising to have (or help to have) a shower, bath or bed bath have been

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>present form would give a meaningful insight into a provider's quality of service. It would be impossible to determine if patients understood information or whether any of the activities recommended actually took place. This indicator needs to be seen as a meaningful exercise. May be better to reformulate into two indicators:</p> <ul style="list-style-type: none"> Proportion of patients who underwent pre-operative showering using soap on the day before or on the day of surgery <p>If hair removal required, proportion of patients using electric clippers with single-use head on the day of surgery</p>	<p>separated in the final quality standard. Outcome measure now focused on help with washing. The Topic Expert Group felt it was important to focus specifically on advising all people not to shave before surgery rather than focusing only on people for whom hair removal is necessary.</p>
56	Royal Brompton and Harefield NHS Foundation Trust	1	Measures	<p>Our experience suggests patients have to be spoken to <u>pre</u> operatively and then wash checked (ie hair removal sufficient /skin clear of residue from electrodes etc). Patient feedback on wash post operatively is not reliable/complete</p>	<p>The quality standard is not intended to replace minimum surgical checks. Quality measures are intended to form the basis for audit criteria developed and used locally.</p>
57	Royal College of Nursing	1	General	<p>There is a large amount of repetition in this statement as each element is described which could encourage the reader to skim the sections and miss any other information provided within the statement. Would there be a way to change the format so that some sections just need to have the statement once?</p> <p>For example, thinking about what the description means for each audience, would it be possible to detail the four identified audiences in a different way and just put the statement once?</p>	<p>We will shortly be undertaking a user research project on the quality standards template to determine whether any improvements can be made.</p>
58	Royal College of Nursing	1	Definitions	<p>Hair removal - this advises that no hair should be removed before surgery. It fails to make it clear that this is just for the operation site. The way it reads seems to suggest that people should not shave their beards or remove the hair on their legs - it needs to be specific.</p>	<p>Statement 1 in the final quality standard clarifies that this relates to 'hair from the surgical site'.</p>
59	British Association of Dermatologists (BAD)	2	Statement	<p>These are of particular importance and relevance to the sphere of dermatosurgery. Although it is well established that suspected or confirmed skin cancer surgery should, in the vast majority of cases, be carried out by the relevant hospital specialist (dermatologist/plastics/ENT/maxillofacial/facioplastic surgeons), there is still a significant volume of such surgery performed in the community, potentially leading to sub-optimal practices be it either individual technique or the operative environment. These particular statements are very important to try and standardise the care pathway and optimise patient experience.</p> <p>There is a considerable range and variance in standards with regard to</p>	<p>Thank you for your comments.</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				pre-operative and post-operative patient information and counselling, levels of staff expertise and knowledge, the physical surgical environment and the local culture for transparency and self-reflection. Any practical and simple guideline/document which helps to standardise care is to be welcomed. We note that a degree of local autonomy is advocated so that the guideline is not unwieldy or irrelevant.	
60	British Society for Antimicrobial Chemotherapy (BSAC)	2	Statement	Could there be included a statement about the use of surgical masks? Evidence not there scientifically, but it would help with pushing for good theatre practice, to have a statement supporting the use by the surgeons and the anaesthetist. Consider if it would include all those in theatre that are likely to come within 1 m of the patient's would or the sterile theatre equipment. (Comparing this with droplet spread in pandemic influenza guidelines).	Quality statement 4 in the final quality standard covers best practice in theatre wear, which includes scrub suits, masks, hats and overshoes.
61	British Society for Antimicrobial Chemotherapy (BSAC)	2	Statement	There is a practice among cardiac surgeons that they sprinkle vancomycin on the wound as they begin to close. This is covered to some extent in 1.3.15 under intracavity lavage, but we wonder if it is possible to mention vancomycin? Has your research found that this is a widely used practice?	Quality standards are developed using existing NICE or NICE-accredited guidance.
62	British Society for Antimicrobial Chemotherapy (BSAC)	2	Statement	There are chlorhexidine-containing gloves on the market – with some evidence of decreased SSIs. What do you think? Especially if not using 2 sets of gloves? And the evidence for antibiotic-impregnated sutures?	Quality standards are developed using existing NICE or NICE-accredited guidance.
63	Defence Medical Services; MOD	2	Statement	The statement targets peri-operative care but not the post-operative 24-48 hrs.	The Topic Expert Group prioritised the intraoperative phase for minimising the transfer of microorganisms.
64	Healthcare Infection Society (HIS)	2	Statement	Artificial nails No use of artificial nails by clinical staff is already a standard. It is not just specific to theatre staff. This is also true of had jewellery as in “bare below the elbows” guidance on hand hygiene	Thank you for your comment. Quality standards are developed using existing NICE or NICE-accredited guidance.
65	Johnson & Johnson Medical Ltd	2	Statement	Johnson & Johnson (J&J) agree that staff practices play a significant role in minimising the risk of surgical site infections. However, appropriate use of technologies that can inhibit bacterial colonization of the device may be beneficial.	Quality standards are developed using existing NICE or NICE-accredited guidance.
66	Papworth Hospital	2	Statement	Agree with statement	Thank you for your comment.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
67	Patients Association	2	Statement	In order to provide the best possible care for patients, all staff should have adequate training about infection control and the most appropriate skin preparation should always be used prior to surgery. Cleaning and preparing the skin is very important pre and post operatively in order to minimise the subsequent risk of infections in invasive medical procedures. Training for staff ensures that healthcare professionals can follow standard practices that minimise the risk of surgical site infection and in turn provide the highest quality safest care to all patients. For this reason, the Trust Board must ensure sufficient time and other resources are made available for training. Once training has occurred, hospital management also needs to ascertain that compliance with standard infection control practices and procedures are part of all staff appraisals.	The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals and social care and public health practitioners involved in surgery, including surgical site infection and prevention and treatment, should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.
68	Royal Brompton and Harefield NHS Foundation Trust	2	Statement	Agree. We would recommend/add staff competency in aseptic technique for surgical wound dressing	The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals and social care and public health practitioners involved in surgery, including surgical site infection and prevention and treatment, should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.
69	Royal College of Surgeons of Edinburgh	2	Statement	We believe that this particular statement is not specific enough. There are prescribed protocols for surgical scrub technique and, if not followed, skin contamination can result even after washing. We believe that this quality standard requires education and monitoring.	The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals and social care and public health practitioners involved in surgery, including surgical site infection and prevention and treatment, should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.
70	Royal College of Surgeons of	2	Statement	The RCSEd recommends: <ul style="list-style-type: none"> 1.3.1 The operating team should wash their hands prior to the 	Best practice in surgical hand hygiene (defined by recommendations 1.3.1 and

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
	Edinburgh			<p>first operation on the list using an aqueous antiseptic surgical solution, with a single-use brush or pick for the nails, and ensure that hands and nails are visibly clean.</p> <ul style="list-style-type: none"> 1.3.2 Before subsequent operations, hands should be washed using either an alcoholic hand rub or an antiseptic surgical solution. If hands are soiled then they should be washed again with an antiseptic surgical solution. <p>We hope that this would be routinely practiced by theatre staff but we know from OSCE examinations that this is not always performed to the correct standard. Indeed, an audit undertaken at the Liverpool Heart & Chest Hospital identified that even experienced scrub nurses and surgeons did not always comply with the recommended protocol for surgical scrubbing; though their hands were visibly clean.</p>	1.3.2 in NICE clinical guideline 74) is covered by statement 4 in the final quality standard.
71	The British Dental Trade Association Ltd	2	Statement	The BDTA supports these statements.	Thank you for your comment.
72	Chelsea and Westminster Hospital NHS Foundation Trust	2	Measures	I believe it would be very difficult, as well as impractical to count the number of personnel who move in and out of the operating room unnecessarily. The definition is open to personal interpretation and therefore data would be very subjective.	Process measures have been removed from this quality statement in the final quality standard (see statement 4). There is a focus on 'local arrangements' being in place to minimise staff movements in and out of the operating area and to ensure that spot checks are carried out in relation to this. Quality measures are intended to form the basis for audit criteria developed and used locally.
73	Public Health England	2	Measures	<p>Indicator A: The numbers of staff behaving appropriately are unlikely to be all or none and all hospitals will respond 'yes' to the question 'do you follow these practices?' To enable these processes to be quantifiable, suggest that all staff treating the patient should have adhered to the standard.</p> <p>Process:</p> <p>a) Proportion of people having surgery who are cared for by staff who all follow practices for surgical hand decontamination in accordance</p>	The final quality standard (see statement 4) focuses on 'local arrangements' being in place, rather than a requirement for repeated counting. There is also a structure measure on carrying out spot checks relating to surgical hand hygiene, theatre wear, and movement in and out of the operating area.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>with NICE clinical guideline 74 recommendations 1.3.1 and 1.3.2.</p> <p>Numerator – the number of people in the denominator who are cared for by staff who all follow practices for surgical hand decontamination in accordance with NICE clinical guideline 74 recommendations 1.3.1 and 1.3.2.</p> <p>Denominator – the number of people having surgery</p> <p>b) Proportion of people having surgery who are cared for by staff who remove hand jewellery, artificial nails and nail polish before operations – also should this not be at the start of the shift? (appreciate this doesn't tie in with pathway)</p> <p>Numerator – the number of patients in the denominator who are cared for by staff who all remove hand jewellery, artificial nails and nail polish before operations</p> <p>Denominator – the number of patients having surgery</p> <p>c) Proportion of people having surgery who are cared for by staff who do not move in and out of the operating area unnecessarily</p> <p>Numerator: the number of people in the denominator who are cared for by staff who all do not move in and out of the operating area unnecessarily</p> <p>Denominator: the number of people having surgery</p> <p>Indicators B and C may be challenging to collect since the data items for these indicators may not be embedded in existing data collection practices. Indicator B would require a service provider to invest in a theatre monitoring device.</p>	
74	British Society for Antimicrobial Chemotherapy (BSAC)	2	Measures	Will be difficult to measure	Process measures have been removed from this quality statement in the final quality standard (see statement 5). There is a focus on 'local arrangements' being in place, including arrangements for spot

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					checks.
75	Royal Brompton and Harefield NHS Foundation Trust	2	Measures	<p>a) the numerator is too problematic, as many HCP have contact with one patient, at many points of care</p> <p>b) Bare Below the Elbow audit preferred to artificial nail / nail polish audit of staff</p> <p>c) Our Trust is unlikely to audit staff who move in and out of operating area 'unnecessarily' as too subjective</p>	Process measures have been removed from this quality statement in the final quality standard (see statement 4). There is a focus on 'local arrangements' being in place, including arrangements for spot checks.
76	Royal College of Nursing	2	Definitions	Given the Department of Health guidance on bare below the elbow, should we ensure consistency and say all hand, wrist and arm jewellery should be removed? As it reads at present, we can see some colleagues, particularly some medical colleagues arguing that a wrist watch is ok as it is not worn on the hand.	It is important that quality standards are considered alongside current policy documents. See 'policy context' section of final quality standard.
77	Royal College of Nursing	2	Definitions	What about wearing sterile surgical gloves?	The Topic Expert Group felt that this is already embedded in current practice.
78	Arhai	3	Statement	<p>Patient safety issue is stated as being antibiotics omitted or delayed for prophylaxis and treatment. A further issue is more antibiotic given than needed for prophylaxis, when a single dose would be appropriate.</p> <p>The QS standard concentrates on "recording" but should also concentrate on GIVING the appropriate antibiotic</p>	Statement 3 of the final quality standard covers people having surgery (that requires antibiotic prophylaxis) receiving antibiotic prophylaxis in accordance with the local antibiotic formulary. Using a formulary should ensure the most appropriate antibiotic, dose and duration are used.
79	Arhai	3	Statement	Instead of antibiotic prophylaxis: antibiotics to prevent infection	The quality standard is accompanied by information for the public which provides a plain English version of the statements.
80	British Association of Dermatologists (BAD)	3	Statement	The use of antibiotics in dermatosurgery varies widely worldwide. Generally, most consensus documents state that unless the lesion being removed is crusted or ulcerated, routine antibiotic use is not suggested in patients undergoing dermatological surgical procedures. There is evidence in the literature that excision of an eroded (broken skin surface) tumour has a higher incidence of surgical site infection compared to excision of a tumour with an intact surface. Similarly, skin surgery performed in certain anatomic sites (below knee, flexural regions) is also associated with a higher incidence of surgical site infection. Some guidelines differ regarding antibiotic prophylaxis in patients, undergoing skin surgery, who have had recent prosthetic implants. Some scope for local autonomy is to be welcomed. Such anecdotal practices will probably continue until good RCT evidence	Thank you for your comments.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				becomes available in a dermatosurgical setting.	
81	British Society for Antimicrobial Chemotherapy (BSAC)	3	Statement	While documentation that an antibiotic has been given is important, more detail is required to ensure that prophylaxis is appropriate e.g. choice of antibiotic (as per local policy), timing of administration, re-dosing if appropriate. It would be helpful to also include that details of antibiotic prescription should be documented on the medicine chart, rather than is often current practice to document on anaesthetics sheet which makes audit difficult.	Statement 2 of the final quality standard covers people having surgery (that requires antibiotic prophylaxis) receiving antibiotic prophylaxis in accordance with the local antibiotic formulary. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used. Quality measures are intended to form the basis for audit criteria developed and used locally
82	Healthcare Infection Society (HIS)	3	Statement	Antibiotic prophylaxis Record of being given where indicated: This also needs to include assessment of having been given at appropriate time.	The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used.
83	Papworth Hospital	3	Statement	Agree with statement	Thank you for your comment.
84	Royal Brompton and Harefield NHS Foundation Trust	3	Statement	Agree. We would recommend /add antibiotic prophylaxis within one hour knife to skin (Saving Lives/HII to reduce SSI)	The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used.
85	Royal College of Nursing	3	Statement	Also, should the statement in relation to antibiotic prophylaxis be more specific in relation to the timing of administration?	The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
86	Royal College of Surgeons of Edinburgh	3	Statement	Agreed unchanged.	Thank you for your comment.
87	The British Dental Trade Association Ltd	3	Statement	The BDTA supports these statements.	Thank you for your comment.
88	UKCPA (Salford Royal Foundation NHS Trust)	3	Statement	Consider adding in a statement relating to the timing of the first dose in relation to skin incision. For most agents administration within 30 minutes before skin incision is recommended. For procedures lasting longer than 3 hours, additional intra-operative antibiotic doses should be given	The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used.
89	UKCPA (Salford Royal Foundation NHS Trust)	3	Statement	The antibiotics used for prophylaxis should be appropriate based on evidence of the potential organism. Therefore to be referred to as 'appropriate antibiotics'	Statement 2 in the final quality standard refers to use of a 'local antibiotic formulary', which the Topic Expert Group felt should ensure the most appropriate antibiotic is selected.
90	Pfizer Ltd	3	Measures	<p>Pfizer welcomes the inclusion of this Quality Standard. In order to align with the Department of Health's (Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection) Antimicrobial Stewardship: "Start Smart-then Focus" guidance¹, it is suggested that the quality standard is amended to include an outcome measures on page 11 that reflects the Antimicrobial Stewardship guidance:</p> <ul style="list-style-type: none"> - Adherence of prophylaxis protocols to Antimicrobial Stewardship "Start Smart-then Focus" guidance <p>Rationale for amendment:</p> <p><i>"An Antimicrobial Stewardship Programme is a key component in the reduction of healthcare associated infections (HCAI) and contributes to slowing the development of antimicrobial resistance. A Start Smart - then Focus approach is recommended for all antibiotic prescriptions."</i>¹</p>	It is important that quality standards are considered alongside current policy documents.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>Supporting references:</p> <p>1. Nov 2011, Dept of Health, Antimicrobial Stewardship “Start Smart – Then Focus” https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/146981/dh_131181.pdf.pdf</p>	
91	Public Health England	3	Measures	<p>This quality measure could go a lot further by assessing:</p> <ul style="list-style-type: none"> • antimicrobial prophylaxis – agent • antimicrobial prophylaxis – timing • antimicrobial prophylaxis – dose (including re-dosing) <p>For example, Department of Health’s (DH) guidance on antimicrobial stewardship, Start Smart then Focus, states: Prescribe single dose antibiotics for surgical prophylaxis; where antibiotics have been shown to be effective Critical to this advice is that the single dose is administered within the 60 minutes <i>prior</i> to surgical incision or tourniquet inflation to enable peak blood levels to be present at the start of the surgical procedure. A repeat dose of antibiotic prophylaxis is required when the operation has prolonged procedures and where there is significant blood loss. A treatment course of antibiotics may also need to be given (in addition to appropriate prophylaxis) in cases of dirty surgery or infected wounds. The appropriate use and choice of antibiotics should be discussed with Infection Specialists for each case.</p> <p>The Start Smart then Focus guidance is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/146981/dh_131181.pdf.pdf</p>	<p>Quality statement 2 in the final quality standard states that ‘People having surgery that requires antibiotic prophylaxis receive this in accordance with the local antibiotic formulary’. The Topic Expert Group felt this should ensure the most appropriate antibiotic, dose and duration. The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used. It is important that quality standards are considered alongside current policy documents.</p>
92	Royal Brompton and Harefield NHS Foundation Trust	3	Measures	<p>Process. Instead of ABx dichotomous (Y/N) audit, prefer measure ABx prophylaxis given one hour knife to skin. This would reflect best practice and would reduce duplication of data if this measure was the same as the Saving Lives HII to reduce SSI</p>	<p>The Topic Expert Group felt that the timing of antibiotic prophylaxis could depend on the individual clinical circumstances and the pharmacokinetic profile and route of administration of the antibiotic. Using a formulary should ensure the most appropriate antibiotic, dose, timing of administration and duration are used.</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
93	3M Health Care	4	Statement	Many NHS facilities are currently screening surgical patients for MRSA. It is not clear in this quality statement whether the screening for S. Aureus is a replacement for the current MRSA screening or extra to that screening.	This quality statement has been removed from the final quality standard.
94	Arhai	4	Statement	People having surgery are offered screening for MRSA and MSSA before higher risk operations, and offered decontamination if necessary	This quality statement has been removed from the final quality standard.
95	British Association of Dermatologists (BAD)	4	Statement	People having surgery are offered procedure-targeted case-finding for <i>S. aureus</i> and those who are positive are offered suppression. Although, the NICE guidance is that nasal decontamination aimed at elimination of <i>S. aureus</i> should not be routinely undertaken, there is literature to support routine surveillance (by pre-operative nasal swab) in patients undergoing more advanced facial skin cancer excision (Tai YJ et al., Australas J Dermatol 2013; 54:109-14). Thus, this draft statement is of particular relevance to patients undergoing skin surgery on the head-and-neck region, and supports the targeted surveillance in certain dermatosurgery patients.	This quality statement has been removed from the final quality standard.
96	British Society for Antimicrobial Chemotherapy (BSAC)	4	Statement	States: <i>NICE CG71 recommends that nasal decontamination with topical antimicrobial agents aimed at eliminating S. aureus should not be used routinely to reduce the risk of surgical site infection. Therefore, it should be targeted at specific procedures.</i> This statement as it stands is a non-sequitur, but there is evidence for some procedures that pre- and peri-operative staphylococcal suppression can reduce the risk of post-op infection. However it is not known whether for patients having these operations the best strategy is case-finding for <i>S. aureus</i> carriage followed by targeted suppression for all patients without screening. The disadvantages of targeted suppression are that it requires highly complex screening algorithms (particularly if looking also for MRSA specifically) and that any practicable screening methodology will be poorly sensitive (meaning that some carriers will be missed). The disadvantage of universal suppression is the potential risk of resistance but in practice this has not been observed. An advantage of universal suppression, provided it includes some form of body wash, is that it ensures that patients are clean when they go to theatre. We suggest the authors consider amending the recommendation to 'procedure-specific staphylococcal suppression, using either screening and targeting or a universal approach, according to local preference,	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				unless evidence emerges to support one strategy over the other’.	
97	British Society for Antimicrobial Chemotherapy (BSAC)	4	Statement	This statement re <i>S. aureus</i> screening seems very vague and will result in variation in practice and demand for not just pre-op MRSA screening, it refers to the clinical guideline 74 but this actually states in 1.2.7 not to use routine topical agents. Nowhere is it stated what type of operations they are referring to.	This quality statement has been removed from the final quality standard.
98	Chelsea and Westminster Hospital NHS Foundation Trust	4	Statement	Q4 “people offered procedure targeted case-finding for <i>Staphylococcus aureus</i> ” Should this not be Meticillin resistant <i>Staphylococcus aureus</i> (MRSA)? In our trust we do not routinely screen for <i>S aureus</i> and therefore only treat patients who are positive for MRSA. If we treat patients with meticillin sensitive <i>S aureus</i> (MSSA) is the risk of developing resistant bacteria increased?	This quality statement has been removed from the final quality standard.
99	Frimley Park Hospital NHS Foundation Trust	4	Statement	The reference quoted from NICE CG74 (recommendation 1.2.7) actually states ‘Do not use nasal decontamination with topical antimicrobial agents aimed at eliminating <i>Staph aureus</i> routinely to reduce the risk of surgical site infection’. With approximately 30% of the population colonised with MSSA, offering suppression to ‘those who are positive’, would seem to go against this recommendation and make the use of antimicrobial agents quite routine?	This quality statement has been removed from the final quality standard.
100	Healthcare Infection Society (HIS)	4	Statement	: "Screening for <i>S. aureus</i> " is found to be misleading and misguided: Targeted Screening The recommendation to use risk-assessed targeted screening for <i>S. aureus</i> quotes NICE Guideline no 74 as its source. However the introduction of procedure targeted screening is vague for a standard, and will result in variation in practice and demand e.g. from commissioners. The basis for this needs better guidance e.g. “National One Week Prevalence Audit of Meticillin Resistant <i>Staphylococcus aureus</i> (MRSA) Screening study by the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infections (ARHAI).” Provides some basis for MRSA, but basis for MSSA is less easily decided. More guidance is required on defining high risk procedures. Decontamination NICE Guideline no 74 guideline actually states in 1.2.7 " Do not use nasal decontamination with topical antimicrobial agents aimed at eliminating <i>Staphylococcus aureus</i> routinely to reduce the risk of surgical site infection" and offers no evidence in favour of targeted screening.	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				One could argue that the intention of the "Standard" is to force us to accumulate the evidence required for future "recommendations", but such should be deemed research and go through the appropriate ethics and funding channels.	
101	Papworth Hospital	4	Statement	We already screen and offer decolonisation therapy for MRSA. Including this to cover MSSA would have massive resource implications to screen all patients pre-operatively, especially emergency cases as a rapid point of care test for both MSSA and MRSA would need to be available. We have searched many times to find evidence to say that this is based in evidence - it isn't as far as we could find. Additionally the recommendation would need to specify what suppression should be offered, for example would this include nasal mupirocin as well as Octenisan washes? The lack of evidence base is why we took the pragmatic approach of providing Octenisan for pre-operative washing of all our surgical patients, where there is some evidence will lower staph levels on the skin. I think this approach would be a better recommendation.	This quality statement has been removed from the final quality standard.
102	Royal Brompton and Harefield NHS Foundation Trust	4	Statement	Agree. We would recommend/add screening of all individuals considered at high risk. We would recommend (clarification) MRSA as opposed to case-finding to <i>Staphylococcus aureus</i>	This quality statement has been removed from the final quality standard.
103	Royal College of Nursing	4	Statement	Targeted case finding for Staphylococcus aureus – this presumably means MRSA as very few organisations routinely screen for MSSA pre surgery. If one needed to do that on the basis of the costs for MRSA screening treatment and delays in surgery etc one would estimate that this extra test would cost at least an additional £100 million nationally. We would suggest we continue with screening for MRSA. Also there should be more discussions on targeted case findings, based on cost effectiveness and financial implication of screenings. This should refer to the recently published NOW Study and the statement should be considered in the light of the findings. Useful information available on the following web pages: http://idrn.org/audit.php	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				http://idm.org/documents/resources/Final%20report.pdf	
104	Chelsea and Westminster Hospital NHS Foundation Trust	4	Statement	As above regarding the definition of what is to be screened. Is the proposal to move back to risk based screening rather than universal screening of all patients? Is there any plan to screen patients for ESBL colonisation??	This quality statement has been removed from the final quality standard.
105	Royal College of Nursing	4	Statement	This statement did not specify if the screening recommendations was for all categories of surgery or just high risk ones. It needs to be specific.	This quality statement has been removed from the final quality standard.
106	Royal College of Surgeons of Edinburgh	4	Statement	Agreed unchanged.	This quality statement has been removed from the final quality standard.
107	The British Dental Trade Association Ltd	4	Statement	Staphylococcus aureus screening – We have no specific comments on this standard.	This quality statement has been removed from the final quality standard.
108	UKCPA (Salford Royal Foundation NHS Trust)	4	Screening for staph aureus	Should this be referred to as 'Methicillin resistant staph aureus (MRSA)' instead of simply staph aureus?	This quality statement has been removed from the final quality standard.
109	Public Health England	4	Measures	The equations are confusing – e.g. “Numerator – the number of people in the denominator who receive suppression.” Which denominator? That described in a) or b)?	This quality statement has been removed from the final quality standard.
110	3M Health Care	4	Definitions	The QS4 recommends that those patients found to be positive for S. aureus should be offered treatment. No specific guide is given regarding the types of surgery where treatment should be offered nor what the suggested treatment might involve. This is an omission that requires correcting.	This quality statement has been removed from the final quality standard.
111	Public Health England	4	Definitions	Clarification of 'procedure-targeted' groups needed as is 'case-finding' (which presumably refers to screening) and 'suppression' (which presumably refers to decolonisation). Although NICE refers to local risk assessment to identify high-risk procedures, what about clarification of core groups already listed in DH's first national MRSA screening guidance (DH, 2006) http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063187.pdf ?	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
112	Frimley Park Hospital NHS Foundation Trust	4	Data sources	There has been no national guidance for screening patients for <i>S. aureus</i> , other than MRSA, although the statement appears to indicate that hospitals should be screening for both MSSA and MRSA for surgical patients (by just stating ' <i>Staphylococcus aureus</i> '). Therefore collection of data for this indicator would only be possible for MRSA screening.	This quality statement has been removed from the final quality standard.
113	3M Health Care	5	Statement	The statement reflects NICE Guideline no.74 but not the care recommended in DH Care Bundle for SSI (or HPS 2012 review of this Care Bundle) which recommends chlorhexidine 2% in 70% isopropyl alcohol. This difference in recommendation between the specific and less specific could be confusing to those developing local protocols for preparing patients for surgery.	This quality statement has been removed from the final quality standard.
114	3M Health Care	5	Statement	The QS offers no advice or measurements related to the use of incise drapes that is preferred by many surgeons. In common with NICE Guideline No. 74, the QS should offer a quality measure relevant to the recommendation that where an incise drape is used it is an antimicrobial incise drape.	This quality statement has been removed from the final quality standard.
115	Arhai	5	Statement	People having surgery are cleaned with an alcohol-base skin antiseptic immediately before incision	This quality statement has been removed from the final quality standard.
116	British Association of Dermatologists (BAD)	5	Statement	People having surgery receive surgical skin antisepsis using an alcohol-based solution immediately before incision – most studies looking at the use of various perioperative antisepsis regimens have been concerned with clean-contaminated surgery rather than clean surgery (i.e. dermatosurgery) (Darouiche RO et al., N Engl J Med 2010; 362:18-26). It is most surgeon's practice to use alcohol-based antiseptics (or povidone-iodine) although there has been some literature to suggest that simpler decontamination methods may be applicable in clean surgery procedures (Kalantar-Hormozi AJ et al., Plast Reconstr Surg 2005; 116:529-31). Until there is a body of further evidence to support this view, I personally agree with this draft statement in that patients should receive an alcohol-based solution immediately prior to incision.	This quality statement has been removed from the final quality standard.
117	CareFusion	5	Statement	It is noted that the 2008 NICE clinical guidelines (CG74) on Surgical site infection: prevention and treatment of surgical site infection section 1.3.7 state under the heading Antiseptic skin preparation, to 'Prepare the skin at surgical site immediately before incision using an antiseptic (aqueous or alcohol-based) preparation: povidone-iodine or	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>chlorhexidine are most suitable.</p> <p>We recognise the important step that the new draft Quality Statement makes over this previous wording in its recommendation of alcohol-based solutions for surgical skin preparation. However, we believe that the body of evidence suggests that the new Statement should specifically endorse the use of 2% chlorhexidine in alcohol (statement proposed in Comment 1 above in bold type).</p> <p>We agree entirely with the premise that patients undergoing surgery should receive alcohol-based skin cleansing immediately prior to incision. However, we believe that the recommendation should go further, we propose the following:</p> <p>'For people having surgery, a single use, sterile presentation of 2% chlorhexidine gluconate in 70% isopropyl alcohol, which is licensed for use as a medicinal product, should be used for skin preparation* immediately before incision. The solution should be allowed to air dry completely and the area checked for pooling before applying any drapes'.</p> <p>*Except for on mucous membranes, where an aqueous chlorhexidine solution should be used. If a known allergy or hypersensitivity to chlorhexidine exists, povidone iodine should be used.</p> <p>Evidence for this position, is summarised below in this comment and expanded further in the appended document 'SURGICAL SITE INFECTION. Submission on behalf of CareFusion'. We believe that changes should be made to the NICE Draft Quality Statement based on the following compelling data [references provided].</p> <p>Taken together, we believe that this argumentation provides a compelling case for the revision above.</p>	
118	Gloucestershire Hospitals NHS Foundation	5	Statement	Should there be a further suggestion of type of solution such as Chlorhexidine 2% in alcohol?	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
	Trust				
119	Healthcare Infection Society (HIS)	5	Statement	Generally the promotion of alcohol based skin decontamination is welcomed. There are several statements suggesting that chlorhexidine containing products may be favoured over iodine containing products in the absence of contraindications such as allergy.	This quality statement has been removed from the final quality standard.
120	Johnson & Johnson Medical Ltd	5	Statement	Whilst recognising the benefits of steps taken to reduce risk of SSI during the Pre-Operative phase, J&J would like to highlight the significance of Intra-Operative technique alongside pre- and post-operative phases which are already featured in the draft Quality Standard. For example, there are technologies which have been developed to inhibit bacterial colonization of the medical device thereby addressing one of risk factors associated with surgical site infection.	This quality statement has been removed from the final quality standard.
121	Papworth Hospital	5	Statement	Yes agree. However, it would be good if NICE actually made a recommendation on an actual solution (i.e. 2% chlorhexidine in 70% alcohol) based on the evidence so far.	This quality statement has been removed from the final quality standard.
122	Public Health England	5	Statement	Alcohol-based solutions indicated as the preferred preparation – but this is not consistent with existing NICE recommendations; in current form these refer to either alcohol or aqueous-based antiseptic preparations as being suitable. Is this quality standard due to the 2010 Darouiche <i>et al.</i> study in NEJM, published after NICE's SSI recommendations (http://www.ncbi.nlm.nih.gov/pubmed/20054046)? Definition does not appear to be aligned with quality statement.	This quality statement has been removed from the final quality standard.
123	Royal Brompton and Harefield NHS Foundation Trust	5	Statement	Agree. Pleased to see Chloraprep not mandated. Our own evidence shows it to be of no benefit.	This quality statement has been removed from the final quality standard.
124	Royal College of Nursing	5	Statement	The quality statement refers to the need to use an alcohol based solution and yet the definition provided in NICE Clinical Guideline refers to allowing ANTISEPTIC skin preparations to evaporate – we understand that alcohol evaporates and antiseptic solutions air dry and this take time, hence why surgeons wipe off the excess. As this refers to the use of diathermy, we suggest that the wording should be changed to alcohol based skin preparations as it is the alcohol content that causes the problems not the antiseptic solution as far as we understand.	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				We need to ensure that skin preparation is applied correctly not as per manufacturer's instructions.	
125	Royal College of Nursing	5	Statement	Alcohol based solution immediately before surgery - we also know of cases where there has been anaphylaxis cases related to this, we would therefore, suggest that health care professionals ensure that potential allergies are noted.	This quality statement has been removed from the final quality standard.
126	Royal College of Surgeons of Edinburgh	5	Statement	We believe that this needs to be expanded to state that the use of 2% chlorhexidine gluconate 70% isopropyl alcohol skin disinfectant is recommended when undertaking surgical skin antisepsis for: i) Clean surgery, involving the placement of a prosthesis or implant. ii) Contaminated – an incision undertaken during an operation in which there is a major break in sterile technique or gross spillage from the gastrointestinal tract, or an incision in which acute, non-purulent inflammation is encountered. Open traumatic wounds that are more than 12–24 hours old also fall into this category. iii) Dirty or infected – an incision undertaken during an operation in which the viscera are perforated or when acute inflammation with pus is encountered during the operation (for example, emergency surgery for faecal peritonitis). This also includes traumatic wounds where treatment is delayed, and there is faecal contamination or devitalised tissue present.	This quality statement has been removed from the final quality standard.
127	Royal College of Surgeons of Edinburgh	5	Statement	Agreed unchanged.	This quality statement has been removed from the final quality standard.
128	The British Dental Trade Association Ltd	5	Statement	Alcohol-based skin antisepsis - We have no specific comments on this standard as it is not necessarily universally applicable in dental surgery.	This quality statement has been removed from the final quality standard.
129	University of Manchester	5	Statement	In section 5 (page 15) the draft statement says: <u>People having surgery receive surgical skin antisepsis using an alcohol-based solution immediately before incision.</u> However, the briefing notes and the referenced guideline (74) actually state <u>There is no evidence of difference between chlorhexidine and povidone-iodine (either aqueous or alcohol-based preparation) and the costs are similar.</u>	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				I can't find any rationale as to why the included quality standard point focuses only on alcohol when the guideline/briefing include alcohol and aqueous preparations. This decision does not seem at all logical or transparent and may be detrimental to the conduct of further research required to reduce uncertainty in this area. There have been some recent relevant trials that may have informed this decision, however, there is no evidence that they have been systematically synthesised here leading to the change in from the current guideline recommendation. There are outstanding issues to consider – e.g. povidine iodine in alcohol has not been evaluated per se. Also risk-benefit assessments in terms of the incidence of rare but serious adverse events associated with alcohol are required.	
130	CareFusion	5	Equality and diversity	Under the 'Equality and diversity considerations', the text currently reads 'Some people having surgery may be allergic to alcohol. An aqueous antiseptic solution is appropriate for these people.' In light of our proposal to recommend the use of a 2% chlorhexidine in 70% isopropyl alcohol solution, we suggest this wording is changed as below. 'Some people having surgery may be allergic to alcohol. An aqueous antiseptic solution is appropriate for these people. Others may have known allergic/anaphylactic reactions to chlorhexidine-containing medications. If a known allergy or hypersensitivity to chlorhexidine exists, povidone iodine should be used.'	This quality statement has been removed from the final quality standard.
131	3M Health Care	6	Statement	Wound Care -This section contains guidance on providing important information to patients. However, regarding its title it offers no advice on the wound care of surgical wounds. We strongly recommend that the guidance includes the same advice as in NICE Guideline No. 74 to dress surgical wounds with interactive dressings and a Quality Measure associated with this advice should be prepared.	This quality statement is about providing information and advice to patients and carers (see statement 5 of the final quality standard).
132	British Association of Dermatologists (BAD)	6	Statement	These are of particular importance and relevance to the sphere of dermatosurgery. Although it is well established that suspected or confirmed skin cancer surgery should, in the vast majority of cases, be carried out by the relevant hospital specialist (dermatologist/plastics/ENT/maxillofacial/facioplastic surgeons), there is still a significant volume of such surgery performed in the community, potentially leading to sub-optimal practices be it either	Thank you for your comments.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>individual technique or the operative environment. These particular statements are very important to try and standardise the care pathway and optimise patient experience.</p> <p>There is a considerable range and variance in standards with regard to pre-operative and post-operative patient information and counselling, levels of staff expertise and knowledge, the physical surgical environment and the local culture for transparency and self-reflection. Any practical and simple guideline/document which helps to standardise care is to be welcomed.</p> <p>We note that a degree of local autonomy is advocated so that the guideline is not unwieldy or irrelevant.</p>	
133	British Association of Dermatologists (BAD)	6	Statement	The document should also not be prescriptive regarding surgical dressings – this again is a matter of individual preference. The document quite rightly states that there is no convincing evidence of superiority of one dressing over another. Additionally, “people” should read “patients and their guardians or carers”.	<p>Thank you for your comment.</p> <p>Quality statement 5 in the final quality standard covers information and advice for people having surgery and their carers.</p>
134	Chelsea and Westminster Hospital NHS Foundation Trust	6	Statement	It is sometimes difficult enough for healthcare staff to recognise a wound infection so any definitions used for untrained public would have to be extremely clear and unambiguous.	Quality statement 5 in the final quality standard includes information and advice on ‘how to recognise problems with the wound’, rather than how to recognise an infection specifically.
135	Johnson & Johnson Medical Ltd	6	Statement	J&J fully support educating the patient on wound and dressing care, including identification of SSI and subsequent action. However, provision for solutions which maintain integrity of wound dressing post discharge such as topical adhesives are not explored which we feel misses an opportunity within the context of this Quality Standard. We recommend that Statement 6 of the Quality Standard be expanded to include types of dressings and wound care technology which has evidence to support a role in minimising the risk of SSI.	This quality statement is about providing information and advice to patients and carers (see statement 5 of the final quality standard).
136	Papworth Hospital	6	Statement	Agree with statement	Thank you for your comment.
137	Patients Association	6	Statement	The advice and help given to patients before and after surgery are significant factors in preventing surgical site infections as well as detecting them in a reasonable time. Early detection ensures more efficient treatment. We believe this information should be given to patients not only verbally but also in a written format. Patients would then be able to prepare adequately for their surgery according to	Quality statement 5 of the final quality standard covers information and advice for patients and carers.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				general standards and use the written information for further guidance after the surgery (e.g. recognising a surgical site infection, wound care, contact details for further advice).	
138	Royal College of Nursing	6	Statement	It would helpful to consider other elements such as: nutrition, glucose monitoring, oxygenation etc. Also helpful to ensure layers are closed and no pockets are left i.e. surgical technique. Patient education will also be helpful here for instance information on smoking, healthy diet, covering the wound with a sterile dressing and not touching the wound.	This quality statement is about providing information and advice to patients and carers (see statement 5 of the final quality standard) on wound and dressing care, including how to recognise problems with the wound, and who to contact if they are concerned.
139	The British Dental Trade Association Ltd	6	Statement	The BDTA supports these statements.	Thank you for your comment.
140	British Society for Antimicrobial Chemotherapy (BSAC)	6	Measures	Provision of information to patients about SSI and wound care may be difficult to measure unless this is documented in a specific place.	Thank you for your comment. Quality measures are intended to form the basis for audit criteria developed and used locally.
141	Public Health England	6	Data source	Very difficult to monitor meaningfully without a standard post-discharge questionnaire. A universal post-discharge patient wound healing questionnaire would have a list of standard SSI criteria using lay terms.	Quality measures are intended to form the basis for audit criteria developed and used locally.
142	UKCPA (Salford Royal Foundation NHS Trust)	7	Treatment of infection	Should the statement include the need to obtain cultures (blood or swab sample) once infection suspected, to clarify sensitivities to determine choice of antibiotic?	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.
143	Arhai	7	Statement	... offered treatment with an antibiotic that is likely to be effective against the organism present	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.
144	British Association of Dermatologists (BAD)	7	Statement	Dermatological surgeons and specialist dermatology nurses are well accustomed to managing wounds left to heal by secondary intention – the involvement of a tissue viability nurse routinely is superfluous. People who have the recognised clinical features of surgical site infection are offered treatment with an antibiotic that covers the likely	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				organisms. This statement is to be supported, though it should also mention that the relevant specimen (skin swab/pus/fluid) should be sampled and sent to microbiology BEFORE initiation of treatment so that antimicrobial therapy can be directed against the actual causal agent. It also helps to potentially outrule actual infection and differentiate vs. non-infection related wound inflammation.	
145	Chelsea and Westminster Hospital NHS Foundation Trust	7	Statement	Draft quality statement should include 'if appropriate', as not every wound infection will need to be treated with antibiotics. This statement should be seen to explicitly promote antibiotic stewardship and discourage inappropriate prescribing.	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.
146	Department of Health	7	Statement	We request that the wording of this is amended to 'people who have recognised clinical feature of SSI are offered treatment with an antibiotic that covers the likely causative organisms based on local resistance patterns and the results of microbiological tests' This wording is taken from NICE clinical guidance 74. <u>Rationale</u> CMO in her annual report published in March 2013 on antimicrobial resistance stressed the importance of antimicrobial stewardship, one element of which is having an awareness of local resistance patterns and avoiding empirical prescribing where possible. A five year UK antimicrobial strategy will be published over the course of the summer which will re-emphasise the importance of antimicrobial stewardship. This is why we would like NICE to consider including the additional wording to draft quality statement 7 to include elements of antimicrobial stewardship.	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests. It also signposts to the Department of Health UK 5 Year Antimicrobial Resistance Strategy 2013 to 2018.
147	Johnson & Johnson Medical Ltd	7	Statement	<i>"Antimicrobial resistance poses a catastrophic threat. If we don't act now, any one of us could go into hospital in 20 years for minor surgery and die because of an ordinary infection that can't be treated by antibiotics. And routine operations like hip replacements or organ transplants could be deadly because of the risk of infection."</i> – Professor Dame Sally Davies. Chief Medical Officer J&J would like to echo comments made in the Chief Medical Officer's annual report: - <i>"champion the responsible use of antibiotics"</i>	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>- <i>“Better management of process, such as standardisation of surgical practice, needs to occur.”</i></p> <p>Davies, S.C. “Annual Report of the Chief Medical Officer, Volume Two, 2011, Infections and the rise of antimicrobial resistance” <i>London: Department of Health (2013)</i></p>	
148	Papworth Hospital	7	Statement	Agree with statement	Thank you for your comment.
149	Pfizer Ltd	7	Statement	<p>Pfizer welcomes the inclusion of quality standard 7. Pfizer suggests that the quality statement should be reworded to include ensuring that the antibiotic treatment is site appropriate, and ensures good compliance and timely discharge as follows:</p> <p><i>People who have the recognised clinical features of surgical site infection are offered treatment with an antibiotic that covers the likely causative organisms, is site appropriate, and ensures good compliance and timely discharge.</i></p> <p>Rationale for amendments:</p> <ol style="list-style-type: none"> 1. The quality standard would benefit from capturing the entire patient journey for the treatment of surgical site infections beyond the immediate treatment of the infection, i.e. treatment in hospital and discharge from hospital either on an outpatient parenteral antibiotic treatment (OPAT) service or an oral antibiotic. It is important to consider the entire patient journey to prevent re-admissions, encourage discharge to care closer to home, reduce length of stay and overall patient satisfaction and wellbeing. 2. The quality standard should include a measurable indicator of the importance of considering the route of antibiotic administration (IV or oral) and the pharmacokinetic properties of the antibiotic (e.g. tissue penetration) on top of the currently mentioned <i>in vitro</i> susceptibility profile; <i>“that covers the likely causative organism.”</i> These and several other best practice points for antibiotic prescribing are covered in depth by the Department of Health Antimicrobial Stewardship guidance: <i>“Start Smart-then Focus”</i>¹. In particular, these guidelines 	<p>Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests. These issues were prioritised by the Topic Expert Group. It is important that the quality standard is considered alongside current policy documents.</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>mention that IV administration should only be given to patients who are severely ill and unable to tolerate oral treatment or where oral treatment would not provide adequate coverage or tissue penetration. Prescribers need to switch any IV antibiotics to the oral route promptly according to local IV to oral switch guidance¹. Reducing the number of IV therapy days can decrease the risk of line infection¹.</p> <p>3. In some cases, admission of patients with an infected surgical site infection could also be avoided by using an oral antibiotic with appropriate monitoring in the community. Treatment out of hospital can reduce the risk of transmitting / acquiring further healthcare associated infections⁴.</p> <p>4. Patients who are well enough to be discharged from hospital should be provided with the relevant information and advice to complete their antibiotic treatment out of hospital. They should be informed about whom to contact if they are concerned or experience any side effects. Arrangements must be made for conducting relevant monitoring for the antibiotic prescribed (drug levels, blood count check, liver and renal function tests etc.) either by attending outpatient clinics in hospital or via the patient's GP; this will help to improve efficacy and minimise toxicity due to antibiotic treatment. Several UK studies have highlighted the benefit of early discharge using oral antibiotics for suitable patients^{2,3,4,5}.</p> <p>Supporting references:</p> <p>2. Nov 2011, Dept of Health, Antimicrobial Stewardship “Start Smart – Then Focus” https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/146981/dh_131181.pdf.pdf</p> <p>3. Desai et al. BMC Infectious Diseases 2006, 6:94</p> <p>4. Bamford et al. Injury, Int. J. Care Injured 42 (2011) S5, S24–S2</p> <p>5. Dryden et al. J Antimicrob Chemother 2012; 67: 2289–2296</p> <p>6. Gray et al. J Antimicrob Chemother 2012; 67: 2297–2302</p>	
150	Royal College of Surgeons of Edinburgh	7	Statement	The recommendation for routine use of antibiotics in all infected surgical wounds requires a distinction to be made between infection and colonisation, which can be difficult in open surgical wounds. There	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				is a potential risk of overtreatment with antibiotics based on culture results only with promotion of resistance and clostridium difficile.	selected based on local resistance patterns and the results of microbiological tests.
151	The British Dental Trade Association Ltd	7	Statement	The BDTA supports these statements.	
152	UKCPA (Salford Royal Foundation NHS Trust)	7	Statement	Choice of antibiotic for treatment should be different to prophylaxis – different dose or agent. Again, this should be appropriate based on likely causative organism.	Quality statement 6 in the final quality standard refers to antibiotic treatment that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests.
153	British Association of Dermatologists (BAD)	7	Question 3	Surgical site infections occur in a variety of surgical settings from minor invasive skin surgery to major surgery categories where body cavities/viscera are incised. Thus, different wound scoring systems will differ in their suitability and applicability depending on the surgical scenario involved. The CDC definition and criteria for diagnosis of a SSI is the most frequently used (in the literature) for dermatological surgery, though the ASEPSIS scoring system also seems applicable.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
154	British Orthopaedic Association	7	Question 3	We are concerned that use of the ASSPSIS score may encourage wound dressings to be removed unnecessarily so this needs to be made explicit that this shouldn't happen for monitoring purposes. Many orthopaedic surgeons would not want the wound dressing interfered with. When diagnosing infection it seems sensible to use the system used by Public Health England (formally the Health Protection Agency) as all English trusts are using this score for their surveillance of joint replacement infections anyway.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
155	Chelsea and Westminster Hospital NHS Foundation Trust	7	Question 3	The tool we use in this Trust for classification of Surgical Site Infection is that developed by the Health Protection Agency – now Public Health England, which they require us to use for reporting of SSI data. http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947388966	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
156	Frimley Park Hospital NHS Foundation Trust	7	Question 3	Regarding ASEPSIS tool for SSI determination: Mandatory Orthopaedic surgical site infection surveillance via the HPA/ PHE use the CDC (1992) definitions and classifications of SSI. It would seem appropriate to use the same definition as mandatory reporting, rather than using a different tool.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
157	Healthcare Infection Society (HIS)	7	Question 3	"Treatment of Infections" we are asked specifically about the use of the ASEPSIS tool. Whilst I have no problem with this useful tool, it is very different from	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>the definitions and monitoring used in the national SSISS programme. One could argue that it may be less subjective, but I don't think it should be recommended embedded in a Quality Standard until the national surveillance programme is adjusted to accommodate its use. Also, the ASEPSIS scheme requires the wound to be inspected on 5 of the 7 days post surgery which makes no allowance for the fact that the majority of our patients are discharged early these days and there simply aren't the resources to follow patients up to that extent in the community (perhaps there were when the scoring system was devised in 1986). Either way, a bit of joined up thinking is required. Use of ASEPSIS as suggested SSI assessment tool. Why is this being promoted when the HPA (PHE) SSI surveillance programme already uses a different assessment tool? Most Trusts will be using SSI surveillance as required for mandatory schemes</p> <p>A bit of joined up thinking is required recognising service needs.</p>	<p>presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992;13: 606-608.)</p>
158	Papworth Hospital	7	Question 3	<p>This is a strange question as the UK uses the PHE (formerly HPA) SSI definitions to identify and classify SSIs and it works well. ASEPSIS tool is quite difficult to use, and requires staff to take dressings down far too frequently. I would not recommend ASEPSIS tool.</p>	<p>The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992;13: 606-608.)</p>
159	Public Health England	7	Question 3	<p>Hospitals should be encouraged to use tools provided by the national SSI Surveillance Service operated by PHE.</p>	<p>The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013),</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
160	Royal Brompton and Harefield NHS Foundation Trust	7	Question 3	ASEPSIS is not an appropriate tool to determine if someone has a surgical site infection. It can be a useful tool to determine 'wound concerns' (such as delayed healing, wound breakdown), including infection. In addition, ASEPSIS categories do not seem to reflect wound severity in a satisfactory manner (for instance >80 incision with deep separation of tissue and purulent discharge =20/'minor wound infection'). The Public Health England (previously Health Protection Agency) definitions and classifications are used in a number of Trusts, which provides for national benchmarking and contribute to clinical governance. It evidences the role of bacteria in its criteria for SSI: either the likely pathogen is identified along with the host's inflammatory response, or the symptoms are so linked with a clinician's review as to likely point to SSI.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
161	Royal College of Nursing	7	Question 3	ASEPSIS - the national system is better and is directly comparable. We use ASEPSIS and it is not as easy as it may seem. The observers have to estimate ooze and blood loss just from the staining on the dressing. If documentation is poor or not up-to-date the dressing may be changed and no record of it. In many instances the surveillance team leaves the ASEPSIS score largely blank as they cannot see the wound as it is covered.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					606-608.)
162	Royal College of Nursing	7	Question 3	We are not aware of any other tool that could be used to determine surgical site infections. We support the use of the proposed tool.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
163	Royal College of Surgeons of Edinburgh	7	Question 3	The RCSEd believes that ASEPSIS is a good tool and supports its use.	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. <i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
164	British Society for Antimicrobial Chemotherapy (BSAC)	7	Measures	This standard suggests that some SSIs may not be treated? Is what requires to be measured not compliance with local antibiotic policy and/or advice from microbiology.	Quality statement 6 in the final quality standard refers to antibiotic treatment for surgical site infections that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests. It also states that

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					antibiotics should be prescribed in accordance with the local antibiotic formulary.
165	Pfizer Ltd	7	Measures	In addition, on review of the draft quality measures on page 18, Pfizer suggests that 4 additional outcome measures should be added: <ul style="list-style-type: none"> - Evidence that appropriate information is provided to people about all available treatment options, - % patients using IV administration - % discharge to care closer to home - Readmission rates 	The Topic Expert Group prioritised measures they felt related most closely to the quality statements.
166	Public Health England	7	Measures	This quality measure should incorporate microbiological sampling and switching of antimicrobial agents following microbiological confirmation of the pathogen, rather than just being based on empiric therapy	Quality statement 6 in the final quality standard refers to antibiotic treatment for surgical site infections that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests. It also states that antibiotics should be prescribed in accordance with the local antibiotic formulary.
167	Royal Brompton and Harefield NHS Foundation Trust	7	Measures	Our experience suggests that audit re: treatment to cover likely causative organism(s) would be difficult. Patient allergies/ policy/ clinician preference/ presence of other infection requiring treatment/ negative culture in the majority of cases would require high level of review/expertise and be very time-consuming.	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and used locally.
168	Public Health England	7	Definitions	Important issues to consider: <ul style="list-style-type: none"> • This quality measure should make clear the recognised method to be used to diagnose clinical features of SSI. The standard definitions in the English SSI surveillance system should be applied. The standard definitions in the English surveillance system are concordant with CDC NHSN and ECDC • Note: “A precise definition of surgical site infection is vital for personnel measuring infection rates. Use of a standard definition allows comparison of rates across surgeons and hospitals.” (page 46 of the World Health Organisation guidelines for safe surgery, 2009*) • Note: The NNIS definitions (page 47 of the WHO guidelines for safe surgery, 2009*) are widely used across the world including the 	The final quality standard signposts to the surgical site infection surveillance service (SSISS) definitions to determine the presence of a surgical wound infection Protocol for the surveillance of surgical site infection: Surgical site infection surveillance service (Public Health England, 2013), which are modified from those used by the US Centers for Disease Control (Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				SSISS at PHE who collect the mandatory orthopaedic SSI surveillance data for DH. Any tool to determine if someone has a SSI should be based on these definitions e.g. a decision algorithm *http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf	<i>Infect Control Hosp Epidemiol</i> 1992; 13 : 606-608.)
169	Chelsea and Westminster Hospital NHS Foundation Trust	7	Data sources	Also local data collection for this standard may be difficult as post-operative wound surveillance processes are underdeveloped and difficult to implement. Suggestions how to collect this data would be welcomed!	Thank you for your comments. Quality measures are intended to form the basis for audit criteria developed and used locally.
170	3M Health Care	8	Statement	There is growing evidence to show that increasing a patient's peripheral temperature through prewarming, reduces the gradient between the periphery and core. This helps to reduce the risk of inadvertent perioperative hypothermia due to redistribution temperature drop. It may be prudent to consider the evidence and include a suitable measurement in the quality standard.	This quality statement is based on NICE clinical guideline 65: Perioperative hypothermia (inadvertent).
171	Arhai	8	Statement	Term "normothermia" should be replaced with plain English: "kept at normal body temperature" or "comfortably warm". Standard includes importance of keeping warm when being transferred to theatre, and walking when possible. Walking in only a surgical gown often compromises dignity, and can make patient cold. Should be given additional cover/blanket if not allowed to take own gown.	The quality standard is accompanied by information for the public which provides a plain English version of the statements. Quality measures are intended to form the basis for audit criteria developed and used locally.
172	British Association of Dermatologists (BAD)	8	Statement	This draft statement does not apply to dermatosurgical procedures.	Thank you for your comment.
173	British Society for Antimicrobial Chemotherapy (BSAC)	8	Statement	The emphasis on temperature of the patient is welcome. However, there are patients, eg cardiac patients, who undergo cooling during their surgery deliberately as part of bypass and cerebral protection. It might need the statement modifying to mention exceptions like this.	The exception: 'unless active cooling is part of the procedure' is included in the final quality statement.
174	Healthcare Infection Society (HIS)	8	Statement	Should there not also be measures of diabetic control?	The Topic Expert Group prioritised patient temperature as the quality improvement area.
175	Papworth Hospital	8	Statement	This is complex and depends on the surgery. For example cardiac surgery and pulmonary endarterectomy require (often prolonged) elective cooling as part of these procedures. It would be more helpful	The exception: 'unless active cooling is part of the procedure' is included in the final quality statement.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				to have a requirement for adequate rewarming of the patient after cardiac surgery. We monitor post-op temperatures through our SSI surveillance.	
176	Public Health England	8	Statement	Glucose control for diabetic patients should be included as part of homeostasis	The Topic Expert Group prioritised patient temperature as the quality improvement area.
177	Royal College of Surgeons of Edinburgh	8	Statement	<p>This needs to be amended to recognise the need for hypothermia as a cardio-protective and neuro-protective in certain operative procedures and that these patients will need several hours to regain normothermia in the recovery area, be it an intensive care unit or a high dependency specialised recovery unit.</p> <p>Hypothermia is utilised in most cardiac valve operations; some cardiac bypass operations and for aortic aneurysm repair. Hypothermia is currently considered as the most effective neuro-protective method. Hypothermia has been widely used also during complicated neurosurgical operations particularly cerebral aneurysm surgery.</p>	The exception: 'unless active cooling is part of the procedure' is included in the final quality statement.
178	The British Dental Trade Association Ltd	8	Statement	The BDTA supports these statements.	Thank you for your comment.
179	3M Health Care	8	Measures	Maintaining patient homeostasis is an important factor in reducing the incidence of SSIs. Quality measures associated with maintenance of patient normothermia are important measures of the quality of care that patients receive. However, we challenge whether the complexity of having 5 quality measures for normothermia is needed to audit patient care. Indeed the presence of 5 different measures may well discourage compliance with the quality measure. CG 65 says that a patient should not be anaesthetised if their body temperature is < 36°C, unless there is need to expedite surgery. It is important therefore to have a therapy base line beforehand. Temperature should be measured pre-induction of anaesthesia and then continuously throughout until the patient is discharged back to the ward.	Process measures have been revised in the final quality standard to address measurement and documentation of temperature throughout the surgical pathway.
180	3M Health Care	8	Measures	There are inconsistencies in the times at which denominator and numerator are measured in several of the Quality Measures c) and d) that need to be corrected to be consistent.	Process measures have been revised in the final quality standard to address measurement and documentation of temperature throughout the surgical

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
					pathway.
181	Defence Medical Services; MOD	8	Measures	Guideline 65 states that the postoperative phase is 24 hrs. This statement should be more specific with regards to time i.e. "Proportion of people, who have had surgery, whose temperature is below 36.0°C in the 24 hrs following surgery"	Process measures have been revised in the final quality standard to address measurement and documentation of temperature throughout the surgical pathway.
182	Healthcare Infection Society (HIS)	8	Measures	Draft Quality measure - process c & d: confusion about times, 30 minutes, 1 minute & 15 minutes all stated, none matching across numerator/denominator	Process measures have been revised in the final quality standard to address measurement and documentation of temperature throughout the surgical pathway.
183	Inditherm plc	8	Measures	Draft quality measures. It is noted that the proposal includes measurement of the proportion of patients who are hypothermic before they are transferred from the ward to theatres but no measure of the proportion of patients who are hypothermic on arrival in theatres or at induction of anaesthesia. It is understood that there is a limit to the number of measures that can be collected, but this does seem an important factor. The scientific literature establishes a clear link between perioperative hypothermia and SSIs (referenced in NICE CG65) and it is also well established that patient core temperature will fall on induction of anaesthesia. It therefore seems that a measure which tries to establish a quality target where patient temperature is ideally somewhat above 36.0°C on arrival in theatres would prove of benefit in reducing the incidence of SSIs.	Statement 3 in the final quality standard includes an outcome measure on achievement of normothermia throughout the surgical pathway. It also includes process measures on measuring and documenting patient temperature at specified points on the pathway which includes at induction of anaesthesia.
184	Inditherm plc	8	Measures	Draft quality measure. There are several references to measurement of patient temperature in this section and it is suggested that these references should be clarified to state "core temperature".	The revised process measure in the final quality standard (see statement 3) refer to core temperature.
185	Inditherm plc	8	Measures	Draft quality measure: Process: b). The proposal is that patients are identified if temperature is 36.0°C or above before transfer from ward to theatre. It is likely that patient temperature will fall during transfer so it is probably appropriate to consider whether the target set by the standard should be higher (say 36.5°C) to give higher probability of normothermia at time of induction of anaesthesia. NICE CG65 recommends that the patient should not be anaesthetised if core temperature is below 36.0°C.	Statement 3 in the final quality standard includes an outcome measure on achievement of normothermia (defined as 36.5-37.5°C) throughout the surgical pathway. It also includes process measures on measuring and documenting patient temperature at specified points on the pathway which includes at induction of anaesthesia.
186	Inditherm plc	8	Measures	Draft quality measure: Process: c). The proposal is temperature	Process measures have been revised in

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				measurement every 30 minutes from induction of anaesthesia but the proposed Numerator states measurement every 1 minute. It is suggested that 30 minutes is appropriate and the Numerator definition should be changed to reflect this.	final quality standard (see statement 3).
187	Inditherm plc	8	Measures	Draft quality measure: Process: d). The proposal is temperature measurement every 30 minutes from admission to the recovery room but the proposed Numerator states measurement every 15 minutes. It is suggested that 30 minutes is appropriate and the Numerator definition should be changed to reflect this. It is noted that 15 minute measurement intervals might allow earlier discharge from recovery room and may have some advantages, but would possibly add unacceptable and unnecessary burden on staff and is unlikely to give any extra patient benefit.	Process measures have been revised in final quality standard (see statement 3).
188	Inditherm plc	8	Measures	Draft quality measure: Process: e). It is not clear at what point in the process the proposed measurement of temperature below 36.0°C applies. It is also not clear if the reference in the proposed Denominator relates to discharge from the recovery room or from hospital (or any other location). It is assumed that this is intended to relate to the number of patients who are hypothermic on admission to or during their stay in the recovery room. This seems an important measure and is supported, but it should be noted that there are two possible and different measures: temperature on arrival in recovery relates to effectiveness of treatment during anaesthesia/surgery whereas temperature in the subsequent period through to discharge relates also to effectiveness of treatment in the recovery room. It is understood that most if not all published clinical data that has established the link between maintenance of normothermia and reduction in SSIs relates to the period of anaesthesia or surgery and therefore temperature on admission to recovery seems to be the more appropriate measure. Temperature on admission to recovery is also likely to have most impact on the patient experience in relation to having a “comfortable and safe temperature” after surgery as stated in the description of what the quality statement means for people having surgery.	Measures and definitions have been revised and clarified in the final quality standard (see statement 3).
189	Public Health England	8	Measures	Indicators A and B relate to a sub-group of the patient population and depend on data collection for these sub-groups.	Thank you for your comments. Measures and definitions have been revised and clarified in the final quality standard (see

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>Indicators C and D (peri-operative and post-operative phase respectively) involve all patients in the denominator which is likely to be more amenable to data collection. However these two indicators are not complemented by a pre-operative indicator – this seems to be omitted.</p> <p>Indicator E may be unnecessary if you have main trio (pre-operative, peri-operative and post-operative phases)</p> <p>Potential for confusion as to which denominator is being referred to</p>	statement 3).
190	Royal College of Nursing	8	Measures	It would be useful to include a recommendation for measuring temperature once patients have returned to the ward.	The temperature measurement schedule in the final quality standard includes postoperative arrival at the ward (see measures in statement 3).
191	British Association of Dermatologists (BAD)	9	Statement	<p>These are of particular importance and relevance to the sphere of dermatosurgery. Although it is well established that suspected or confirmed skin cancer surgery should, in the vast majority of cases, be carried out by the relevant hospital specialist (dermatologist/plastics/ENT/maxillofacial/facioplastic surgeons), there is still a significant volume of such surgery performed in the community, potentially leading to sub-optimal practices be it either individual technique or the operative environment. These particular statements are very important to try and standardise the care pathway and optimise patient experience.</p> <p>There is a considerable range and variance in standards with regard to pre-operative and post-operative patient information and counselling, levels of staff expertise and knowledge, the physical surgical environment and the local culture for transparency and self-reflection. Any practical and simple guideline/document which helps to standardise care is to be welcomed.</p> <p>We note that a degree of local autonomy is advocated so that the guideline is not unwieldy or irrelevant.</p>	This quality statement has been removed from the final quality standard.
192	British Association of Dermatologists (BAD)	9	Statement	Should “environment” read “approved location” to tie in with CQC? Prevention of infection following minor surgery being carried out in a community setting, either in a community hospital or a GP surgery, may need to be separately addressed, particularly with reference to recommendations for commissioners.	This quality statement has been removed from the final quality standard.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
193	Gloucestershire Hospitals NHS Foundation Trust	9	Statement	Very broad – shouldn't this be narrowed down to specifics i.e. cleaning scores, hand hygiene scores, Infection rates?	This quality statement has been removed from the final quality standard.
194	Johnson & Johnson Medical Ltd	9	Statement	J&J agree with the statement that people having surgery should be cared for in an environment that minimises the risk of surgical site infection. However, Intra-operative factors, such as technique and technology adoption, should also reflect the ambition to reduce risk of SSI as far as possible.	This quality statement has been removed from the final quality standard.
195	Papworth Hospital	9	Statement	Agree with statement	This quality statement has been removed from the final quality standard.
196	Public Health England	9	Statement	This statement is too vague.	This quality statement has been removed from the final quality standard.
197	Royal College of Surgeons of Edinburgh	9	Statement	Agreed unchanged.	This quality statement has been removed from the final quality standard.
198	The British Dental Trade Association Ltd	9	Statement	The BDTA supports these statements.	This quality statement has been removed from the final quality standard.
199	Public Health England	9	Measures	The numerator has problems: no definition of 'maintenance tasks' which may differ between centres. Also no definition of 'infection prevention and control objectives' which may also differ between centres. More importantly, these activities are done at organisational level so it is not possible to obtain a proportion from this.	This quality statement has been removed from the final quality standard.
200	British Association of Dermatologists (BAD)	10	Statement	These are of particular importance and relevance to the sphere of dermatosurgery. Although it is well established that suspected or confirmed skin cancer surgery should, in the vast majority of cases, be carried out by the relevant hospital specialist (dermatologist/plastics/ENT/maxillofacial/facioplastic surgeons), there is still a significant volume of such surgery performed in the community, potentially leading to sub-optimal practices be it either individual technique or the operative environment. These particular statements are very important to try and standardise the care pathway and optimise patient experience. There is a considerable range and variance in standards with regard to	Thank you for your comments.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				pre-operative and post-operative patient information and counselling, levels of staff expertise and knowledge, the physical surgical environment and the local culture for transparency and self-reflection. Any practical and simple guideline/document which helps to standardise care is to be welcomed. We note that a degree of local autonomy is advocated so that the guideline is not unwieldy or irrelevant.	
201	British Association of Dermatologists (BAD)	10	Statement	Should this read “infection rates” instead of “infection levels”? Who should the healthcare professional feedback infection rates/levels to?	The final quality standard uses ‘rates’ rather than ‘levels’ (see statement 7). Relevant staff and stakeholders who should be provided with feedback are defined in the definitions section of this quality statement.
202	Gloucestershire Hospitals NHS Foundation Trust	10	Statement	Personally, I would like to see some kind of recommendation that says specifically that Trusts are expected to monitor infection rates routinely and robustly both as an inpatient and post discharge. Similarly to the current Health Protection Agency SSIS data on mandatory Hip and Knee replacement infections. There is recent research by De Montford university that says that people recovering from surgery get infections far more often than is currently reported because there are “worrying inconsistencies” between how surgical site infections are defined and how thoroughly hospitals looked for them, and that hospitals that conduct robust and high quality surveillance may well be penalised rather than hospitals with lower infection rates but less robust and less quality surveillance. Should therefore it be mandated that the top 20 procedures/specialities by routinely monitored, i.e. In addition to Hips and Knees, Colorectal – Resectional work, Upper GI – Oesopho/Gastrectomy, Head and Neck- Major Cancer work, Gynaecology – Hysterectomy, Vascular – Graft work, etc.	Statement 7 in the final quality standard addresses surveillance of surgical site infection rates, including post-discharge infections. Quality standards aim to improve care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators.
203	Healthcare Infection Society (HIS)	10	Statement	There is no mention of primary care. How will general practitioners or SSIs post discharge be detected? Infection rates should be fed back to primary care practitioners – although it says all stakeholders it may be useful to be explicit that they will be involved.	GPs are included under the definition of staff and stakeholders (see statement 7 of the final quality standard).
204	Johnson & Johnson Medical Ltd	10	Statement	Johnson & Johnson agree with Statement 10 of the Quality Standard, but suggest surveillance and reporting should include all causative organisms not just those subject to mandatory surveillance and this information should be published in the interests of transparency to	Quality measures are intended to form the basis for audit criteria developed and used locally. The definition of stakeholders who should receive feedback on surgical site

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				patients on a regular basis.	infection rates includes patients (see statement 7 of final quality standard).
205	Papworth Hospital	10	Statement	Agree with statement	Thank you for your comment.
206	Pfizer Ltd	10	Statement	Pfizer welcomes the inclusion of this quality statement.	Thank you for your comment.
207	Royal College of Surgeons of Edinburgh	10	Statement	Methodology and cost of routine, comprehensive, accurate wound surveillance with coordination between primary, secondary and tertiary care will be difficult to deliver.	Thank you for your comment. NICE has produced a support for commissioning document that considers the commissioning implications and potential resource impact of this quality standard.
208	The British Dental Trade Association Ltd	10	Statement	The BDTA supports these statements.	Thank you for your comment.
209	Healthcare Infection Society (HIS)	10	Measures	Process statement: I do not understand this statement or the numerator definition, I have no idea what they want measuring? Also more than one organisation is likely to be involved in the patient pathway, following discharge from hospital into home, community and general practice care.	Process measure has been removed in the final quality standard (see statement 7).
210	Pfizer Ltd	10	Measures	<p>On review of the draft quality measures on page 24 Pfizer suggests that three 3 additional outcome measures should be added:</p> <ol style="list-style-type: none"> 1. Failure of antibiotic treatment for surgical site infections 2. Any toxicity related to treatments used for surgical site infections 3. Resistance relating to treatment with surgical site infections <p>Rationale for amendments</p> <ol style="list-style-type: none"> 1. Suggested to encourage centres to monitor the success of their initial antibiotic therapy. Measuring this outcome measure will allow a thorough evaluation of the effectiveness of their protocols and lead to investigations if there are failures in the system. This will ensure good control over antibiotic prescribing and the use of more appropriate treatments, in turn leading to better treatment success rates and possibly lower morbidity and mortality. 2. Measuring toxicity is essential for good pharmacovigilance and for effective monitoring of the patient to make sure they are not reacting badly to a medicine, so that they can be 	<p>The Topic Expert Group prioritised outcome measures they felt measured the quality statements most closely.</p> <p>It is important that quality standards are considered alongside current policy documents.</p>

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				<p>switched either to an easier to manage formulation or to another antimicrobial altogether. Good toxicity monitoring may help clinicians to deliver appropriate medicines and reduce side effects and morbidity; it could also help gather additional data on the toxicity of medicines for wider consumption.</p> <p>3. Monitoring resistance is essential when it comes to good antimicrobial stewardship¹ ensuring that the development of resistance is avoided and that clinicians are prepared to switch to an antimicrobial with less resistance in a timely fashion. This could result in reduced resistance rates thereby preserving the utility of antimicrobials for the future.</p> <p>References</p> <p>1. Nov 2011, Dept of Health, Antimicrobial Stewardship “Start Smart – Then Focus” https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/146981/dh_131181.pdf.pdf</p>	
211	Public Health England	10	Measures	<p>The process is a little vague. Does it mean:</p> <ul style="list-style-type: none"> • Process: Proportion of people having surgery who are cared for by healthcare providers that monitor and feedback infection levels <u>for at least 1 surveillance period in any surgical category in the financial year somewhere in the trust</u> and use this information to adjust clinical practice, where necessary <p>Or</p> <ul style="list-style-type: none"> • Process: Proportion of people having surgery who are cared for by healthcare providers that monitor and feedback infection levels <u>for at least 1 surveillance period in the same surgical category in the financial year in the same hospital</u> and use this information to adjust clinical practice, where necessary <p>Or</p> <ul style="list-style-type: none"> • Process: Proportion of people having surgery who are cared for by healthcare providers that monitor and feedback infection levels <u>in the same surveillance period as surgery in the</u> 	Process measure has been removed in the final quality standard (see statement 7).

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments	Response
				same surgical category in the same hospital and use this information to adjust clinical practice, where necessary	
212	Public Health England	10	Definitions	On a separate point, there is no mention of primary care. How will SSIs post discharge be detected? Infection rates should be fed back to primary care practitioners – although it says all stakeholders, it may be useful to be explicit that they will be involved.	GPs are included under the definition of staff and stakeholders (see statement 7 of the final quality standard).

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.