

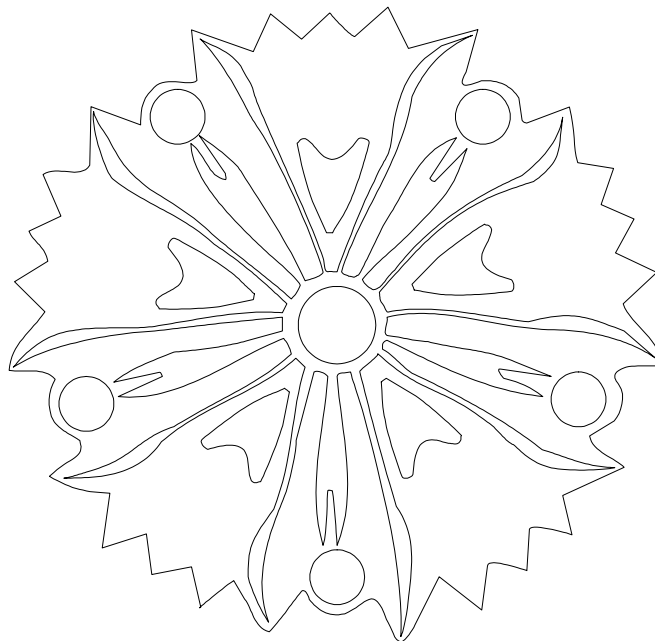
済生会新潟第二病院

# 院内感染症 対策マニュアル

別冊：手術部位感染予防  
SSI防止ガイドライン

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## Guideline for the Prevention of Surgical Site Infection, 1999 (ほぼ全訳)

Department of Health and Human Services  
Centers for Disease Control and Prevention

この文書はCDCが公開している「Guideline for the Prevention of Surgical Site Infection, 1999」を訳したものです。もとの文書(Guideline for the Prevention of Surgical Site Infection)はインターネット上で公開されています。

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### 全体的なまとめ

「Guideline for the Prevention of Surgical Site Infection, 1999」は、以前は手術創感染(surgical wound infection)と呼ばれていた手術部位感染(surgical site infections、SSIs)に対する、アメリカ疾病予防局(Center for Disease Control and Prevention, 以下CDC)の勧告である。(12)

第一部：手術部位感染(Surgical Site Infection、以下SSI)概要では、SSIに関する疫学(epidemiology)、定義(definitions)、微生物学(microbiology)、病因論(pathogenesis)、サーベイランス(surveillance)が述べられている。

SSIの原因に関係している術前、術中、術後の問題の詳細な検討も含まれている。

第二部：手術部位感染の予防のための勧告(Recommendations for the Prevention of Surgical Site Infection)では、SSIを防ぐために勧められる実践法について、院内感染制御実施諮問委員会(Hospital Infection Control Practices Advisory Committee、以下HICPAC)での合意が記載されている(3)。

第二部に記載されている勧告は、できる限りよく計画された科学研究によって得られたデータに基づいている。

しかしながら、SSIの危険因子とSSIの予防方法の正当性を証明した研究は極めて少ない。

やむを得ず、利用できる研究は限定された患者集団や、特別な種類の手術を対象にして研究した調査結果を一般論として、全ての特別であったり、潜在的に問題のある種類の手術にも適応している。

このことはSSIの予防法を実行するにあたっては間違っていない。

最終的には、手術チームで通常行われている幾つかの感染制御手技(滅菌手袋を着用するかしないかなど)に関しては、倫理的・論理的理由から厳密には検討されていない。

このため第二部の勧告の中には、強い理論的合理性と暗示的な証拠に基づいているだけで、科学的な知見による確証が欠如しているものもある。

アメリカ合衆国では、次世紀には全手術の約75%が「緊急」あるいは「同日」つまり「日帰り」手術になると予測されている(4)。

勧告されている幾つかのSSI予防策では、これらの状況における外科的処置と、伝統的な入院して手術室で行われる外科的処置の区別はしていない。

この文書は、主に外科医、手術室看護婦、術後を診る入院または診療所看護婦、感染対策の専門家、麻酔科医、病院の疫学者、その他、院内感染対策に関与する関係者に向けて書かれたものである。

ただしこの文書は、：

熱傷、外傷、移植に関して、また、医療従事者から血液を介しての患者への感染など、特殊なものに関して特に述べていない。

また小児外科におけるSSIの予防の詳細についても述べていない。

最近の小児手術患者の多施設研究で、患者の身体状態に関する因子よりも、手術に関する因子のほうがより重要であることが示されて来ている(5)。

一般的に、成人で効果的な全てのSSI予防策は、小児外科手術においても適応できる。手術室外で行われる手技（内視鏡）や心臓カテーテルや放射線科的処置のような侵襲的処置における感染予防の案内もしていない。

しかし、勧告されるものの多くは、これらの手技にも適応でき感染による合併症を減少させると考えられる。

侵襲の少ない手技（腹腔鏡手術など）に特徴的なSSI予防策も示していない。

SSIサーベイランスのデータから、普通、腹腔鏡手術は開腹手術よりもSSIの危険性は少ないか同等である(6-11)。

開腹手術（開腹胆嚢摘出術など）で適応されるSSI予防策は、腹腔鏡的手技（腹腔鏡的胆嚢摘出術など）にも使用する。

術前の患者皮膚消毒や病院職員の手・前腕の消毒薬についての特定の消毒薬は勧めない。

病院では食品医薬品局（Food and Drug Administration、以下FDA）によって分類された最新の情報の中から適切なものを選ぶべきである(12)。

## 第一部：手術部位感染（SSI）：

### 概要

#### A．はじめに

19世紀半ばまで手術患者は、通常術後に発熱をきたし、手術創からの排膿があり、重症の敗血症となり、時には死亡した。

手術後の感染による死亡が減少するようになったのはJoseph Listerが1860年代の後半に抗菌という原理を導入してからである。

Listerの仕事によって、外科手術は感染と死を伴う作業から病気を終わらせて生命を永らえる技術へと劇的に変わった。

近年アメリカ合衆国では、年間手術症例は二千七百万件である(13)。

CDCの院内感染調査機構（National Nosocomial Infections Surveillance、以下NNIS）システムは1970年に設立され、急性期病院での院内感染の調査を行っている。

NNISシステムのレポートによると、SSIは院内感染の原因の第三位であり、入院患者の14～16%である(14)。

1986～1996年の間、NNISシステムでの病院で行われた59万3千3百44件の手術において、1万5千5百23件のSSIが報告されている(CDC、未公表データ)。

手術患者の院内感染の中では、SSIが38%と最も多い。

SSIのうち、2/3は創部感染、1/3は手術に関係した臓器/体腔感染である。

院内SSIを持った患者が死亡した場合、死亡の77%は感染に関係しており、その大半(93%)の患者は手術に関係した臓器/体腔を含む重症感染症である。

1980年Cruseは、SSIは在院日数を10日間、コストを2千ドル増加させたと評価した(15,16)。

1992年の検討で、SSIは在院日数を7.3日間、コストを3千52ドル増加させた(17)。

他のいくつかの研究でもSSIが入院期間と費用を増すことを裏付けている(18,19)。

SSIのうちでも深部(臓器/体腔)のSSIの方が浅部(切開部)のSSIより入院費用がさらに多くなる(20,21)。

感染の制御の実践は手術室の換気や滅菌法、無菌的処置法、手術手技、予防的抗菌薬の有効性を改善することによって進歩してきた。

これらの活動にもかかわらず、SSIは入院患者の発病や死亡の重要な原因であり続けている。

耐性菌の出現や、今日の手術患者の多くが、高齢となっており、慢性、消耗性、免疫抑制をきたす疾患を背景に持っているためと考えられている。

また、器具の挿入や、臓器移植手術の著しい増加があげられる。

このようなSSIの危険性を減らすため、この危険性が患者、手術、職員そして病院の特質により影響を受けるということを常に認識して、組織的で実際的な対策を行わなければならない。

## B. ガイドラインで使用される基本用語

### 1. SSIの定義分類

SSIとの認識は、臨床的および検査学的解釈を含むし、サーベイランスでしっかりとした標準化された定義を使用することが非常に大切である。

そうでなければ、不正確な解釈不可能なSSI発生頻度が計算され報告されることになる。CDCのNNISシステムはSSI定義のための標準化したサーベイランス分類を開発してきた(表1)(22)。

これらの基準により、SSIは切開部SSIと臓器/体腔SSIに分類される。

切開部SSIは皮膚と皮下組織に限局する表層切開部SSIとさらに深部の軟部組織を含む深層切開部SSIに分類される。

臓器/体腔SSIは手術中に切開又は操作の加わった、体壁以外の全ての解剖学的構造物(たとえば臓器又は体腔)を含む(図1)。

例えば、虫垂摘出後、横隔膜下膿瘍を発症した患者では、感染は腹腔内の特定の部位にある臓器/体腔SSIとして報告される。

SSIを定義するための客観的な基準を使用しないと、SSIの発生割合は大きく影響されることが示されている(23,24)。

サーベイランスや手術に関係する人たちは、多くの環境下で首尾一貫してCDCのNNIS

## 表1 - 手術部位感染 ( S S I ) 診断基準

## 表層切開部位 S S I

手術後30日以内に起こった感染で、切開部の皮膚又は皮下組織のみであり、さらに少なくとも以下の1つが認められる

1. 切開部の表面から、検査上の確診の有無を問わず、排膿がある。
2. 切開部の表層から無菌的に採取された、液体又は組織の培養から病原菌が分離される。
3. 以下の感染の症状や愁訴のうち少なくとも1つがある。  
疼痛または圧痛  
限局性腫脹  
発赤、発熱  
切開部の培養が陰性でも外科医が意図的に皮膚浅層の縫合を開けた場合
4. 外科医又は主治医が浅部切開部位 S S I と診断した

以下の状態は S S I とはしない

1. 縫合系膿瘍 ( 縫合系の穿通した穴に限局した最小単位の炎症又は浸出 )
2. 会陰切開部や新生児の包皮切開層の感染
3. 熱傷の感染
4. 筋膜や筋層に波及した切開部 S S I ( 深部 S S I を参照 )

注：感染した会陰切開、環状切開部および熱傷には別の特別な基準がある<sup>433</sup>

## 深部切開部位 S S I

人工物の埋めこみが行われなかった場合には術後30日以内、移植人工物が残された場合には術後1年以内に手術に関連して感染が起こり、さらに手術切開部位の深部組織 ( たとえば、筋膜や筋層 ) を含む。

さらに以下のうちの少なくとも1つが認められる

1. 手術部位の器官・体腔からではなく、切開深部からの排膿。
2. 深部切開創が自然に離開したか、切開創の培養は陰性であっても、次の感染の症状や徴候が少なくともいずれか1つがあり、外科医が創を意図的に開放した場合：38以上の発熱、限局した疼痛、圧痛。
3. 深部切開創の膿瘍やほかの感染の証拠が、直接的あるいは再手術や組織病理学、放射線医学検査で発見される。
4. 外科医または主治医が深部 S S I と診断した。

注：1. 浅部深部両方に感染が及ぶ場合は深部 S S I として報告。

2. 切開創からのドレーンされる臓器・体腔 S S I は深部 S S I として報告。

## 臓器・体腔 S S I

移植人工物†が入っていない場合には術後30日以内、移植人工物が残された場合には術後1年以内に手術に関連した感染や、切開部以外に術中開かれたり操作された ( 例えば臓器や体腔など ) 身体のいずれかの部分に感染が生じた場合。

さらに次の少なくとも1つが認められる

1. 臓器 / 体腔に入っている刺し創‡からのドレーンから排膿がある。
2. 臓器 / 体腔から無菌的に採取された液又は組織から病原体が分離された。
3. 臓器 / 体腔から膿瘍またはほかの感染の証拠が、直接的な検査や再手術、組織病理学又は放射線医学検査で認められる。
4. 臓器 / 体腔感染が外科医又は主治医によって診断される。

\* Horan TC et al.<sup>22</sup>

† N N I S 定義：ヒト由来でない埋め込み可能な異物 ( 例えば、心臓人工弁、ヒト由来でない移植血管、人工心臓、人工股関節など ) で手術により永久的に患者に埋めこまれるもの。

‡ もしその穿通創の周りに感染が起こったら、S S I としない。  
それは深さにもよるが、皮膚もしくは軟部組織の感染と考えられる。

図 1

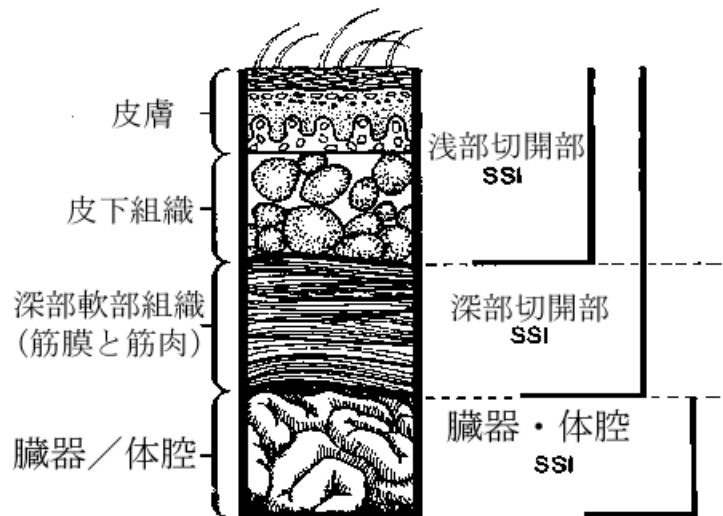


表 2 - 臓器・体腔 S S I の特定の部位

動脈、静脈感染、	髄膜炎、脳室炎、
乳房膿瘍または乳腺炎、	心筋炎、心膜炎、
椎間板腔、	口腔内（唇、舌、歯肉）、
耳、乳様突起、	骨髄炎、
心内膜炎、	下気道の他の感染（膿瘍、膿胸）、
子宮内膜炎、	男女の生殖路、
目、結膜炎以外、	副鼻腔炎、
胃腸管、	髄膜炎を伴わない脊髄膿瘍、
腹腔、	上気道、咽頭炎、
頭蓋内脳膿瘍、硬膜、	腔断面
関節又は滑液嚢、	
縦隔炎、	

\*HoranTC et al.<sup>22</sup>

表 3 - N N I S システムによる S S I から検出された病原菌、1986-1996

	分離率 (%)	
	1986-1989(79) ( N=16,727 )	1990-1996(26) ( N=17,671 )
病原菌		
黄色ブドウ球菌	17	20
表皮ブドウ球菌	12	14
大腸菌	10	8
腸球菌属	8	12
緑膿菌	8	8
Enterobacter 属	8	7
Pseudomonas・Mycobacterium	4	3
Streptococcus・Clostridium	3	3
他の連鎖球菌属	3	3
カンジダ	2	3
D群連鎖球菌	*	2
他のグラム陽性好気性菌	*	2
Bacteroides・Fusillus	*	2

\* : 2%以下の検出は除外してある

による S S I の定義を適用してきており、現在は事実上の国家的標準である(16,17)。

(訳者注：C D C の診断基準は I C P の会に参照すること。

またはメディカ出版からサーベイランス用の診断基準の訳本が出ている。)

## 2 . 手術棟

手術室、廊下および手洗い場などの付帯設備を含んだ物理的に分離された区域である。病院の建物の中であろうと独立した建物であろうと、伝統的な入院患者用の病院の中にある手術棟であろうと日帰り手術に使われる手術棟であろうと、その区別はない。

## 3 . 手術室

手術が行われる手術棟内の部屋。

## 4 . 外科系職員 (Surgical personnel)

手術患者に術前、術中および術後の期間、ケアを提供する全ての医療関係者。

## 5 . 手術チーム構成員 (surgical team member)

手術処置に関する原則を理解して、手術中手術室内にいる全ての医療関係者。

構成員は " 手術時手洗い " を行う者とそうでない者に分けられる ; 手術時手洗いを行った構成員は、滅菌手術野または術野で使用される滅菌器具や医療材料に直接接触する。

(手術前の手・前腕の消毒の項を参照)

## C . 微生物学

S S I から分離された病原体は、N N I S システムによるとこの 1 0 年間で大きな変化はない。(表 3) (26,27)

黄色ブドウ球菌、コアグラゼ陰性ブドウ球菌、腸球菌、大腸菌が最も頻繁に分離される病原菌である。

S S I の増加の大きいものは、抗菌薬に耐性を持つ病原菌、例えばメチシリン耐性黄色ブドウ球菌 ( M R S A ) (28,29)、またはカンジダである(30)。

1 9 9 1 から 1 9 9 5 の間に N N I S による病院調査で、真菌類による S S I の発生頻度は 1 0 0 0 検体あたり 0 . 1 から 0 . 3 に増加していた(30)。

耐性菌やカンジダ属の S S I に占める率の増加は、病態がより悪い手術患者や、免疫抵抗性の落ちた患者が増加していること、予防的かつ治療的な抗菌薬投与がより広範囲に行われていることを反映しているかもしれない。

珍しい病原体、例えば *Rhizopus oryzae*、*Clostridium perfringens*、*Rhodococcus bronchialis*、*Nocardia farcinica*、*Legionella pneumophila*、*Legionella dumoffii*、*Pseudomonas multivorans* などによって S S I のアウトブレイクや群発が起こることがある。

これらの稀なアウトブレイクを追跡していくと汚染された粘着包帯であったり(31)、弾性包帯(32)、保菌した医療従事者であったり(33,34)、水道水(35)や汚染された消毒液(36)であったりする。

珍しい病原体の S S I が群発する場合には、正規の疫学的調査を行うべきである。

## D . 病因

SSIには必然的に手術部位の細菌汚染が先行する。

SSIの危険性は次のような関係に概念化することができる(37,38)。

$$\frac{\text{汚染した細菌量} \times \text{毒力}}{\text{宿主の抵抗力}} = \text{SSIの危険性}$$

量的に細菌汚染が組織1グラム当たり10の5乗以上になるとSSIの危険性が著しく増加する(39)。

しかしながらその部位に異物が存在すると、感染を起こすに必要な微生物の量はずっと少なくなくて済む(例えば、シルク縫合糸の存在下では、組織1g当たり100個のブドウ球菌で起こる)(40-42)。

微生物は宿主に侵入する能力を高めたり、宿主内で障害を起こしたり、感染した宿主の組織の中で生存したりするための、いろいろな物質や毒素を含有あるいは産生してSSIの発現を促進する。

例えば、多くのグラム陰性細菌はエンドトキシンを産生し、サイトカイン産生を刺激する。次には、サイトカインが時には多臓器不全をもたらすSIRS(systemic inflammatory response syndrome)を惹き起こすかもしれない(43-45)。

ある種の細菌の表面の構成物(特に多糖類カプセル)は、食作用(48)や細菌汚染に対する大切な最初の宿主防御反応を抑制する。

クロストリジウム属のある種のものや連鎖球菌は、細胞膜を破壊したり細胞代謝を変化させる強力な細胞外毒素を産生する(49)。

表皮ブドウ球菌のようなグラム陽性菌を含む様々な微生物は、物理的に食作用から菌を守ったり、抗菌薬が接触あるいは貫通するのを抑制する(56)糖皮(glycocalyx)、いわゆる「スライム」(50-55)と呼ばれる付随物を産生する。

これらのことや他の毒性因子もよく分かって来ているが、SSIの進展との因果関係は十分にはわかっていない。

多くのSSIで、病原体の多くは患者の皮膚、粘膜や中空の臓器などの内因性細菌叢である(57)。

粘膜や皮膚が切開されると、組織は内因性細菌叢の汚染の危険にさらされる(57)。

これらの微生物は通常好気性グラム陽性球菌である(例えば、ブドウ球菌)が、切開が会陰や鼠径に近いと便の細菌叢(例えば、嫌気性菌やグラム陰性好気性菌)を含むかもしれない。

手術中消化管が損傷され病原体の発生源となると、グラム陰性桿菌(大腸菌など)、グラム陽性菌(腸球菌など)や時には嫌気性菌(Bacillus fragilisなど)が典型的にSSIから分離される。

表4に手術とそれに関係するSSI病原菌を提示した。

離れた病巣からの細菌の播種はSSI病原体のもう一つの供給源でありうる(59-68)し、特に手術中、人工器官が埋め込められる患者では特に重大である。

これらの器具が、細菌が付着する病巣を提供する(50,69-73)。

SSIの病原体の外因性の起源は、手術室の環境や病院職員(特に手術チーム構成員)(74-78)、手術室環境(空気を含む)、そして手術中に滅菌野に運ばれた全ての道具、器具、物である。(「術中の問題」の項参照)



表4 - 手術およびSSIで可能性のある病原体と予防的抗菌薬の使い方の文献

手術	可能性のある病原体†‡	文献
全てのグラフト、人工物、インプラントの移植	黄色ブドウ球菌、表皮ブドウ球菌	269,282-284,290
心臓	黄色ブドウ球菌、表皮ブドウ球菌	251-253,462,463
脳神経外科	黄色ブドウ球菌、表皮ブドウ球菌	241,249,258,259,261,464,465
胸壁	黄色ブドウ球菌、連鎖球菌、グラム陰性桿菌	242,248
眼科（データが限られているが硝子体手術、ハックリングなどで）	黄色ブドウ球菌、表皮ブドウ球菌	466
整形外科（関節全置換、人工物や骨移植を行う骨接合、外傷など）	黄色ブドウ球菌、表皮ブドウ球菌、グラム陰性桿菌	60,243-246,254,255,467-473
胸部（開胸肺手術、心臓でない胸骨切開）	黄色ブドウ球菌、表皮ブドウ球菌、肺炎球菌、グラム陰性桿菌	240,247,474,475
血管	黄色ブドウ球菌、表皮ブドウ球菌	250,463,476,477
虫垂切除	グラム陰性桿菌、嫌気性菌	263,452,478
胆道	グラム陰性桿菌、嫌気性菌	260,262,479-484
結腸直腸	グラム陰性桿菌、嫌気性菌	200,239,256,287,289,485-490
胃十二指腸	グラム陰性桿菌、連鎖球菌、口腔内嫌気性菌	256,257,491-493
頭部・首（口咽頭粘膜までの）	黄色ブドウ球菌、連鎖球菌、口腔内嫌気性菌	494-497
婦人科産科	グラム陰性桿菌、腸球菌、B群連鎖球菌、嫌気性菌	270-280,435
泌尿器（もし尿が無菌であれば必要ない）	グラム陰性桿菌	267

"Antimicrobial prophylaxis in surgery" The Medical Letter 1997 (266) による。

†内因性、外因性、両方の可能性のあるもの

‡ブドウ球菌は全ての種類の手術後SSIに合併する

内因性および外因性の真菌はSSIの原因としては稀であるし、それらの病原性はよく分かっていない(79)。

#### E . 危険性と予防

疫学において「危険因子 (risk factor)」という言葉は特別の意味を持っている。

SSIの病態生理と予防という文脈において、危険因子とは正確にはSSIの進展に重要な意味を持つと共に、独立した変数を意味する。

危険因子は疫学的に多変量解析によって確定される。

表5：SSI発生に影響する患者および手術の特性(25,37)

患者：

年齢、  
 栄養状態、  
 糖尿病、  
 喫煙、  
 肥満、  
 離れた体の部位に感染が存在、  
 微生物の保菌、  
 免疫反応の変化、  
 術前入院期間

手術：

手術時手洗いの長さ、  
 皮膚消毒法、  
 術前剃毛、  
 術前皮膚処置、  
 手術時間、  
 予防的抗菌薬投与、  
 器具の滅菌不十分、  
 手術部位の異物、  
 ドレーン、  
 外科手術手技（止血のまずさ、死腔の残存、組織損傷）

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SSIの危険因子（表5）は二つの点で有用である。

（1）手術の階層化が可能になって、調査データがより分かりやすくなる。

（2）危険因子を術前に知ることにより予防が可能となる。

例えば、患者が離れた部位の感染症を起こしている場合には、手術チームは感染が治るまで予定手術を延期してSSIの危険を減少させようとするかもしれない。

SSIの予防法とは、医療従事者が意図的にSSIの危険因子を減少させるような行為、またはまとまった複数の行為と定義される。

続いて述べられる技術の多くは、患者の組織や滅菌した手術器具が微生物で汚染される機会を減少させることを含んでいる。

その他の技術として、抗菌薬の予防的投与や不必要な外傷性の組織切開を避けるといったような補助的なものである。

SSI防止策を最適に応用するためには、さまざまな患者および手術の特性を注意深く考慮する必要がある。

## 1. 患者特性

ある種類の手術で、SSIの危険性を増すことに関連すると思われる患者の特質には、同時に存在する離れた部位の感染(59-68)や保菌(81-83)、糖尿病(84-87)、喫煙(85,88-92)、ステロイドの全身投与(84,87,93)、肥満（理想体重の20%以上）(85-87,94-97)、極端な年齢（訳者注：高齢や未熟児）(92,98-102)、低栄養状態（85,94,98,103-105）、そして周術期のある種の血液製剤の投与(106-109)があげられる。

### a . 糖尿病

糖尿病が S S I の危険性に対し独立にどの程度関与しているか、いくつかの潜在的な要因の弁別をしっかりと行って評価した例がないため、糖尿病の関与の程度については議論の余地がある(84-86,98,110)。

最近の予備的な冠動脈バイパス術患者での研究で、H b A 1c と S S I の危険性について評価がなされ、H b A 1c の増加と S S I の発生頻度に有意の相関が認められている(111)。

また、( 4 8 時間以内の ) 術直後の血糖が ( 2 0 0 mg/dl 以上 ) 高いと S S I の危険性が増加した(112,113)。

追加処置としての周術期の血糖コントロールの有効性の評価にはさらなる研究が必要である。

### b . ニコチンの使用

ニコチンを使用すると創の一次治癒が遅れるため、S S I の危険性が増すかもしれない(85)。

大きな前方向の研究で、最近の喫煙が心臓外科術後の胸骨と縦隔の S S I に対して独立した危険因子であった(85)。

他の複数の研究でも喫煙が S S I の重要な危険因子であることを確証している (88-92)。

しかしながら、これらの研究の限界は"最近の喫煙"や"活動性の喫煙者"なる用語が常には正確に定義されていないことである。

喫煙が S S I の危険性に寄与することを適切に決定するには、「喫煙歴の標準化された定義」が、区別の困難なさまざまな変数をコントロールするために計画された研究に適応され、使用されなければならない。

### c . ステロイドの使用

ステロイドや他の免疫抑制剤を術前に投与されている患者もまた S S I に進展しやすいかもしれない(84,87)が、この関係を支持しているデータには矛盾がある。

クロ - ン病でのステロイドの長期使用の研究では、術前にステロイドを使用していない患者の S S I 発生が 6 . 7 % だったのに対し、ステロイドを使用した患者では 1 2 . 5 % と有意に多かった(93)。

対照的に他の研究者はステロイドの使用と S S I の危険性の間に関係を見いだしていない(98,114,115)。

### d . 栄養不良

いくつかの手術で、重度の蛋白・熱量栄養不良は高率に術後の院内感染を合併し、創傷治癒機転の障害、または死をもたらす(116-124)。

The National Academy of Sciences/National Research Council (NAS/NRC)(94), Study on the Efficacy of Infection Control (SENIC)(125) と N N I S (126) の S S I の危険の層分類計画では、はっきりとは予測因子として栄養状態を受け入れていないが、後の二つでは間接的に述べている。

よく引用される 1 9 8 7 年の 4 0 4 例の高リスクの一般外科手術患者での研究で、Christouらは S S I の可能性のある因子として、年齢、手術時間、血清アルブミン値、遅延過敏反応試験スコアと、もともとの傷の汚染レベルを最終的にあげている(117)。

この指標は 4 0 4 例のその後の患者の S S I の危険を予測するのに十分であったし、S S I の危険の層分類に非常に役立ったと一般に受け入れられてはいるが、S S I サーベイランスのデータ解析や、手術感染研究、分析疫学には広く利用されていない。

重度の術前栄養不良が切開部および臓器 / 体腔 S S I の両方のリスクを増加させるというこ

とを、論理的に主張することはできる。

しかし、全ての外科系下位専門分野に対し、切開部 S S I と栄養不良の疫学的関連を一貫して示すことは困難である(118-120, 124, 127-131)。

多変量解析では、術前蛋白・熱量栄養不良は心バイパス手術後の縦隔炎の独立した予測因子ではなかったことが示されている(85, 132)。

近代において、完全静脈栄養(TPN)と完全腸管栄養(TEA)は外科医と集中治療専門家によって熱烈に受け入れられてきた(118, 133-137)。

しかし、S S I の危険を減らすため、栄養不良患者に対し術前の栄養の充実がよかったという証明はなされていない。

二つの臨床的無作為抽出試験で、術前の「栄養療法」は切開部および臓器/体腔 S S I の危険を減らさなかった(138-141)。

最近の担癌の高リスクの膵臓切除術患者での研究で、術前の T P N 処置は S S I の危険に対しなんら有効ではなかった(142)。

395名の一般及び胸部外科手術患者での前方向無作為抽出試験で、栄養不良患者で術前7～15日間 T P N を受けていた例と普通の病院食をとっていた例の比較が行われた。

全ての患者が術後90日間追跡調査された。

T P N 投与が切開部または臓器/体腔 S S I の発生に利益があるということは見出せなかった(143)。

T P N および T E A は多くの状態で適用されるであろうが、臓器/体腔または切開部 S S I の危険の予防処置としては重要とは受け取られない。

非常に重篤な栄養状態の患者が大きな予定手術を受ける場合は、経験のある外科医は数多くの重篤な合併症を伴う疾病 - その唯一のものが臓器/体腔 S S I である - も考慮しながら、しばしば術前・術後に栄養療法を行う(118, 124, 130, 133, 137, 138, 144-149)。

さらに術後栄養療法は、ある種の大きな癌の手術(135, 136)や、大きな外傷患者の多くの手術の後、または食事が妨げられたり代謝過多状態になりやすい、さまざまな破局的な外科的合併症の患者に重要である。

栄養療法がある特殊な患者-手術関連で、S S I の危険を変化させるかどうか見極めるには、臨床的な無作為抽出試験が必要であろう。

#### e . 長い術前入院期間

術前入院期間が長いと患者の S S I の危険性が増加するとしばしば示唆されてきた。

しかし、患者の術前入院期間が長いのは、病気の重症度と合併症のために術前に治療が必要なことを示しているようである(16, 26, 65, 85, 94, 100, 150, 151)。

#### f . 黄色ブドウ球菌の術前鼻腔保菌状態

黄色ブドウ球菌はよく S S I から分離される。

この病原菌は健康人の20～30%の鼻腔に存在する(81)。

長い間、黄色ブドウ球菌による S S I の発生は、手術患者が病原菌を術前に鼻腔に持つことと明確に関連すると信じられてきた(81)。

最近の多変量解析で、このような保菌は心臓胸部手術に引き続く S S I の最も重要な独立の危険因子であることが示された(82)。

ムピロシン軟膏(バクトロバン(R))は保菌患者または医療従事者の鼻腔から黄色ブドウ球菌を除去する局所薬として効果的である。

Kluytmansらの最近の報告では、保菌状態の有無に関らず、術前にムピロシンを鼻腔に投与することで、心臓胸部手術の患者における S S I の危険は低下した(152)。

この研究では752例のムピロシン治療患者の S S I 頻度が、以前の928例のムピロシン

非治療の履歴上の対象患者のそれと比較され、重要な S S I の頻度の減少は、ムピロシン治療によるためとした。

この二つの患者グループの同等性に関心がもたれている(153)。

さらに、治療期間が短い時には稀であるとしても、ムピロシンの耐性が問題になってきている(81)。

心臓手術で黄色ブドウ球菌の除去が S S I の予防に効果的であるかは、前方向無作為抽出試験が必要であろう。

この種の試みは最近アイオワ州で 3, 909 名の患者で行われた(83)。

二つの施設で 5 種類の手術が観察された。

予備的な解析で、黄色ブドウ球菌の鼻腔保菌と引き続く S S I の発生に重要な相関が見られている。

S S I の危険を減らすムピロシンの効果についての結論はまだ出ていない。

## g . 周術期輸血

白血球を含む同種血液成分の周術期輸血は、S S I を含む術後細菌感染発生のはっきりとした危険因子である(106)。

予定の癌のための結腸切除術を受ける患者における、5 つの無作為抽出試験のうち 3 つで、S S I の危険は輸血を受けると少なくとも二倍になった(107-109)。

しかし、疫学的に詳細に再検討したところ、12 ほどの区別の困難な変数が報告の中に影響しており、S S I の危険における輸血の効果は小さいか存在していなかった(106)。

輸血時期を含め、標準化されていない S S I の診断基準の使用など方法論の問題から、利用できるデータの解釈に限界がある。

公表されている研究のメタ解析が、論争の解決におそらく必要であろう(154)。

今のところ、切開部および臓器 / 体腔 S S I の危険を減らすために手術患者に血液製剤を差し控える必要性を示す科学的根拠はない。

## 2 . 手術特性：術前の問題点

### a . 術前の消毒剤によるシャワー

術前の消毒剤によるシャワーや入浴は、患者の皮膚の細菌のコロニー数を減少させるだろう。

術前、消毒薬によるシャワーを受けた 700 人以上の患者での研究では、クロルヘキシジンがコロニー数を 2.8 (×10 の 2 乗) から 0.3 へと 9 分の 1 に減少させ、ポビドンヨードとトリクロルカーボンを加えた石鹸ではそれぞれ 1.3 と 1.9 分の 1 に減少させた(155)。

他の研究でもこれらの結果を支持している(156,157)。

グルコン酸クロルヘキシジン含有製品は最大の抗菌効果を得るまでに数回の使用を必要とするため、通常くり返しの消毒剤によるシャワーが必要である(158)。

術前のシャワーが皮膚の細菌のコロニー数を減少する事実にもかかわらず、S S I の頻度を減少させる事は明確には示されていない(159-165)。

### b . 術前の除毛

手術前夜の手術部位の剃毛は S S I の危険性を有意に増加させる。

この危険性は脱毛剤を用いたり除毛しない群より大きい(16,100,166-169)。

ある研究では S S I 頻度は安全かみそりで剃毛した患者が 5.6% だったのに対して脱毛剤で除毛するか除毛をしない群では 0.6% であった(166)。

剃毛による S S I の危険性の増加は皮膚の顕微鏡的な切創のため後にこれが感染巣にな

る。

手術直前での剃毛は24時間および24時間以上前の剃毛と比較すると、SSI発生頻度は低い(それぞれ3.1%、7.1%、20%)(166)。

手術直前に毛を刈るのは、手術前夜に剃毛または刈る場合よりもSSI発生の頻度は低い(1.8%と4.0%)(170-173)。

脱毛剤の使用は剃毛や刈るよりSSIの危険性は低い(166,167)が、脱毛剤は時に過敏症を起こすことがある(166)。

他の研究でも術前の剃毛は、SSIの発生頻度を増加させるため、剃毛はしない方が良いとされている(100,174,175)。

### c. 手術室での患者の皮膚の準備

皮膚の切開部に対してさまざまな消毒薬が使用可能である。(表6)

ヨードホルム(以下ポビドンヨード、訳者注:イソジン(R))、アルコール含有剤、グルコン酸クロルヘキシジン(ヒビテン(R))が最もよく用いられる製剤である。

SSIの危険性に関してこれらの術前の消毒薬の効果を正確な方法で比較した研究はない。FDAによってアルコールとは以下の活性成分の一つを持つものと定義されている:容量で60~90%のエチルアルコール水溶液か、50.3~91.3%のイソプロピルアルコールを含むもの(12)。

アルコールはすぐに入手できて安価であり今でも最も効果的で即効性のある皮膚消毒薬である(176)。

70~92%アルコール溶液は細菌、真菌、ウィルスに対して殺菌力を持つが、芽胞は抵抗力を持つ(176,177)。

手術室でのアルコール使用で最大の欠点はその可燃性である(176-178)。

グルコン酸クロルヘキシジンとポビドンヨードは両方とも広い抗菌力を持っている(177,17-181)。

術前の手術時手洗いにおいて、両者の比較ではポビドンヨードよりグルコン酸クロルヘキシジンが皮膚の細菌数を減少させ、さらに1回使用後の残存効果も強かった(182-184)。

さらにグルコン酸クロルヘキシジンは血液や血清の蛋白で不活性化されない(176,179,185,186)。

ポビドンヨードは血液や血清の蛋白で不活化されたが、皮膚にある間は静菌作用を示した(178,179)。

患者の皮膚の準備を始める前に皮膚の(汚れや土、その他の残渣などの)大きな汚染物を除去しなければならない(187)。

患者皮膚の準備は消毒薬を切開予定部から始めて同心円状に(外側に)円を描くように塗ってゆく。

準備する範囲は、必要なら切開を広げたり、別の新しい切開やドレーン挿入部を作る場合にも十分に越えるように広くなければならない(1,177,187)。

皮膚の準備は(熱傷など)皮膚の状態によって、または(顔面など)場所によって修正する必要があるかもしれない。

術前皮膚準備の修正には(1)消毒薬塗布後の除去、乾燥、ふき取り(2)消毒薬を染み込ませた粘着性ドレープの使用(3)伝統的な手洗いの代わりに消毒薬を皮膚に塗る(4)滅菌に対して清潔な外科皮膚用消毒キットを使うなどがある(188-191)。

しかし、これらの修正法はいずれも有効であると示されてはいない。

表 6 - 術前の皮膚処置と手術消毒に一般的に使用される消毒剤の作用機序と作用範囲

薬剤	作用機序	グラム陽性菌	グラム陰性菌	結核菌	真菌	ウイルス	作用発現	残存効果	毒性	使用目的
アルコール	蛋白変性	E	E	G	G	G	最早	なし	乾燥、可燃性	SP,SS
クロルヘキシジン	細胞壁破壊	E	G	P	F	G	中等度	E	聴神経毒、角膜炎	SP,SS
ヨウ素・ヨードホル	酸化フリーヨウ素による置換	E	G	G	G	G	中等度	最小	毒性の危険のある皮膚からの吸収、皮膚刺激	SP,SS
PCMX**	細胞壁破壊	G	F*	F	F	F	中等度	良好	データ不足	SS
トリクロサン	細胞壁破壊	G	G	G	P	U	中等度	E	データ不足	SS

略語：E--excellent. G--good. F--fair. P--poor. U--unknown、

SP--皮膚処置、SS--手術時手洗い

\*緑膿菌以外に良好、EDTA などのキレートなどで活性が上がる

\*\*PCMX-Para-chloro-meta-xyleneol、

Larson E.(176)

#### d . 手術前の手・前腕の消毒

滅菌の手術野や術野で使用される滅菌器械・医療用具に直接接触する手術チーム構成員は、滅菌ガウンと滅菌手袋を着用する直前に、伝統的ないわゆる手術時手洗の方法で手と前腕を洗う。

理想的には最適の消毒薬は広範囲の活性と速効性、持続性を持つべきである(1,192,193)。合衆国で商品として使用できる消毒薬はアルコール、クロルヘキシジン、ヨード/ポビドンヨード、PCMX、トリクロサンが含まれる(表6)(176,177,179,194,195)。

アルコールはヨーロッパの諸国のいくつかでは手術時手洗いの標準(gold standard)と考えられている(196-199)。

アルコールを含んだ消毒薬は合衆国ではヨーロッパほどは使われていない。

これは可燃性と皮膚の刺激性によると思われる。

合衆国で手術チームによって最も頻りに用いられているのはポビドンヨードとグルコン酸クロルヘキシジンである(177)。

しかしながら7.5%ポビドンヨードあるいは4%グルコン酸クロルヘキシジンをクロルヘキシジンアルコール(60%イソプロピルアルコールと0.5%クロルヘキシジン加70%イソプロピルアルコール)を比較するとクロルヘキシジンアルコールの方が抗菌活性の残存効果がより強力であった(200,201)。

すべての状況に理想的な薬剤は存在しない。

効能はさておき(受け入れられるかどうかの)最大の要因は、手術室の勤務者が反復使用しての満足度によっている。

残念なことに手術時手洗いの消毒薬の評価は手の細菌のコロニー数に焦点が当てられている。

SSIの危険性における、手指消毒薬選択の影響についての臨床的な試験は行われていない(195,202-206)。

消毒薬選択以外のさまざまな要因が手術時手洗いの有効性に影響する。

手洗いの技術や、手洗い時間、手の状態、手洗い後の乾燥法や手袋着用法がそのような要因の例である。

最近の研究では手の細菌のコロニー数を減少するためには伝統的に行われている10分の手洗いとほぼ同様の効果が少なくとも2分間の手洗い時間で得られる(207-211)が、最適な手洗い時間はわかっていない。

その日の最初の手洗いは、十分な爪床の下の清浄も含んだやり方にすべきである(大抵はブラシを使う)(180,194,212)。

一日を通して、その後の手洗いに同じような清浄が必要かどうかははっきりしていない。

手術時手洗いの後、手を身体から離し(肘を曲げた状態)、水が指先から肘に滴るように、拳上しておく。

滅菌タオルを使って滅菌ガウンと手袋を着用する前に手指・前腕を乾燥させる(212)。

つけ爪をつけている外科チームの一人は適切な手洗い後ですら手の細菌や真菌のコロニー数が増加しているかもしれない(212,213)。

手におけるグラム陰性細菌の運搬は、つけ爪をつけたほうが多いことが示されている(213)。

心臓血管外科の患者の間でセラチアによるSSIのアウトブレイクが、つけ爪をつけた看護婦に関係していた事例報告がある(214)。

爪の長さやSSIの危険性の関係は知られていないが、つけ爪であれ生爪であれ長い爪は手袋を破ってしまうだろう(177,180,212)。

手術室のスタッフの爪のマニキュアや宝石によるSSIの危険性の影響については、適切な研究はされていない(194,212,215-217)。

#### e. 感染症を保持したり保菌している手術関係職員の扱い

ある種の微生物の感染や保菌をしている手術関係職員は、SSIのアウトブレイクや群生に関係づけられてきた(33,34,76,218-237)。

このように病院が、職員から患者への微生物の伝播を防ぐ方針を実行させることは重要である。

これらの方針には、職業関連疾患の扱い、職業に関連した被爆後の予防処置、そして必要なら病気の職員を一時休ませたり、患者と接触させない仕事に配置替えすることが含まれるべきである。

勤務の禁止の方針を実行すべきであるし、当局による病気の職員の就業制限の指示があったとしても、職員には病状や被爆の状況の報告をするよう促し、賃金、利益や地位を奪うような個人的な罰則を科してはならない。

#### f. 抗菌薬の予防的投与

手術時予防的抗菌薬投与(antimicrobial prophylaxis,以下AMP)はまさに手術が始まる直前に開始される抗菌薬の短期間投与のことである(239-265)。

AMPは無菌の組織にしようというのではなく、宿主の防御機構が破綻されないレベルに手術中の細菌汚染を減らそうと厳格に時間を考慮して使用される。

AMPは術後の汚染によるSSIの予防には関らない(265)。

静脈点滴が近代外科処置で最も普通のAMPの投与経路である(20,26,242,266-281)。

本質的に、全ての確立されたAMPの適応は、手術室で皮膚切開が閉じられる予定手術である。



A M P の利益を最大にするために以下の4つの原則を守るべきである：

A M P 薬は、臨床的研究による事実に基づいて S S I 頻度を減少させることがはっきりしている全ての手術、または切開部や臓器 / 体腔 S S I が破局的になりそうな手術に使用される (266, 268, 269, 282-284)。

A M P 薬は安全であり、安価であり、手術中に可能性のあるほとんどの汚染菌に対しデータ上は殺菌的であるものを使用する。

皮膚切開時までに血清および組織中の薬剤の殺菌性濃度が確立しているように、初回量の投与時間を決定する。

薬剤の治療域濃度を術中ずっと、血清と組織の両方において維持し、また少なくとも手術室で創が閉じられてから 2、3 時間まで維持させる

(179, 266-268, 282, 284, 286)。

全ての手術創に凝固血が存在するので、A M P 薬の治療血清濃度は、治療組織濃度とともに必然的に重要である。

フィブリン膜に付着した細菌は食作用や創の腔から広がる抗菌薬との接触に抵抗する。

表 4 は手術における A M P の効果を確立するために行われた、手術・部位研究に従った典型的な病原体をまとめたものである。

A M P の適用を管理する簡単な方法は、術中の細菌汚染の程度を、術後に分類した症例表現であるいわゆる「手術創分類」(表 7) を使用することが基本である。

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## 表 7 : 手術創分類

クラス / 清潔 (Clean) :

感染していない手術創で炎症はないもの。

ただ、呼吸、消化管、生殖器、感染していない尿路は入れない。

さらに、清潔創が一期的に閉鎖されて、必要な場合には閉鎖ドレーンが入っている。

非貫通性 (鈍的) 外傷後の切開創も基準を満たせばここに含めるべき。

クラス / 準汚染 (Clean-Contaminated) :

呼吸器、消化器、生殖器、尿路を含む、よく管理された状態で、異常な汚染がない手術創。

特に、胆道、虫垂、膣、口咽頭はここに含め、明らかな感染がなく、または手術で大きな損傷を起こしていないこと。

クラス / 汚染 (Contaminated) :

開放性の、新鮮な、偶発的な傷。

加えて、滅菌操作を損なう操作 (e.g. 開胸心マッサージ) か、消化管からの大きな漏出や、急性の膿をもたない炎症のある創はここに含める。

クラス / 不潔・感染 (Dirty-Infected) :

古い外傷性の傷で壊死組織が残っていたり、臨床的に感染が存在していたり、内蔵穿孔がある。

この定義は術後感染を起こす細菌が、手術前から術野に存在することを示唆している。

Garner JS (1) と Simmons BP (2)

(訳者注：ここでクラスを「準汚染」と訳した。他で準清潔と訳す例もあるが、マイルズ氏手術もここに含めるという記載をみると、準汚染としたくなる。)

術者は行う手術の術前から手術創分類を予想してAMPの使用を決定する。

AMPは、管理された状態でも管腔臓器への侵襲が明らかに加えられる全ての手術に適応される。

このような準汚染手術で最も頻度の高いSSI病原体を表4に示した。

予定結腸手術、直腸低位前方切除術や直腸腹会陰切除術などの、ある種の準汚染手術では、腸管の内容物を空にし、生きている微生物の量を減らす、いわゆる「結腸の準備」といわれる術前の追加処置が必要である(200,239,256,268,284,287)。

この処置には、手術前日から非吸収性の抗菌薬の経口分割投与に引き続き、浣腸と下剤の投与が含まれる(200,288,289)。(訳者注：現在保険では認められていない)

AMPは時には、内臓への操作もなく、なんら炎症や感染のないことがはっきりしている正常な組織だけに対する切開手術時にも適応される。

これら清潔手術でのAMPの適応で二つのことが良く理解されている：

- (1) なんらかの人工血管や人工関節が埋めこまれる時。
- (2) 切開創ないし臓器/体腔SSIが破局的な危険となるような手術。

例えば、心臓ペースメーカー植え込み術を含む全ての心臓手術(290)、全ての部位での人工動脈移植や下肢の血行再建を含む血管手術、ほとんどの脳外科手術である(表4)。

何人かは胸部の全ての手術でAMPの使用を勧めている(80,242,264)。

定義から、表7の汚染または不潔手術ではAMPは適応されない。

これらの手術ではしばしば、患者は既に存在する感染に対し、周術的に治療のための抗菌薬を投与されている。

セファロスポリン(複数)は最もよく研究されたAMP薬である(284)。

これらは多くのグラム陽性およびグラム陰性の微生物に効果がある。

これらは安全であり、好ましい薬理動態で、正当な価格である(242)。

特に、セファゾリン(訳者注：セファメジン(R))は広く使用されており、一般的に清潔手術の第一選択のAMP薬と見られている(266)。

もし患者がペニシリン・アレルギーのためセファロスポリンを使用できない場合は、グラム陽性菌をカバーする、クリンダマイシン(訳者注：リンコマイシンのダラシン(R))またはバンコマイシンが代用とされる。

セファゾリンは多くの準汚染手術に適応されるが(268,291)、遠位腸管手術には嫌気性菌をカバーするセフォキシチン(訳者注：セファマイシンのマーキシン(R))など(又は他の第2世代セファロスポリン)にすること。

もし患者がアレルギーのためセファロスポリンを安全に使用できない場合は、グラム陰性菌をカバーするものとしてアズトレオナム(訳者注：モノバクタムのアザクタム(R))を代用する。

しかしながら、クリンダマイシンやメトロニダゾール(訳者注：フラジール(R)、ただし日本で静注薬はない)のような薬剤は、嫌気性菌のカバーを確実にするものにも含まれる。

アミノグリコシドは単独、混合としても、AMPとしての第一選択としては、滅多に勧められない(242,264)。

表4に引用された文献には、AMP選択や用量、抗菌スペクトラムや適応に関する詳細や、他の臨床的な実用情報が提供されている。

AMPとしてバンコマイシンをルーチンに使用することはいかなる種類の手術でも勧められない(242,266,283,292)。

しかしながら、MRSA縦隔炎やメチシリン耐性の表皮ブドウ球菌による切開部SSIが多

数見つかるような場合などの、特殊な臨床の場ではバンコマイシンがAMPの選択になるかもしれない。

どのような場合に、AMPとしてバンコマイシンを使うかの決定は、科学的にはっきりしているわけでない。

使用の決断は、局所で分離されるMRSAの頻度、特別な手術でのSSIの頻度、感染対策の実行のコンプライアンスの再検討（訳者注：職員が実行しているか）、術者と感染症専門医の相談等を踏まえて行われるべきである。

菌の同定とAMP薬の感受性を決定するため、注意深いタイムリーなSSI分離菌の培養による効果的なSSIサーベイランスを行うべきである(80)。

AMPに使われるほとんどの薬剤（セファロスポリンなど）は、時間依存性殺菌作用を持つ。

これらの薬剤の治療効果は、そのレベルが試験管内での目標の病原体に対する最小殺菌濃度に大体近い域値を持続的に越えている時、おそらく最大である。

AMP薬の治療レベルが維持できる時間を手術時間が越えていると考えられる場合は、AMP薬の追加投与がなされるべきである。

セファゾリンのそれは3～4時間と考えられている。

一般に、2回目（ないし3回目）のAMP薬の投与時期は、以下の3つのパラメーターで評価する。

標準治療量での正常な患者での組織到達濃度、薬剤の大体の半減時間、予想されるSSI病原体の大体のMIC<sub>90</sub>の認識である。

表6の文献で、これらの詳細およびさまざまな特殊事情でAMPとして使用される抗菌薬の重要な特性などを参照すべきである。

基本的な「親指の原則」方針でAMPの量と時間を決める。

例えば、セファゾリンの十分な治療量（1～2g）は成人患者では、皮膚切開前30分以上前に投与すべきでない(242,285)。

この基本的指針にはわずかの例外がある。

投与量に関して、病的に肥満している患者で適切な効果を得るためには、より多くの量が必要であることが分かっている(293)。

時間に関して、AMPが適応である帝王切開術を受ける患者では例外がある：初回投与は臍帯がクランプされた後に直ちに投与する(266,272,273)。

バンコマイシンは、標準量では約一時間をかけて投与する。

はっきりしていることは、搬送が遅くなったり手術予定が変更されたりと、手術が開始される時には、組織および血清の濃度が適正以下になっている可能性があるため、いわゆる「オンコール」のAMP投与は簡単にだいなしになってしまう(242,294)。

AMPのタイミングと手落ちの責任についての簡単なプロトコールを、実際的にかつ効果的であるように各病院で作成すべきである。

### 3．手術特性：術中の問題

#### a．手術室環境

##### (1) 換気

手術室の空気には微生物の付いた埃、糸くず、皮膚表皮、呼吸飛沫を含んでいるかもしれない。

手術室内の空気の微生物レベルは室内で動く人数に直接的に比例する(295)。

このため、手術中に行き来する人数をできるかぎり最小にするように努力しなければならない

い。

A群ベ - タ溶血性連鎖球菌による S S I のアウトブレイクが、保菌した手術室勤務者から患者への空気経路感染であることが追跡調査により発見されたことがある

(233,237,296,297)。

これらのアウトブレイクで原因となった菌株は、手術室の空気中から回収された

(237,296)。

運動や着替えが、腔や直腸の保菌ヶ所から A 群連鎖球菌の空気撒布を惹き起こす可能性が明らかにされている(233,234,237,297)。

手術室は廊下や隣接した部屋よりも気圧を高く維持しなければならない(298)。

陽圧は清潔度の低い部屋からより清潔な部屋に空気が流入することを防ぐ。

病院の全ての換気又は空調は手術室も含め、一つは 30%以上、もう一つは 90%以上の効率を持つ二つのフィルター層を一連で持つべきである(299)。

(訳者注：プレフィルターとして上流に粗塵除去、空調機の機能維持に用いられるものと、最終フィルターとして、細菌等を 90%以上除去するものとを直列に設置して空気清浄を行うこと)

手術室の換気系統は慣習的に一時間あたり最低 15 回、濾過された空気によって空気を交換し、このうち 3 回 (20%) は新鮮な空気でなければならない(299,300)。

空気は天井から導入されて床の近くから排気されなければならない(300,301)。

手術室の換気に関しての詳細はアメリカ建築協会(American Institute of Architects)と U.S. Department of health and Human Service)によって公表されている(299)。(表 8)

表 8 手術室の換気パラメ - タ -

American Institute of Architects, 1996、(299)

室温：	20 ~ 23	(68 ~ 73 ° F)	普通の周辺温度による
相対湿度：	30 ~ 60 %		
空気の動き：	清潔域からより清潔度の低い域に		
換気回数：	一時間あたり最低 15 回の全空気交換 そのうち最低 3 回は外気を入れる		

層流と紫外線の使用はある種の手術室においては S S I の危険を減少させる追加処置として考えられてきた。

層流とは微粒子を含まない空気(いわゆるultraclean air ; 以下超清潔空気)が無菌手術野を一定の速度(0.3 ~ 0.5 μm/sec)で動いて通路内の微粒子を掃き出すように設計されている。

空気の流れは垂直又は水平の方向で、再流する空気は一般に H E P A (high efficiency particular air) フィルターを通す(302,303)。

H E P A フィルターは直径 0.3 μm 以上の粒子を 99.97% 除去する(64,300,302,304)。

超清潔空気の効果調べた研究のほとんどは整形外科手術しか含んでいない(298,305-311)。

Charnley と Eftaknan が垂直層流と換気排出着(訳者注：いわゆる手術室での宇宙服?)を研究し、S S I 頻度を 9% から 1% に減少させたとした(305)。

しかしながら他の変数（例えば術者の経験や技術）が同時に、換気方式としても変化していたので、この研究が学会を困惑させたと思われる。

Lidwellらは、股関節および膝関節の全置換術の8,000例を超える多施設研究で、超清潔空気のみ、AMP投与のみ、AMP投与と超清潔空気の組み合わせの各々で深部SSIの頻度を比較した(307)。

超清潔空気単独使用でのSSI頻度は3.4%から1.6%に減少したが、一方、AMP投与単独でも3.4%から0.8%に減少した。

また両方の使用でSSI頻度は3.4%から0.7%に減少した。

これらの結果から超清潔空気とAMPは共に整形外科インプラント手術でSSI発生を減少させるが、AMPの方が超清潔空気より効果的であることを示している。

術中紫外線照射がSSIの危険を全体的に減少させることは示されていない(94,312)。

## (2) 環境表面

合衆国内の手術室におけるSSIの重要な原因として内装（例えばテーブルや床、壁、天井、ライト、などなど）の表面が関係づけられることはまれである。

しかしながら各手術後に内装面を型通りに掃除して清潔環境を回復することは重要である(180,212,300,302)。

汚染や目に見える汚れがない場合には、日常的に手術と手術の間に環境表面や備品を消毒することを支持するデータはない。

手術の間に表面や備品に見えるような汚れがある場合には、環境保護庁

(Environmental Protection Agency、以下EPA)が承認した病院用の消毒薬を使って、次の手術までに汚染された範囲の汚れを除去すべきである(180,212,300-302,313-315)。

これは全ての備品と環境表面が、血液や他の感染性のある物質に接触したら掃除と消毒をすべきという労働安全健康局(Occupational Safety and Health Administration;以下OSHA)の要求に合致している(315)。

その日あるいは夜の最後の手術の後に、日常的にEPAが承認した病院用消毒薬を用いてWet vacuuming(機械を使った湿式吸引清掃)を行う。

手術室内に残されている医療器具には覆いを掛けて、滅菌された装置や備品に掃除と消毒の間、溶液がかからないように注意する(316)。

汚染手術や不潔手術後に特別の掃除方法や手術室を閉鎖することを支持するデータはない(300,301)。

手術棟・室の入り口の外側に粘着性のマットをおいても靴やストレッチャーの車輪の細菌数を減少することは示されていなく、SSIの危険性を減少させることもない(1,179,295,301)。

## (3) 細菌学的サンプリング

手術室内の周辺の空気や環境表面の微生物レベルについての標準的なあるいは受け入れられたパラメータはないため、日常的な細菌学的サンプリングは正当化できない。

このような環境の資料採取は疫学的研究でのみ行うべきである。

## (4) 手術器具の伝統的な滅菌法

手術器具の滅菌が不適切だとSSIのアウトブレイクを起こす(302,317,318)。

高圧蒸気、乾熱、エチレンオキサイドあるいはその他の承認された方法で手術器具の滅菌が可能である。

滅菌方法の質を日常的にモニターすることの重要性については確立している(1,180,212,299)。

蒸気オートクレーブの性能の微生物学的モニタリングは必要であり、生物学的インジケー

用いて達成される(212、314、319)。

手術器具の滅菌の詳細な勧告が公表されている(212、314、320、321)。

#### (5) 手術器具のハイスピード滅菌

「患者治療器具を即座に使用するために蒸気滅菌する過程」を医療器具推進協会

(The Association for the Advancement of Medical Instrumentation; 以下 AAMI) はハイスピード滅菌 (flash sterilization) と定義している(321)。

(不注意に落とした器具を再処理するなど) いかなる手術でも緊急に器具を滅菌する必要がある可能性がある。

ハイスピード滅菌は手術器具や他の品目の緊急の滅菌に使うことを意図されており、追加の器具セットを買うかわりとか、一般的な時間の節約のために好都合だとして使ってはならない。

さらにハイスピード滅菌は重大な感染の危険が高いので埋めこまれる装置(\*)には推薦できない(314、320、321)。

(\*) FDAによれば埋めこまれる装置とは「手術的に作られたか、あるいはもともとある人体内の空間に、30日以上残すことを目的に置かれる装置」と定義される

(ANSI/AAMI ST37-1996)。

ハイスピード滅菌が日常の滅菌に勧められない理由のいくつかには、適時に性能をモニターする生物学的な指針になるものがないことや、滅菌後に保護する包装がない、手術室への搬送時に汚染する可能性がある、使用するサイクルパラメータが少なすぎる(時間、温度、圧)ことがある(319)。

この事に関して幾つか追加すると、多くの病院では手術室に極めて近くにハイスピード滅菌器を置き、1~3時間で結果がわかる新しい生物学的インジケータが今ではハイスピード滅菌に利用できる(322-325)。

しかしながらハイスピード滅菌がSSIの危険から見て、伝統的な滅菌法と同等であるとの研究がなされるまで、本来の目的のみに限定すべきである。

ハイスピード滅菌のための滅菌サイクルのパラメータを表9に示した。

表9 - スピード滅菌工程のパラメーター (AAMI) (321)

重力置換方式	最少曝露時間と温度
穴の空いていない器具	132 3分
穴の空いていないものと空いているもの	132 10分
事前真空方式	
穴の空いていない器具	132 3分
穴の空いていないものと空いているもの	132 4分

#### b. 手術時の服装 (surgical attire) と覆い布.

この節での「手術時の服装」という言葉は手術着、帽子とフード、靴カバー、マスク、手袋、ガウンを指す。

実験データで手術室の職員の髪や露出した皮膚や、粘膜面から生きた微生物が落下することが示されているが(75、181、326-330)、SSIの危険性と手術衣装使用の関係を評価した計画

された臨床研究は少ない。

しかしながら防護具の使用は、患者が手術チームや手術室勤務者の皮膚や粘膜や毛髪に暴露されるのを最小にするとともに、(HIVや肝炎ウイルスのような)患者血液中の感染源から手術室勤務者を防護すると思われる。

### (1) 手術衣 scrub suit

手術チーム構成員はたいていいわゆる「手術衣」と呼ばれるズボンとシャツからなるユニフォームを着ている。

手術衣の洗濯、着用、包装、交換の手順は非常にさまざまである。

ある施設では手術衣は、病院でのみ洗濯されるのに対し、病院の勤務者に洗濯をさせているところもある。

病院での洗濯と自宅での洗濯とでSSIの危険性について評価した、適切に計画された研究はない(331)。

ある施設では手術衣は手術室でのみ着用するように要求されているが、他の施設では手術室を離れるときに手術衣の上にガウンを着ることを許しているところもある。

手術室看護職員協会(The Association of Operating Room Nurses; 以下AORN)は、手術衣に汚れを見つけたら着替え、許可され管理されている洗濯施設で洗うよう勧告している(212)。

さらにOSHAは、「衣服に血液や他の感染物質が染み込んだら、直ちにあるいは可能な限り速く、脱ぐ」ように求めている(315)。

### (2) マスク

切開部位の可能性のある細菌汚染を予防するために手術中外科用マスクを着けることは、長い間の手術の伝統である。

しかしながら、SSIの危険を減らすための外科用マスクの効果対費用利益に関して、いくつかの疑問があげられている(328, 332-338)。

しかし、マスクは(飛散)血液や体液の不意の暴露から着用者の鼻と口を守る。

OSHAは血液や他の強力に感染性のある物質の跳ね掛かりや、しぶき、飛沫があって、それが目や鼻や口を汚染することが合理的に予想される場合には常にマスクと一緒にゴーグルや頑丈に保護する眼鏡や顎まで被う顔面シールドを着用するように求めている(315)。

さらに労働安全健康国際機関(National Institute for Occupational Safety and Health)によって証明されたN95またはそれ以上のレスピレーターが、患者が感染性の結核を持っているかその疑いのある時は必要としている(339)。

(訳者注：いわゆるN95マスクはN95レスピレーターという)

### (3) 手術帽子/フード、靴カバー

手術帽子/フードは安価で髪の毛と頭皮の微生物の落下による微生物から術野の汚染を減少させる。

手術中に帽子を着用して手術衣を着ていても、稀にSSIのアウトブレイクが、毛髪や頭皮から分離された微生物によることが突き止められることがある(黄色ブドウ球菌、A群連鎖球菌)(75,76)。

靴のカバーはSSIの危険性や床の細菌数を減少しないことが示されている(340,341)。

しかし靴カバーは医療従事者が、手術中血液や体液に触れるのを防ぐかもしれない。

OSHAは(整形外科手術や穿通外傷症例など)大きな汚染が合理的に予想される場合には手術帽とフードそして靴カバーまたは長靴を着用すべきと規定している(315)。

## (4) 滅菌手袋

滅菌ガウンを着用してから滅菌手袋をはめる。

手術チームの手洗いをする全員が滅菌手袋を着用することには強い理論的合理性がある。滅菌手袋は手術室勤務者の手から患者に細菌が伝播するのを最小にし、勤務者の手が患者の血液や体液で汚染されるのを防ぐ。

手袋が(針刺しなどで)破損したらできるだけ早く交換すべきである(315, 342, 343)。

手袋を2枚重ねて着用すること(二重手袋)は、一重に比べ患者の血液・体液で手が汚れることを少なくする(344, 345)。

## (5) ガウンと覆い布

手術切開部位と細菌の感染源となる可能性のある部位の無菌操作のために、滅菌ガウンと覆い布を用いてきた。

ガウンは手術時手洗いを行う手術チーム構成員全員が着用し、覆い布は患者にかけられる。手術ガウンと覆い布がSSIの危険性を減少するという効果を実証した資料は限られている。

研究結果と研究デザインは非常にさまざまであるため、得られたデータの解釈は困難である(329, 346-350)。

ガウンと覆い布は(1回使用の)使い捨て製品と(多数回使用の)再生品に分類される。製造されたガウンと覆い布の材料にかかわらず、これらの用品は液体とウィルスに対して不浸透性でなければならない(351, 352)。

一般に薄膜や、上塗り、膜で補強されたガウンのみがアメリカ品質検査学会(American Society for Testing and Material; 以下ASTM)によって開発された基準を満たす(351-353)。

しかしこれらの「防水ガウン」は、着用者の体からの汗の蒸発や熱の発散を妨げるため快適ではない。

ガウンを選択するときにはこれらの要因を考慮すべきである(353, 354)。

血液由来病原体の伝播の防止におけるガウンと覆い布の基準の討議はこの文章の守備範囲を超えている(355)。

## c. 無菌手技と手術手技

## (1) 無菌手技

手術時手洗いを行う職員全員による、無菌手技の原則の正確な厳守はSSI防止の基本である。

覆い布での隔壁で隔てられているだけの麻酔関係職員などの、滅菌野に密接して働く他の職員もこれらの原則を厳格に守るべきである。

麻酔関係者が起源となる病原菌によるSSIが起こっている(34, 231, 234, 356-358)。

麻酔科医と麻酔看護師は、静脈内留置針の確保や気管内挿管、静脈内薬剤・溶液投与のようなさまざまな侵襲的な処置を行う。

注射器の使い回し(360, 361)や汚染された注入ポンプ(359, 362-364)、更なる処置のために器具を組み立てたり薬液を準備したり(316, 360)という、これらの処置の間に無菌の原則を順守しないことが、SSIを含めて術後感染のアウトブレイクに関係してきた。

麻酔科学領域における感染防止の勧告はすでに公表されている(212, 365-367)。

## (2) 手術手技

華麗な手術は、SSIの危険を減少させることができると広く信じられている(26, 49, 179, 180, 368, 369)。



これらの技術としては、適当な血液供給を維持しつつ効果的な止血を行ない、低体温を防止し、やさしく組織を扱い、臓器内へ不用意に手を入れ損傷させることを避けながら（壊死組織や黒焦げになったような）生命活動のない組織を除去し、ドレーンや縫合材料を適切に使い、死腔を作らず、適切な術後創の管理などである。

縫合材料や人工器官、ドレーンを含むいかなる異物も手術部位の炎症を促進し(94)、組織汚染がたいしたことがないレベルでもSSIの可能性を増加する。

縫合材料の差異によるSSIの危険性との関係について調べた文献はたくさんある(370-379)。

一般に単繊維（monofilament）の縫合糸が感染の助長効果がもっとも低い(3, 94, 179, 180)。

ドレーンの設置に関する決定は当文献の守備範囲を越えているとはいえ、一般的なポイントを簡潔に記す。

手術切開創を通して設置されたドレーンはSSIの危険性を増加する(380)。

多くの研究者はドレーンのための切開は手術切開創とは離しておくことを提唱している(283, 381)。

閉鎖吸引ドレーンを置くと開放ドレーンよりもSSIの危険性が減少することが示されている(174)。

閉鎖吸引ドレーンは術後血腫、血清腫、化膿した物質の排泄に有効であるが、抜去時期も重要である。

ドレーンの設置時間が長いほど、当初滅菌であったドレーンの細菌の付着が多くなる(382)。

手術患者における低体温とは、深部温で36以下と定義され、全身麻酔や寒冷にさらされたり、心筋や中枢神経の保護のための心臓外科の処置のような意図的な冷却のためである(302, 383, 384)。

大腸直腸手術を行った患者の研究で、低体温がSSIの危険性を増加させた(385)。

中等度低体温は血管収縮、創部への酸素供給の低下と引き続き起こる（白血球などの）食細胞の機能障害などでSSIの危険が増加する(391)。

最近のヒトでの研究で、電気による包帯での切開部の局所加温により組織の酸素化の改善が示された(392)。

これらの処置が創部の腔の酸素化を改善しSSIの危険を減少させることができるかははっきりさせるために、無作為臨床試験が必要である。

#### 4．手術特質：術後の問題

##### a．創部処置

切開層が一次的に閉鎖されるか（皮膚断端が手術終了時に再び接触している）、後で閉鎖されるために開放するか、つまり2次的に処置するべく開放されるかで、術後の創管理の細部が決まる。

ほとんどの場合そうであるが、一次的に閉鎖された場合、切開部は通常24～48時間滅菌ドレッシングで被われる(393, 394)。

48時間以降については、切開創をドレッシングしておくべきかどうか、あるいはシャワーや入浴が有害かどうかについてははっきりしていない。

手術創が後に閉鎖するまで2、3日開放された場合には（delayed primary closure）、創は汚染されており、患者の状態が（創部の浮腫など）一次的閉鎖を妨げると外科医は断定し

てきた。

そのような場合、創部は滅菌ドレッシングで包み込まれる。

2次的に処置すべく手術創が開放されていた場合、創部は濡れた滅菌ガーゼで覆い、滅菌ドレッシングで包んでおく。

アメリカ外科大学やCDCその他でも、どんな種類の手術創でも、包帯交換は滅菌した手袋や備品を使うように記載している(180、395-387)。

#### b. 退院計画

今日、多くの患者は手術後非常に速く、手術創が完全に癒える前に退院させられる(398)。

家庭での創管理の適切なプロトコールは存在しないため、家庭で患者本人や家族、訪問看護要員によって行われることの多くは、個別に行われざるをえない。

退院計画の目的は、創の治癒の統合性を維持するために感染の徴候と症状を患者に教育して、何らかの問題が生じたときに誰に連絡をすればよいかを知らせることである。

## F. S S Iサーベイランス

S S Iのサーベイランスを行い、適切なデータを外科医にフィードバックすることが、S S Iの危険性を減らす上で重要であることが示されている(16、399、400)。

サーベイランスを成功させるには、疫学的に意味のある感染の定義(表1、2)、有効な調査方法、およびS S I進展に関連する危険因子に基づくS S I発生率の等級別分類とデータのフィードバックが肝要である(25)。

### 1. S S Iの危険性の等級別分類

#### a. 概念

S S Iに関連することが判明した因子のうち、以下の3群の変数が良い予測因子になることが分かった。

- (1) 手術部位の細菌汚染の程度そのものを予測する変数、
- (2) 手術時間を示す変数、
- (3) 宿主の感受性の目安となる変数(25)。

手術部位の細菌汚染の程度そのものを評価するための方式として広く認められているものとしては、1964年にNational Academy of ScienceとNational Research Council (NAS/NRC)共同で作成されたものがあり、これは1982年にCDCによってS S I調査用に改変された(表7)(2,94)。

この方式では、外科チームが手術終了時に患者の創部を評価する。

簡単で、広く適用できるため、この創部評価法はS S Iの危険性を予測するために使われてきた(16、94、126、401-405)。

ある研究者達は、外科医が清潔創のS S I頻度を他の外科医のそれと比較することを提案した(16、399)。

しかし、CDCの2つの研究 - 院内感染の有効性に関する研究: SENIC、およびNNIS方式 - ではS S Iの危険性の指標として他の予測変数を導入した。

これらの研究によれば、清潔創に分類されるものの中でもS S Iの危険性は各々、1.1%から15.8%(SENIC)、および1.0%から5.4%(NNIS)とばらついていることが示されている(125、126)。

さらに、切開創は手術時に評価されていなかったり、外科チームによって評価されていなかったりしており、この方式の信頼性が疑問になった。

このため、創部評価のみによって S S I 発生率を等級別に分類して報告することは推奨できない。

S E N I C 計画で集められた 10 個の変数に関するデータは、多変量解析モデルによって解析され、単純な相加的な S S I の危険性の指標が導かれた(125)。

これらのうちの以下の 4 つは、各々独立して S S I の危険性に関与していることが判明した：

- ( 1 ) 腹部手術、
- ( 2 ) 2 時間以上の手術、
- ( 3 ) 創部分類で汚染または不潔・感染に分類された創部、
- ( 4 ) 退院時に 3 つ以上の診断名を持つ患者に対して行われた手術。

これらの因子は等しい重みを持ち、該当すれば各 1 点を加え、このため危険性の指標は 0 から 4 点の値を取る。

この因子を使うことにより、S E N I C 指標では従来の創部分類要綱単独使用に比較して 2 倍も S S I の危険性を予測することができた。

N N I S 危険指標は手術特異的であり、前方向調査で集められたデータに対して適用された。

指標は 0 から 3 点の値を取り、3 つの独立した等しい重みを持つ因子から決められる。

手術患者は以下のどれかがあれば 1 点加算される：

- ( 1 ) アメリカ麻酔学会 ( A S A ) 分類で 3 以上 ( 表 1 0 )。
- ( 2 ) 創分類が汚染または不潔・感染 ( 表 7 )。
- ( 3 ) 手術時間が T 時間を越える、ただし T は行われた特定の手術につき手術時間分布の 7 5 パーセントイルに相当する時間(126)。

患者の重症度 ( 宿主の感受性 ) (406, 407) を見積もるため、S E N I C 危険指数の退院時診断の代わりに A S A 分類が用いられており、これは患者が入院中でもカルテから容易に得ることができる ( 表 1 0 )。

S E N I C の固定した 2 時間という変化点の代わりに、手術特異的变化点を使用することにより、N N I S 危険指数の判別能力が増すことが示された(126)。

( 訳者注：ここでの標準手術時間 T は、既に N N I S のサーベイランスで使用されており、その一覧を表 1 1 として、巻末に示した。このガイドラインの中にはもともとはなかったものである。 )

表 1 0 - アメリカ麻酔学会 ( A S A ) Physical Status 分類(406)

分類	患者の術前状態
1	一般的に健康な患者
2	中等度の全身疾患
3	重症の全身疾患があるが日常生活は可能
4	常に生命を脅かすような重症の全身疾患がある
5	手術の有無にかかわらず 2 4 時間以内に死亡すると思われる
6	脳死患者で移植のドナーとして

( 訳者注：1999年3月時点で、脳死患者で移植のドナーとしての麻酔を行う場合、分類 6 とすることと定められている。 )

## b . 問題点

術者あるいは病院間での S S I の頻度をしっかり比較するには、頻度の評価を混乱させていると分かっている変数の調整が不可欠である(408)。

前述したような、危険の等級的分類は目的の為に有効である分かっている、しかしこれは一貫して正確にデータを発見、記録するサーベイランス実施者の能力に依存している。

NNIS 危険指数に使われている 3 変数に関していえば、これらの変数が如何に正確に記録されているかに焦点を当てた研究はたった一つである。

Cardoらによると、手術チームの構成員が行った一般および外傷外科手術の創部分類評価の正確度は 88% (95%信頼区間: 82% - 94%) である(409)。

しかし、Cardoらの結果の再現性に関する懸念に請け合うには、創部分類定義そのものにかかなりの曖昧さがある。

手術時間(つまり、皮膚切開から皮膚縫合までの時間)の記録、および A S A 分類の正確さに関しては研究されていない。

NNIS システムからの未公表の報告では、幾つかの病院では高い A S A 分類であったと過剰に報告している事実があった。

危険指数の変数の記録の信頼性の、さらなる確認が必要である。

さらに、NNIS 危険指数は全ての種類の手術に対して、その S S I の危険を適切に識別しているわけではない(27,410)。

ある手術を受ける患者に特徴的な危険因子の組み合わせのほうが、より予測に便利に思える。

処置に特徴的な危険指数を見つける幾つかの研究が行われており(218,411-414)、この分野の研究は CDC の NNIS システムの中で続けられている。

## 2 . S S I サーベイランスの方法

SENIC 計画および NNIS システムの両者で使用されている S S I サーベイランスの方法は、急性期病院の入院患者を調べるために作られた。

過去 10 年間で、入院から外来(いわゆる外来とか日帰り手術)へと外科的処置の移行は劇的であった。

アメリカ合衆国では 2000 年までに全ての手術の 75% が日帰り手術で行われると予想されている(4)。

入院と外来の患者に対して共通の S S I の定義を使用することが適切かもしれない(415)、監視する手術の種類、評価する危険因子や症例検出法は異なるかも知れない。

新たな予測変数が、日帰り手術患者の S S I の分析から現れるかも知れず、これらの患者に対しては、S S I の危険の評価は違った方法となるかもしれない。

どの手術を監視するかは、術者と感染対策担当者が共同で決定すべきである。

ほとんどの病院では全ての手術患者を常時監視する余力は持っていないし、危険性の低い幾つかの処置に関しては同じような監視は必要でも無い。

代わりに病院はサーベイランス努力を危険性の高い処置に向けるべきである(416)。

## a . 入院患者の S S I サーベイランス

以下の二つの方法が、単独あるいは一緒に、S S I を有する入院患者を同定するために使用されてきた:

- (1) 術者、訓練された看護婦サーベイヤー、または感染対策担当者による手術部位の直接観察(16,97,399,402,409,417-420)
- (2) 検査結果、カルテ、主治医達との議論等で感染対策担当者が調べる間接的な方法(15,84,399,402,404,409,418,421-427)。

外科系の文献によると、手術部位の直接観察が S S I 検出の最も正確な方法であるが、感度のデータが欠如している(16,399,402,417,418)。

感染対策の文献に報告されている S S I データの多くは、間接的な症例検出法に基づいているが(125,126,422,425,426,428-430)、幾つかの直接的な方法を用いた研究も行われている(97,409)。

幾つかの研究では両方の検出法を用いている(84,409,424,427,431)。

間接的方法による S S I 検出の感度と特異度に単に焦点を当てた研究では、

83.8% (95%信頼区間: 75.7% - 91.9%) の感度と 99.8% (95%信頼区間: 99% - 100%) の特異度が見出されている(409)。

他の研究では、帝王切開後の患者に対して抗菌薬の指示をコンピュータで検索して、カルテの調査を行ったところ、子宮内膜炎検出の感度は 89% であった(432)。

間接的な S S I の検出は感染対策担当者が調査回診中に容易に行うことができる。

作業には、該当する手術を受けた患者の人口学(訳者注: 民族・性別などなど)、感染、手術および検査結果のデータを集めることが含まれる(433)。

これらのデータは、細菌学および病理組織学、検査、薬局データの記載のある患者のカルテおよび放射線科報告、手術記録から得ることができる。

さらに、入院、救急外来および外来受診の記録は、再入院又は経過観察中の退院患者のデータの源である。

いずれの方法でも、S S I 症例発見のための最適な頻度は知られておらず、毎日から週 3 回以下までさまざまであり、患者が退院するまで続けられる。

入院期間がしばしば非常に短いため、正確な S S I 頻度を求めるためには退院後の S S I サーベイランスがますます重要になっている(「退院後の S S I サーベイランス」の項を参照)。

意味のある S S I 頻度を計算するためには、該当する手術を受ける患者(すなわち危険性のある人々)全員のデータを収集する必要がある。

目的の一つが危険性の等級的分類のための方法論を確立することであったので、N N I S システムは、全ての手術患者の調査で以下のデータを収集した:

手術日; N N I S 手術法分類(434); 術者 I D; 患者 I D; 年齢と性別; 手術時間; 創部分類; 全身麻酔; A S A 分類; 緊急; 外傷; 複数個所処置; 内視鏡下処置; 退院日。

退院日を除けば、これらのデータは手術室記録から手作業で集めるか、またはサーベイランス用のソフトに電子的にダウンロードされ、後者の場合は手作業による書き換えやデータ入力のエラーを大幅に減らすことができる(433)。

危険性で分類された S S I 頻度の必要性は、感染対策、手術および品質保証に関る人によって違うので、全てのデータ項目があらゆる種類の手術に必要とされるわけではない。

しかし、最低でも S S I の危険性増加の予測変数であることがわかっているものに関してはデータを集める必要がある(「S S I の危険性の等級的分類」の項を参照)。

#### b. 退院後 S S I サーベイランス

退院後 1.2% ~ 8.4% の S S I が検出されている(98,337,402,428,435-454)。

少なくとも 2 つの研究で、手術後 21 日以内にほとんどの S S I が明らかになるとされている(446,447)。

手術後の病院滞在日数も引き続き短くなってきているので、多くの S S I は退院後数週間は発見されず、また手術した病院への再入院の要求もないのかもしれない。

入院患者に限った症例発見では、ある手術では S S I 頻度は低く見積もられる

(例えば、C A B G) (C D C / N N I S システムでの未公表データ、1998年)。

SSI頻度のどんな比較でも、症例発見が退院後に見つかったSSIを含めていたとしても計算に入れるべきである。

比較が正しくあるためには、たとえ同じ施設で時間が経っていたとしても、退院後サーベイランスは同じ方法でなされるべきである。

退院後サーベイランスの方法は、病院によって異なる方法で使用され、成功例から失敗例までさまざまである。

その中には：

- ( 1 ) 患者が、外科または内科診療所への経過観察のため見えた時に直接傷を調べる (150, 399, 402, 404, 430, 436, 440, 441, 447, 452, 455)。
- ( 2 ) 外科診療所の患者カルテを再検討する (404, 430, 439)。
- ( 3 ) 患者への手紙または電話での調査 (435, 437, 438, 441, 442, 444, 445, 448, 449, 455-457)。
- ( 4 ) 外科医への手紙または電話での調査 (98, 428, 430, 437-439, 443, 444, 446, 448, 450, 451, 455)。

(訳者注：3と4について、アメリカではコミュニティホスピタルが多いので、患者はもちろん、術者も病院には常時いない)

ある研究で、患者は自身の傷の感染の評価が困難であることがわかっている (52%の特異性、26%の陽性予測値) (458)、患者への質問によるデータは実際のSSI頻度を正確に表していないと思われる。

最近 Sandsらは最もSSIを識別するデータベースを決定するため、3種類をコンピュータ検索した。

外来で行われた診断、検査、治療コードの記録；特別な抗菌薬の処方の薬局記録；そして再入院または救急外来訪問の入院記録である (446)。

この研究では、一般に軟部組織感染の治療に使用される抗菌薬の投与を受けていた患者の薬局記録が、高い感度 (50%) と陽性予測値 (19%) を示したが、この方法だけではあまり効果的ではないことも示された。

統合された健康情報システムが進むと、治療の全ての過程を通しての手術患者の追跡が便利に、実際に、効果的に行われるようになるだろう。

今のところ、退院後サーベイランスの方法でどれが最も感度が良く、特徴をつかみ、実際的であるかの合意はない。

方法の選択は、手術、人的資源と必要とするデータに基づき、病院の特徴を反映させる必要があるだろう。

#### c . 外来患者SSIサーベイランス

外来患者手術に合併するSSI検出に、直接および間接的方法の両方が使われてきた。

地区看護婦の家庭訪問では、8年間にわたるヘルニアと静脈瘤手術の研究成果が、SSI認識のために術後2週間目の診療所訪問で術者によってなされた調査結果とともに使用されてきた (459)。

正確性が本質的に100%なのであるが、この方法は広く実行するには困難である。

術者への手紙での質問票の高い回収率が得られている (72% 90%)

(443, 444, 446, 455, 459-461)。

患者への電話での質問への回答頻度はさまざまである (38% (444)、81% (457)、85% (455))。

患者への手紙での質問票への回答はかなり低い (15% (455)、33% (446))。

今のところ、一つだけではどの方法も推奨できない。

利用できる資源や必要とされるデータによって、どの方法を使うか、どの手術に的を絞るか決める必要がある。

どの検索方法を使うにせよ、外来患者でもCDC/NNISのSSIの定義（表1と表2）をなんら変更を加えることなく使用することが勧告される。

## G. ガイドラインの評価方法

HICPACのガイドラインの価値は、それらを使う人によって決められる。

その価値を求める手助けとして、HICPACは、どのようにガイドラインを使用者の期待に合わせるか、またどのようにいつガイドラインが広め実行されるべきかを学習する為の評価手段を開発している。

## 第2部 手術部位感染防止のための勧告

(Recommendations for the Prevention of Surgical Site Infections)

### A. 理論的根拠

1999年の手術部位感染防止のためのガイドラインは、手術部位感染の危険の削減に関する勧告を提供している。

各々の勧告は、存在する科学的データ、理論的根拠、および適応性に基づき分類されている。

しかしながら、勧告を分類するため、以前のCDCのシステムを若干変更してきている。

カテゴリー 勧告は Aと Bを含み、HICPACおよび外科、感染症、および感染制御の各々の分野の専門家により、効果があると見なされているものである。

カテゴリー Aと Bの勧告は共に、全ての健康管理関係の施設（病院）に適応され、採用されるべきである。

Aと B勧告の違いは支持する科学的根拠の強さのみである。

カテゴリー 勧告は、カテゴリー 勧告よりも支持する科学的データが少ないもの。

これは特殊な院内問題や、特殊な患者集団に対して適応できる。

推薦しないは、効果に関して合意が得られていなかったり、採用を支持するには得られる科学的根拠が十分でないため、提案できないもの。

この様な未解決の問題のために、実践者はそれぞれの組織の中で、これらの行為を採用するかどうか判断すべきである。

連邦政府の規定に則っている勧告は、星印（\*のマーク）が付けてある。

### B. 格付け

カテゴリー A：強く実行することを勧められ、適切に計画された実験的、臨床的、あるいは疫学的な研究に支持されているもの。（以下 A）

カテゴリー B：強く実行することを勧められ、幾つかの実験的、臨床的、あるいは疫学的な研究に支持され、そして強力な理論的合理性がある。（以下 B）

カテゴリー：実行することが提案されており、示唆に富む臨床的あるいは疫学的な研究または理論的合理性で支持されているもの。（以下）

推薦しない、未解決の問題(unsolved issue)：不十分な証拠しかなく、効果に関する意見の一致がない方策。（以下UI）

連邦政府の規定で必要とされる行為には星印（\*のマーク）が付けてある。

## C . 勧告

## 1 . 術前

## a . 術前の患者準備

いつでも可能なら、予定手術の前に手術創に広がる全ての感染を明らかにしそして治療する。

感染が治るまで遠隔部に感染のある患者の手術は延期する。( A )

手術前の除毛は、切開部あるいは周辺の毛が手術の邪魔にならないかぎり行わない。

( A )

除毛する場合には、できれば電気クリッパー(バリカン)を使用して手術直前に除毛する。( A )

全ての糖尿病患者で適切な血清血糖値の管理を行ない、特に過血糖を周術中避ける。

( B )

常に禁煙をすすめる。

少なくとも予定手術の30日前からたばこ、葉巻、パイプ、他のたばこの消費(噛み煙草や嗅ぎ煙草のような)を中止するように教育する。( B )

SSIの予防として、手術患者への必要な血液製剤の投与を差し控えることはしない。

( B )

少なくとも手術前夜に、消毒薬によるシャワーあるいは入浴を指示する。( B )

皮膚消毒する前に、切開部位および周辺を十分に洗浄清浄化して大きな汚れを除く。

( B )

皮膚消毒には基準に合った消毒薬を用いる(表6)。( B )

術前の皮膚消毒は中心から同心円を描くように次第に外に広げて行く。

必要な時に切開創を広げたり新しくしたり、ドレーンを入れても十分なように消毒範囲を広くとる。( )

患者の術前処置が許す限り、術前の入院期間は可能なかぎり短縮する。( )

予定手術前のステロイドの漸減や中止(もし医学的に許容されれば)は勧告しない。

( UI )

ただSSIの予防のために、手術患者に栄養療法を許可することは勧告しない。( UI )

SSIを予防するために術前、鼻腔にムピロシンを使うことは勧告しない。( UI )

SSIを予防するために創部腔の酸素化を強化する方策をとることは勧告しない。

( UI )

## b . 手術チーム構成員による手指・腕の消毒

爪を短く、付け爪はしない。( B )

適切な消毒薬(表6)を用いて少なくとも2~5分間の手術時手洗いを行う。

手洗いは肘までの手および前腕まで行う。( B )

手洗いを行った後は、水が指から肘に滴るように、手を身体から離し(肘を曲げた状態)、拳上しておく。

滅菌タオルで手指を乾燥させ、滅菌ガウンと手袋を着用する。( B )

その日の最初の手術時手洗いの前に、全ての爪床の下を清潔にする。( )

手または腕に装飾具を付けない。( )

マニキュアに関する勧告はない。( UI )



## c . 感染または保菌している手術関係者の管理

感染性の感染症の症状や症候が出ている手術関係者は、上司や健康管理職員に正確に報告を出すことを教育し奨励する。( B )

職員が感染性のある状態であるなら、患者処置の責任に関する明確に定義された方針を行う。

これらの方針は以下のことを管理する：

( a ) 治療を受け、病状を報告する職員の責任

( b ) 就業制限

( c ) 就業制限の必要な病気後の、仕事復帰のための解除処置

この方針は職員を義務から外す権限のある人がだれであるかもはっきりさせておく。

( B )

義務ではないが、皮膚の損傷から浸出液がある手術関係者から、感染症が除外されるか、適切な治療で感染症が治癒するまで、適切に細菌培養を行う。( B )

もし患者管理区域において疫学的に病原体の飛散と関係しているとされない限り、黄色ブドウ球菌(鼻、手や他の身体部位)やA群連鎖球菌のような病原体を保菌している手術関係職員を、日常的に排除してはならない。( B )

## d . 抗菌薬の予防投与

抗菌薬の予防投与は必要な場合にのみ行ない、特別な手術にはその最も一般的なSSIの原因となる菌(表4)に対して効果的な、または出版されている推薦

(266,268,269,282-284)に基づいて薬剤を選択する(表6)。( A )

初回の抗菌薬の予防投与は静注し、切開が行われる時に血清および組織に薬剤の殺菌濃度が確立している時間とすること。

手術中を通じおよび、少なくとも手術室で傷が閉じられてから2、3時間後まで血清および組織の薬剤の治療濃度を維持すること。( A )

予定の大腸・直腸の手術の前には、上記のd2に加え、浣腸や下剤を使用して機械的に結腸の準備を行なうこと。

非吸収性の経口抗菌薬を手術の前日に分割投与する。( A )

高リスクの帝王切開では、臍帯がクランプされた直後に予防的抗菌薬を投与する。

( A )

バンコマイシンを予防的抗菌薬として日常的に使用してはならない。( B )

## 2 . 術中

## a . 換気

手術室から廊下や隣接区域に向かう換気を陽圧に維持する。( B )

少なくとも1時間に最低15回の換気を行い、そのうち最低3回は新鮮な空気とする。

( B )

アメリカ建築協会(American Institute of Architects)で勧告されているフィルターを使って、全ての空気(再循環空気、新鮮空気とも)をろ過する。( B )

全ての空気は、天井送気し、床に近いところから排気する。( B )

SSIを予防する目的で、紫外線を手術室内で使用しない。( B )

器械や、職員や、患者の出入りなど必要時以外、手術室ドアは閉めておく。( B )

整形外科手術でインプラントが入るものでは超清潔空気の手術室での施行を考慮する。

( )

手術室に入る人数を必要人数だけに制限する。( )

b . 環境表面の清掃と消毒

表面や器械に目に見える血液や、体液による汚れや汚染がある場合、E P Aが承認した病院消毒剤を用いて汚染部を次の手術の前に清掃する。( B \* )

準汚染または汚染手術後でも、特別な清掃や消毒は行わない。( B )

感染制御のために手術棟および個々の手術室の入り口に粘着マットを使用することはしない。( B )

湿式吸引清掃での手術室の床の清掃は、E P Aが承認した病院消毒剤で、その日または夜の最後の手術終了後に行う。( )

表面や器械に目に見える汚染がなければ、手術と手術との間で手術室を消毒することは勧告されていない。( U I )

c . 細菌学的検体採取

手術室の日常的な環境検体採取は行わない。疫学的調査の一部として環境表面や、空気の細菌学的検体採取を行うようにする。( B )

d . 手術器械の消毒

全ての手術器械を出版されている指針に従って滅菌する(212,299,314,321)。( B )

ハイスピード滅菌は緊急に治療用具必要になった時にのみ行うこと(例えば、不用意に落した道具の再処理など)。

ハイスピード滅菌を、便利だから、追加の器具セットを買うかわりとか、時間の節約のために使ってはならない。( B )

e . 手術着および覆い布

手術が始まる直前やすでに手術が始まっていたり、滅菌器械が展開されていた場合は、手術室入室時、完全に口と鼻を覆うマスクを着用する。

手術の間中、マスクは着けている。( B \* )

手術部に入るときは、頭部および顔面の髪を完全に覆うように帽子かフードをつける。

( B \* )

S S Iの防止のためにシューズカバーをつけるのではない。( B \* )

手術時手洗いを行う手術チーム構成員は滅菌手袋を着用する。

手袋は滅菌ガウンを着た後に着用する。( B \* )

滅菌ガウンや滅菌覆い布には、濡れてもバリアー効果のある材質ものを用いる(つまり防水のもの)。( B )

手術着が目に見えて汚れたり、血液や感染性の物質で汚染、染み込んだ場合は交換する。

( B \* )

手術着(scrub suits)をどのようにどこで洗濯するか、着用を手術部のみに限定するか、手術室の外に出るときに白衣を着るかについての勧告はない。( U I )

f . 無菌法と手術手技

血管内用具留置時(例えば、中心静脈カテーテル)、脊椎麻酔時、硬膜外カテーテル挿入時、また静脈内投与薬剤の準備と投与の時は無菌法の原則を順守する。( A )

滅菌器具や滅菌液体は使う直前に開ける。( )

組織を丁寧に取り扱い、効果的な止血を維持し、死滅組織や異物（糸、焦げた組織、壊死組織片など）を最小限に止め、手術部位の死腔をなくす。（ B ）

もし術者が手術部位が極度に汚染していると考えた場合（汚染創または不潔・感染創）、一次縫合を遅らせるかまたは開放創として、二次的に閉鎖する。（ B ）

ドレナージが必要と考えられる時は、閉鎖式吸引ドレーンを用いる。

ドレンは手術切開創からではなく、離れたところに切開し挿入する。

ドレーンはできるだけ速やかに抜去する。（ B ）

### 3．手術後の創処置

a．一期的に閉鎖した切開創は、術後24 - 48時間は滅菌ドレッシング材で保護する。（ B ）

b．包交や手術部位に接触する前後には手洗いを行う。（ B ）

c．創部のドレッシングを交換する時は、滅菌テクニックを用いる。（ ）

d．適切な切開創処置の行い方、SSIの徴候、これらの徴候の報告する必要性について、患者と家族に教育を行う。（ ）

e．一期的に閉鎖した切開創を、48時間以降覆うべきかどうか、また被覆なしでシャワー・入浴を行う適切な時期についての勧告はない。（ UI ）

### 4．サーベイランス

a．入院患者でも外来患者でもSSIの診断のために、CDCのSSIの定義（表1）を変更することなく用いること。（ B ）

b．入院患者症例発見のために（再入院も含める）、入院中の直接的前向き観察検出、間接的前向き観察検出、あるいはその両者を入院の期間中ずっと用いること。（ B ）

c．ある種の手術（例えば、CABGなど）に引き続くSSIの発見のための退院後サーベイランスが行われる時には、利用できる資源と必要とするデータに見合った方法をとること。（ ）

d．外来患者感染症例の発見に、利用できる資源と必要とするデータに見合った方法をとること。（ B ）

e．手術終了時、手術チームの構成員が手術創分類を決める。（ ）

f．サーベイランスの対象となった手術を受けるそれぞれの症例に対し、SSIの危険の増加に関する変数（例えば、手術創分類、ASA分類、手術時間など）を記録する。

（ B ）

g．SSIの危険の増加に関係すると分かっている変数（例えば、NNIS危険指数）により、定期的に手術別特異的SSI頻度の階層分類を計算する。（ B ）

h．適宜、手術チーム構成員に階層分類した手術特異的SSI頻度を報告する。

これらの頻度計算の適切な回数と形式は、階層化される症例数（これで主に決まる）や目的、持続的に改善しようとするイニシャチブによって決められる。（ B ）

i．感染対策委員会が外科医別資料を利用できるようにするべきという勧告はない（ UI ）

表 1 1 - N N I S 術式別の手術のT時間

術式	T 値 (時間)
C A B G	5
心臓外科	5
その他の心血管系	2
胸部	3
他の呼吸器系	1
虫垂切除	1
胆管・肝・膵臓	4
胆嚢摘出	2
結腸手術	3
胃手術	3
小腸手術	3
開腹術	2
他の消化器官	3
四肢切断	1
脊椎固定	3
骨折の手術固定	2
人工関節	3
他の筋骨格系	2
帝王切開	1
開腹子宮摘出	2
経腔的子宮摘出	2
他の婦人科手術	1
腎摘	3
前立腺摘出	4
他の性腺泌尿器科系	2
頭部・頸部手術	4
他の耳、鼻、 口、咽頭	3
開頭術	4
脳室シャント	2
他の神経系	2
ヘルニア手術	2
乳房切除	2
臓器移植	7
皮膚移植	2
脾摘	2
血管手術	3
他の内分泌系	2
他の目	2
他の血管・リンパ系	2
他の皮膚関係	2

## 編集協力

## 1. 感染対策実行委員会

市川高夫（麻酔科）  
 太田宏信（消化器内科）  
 田崎和之（腎臓内科）  
 田村雄助（循環器内科）  
 寺下美恵子（看護部副部長）  
 本間美菜子  
 鈴木綾子  
 斎藤まり子  
 皆川ユリ  
 田村晶子（薬剤部）

## 2. リンクナース

大湊愛子  
 松岡長子  
 星 義弘  
 鈴木まゆみ  
 天木 薫  
 田辺 綾  
 清水千香子  
 影山美和  
 高橋知子  
 平松和美  
 高橋美絵  
 西巻奈美  
 中野ともみ  
 長谷川紋子  
 深沢和子  
 渡辺紀和子  
 小竹アサ子  
 阿部みゆき  
 吉沢弘子  
 早福久美子

## 3. その他

小出 勝（検査科）

\* 所属のない方は看護婦です

## Guideline for Prevention of Surgical Site Infection, 1999

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The Hospital Infection Control Practices Advisory Committee

## Sections

## Abstract

## I. Surgical Site Infection (SSI): an Overview

## II. Recommendations For Prevention of Surgical Site Infection

## Publishing and Reprint Information

## Abstract

## EXECUTIVE SUMMARY

The "Guideline for Prevention of Surgical Site Infection, 1999" presents the Centers for Disease Control and Prevention (CDC)'s recommendations for the prevention of surgical site infections (SSIs), formerly called surgical wound infections.

This two-part guideline updates and replaces previous guidelines.<sup>1,2</sup>

Part I, "Surgical Site Infection: An Overview," describes the epidemiology, definitions, microbiology, pathogenesis, and surveillance of SSIs. Included is a detailed discussion of the pre-, intra-, and postoperative issues relevant to SSI genesis.

Part II, "Recommendations for Prevention of Surgical Site Infection," represents the consensus of the Hospital Infection Control Practices Advisory Committee (HICPAC) regarding strategies for the prevention of SSIs.<sup>3</sup>

Whenever possible, the recommendations in Part II are based on data from well-designed scientific studies.

However, there are a limited number of studies that clearly validate risk factors and prevention measures for SSI. By necessity, available studies have often been conducted in narrowly defined patient populations or for specific kinds of operations, making generalization of their findings to all specialties and types of operations potentially problematic.

This is especially true regarding the implementation of SSI prevention measures. Finally, some of the infection control practices routinely used by surgical teams cannot be rigorously studied for ethical or logistical reasons (e.g., wearing vs not wearing gloves).

Thus, some of the recommendations in Part II are based on a strong theoretical rationale and suggestive evidence in the absence of confirmatory scientific knowledge.

It has been estimated that approximately 75% of all operations in the United States will be performed in "ambulatory," "same-day," or "outpatient" operating rooms by the turn of the century.<sup>4</sup> In recommending various SSI prevention methods, this document makes no distinction between surgical care delivered in such settings and that provided in conventional inpatient operating rooms.

This document is primarily intended for use by surgeons, operating room nurses,

postoperative inpatient and clinic nurses, infection control professionals, anesthesiologists, healthcare epidemiologists, and other personnel directly responsible for the prevention of nosocomial infections. This document does not:

Specifically address issues unique to burns, trauma, transplant procedures, or transmission of bloodborne pathogens from healthcare worker to patient, nor does it specifically address details of SSI prevention in pediatric surgical practice.

It has been recently shown in a multicenter study of pediatric surgical patients that characteristics related to the operations are more important than those related to the physiologic status of the patients.<sup>5</sup>

In general, all SSI prevention measures effective in adult surgical care are indicated in pediatric surgical care.

Specifically address procedures performed outside of the operating room (e.g., endoscopic procedures), nor does it provide guidance for infection prevention for invasive procedures such as cardiac catheterization or interventional radiology. Nonetheless, it is likely that many SSI prevention strategies also could be applied or adapted to reduce infectious complications associated with these procedures.

Specifically recommend SSI prevention methods unique to minimally invasive operations (i.e., laparoscopic surgery).

Available SSI surveillance data indicate that laparoscopic operations generally have a lower or comparable SSI risk when contrasted to open operations.<sup>6-11</sup> SSI prevention measures applicable in open operations (e.g., open cholecystectomy) are indicated for their laparoscopic counterparts (e.g., laparoscopic cholecystectomy).

Recommend specific antiseptic agents for patient preoperative skin preparations or for healthcare worker hand/forearm antiseptics. Hospitals should choose from products recommended for these activities in the latest Food and Drug Administration (FDA) monograph.<sup>12</sup>

## I. Surgical Site Infection (SSI): An Overview

## A. INTRODUCTION

Before the mid-19th century, surgical patients commonly developed postoperative "irritative fever," followed by purulent drainage from their incisions, overwhelming sepsis, and often death. It was not until the late 1860s, after Joseph Lister introduced the principles of antiseptics, that postoperative infectious morbidity decreased substantially. Lister's work radically changed surgery from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.

Currently, in the United States alone, an estimated 27 million surgical procedures are performed each year.<sup>13</sup>

The CDC's National Nosocomial Infections Surveillance (NNIS) system, established in 1970, monitors reported trends in nosocomial infections in U.S. acute-care hospitals.

Based on NNIS system reports, SSIs are the third most frequently reported nosocomial infection, accounting for 14% to

16% of all nosocomial infections among hospitalized patients.<sup>14</sup> During 1986 to 1996, hospitals conducting SSI surveillance in the NNIS system reported 15,523 SSIs following 593,344 operations (CDC, unpublished data). Among surgical patients,

SSIs were the most common nosocomial infection, accounting for 38% of all such infections. Of these SSIs, two thirds were confined to the incision, and one third involved organs or spaces accessed during the operation.

When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection, and the majority (93%) were serious infections involving organs or spaces accessed during the operation.

In 1980, Cruse estimated that an SSI increased a patient's hospital stay by approximately 10 days and cost an additional \$2,000.<sup>15,16</sup>

A 1992 analysis showed that each SSI resulted in 7.3 additional postoperative hospital days, adding \$3,152 in extra charges.<sup>17</sup> Other studies corroborate that increased length of hospital stay and cost are associated with SSIs.<sup>18,19</sup>

Deep SSIs involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs.<sup>20,21</sup>

Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis.

Despite these activities, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients.

This may be partially explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly and/or have a wide variety of chronic, debilitating, or immunocompromising underlying diseases. There also are increased numbers of prosthetic implant and organ transplant operations performed.

Thus, to reduce the risk of SSI, a systematic but realistic approach must be applied with the awareness that this risk is influenced by characteristics of the patient, operation, personnel, and hospital.

## B. KEY TERMS USED IN THE GUIDELINE

## 1. Criteria for defining SSIs

The identification of SSI involves interpretation of clinical and laboratory findings, and it is crucial that a surveillance program use definitions that are consistent and standardized; otherwise, inaccurate or uninterpretable SSI rates will be computed and reported.

The CDC's NNIS system has developed standardized surveillance criteria for defining SSIs (Table 1).<sup>22</sup>

Table 1. Criteria for Defining a Surgical Site Infection (SSI)\*

## Superficial Incisional SSI

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without

laboratory confirmation, from the superficial incision.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.

4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do not report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).

2. Infection of an episiotomy or newborn circumcision site.

3. Infected burn wound.

4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.<sup>433</sup>

#### Deep incisional SSI

Infection occurs within 30 days after the operation if no implant<sup>•</sup> is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever ( $>38^{\circ}\text{C}$ ), localized pain, or tenderness, unless site is culture-negative.

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

#### Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.

2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

#### Organ/space SSI

Infection occurs within 30 days after the operation if no implant<sup>•</sup> is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound<sup>•</sup> into the organ/space.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.

3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

\* Horan TC et al. 22

• National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery.

• If the area around a stab wound becomes infected, it is not an SSI.

It is considered a skin or soft tissue infection, depending on its depth.

By these criteria, SSIs are classified as being either incisional or organ/space. Incisional SSIs are further divided into those involving only skin and subcutaneous tissue (superficial incisional SSI) and those involving deeper soft tissues of the incision (deep incisional SSI).

Organ/space SSIs involve any part of the anatomy (e.g., organ or space) other than incised body wall layers, that was opened or manipulated during an operation (Figure).

Figure. Cross-section of abdominal wall depicting

CDC classifications of surgical site infection.<sup>22</sup>

Table 2 lists site-specific classifications used to differentiate organ/space SSIs.

For example, in a patient who had an appendectomy and subsequently developed an intra-abdominal abscess not draining through the incision, the infection would be reported as an organ/space SSI at the intra-abdominal site.

Failure to use objective criteria to define SSIs has been shown to substantially affect reported SSI rates.<sup>23,24</sup>

The CDC NNIS definitions of SSIs have been applied consistently by surveillance and surgical personnel in many settings and currently are a de facto national standard.<sup>22,25</sup>

#### 2. Operating suite

A physically separate area that comprises operating rooms and their interconnecting hallways and ancillary work areas such as scrub sink rooms.

No distinction is made between operating suites located in conventional inpatient hospitals and those used for "same-day" surgical care, whether in a hospital or a free-standing facility.

#### 3. Operating room

A room in an operating suite where operations are performed.

#### 4. Surgical personnel

Any healthcare worker who provides care to surgical patients during the pre-, intra-, or postoperative periods.

#### 5. Surgical team member

Any healthcare worker in an operating room during the operation who has a surgical care role. Members of the surgical team may be "scrubbed" or not; scrubbed members have direct contact with the sterile operating field or sterile instruments or supplies used in the field (refer

to "Preoperative Hand/Forearm Antisepsis" section).

#### C. MICROBIOLOGY

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade (Table 3).<sup>26,27</sup>

Table 3. Distribution of Pathogens Isolated\*

From Surgical Site Infections, National Nosocomial Infection Surveillance System, 1986 to 1996

Staphylococcus aureus, coagulase-negative staphylococci, Enterococcus spp., and Escherichia coli remain the most frequently isolated pathogens.

An increasing proportion of SSIs are caused by antimicrobial-resistant pathogens, such as methicillin-resistant S. aureus (MRSA),<sup>28,29</sup> or by Candida albicans.<sup>30</sup>

From 1991 to 1995, the incidence of fungal SSIs among patients at NNIS hospitals increased from 0.1 to 0.3 per 1,000 discharges.<sup>30</sup>

The increased proportion of SSIs caused by resistant pathogens and Candida spp. may reflect increasing numbers of severely ill and immunocompromised surgical patients and the impact of widespread use of broad-spectrum antimicrobial agents.

Outbreaks or clusters of SSIs have also been caused by unusual pathogens, such as Rhizopus oryzae, Clostridium perfringens, Rhodococcus bronchialis, Nocardia

farcinica, Legionella pneumophila and Legionella dumoffii, and Pseudomonas multivorans.

These rare outbreaks have been traced to contaminated adhesive dressings,<sup>31</sup> elastic bandages,<sup>32</sup> colonized surgical personnel,<sup>33,34</sup> tap water,<sup>35</sup> or contaminated disinfectant solutions.<sup>36</sup>

When a cluster of SSIs involves an unusual organism, a formal epidemiologic investigation should be conducted.

#### D. PATHOGENESIS

Microbial contamination of the surgical site is a necessary precursor of SSI.

The risk of SSI can be conceptualized according to the following relationship<sup>37,38</sup>:

Quantitatively, it has been shown that if a surgical site is contaminated with  $>10^5$  microorganisms per gram of tissue, the risk of SSI is markedly increased.<sup>39</sup>

However, the dose of contaminating microorganisms required to produce infection may be much lower when foreign material is present at the site (i.e., 100 staphylococci per gram of tissue introduced on silk sutures).<sup>40-42</sup>

Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue.

For example, many gram-negative bacteria produce endotoxin, which stimulates cytokine production.

In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure.<sup>43-45</sup>

One of the most common causes of multiple system organ failure in modern surgical care is intra-abdominal infection.<sup>46,47</sup>

Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,<sup>48</sup> a critical and early host defense response to microbial contamination.

Certain strains of clostridia and streptococci produce potent exotoxins that disrupt cell membranes or alter cellular metabolism.<sup>49</sup>

A variety of microorganisms, including gram-positive bacteria such as coagulase-negative staphylococci, produce glycocalyx and an associated component called "slime,"<sup>50-55</sup> which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.<sup>56</sup>

Although these and other virulence factors are well defined, their mechanistic relationship to SSI development has not been fully determined.

For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera.<sup>57</sup>

When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.<sup>58</sup>

These organisms are usually aerobic gram-positive cocci (e.g., staphylococci), but may include fecal flora (e.g., anaerobic bacteria and gram-negative aerobes) when incisions are made near the perineum or groin.

When a gastrointestinal organ is opened during an operation and is the source of pathogens, gram-negative bacilli (e.g., *E. coli*), gram-positive organisms (e.g., enterococci), and sometimes anaerobes (e.g., *Bacillus fragilis*) are the typical SSI isolates.

Table 4 lists operations and the likely SSI pathogens associated with them.

Table 4. Operations, Likely Surgical Site Infection (SSI) Pathogens, and References on Usage of Antimicrobial Prophylaxis\*

Seeding of the operative site from a distant focus of infection can be another source of SSI pathogens,<sup>59-68</sup> particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.<sup>50,69-73</sup>

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),<sup>74-78</sup> the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation (refer to "Intraoperative Issues" section).

Exogenous flora are primarily aerobes, especially gram-positive organisms (e.g., staphylococci and streptococci).

Fungi from endogenous and exogenous sources rarely cause SSIs, and their pathogenesis is not well understood.<sup>79</sup>

## E. RISK AND PREVENTION

The term risk factor has a particular meaning in epidemiology and, in the context of SSI pathophysiology and prevention, strictly refers to a variable that has a significant, independent association with the development of SSI after a specific operation.

Risk factors are identified by multivariate analyses in epidemiologic studies.

Unfortunately, the term risk factor often is used in the surgical literature in a broad sense to include patient or operation features which, although associated with SSI development in univariate analysis, are not necessarily independent predictors.<sup>80</sup> The literature cited in the sections that follow includes risk factors identified by both univariate and multivariate analyses.

Table 5 lists patient and operation characteristics that may influence the risk of SSI development.

Table 5. Patient and Operation Characteristics That May Influence the Risk of Surgical Site Infection Development

These characteristics are useful in two ways: (1) they allow stratification of operations, making surveillance data more comprehensible; and, (2) knowledge of risk factors before certain operations may allow for targeted prevention measures.

For example, if it is known that a patient has a remote site infection, the surgical team may reduce SSI risk by scheduling an operation after the infection has resolved.

An SSI prevention measure can be defined as an action or set of actions intentionally taken to reduce the risk of an SSI. Many such techniques are directed at reducing opportunities for microbial contamination of the patient's tissues or sterile surgical instruments; others are adjunctive, such as using antimicrobial prophylaxis or avoiding unnecessary traumatic tissue dissection.

Optimum application of SSI prevention measures requires that a variety of patient and operation characteristics be carefully considered.

### 1. Patient characteristics

In certain kinds of operations, patient characteristics possibly associated with an increased risk of an SSI include coincident remote site infections<sup>59-68</sup> or colonization,<sup>81-83</sup> diabetes,<sup>84-87</sup> cigarette smoking,<sup>85,88-92</sup> systemic steroid use,<sup>84,87,93</sup> obesity (>20% ideal body weight),<sup>85-87,94-97</sup> extremes of age,<sup>92,98-102</sup> poor nutritional status,<sup>85,94,98,103-105</sup> and perioperative transfusion of certain blood products.<sup>106-109</sup>

#### a. Diabetes

The contribution of diabetes to SSI risk is controversial,<sup>84-86,98,110</sup> because the independent contribution of diabetes to SSI risk has not typically been assessed after controlling for potential confounding factors.

Recent preliminary findings from a study of patients who underwent coronary artery bypass graft showed a significant relationship between increasing levels of

HgA1c and SSI rates.<sup>111</sup>

Also, increased glucose levels (>200 mg/dL) in the immediate postoperative period (48 hours) were associated with increased SSI risk.<sup>112,113</sup>

More studies are needed to assess the efficacy of perioperative blood glucose control as a prevention measure.

#### b. Nicotine use

Nicotine use delays primary wound healing and may increase the risk of SSI.<sup>85</sup>

In a large prospective study, current cigarette smoking was an independent risk factor for sternal and/or mediastinal SSI following cardiac surgery.<sup>85</sup>

Other studies have corroborated cigarette smoking as an important SSI risk factor.<sup>88-92</sup>

The limitation of these studies, however, is that terms like current cigarette smoking and active smokers are not always defined.

To appropriately determine the contribution of tobacco use to SSI risk, standardized definitions of smoking history must be adopted and used in studies designed to control for confounding variables.

#### c. Steroid use

Patients who are receiving steroids or other immunosuppressive drugs preoperatively may be predisposed to developing SSI,<sup>84,87</sup> but the data supporting this relationship are contradictory.

In a study of long-term steroid use in patients with Crohn's disease, SSI developed significantly more often in patients receiving preoperative steroids (12.5%) than in patients without steroid use (6.7%).<sup>93</sup>

In contrast, other investigations have not found a relationship between steroid use and SSI risk.<sup>98,114,115</sup>

#### d. Malnutrition

For some types of operations, severe protein-calorie malnutrition is crudely associated with postoperative nosocomial infections, impaired wound healing dynamics, or death.<sup>116-124</sup>

The National Academy of Sciences/National Research Council (NAS/NRC),<sup>94</sup> Study on the Efficacy of Infection Control (SENIC),<sup>125</sup> and NNIS<sup>126</sup> schemes for SSI risk stratification do not explicitly incorporate nutritional status as a predictor variable, although it may be represented indirectly in the latter two.

In a widely quoted 1987 study of 404 high-risk general surgery operations, Christou and coworkers derived an SSI probability index in which final predictor variables were patient age, operation duration, serum albumin level, delayed hypersensitivity test score, and intrinsic wound contamination level.<sup>117</sup>

Although this index predicted SSI risk satisfactorily for 404 subsequent patients and was generally received as a significant advance in SSI risk stratification, it is not widely used in SSI surveillance data analysis, surgical infection research, or analytic epidemiology.

Theoretical arguments can be made for a belief that severe preoperative malnutrition should increase the risk of both incisional and organ/space SSI.

However, an epidemiologic association between incisional SSI and malnutrition is difficult to demonstrate consistently for

all surgical subspecialties.118-120,124,127-131

Multivariate logistic regression modeling has shown that preoperative protein-calorie malnutrition is not an independent predictor of mediastinitis after cardiac bypass operations.85,132

In the modern era, total parenteral nutrition (TPN) and total enteral alimentation (TEA) have enthusiastic acceptance by surgeons and critical care specialists.118,133-137

However, the benefits of preoperative nutritional repletion of malnourished patients in reducing SSI risk are unproven. In two randomized clinical trials, preoperative "nutritional therapy" did not reduce incisional and organ/space SSI risk.138-141

In a recent study of high-risk pancreatic resection patients with cancer, the provision of TPN preoperatively had no beneficial effect on SSI risk.142

A randomized prospective trial involving 395 general and thoracic surgery patients compared outcomes for malnourished patients preoperatively receiving either a 7- to 15-day TPN regimen or a regular preoperative hospital diet.

All patients were followed for 90 days postoperatively.

There was no detectable benefit of TPN administration on the incidence of incisional or organ/space SSI.143

Administering TPN or TEA may be indicated in a number of circumstances, but such repletion cannot be viewed narrowly as a prevention measure for organ/space or incisional SSI risk.

When a major elective operation is necessary in a severely malnourished patient, experienced surgeons often use both pre- and postoperative nutritional support in consideration of the major morbidity associated with numerous potential complications, only one of which is organ/space SSI.118,124,130,133,137,138,144-149

In addition, postoperative nutritional support is important for certain major oncologic operations,135,136 after many operations on major trauma victims,134 or in patients suffering a variety of catastrophic surgical complications that preclude eating or that trigger a hypermetabolic state.

Randomized clinical trials will be necessary to determine if nutritional support alters SSI risk in specific patient-operation combinations.

#### e. Prolonged preoperative hospital stay

Prolonged preoperative hospital stay is frequently suggested as a patient characteristic associated with increased SSI risk. However, length of preoperative stay is likely a surrogate for severity of illness and co-morbid conditions requiring inpatient work-up and/or therapy before the operation.16,26,65,85,94,100,150,151

#### f. Preoperative nares colonization with *Staphylococcus aureus*

*S. aureus* is a frequent SSI isolate. This pathogen is carried in the nares of 20% to 30% of healthy humans.81 It has been known for years that the development of SSI involving *S. aureus* is definitely associated with preoperative nares carriage of the organism in surgical patients.81

A recent multivariate analysis demon-

strated that such carriage was the most powerful independent risk factor for SSI following cardiothoracic operations.82

Mupirocin ointment is effective as a topical agent for eradicating *S. aureus* from the nares of colonized patients or healthcare workers.

A recent report by Kluytmans and co-workers suggested that SSI risk was reduced in patients who had cardiothoracic operations when mupirocin was applied preoperatively to their nares, regardless of carrier status.152

In this study, SSI rates for 752 mupirocin-treated patients were compared with those previously observed for an untreated group of 928 historical control patients, and the significant SSI rate reduction was attributed to the mupirocin treatment.

Concerns have been raised regarding the comparability of the two patient groups.153 Additionally, there is concern that mupirocin resistance may emerge, although this seems unlikely when treatment courses are brief.81

A prospective, randomized clinical trial will be necessary to establish definitively that eradication of nasal carriage of *S. aureus* is an effective SSI prevention method in cardiac surgery.

Such a trial has recently been completed on 3,909 patients in Iowa.83

Five types of operations in two facilities were observed.

Preliminary analysis showed a significant association between nasal carriage of *S. aureus* and subsequent SSI development. The effect of mupirocin on reducing SSI risk is yet to be determined.

#### g. Perioperative transfusion

It has been reported that perioperative transfusion of leukocyte-containing allogeneic blood components is an apparent risk factor for the development of postoperative bacterial infections, including SSI.106

In three of five randomized trials conducted in patients undergoing elective colon resection for cancer, the risk of SSI was at least doubled in patients receiving blood transfusions.107-109

However, on the basis of detailed epidemiologic reconsiderations, as many as 12 confounding variables may have influenced the reported association, and any effect of transfusion on SSI risk may be either small or nonexistent.106

Because of methodologic problems, including the timing of transfusion, and use of nonstandardized SSI definitions, interpretation of the available data is limited. A meta-analysis of published trials will probably be required for resolution of the controversy.154

There is currently no scientific basis for withholding necessary blood products from surgical patients as a means of either incisional or organ/space SSI risk reduction.

#### 2. Operative characteristics: Preoperative issues

##### a. Preoperative antiseptic showering

A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts ninefold (2.8•~102 to 0.3), while

povidone-iodine or triclocarban medicated soap reduced colony counts by 1.3- and 1.9-fold, respectively.155

Other studies corroborate these findings.156,157

Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated.158

Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.159-165

##### b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal.16,100,166-169

In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed.166

The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multiplication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%); if shaving was performed >24 hours prior to operation, the SSI rate exceeded 20%.166

Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before = 1.8% vs night before = 4.0%).170-173

Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping,166,167 depilatories sometimes produce hypersensitivity reactions.166

Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed.100,174,175

##### c. Patient skin preparation in the operating room

Several antiseptic agents are available for preoperative preparation of skin at the incision site (Table 6).

Table 6. Mechanism and Spectrum of Activity of Antiseptic Agents Commonly Used for Preoperative Skin Preparation and Surgical Scrubs

The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies.

Alcohol is defined by the FDA as having one of the following active ingredients: ethyl alcohol, 60% to 95% by volume in an aqueous solution, or isopropyl alcohol, 50% to 91.3% by volume in an aqueous solution.12

Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic.176



Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant.<sup>176,177</sup> One potential disadvantage of the use of alcohol in the operating room is its flammability.<sup>176-178</sup>

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity.<sup>177,179-181</sup> In some comparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greater reductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application.<sup>182-184</sup>

Further, chlorhexidine gluconate is not inactivated by blood or serum proteins.<sup>176,179,185,186</sup> Iodophors may be inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.<sup>178,179</sup>

Before the skin preparation of a patient is initiated, the skin should be free of gross contamination (i.e., dirt, soil, or any other debris).<sup>187</sup>

The patient's skin is prepared by applying an antiseptic in concentric circles, beginning in the area of the proposed incision.

The prepared area should be large enough to extend the incision or create new incisions or drain sites, if necessary.<sup>1,177,187</sup>

The application of the skin preparation may need to be modified, depending on the condition of the skin (e.g., burns) or location of the incision site (e.g., face).

There are reports of modifications to the procedure for preoperative skin preparation which include: (1) removing or wiping off the skin preparation antiseptic agent after application, (2) using an antiseptic-impregnated adhesive drape, (3) merely painting the skin with an antiseptic in lieu of the skin preparation procedure described above, or (4) using a "clean" versus a "sterile" surgical skin preparation kit.<sup>188-191</sup>

However, none of these modifications has been shown to represent an advantage.

#### d. Preoperative hand/forearm antisepsis

Members of the surgical team who have direct contact with the sterile operating field or sterile instruments or supplies used in the field wash their hands and forearms by performing a traditional procedure known as scrubbing (or the surgical scrub) immediately before donning sterile gowns and gloves.

Ideally, the optimum antiseptic used for the scrub should have a broad spectrum of activity, be fast-acting, and have a persistent effect.<sup>1,192,193</sup>

Antiseptic agents commercially available in the United States for this purpose contain alcohol, chlorhexidine, iodine/iodophors, para-chloro-meta-xylenol, or triclosan (Table 6).<sup>176,177,179,194,195</sup> Alcohol is considered the gold standard for surgical hand preparation in several European countries.<sup>196-199</sup> Alcohol-containing products are used less frequently in the United States than in Europe, possibly because of concerns about flammability and skin irritation.

Povidone-iodine and chlorhexidine gluconate are the current agents of choice for most U.S. surgical team members.<sup>177</sup> However, when 7.5% povidone-iodine or

4% chlorhexidine gluconate was compared to alcoholic chlorhexidine (60% isopropanol and 0.5% chlorhexidine gluconate in 70% isopropanol), alcoholic chlorhexidine was found to have greater residual antimicrobial activity.<sup>200,201</sup>

No agent is ideal for every situation, and a major factor, aside from the efficacy of any product, is its acceptability by operating room personnel after repeated use. Unfortunately, most studies evaluating surgical scrub antiseptics have focused on measuring hand bacterial colony counts. No clinical trials have evaluated the impact of scrub agent choice on SSI risk.<sup>195,202-206</sup>

Factors other than the choice of antiseptic agent influence the effectiveness of the surgical scrub. Scrubbing technique, the duration of the scrub, the condition of the hands, or the techniques used for drying and gloving are examples of such factors. Recent studies suggest that scrubbing for at least 2 minutes is as effective as the traditional 10-minute scrub in reducing hand bacterial colony counts,<sup>207-211</sup> but the optimum duration of scrubbing is not known.

The first scrub of the day should include a thorough cleaning underneath fingernails (usually with a brush).<sup>180,194,212</sup>

It is not clear that such cleaning is a necessary part of subsequent scrubs during the day.

After performing the surgical scrub, hands should be kept up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows.

Sterile towels should be used for drying the hands and forearms before the donning of a sterile gown and gloves.<sup>212</sup>

A surgical team member who wears artificial nails may have increased bacterial and fungal colonization of the hands despite performing an adequate hand scrub.<sup>212,213</sup>

Hand carriage of gram-negative organisms has been shown to be greater among wearers of artificial nails than among non-wearers.<sup>213</sup>

An outbreak of *Serratia marcescens* SSIs in cardiovascular surgery patients was found to be associated with a surgical nurse who wore artificial nails.<sup>214</sup>

While the relationship between nail length and SSI risk is unknown, long nails?artificial or natural?may be associated with tears in surgical gloves.<sup>177,180,212</sup>

The relationship between the wearing of nail polish or jewelry by surgical team members and SSI risk has not been adequately studied.<sup>194,212,215-217</sup>

#### e. Management of infected or colonized surgical personnel

Surgical personnel who have active infections or are colonized with certain microorganisms have been linked to outbreaks or clusters of SSIs.<sup>33,34,76,218-237</sup> Thus, it is important that healthcare organizations implement policies to prevent transmission of microorganisms from personnel to patients.

These policies should address management of job-related illnesses, provision of postexposure prophylaxis after job-related exposures and, when necessary, exclusion of ill personnel from work or patient contact.

While work exclusion policies should be enforceable and include a statement of authority to exclude ill personnel, they should also be designed to encourage personnel to report their illnesses and exposures and not penalize personnel with loss of wages, benefits, or job status.<sup>238</sup>

#### f. Antimicrobial prophylaxis

Surgical antimicrobial prophylaxis (AMP) refers to a very brief course of an antimicrobial agent initiated just before an operation begins.<sup>239-265</sup>

AMP is not an attempt to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses.

AMP does not pertain to prevention of SSI caused by postoperative contamination.<sup>265</sup> Intravenous infusion is the mode of AMP delivery used most often in modern surgical practice.<sup>20,26,242,266-281</sup> Essentially all confirmed AMP indications pertain to elective operations in which skin incisions are closed in the operating room.

Four principles must be followed to maximize the benefits of AMP:

Use an AMP agent for all operations or classes of operations in which its use has been shown to reduce SSI rates based on evidence from clinical trials or for those operations after which incisional or organ/space SSI would represent a catastrophe.<sup>266,268,269,282-284</sup>

Use an AMP agent that is safe, inexpensive, and bactericidal with an in vitro spectrum that covers the most probable intraoperative contaminants for the operation.

Time the infusion of the initial dose of antimicrobial agent so that a bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised.<sup>285</sup>

Maintain therapeutic levels of the antimicrobial agent in both serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room.<sup>179,266-268,282,284,286</sup>

Because clotted blood is present in all surgical wounds, therapeutic serum levels of AMP agents are logically important in addition to therapeutic tissue levels.

Fibrin-enmeshed bacteria may be resistant to phagocytosis or to contact with antimicrobial agents that diffuse from the wound space.

Table 4 summarizes typical SSI pathogens according to operation type and cites studies that establish AMP efficacy for these operations.

A simple way to organize AMP indications is based on using the surgical wound classification scheme shown in Table 7, which employs descriptive case features to postoperatively grade the degree of intraoperative microbial contamination.

#### Table 7. Surgical Wound Classification

**Class I/Clean:** An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative

incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.

**Class II/Clean-Contaminated:** An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination.

Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

**Class III/Contaminated:** Open, fresh, accidental wounds.

In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.

**Class IV/Dirty-Infected:** Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera.

This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Garner JS1 and Simmons BP.2

A surgeon makes the decision to use AMP by anticipating preoperatively the surgical wound class for a given operation.

AMP is indicated for all operations that entail entry into a hollow viscus under controlled conditions.

The most frequent SSI pathogens for such clean-contaminated operations are listed in Table 4 .

Certain clean-contaminated operations, such as elective colon resection, low anterior resection of the rectum, and abdominoperineal resection of the rectum, also require an additional preoperative protective maneuver called "preparation of the colon," to empty the bowel of its contents and to reduce the levels of live microorganisms.<sup>200,239,256,268,284,287</sup>

This maneuver includes the administration of enemas and cathartic agents followed by the oral administration of non-absorbable antimicrobial agents in divided doses the day before the operation.<sup>200,288,289</sup>

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are: (1) when any intravascular prosthetic material or a prosthetic joint will be inserted, and (2) for any operation in which an incisional or organ/space SSI would pose catastrophic risk.

Examples are all cardiac operations, including cardiac pacemaker placement,<sup>290</sup> vascular operations involving prosthetic arterial graft placement at any site or the revascularization of the lower extremity, and most neurosurgical operations (Table 4 ).

Some have advocated use of AMP during all operations on the breast.<sup>80,242,264</sup>

By definition, AMP is not indicated for an operation classified in Table 7 as contaminated or dirty.

In such operations, patients are frequently receiving therapeutic antimicrobial agents perioperatively for established infections.

Cephalosporins are the most thoroughly studied AMP agents.<sup>284</sup>

These drugs are effective against many gram-positive and gram-negative microorganisms.

They also share the features of demonstrated safety, acceptable pharmacokinetics, and a reasonable cost per dose.<sup>242</sup>

In particular, cefazolin is widely used and generally viewed as the AMP agent of first choice for clean operations.<sup>266</sup>

If a patient is unable to receive a cephalosporin because of penicillin allergy, an alternative for gram-positive bacterial coverage is either clindamycin or vancomycin.

Cefazolin provides adequate coverage for many clean-contaminated operations,<sup>268,291</sup> but AMP for operations on the distal intestinal tract mandates use of an agent such as cefoxitin (or some other second-generation cephalosporin) that provides anaerobic coverage.

If a patient cannot safely receive a cephalosporin because of allergy, a reasonable alternative for gram-negative coverage is aztreonam. However, an agent such as clindamycin or metronidazole should also be included to ensure anaerobic coverage.

The aminoglycosides are seldom recommended as first choices for AMP, either as single drugs or as components of combination regimens.<sup>242,264</sup>

References cited in Table 4 provide many details regarding AMP choices and dosages, antimicrobial spectra and properties, and other practical clinical information.

The routine use of vancomycin in AMP is not recommended for any kind of operation.<sup>242,266,283,292</sup>

However, vancomycin may be the AMP agent of choice in certain clinical circumstances, such as when a cluster of MRSA mediastinitis or incisional SSI due to methicillin-resistant coagulase-negative staphylococci has been detected.

A threshold has not been scientifically defined that can support the decision to use vancomycin in AMP.

The decision should involve consideration of local frequencies of MRSA isolates, SSI rates for particular operations, review of infection prevention practices for compliance, and consultation between surgeons and infectious disease experts.

An effective SSI surveillance program must be operational, with careful and timely culturing of SSI isolates to determine species and AMP agent susceptibilities.<sup>80</sup>

Agents most commonly used for AMP (i.e., cephalosporins) exhibit time-dependent bactericidal action.

The therapeutic effects of such agents are probably maximized when their levels continuously exceed a threshold value best approximated by the minimal bactericidal concentration value observed for the target pathogens in vitro.

When the duration of an operation is expected to exceed the time in which therapeutic levels of the AMP agent can be maintained, additional AMP agent should be infused.

That time point for cefazolin is estimated as 3 to 4 hours.

In general, the timing of a second (or third, etc.) dose of any AMP drug is estimated from three parameters: tissue levels achieved in normal patients by a standard therapeutic dose, the approximate serum half-life of the drug, and awareness of approximate MIC<sub>90</sub> values for anticipated SSI pathogens.

References in Table 6 should be consulted for these details and important properties of antimicrobial agents used for AMP in various specialties.

Basic "rules of thumb" guide decisions about AMP dose sizes and timing.

For example, it is believed that a full therapeutic dose of cefazolin (1-2 g) should be given to adult patients no more than 30 minutes before the skin is incised.<sup>242,285</sup> There are a few exceptions to this basic guide.

With respect to dosing, it has been demonstrated that larger doses of AMP agents are necessary to achieve optimum effect in morbidly obese patients.<sup>293</sup> With respect to timing, an exception occurs for patients undergoing cesarean section in whom AMP is indicated: the initial dose is administered immediately after the umbilical cord is clamped.<sup>266,272,273</sup>

If vancomycin is used, an infusion period of approximately 1 hour is required for a typical dose.

Clearly, the concept of "on-call" infusion of AMP is flawed simply because delays in transport or schedule changes can mean that suboptimal tissue and serum levels may be present when the operation starts.<sup>242,294</sup>

Simple protocols of AMP timing and oversight responsibility should be locally designed to be practical and effective.

3. Operative characteristics: Intraoperative issues

a. Operating room environment

(1) Ventilation

Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets. The microbial level in operating room air is directly proportional to the number of people moving about in the room.<sup>295</sup>

Therefore, efforts should be made to minimize personnel traffic during operations. Outbreaks of SSIs caused by group A beta-hemolytic streptococci have been traced to airborne transmission of the organism from colonized operating room personnel to patients.<sup>233,237,296,297</sup>

In these outbreaks, the strain causing the outbreak was recovered from the air in the operating room.<sup>237,296</sup> It has been demonstrated that exercising and changing of clothing can lead to airborne dissemination of group A streptococci from vaginal or rectal carriage.<sup>233,234,237,297</sup>

Operating rooms should be maintained at positive pressure with respect to corridors and adjacent areas.<sup>298</sup>

Positive pressure prevents airflow from less clean areas into more clean areas. All ventilation or air conditioning systems in hospitals, including those in operating rooms, should have two filter beds in series, with the efficiency of the first filter bed being 30% and that of the second filter bed being 90%.<sup>299</sup>

Conventional operating room ventilation systems produce a minimum of about 15 air changes of filtered air per hour, three

(20%) of which must be fresh air.<sup>299,300</sup>  
Air should be introduced at the ceiling and exhausted near the floor.<sup>300,301</sup> Detailed ventilation parameters for operating rooms have been published by the American Institute of Architects in collaboration with the U.S. Department of Health and Human Services (Table 8).<sup>299</sup>

Table 8. Parameters for Operating Room  
Ventilation, American Institute of Architects, 1996

Laminar airflow and use of UV radiation have been suggested as additional measures to reduce SSI risk for certain operations.

Laminar airflow is designed to move particle-free air (called "ultraclean air") over the aseptic operating field at a uniform velocity (0.3 to 0.5 um/sec), sweeping away particles in its path. Laminar airflow can be directed vertically or horizontally, and recirculated air is usually passed through a high efficiency particulate air (HEPA) filter.<sup>302,303</sup>

HEPA filters remove particles 0.3um in diameter with an efficiency of 99.97%.<sup>64,300,302,304</sup>

Most of the studies examining the efficacy of ultraclean air involve only orthopedic operations.<sup>298,305-311</sup>

Charnley and Eftaknan studied vertical laminar airflow systems and exhaust-ventilated clothing and found that their use decreased the SSI rate from 9% to 1%.<sup>305</sup> However, other variables (i.e., surgeon experience and surgical technique) changed at the same time as the type of ventilation, which may have confounded the associations.

In a multicenter study examining 8,000 total hip and knee replacements, Lidwell et al. compared the effects of ultraclean air alone, antimicrobial prophylaxis alone, and ultraclean air in combination with antimicrobial prophylaxis on the rate of deep SSIs.<sup>307</sup>

The SSI rate following operations in which ultraclean air alone was used decreased from 3.4% to 1.6%, whereas the rate for those who received only antimicrobial prophylaxis decreased from 3.4% to 0.8%.

When both interventions were used in combination, the SSI rate decreased from 3.4% to 0.7%. These findings suggest that both ultraclean air and antimicrobial prophylaxis can reduce the incidence of SSI following orthopedic implant operations, but antimicrobial prophylaxis is more beneficial than ultraclean air.

Intraoperative UV radiation has not been shown to decrease overall SSI risk.<sup>94,312</sup>

#### (2) Environmental surfaces

Environmental surfaces in U.S. operating rooms (e.g., tables, floors, walls, ceilings, lights) are rarely implicated as the sources of pathogens important in the development of SSIs.

Nevertheless, it is important to perform routine cleaning of these surfaces to reestablish a clean environment after each operation.<sup>180,212,300,302</sup>

There are no data to support routine disinfecting of environmental surfaces or equipment between operations in the ab-

sence of contamination or visible soiling. When visible soiling of surfaces or equipment occurs during an operation, an Environmental Protection Agency (EPA)-approved hospital disinfectant should be used to decontaminate the affected areas before the next operation.<sup>180,212,300-302,313-315</sup>

This is in keeping with the Occupational Safety and Health Administration (OSHA) requirement that all equipment and environmental surfaces be cleaned and decontaminated after contact with blood or other potentially infectious materials.<sup>315</sup>

Wet-vacuuming of the floor with an EPA-approved hospital disinfectant is performed routinely after the last operation of the day or night.

Care should be taken to ensure that medical equipment left in the operating room be covered so that solutions used during cleaning and disinfecting do not contact sterile devices or equipment.<sup>316</sup>

There are no data to support special cleaning procedures or closing of an operating room after a contaminated or dirty operation has been performed.<sup>300,301</sup>

Tacky mats placed outside the entrance to an operating room/suite have not been shown to reduce the number of organisms on shoes or stretcher wheels, nor do they reduce the risk of SSI.<sup>1,179,295,301</sup>

#### (3) Microbiologic sampling

Because there are no standardized parameters by which to compare microbial levels obtained from cultures of ambient air or environmental surfaces in the operating room, routine microbiologic sampling cannot be justified.

Such environmental sampling should only be performed as part of an epidemiologic investigation.

#### (4) Conventional sterilization of surgical instruments

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.<sup>302,317,318</sup>

Surgical instruments can be sterilized by steam under pressure, dry heat, ethylene oxide, or other approved methods.

The importance of routinely monitoring the quality of sterilization procedures has been established.<sup>1,180,212,299</sup>

Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.<sup>212,314,319</sup>

Detailed recommendations for sterilization of surgical instruments have been published.<sup>212,314,320,321</sup>

#### (5) Flash sterilization of surgical instruments

The Association for the Advancement of Medical Instrumentation defines flash sterilization as "the process designated for the steam sterilization of patient care items for immediate use."<sup>321</sup>

During any operation, the need for emergency sterilization of equipment may arise (e.g., to reprocess an inadvertently dropped instrument).

However, flash sterilization is not intended to be used for either reasons of convenience or as an alternative to purchasing additional instrument sets or to save time.

Also, flash sterilization is not recom-

mended for implantable devices because of the potential for serious infections.<sup>314,320,321</sup>

Flash sterilization is not recommended as a routine sterilization method because of the lack of timely biologic indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to operating rooms, and use of minimal sterilization cycle parameters (i.e., time, temperature, pressure).<sup>319</sup>

To address some of these concerns, many hospitals have placed equipment for flash sterilization in close proximity to operating rooms and new biologic indicators that provide results in 1 to 3 hours are now available for flash-sterilized items.<sup>322-325</sup>

Nevertheless, flash sterilization should be restricted to its intended purpose until studies are performed that can demonstrate comparability with conventional sterilization methods regarding risk of SSI.

Sterilization cycle parameters for flash sterilization are shown in Table 9.

Table 9. Parameters for Flash Sterilization Cycles, Association for the Advancement of Medical Instrumentation

#### b. Surgical attire and drapes

In this section the term surgical attire refers to scrub suits, caps/hoods, shoe covers, masks, gloves, and gowns.

Although experimental data show that live microorganisms are shed from hair, exposed skin, and mucous membranes of operating room personnel,<sup>75,181,326-330</sup> few controlled clinical studies have evaluated the relationship between the use of surgical attire and SSI risk.

Nevertheless, the use of barriers seems prudent to minimize a patient's exposure to the skin, mucous membranes, or hair of surgical team members, as well as to protect surgical team members from exposure to blood and bloodborne pathogens (e.g., human immunodeficiency virus and hepatitis viruses).

#### (1) Scrub suits

Surgical team members often wear a uniform called a "scrub suit" that consists of pants and a shirt.

Policies for laundering, wearing, covering, and changing scrub suits vary greatly.

Some policies restrict the laundering of scrub suits to the facility, while other facilities have policies that allow laundering by employees.

There are no well-controlled studies evaluating scrub suit laundering as an SSI risk factor.<sup>331</sup> Some facilities have policies that restrict the wearing of scrub suits to the operating suite, while other facilities allow the wearing of cover gowns over scrub suits when personnel leave the suite.

The Association of Operating Room Nurses recommends that scrub suits be changed after they become visibly soiled and that they be laundered only in an approved and monitored laundry facil-

ity.212

Additionally, OSHA regulations require that "if a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible."<sup>315</sup>

#### (2) Masks

The wearing of surgical masks during operations to prevent potential microbial contamination of incisions is a longstanding surgical tradition.

However, some studies have raised questions about the efficacy and cost-benefit of surgical masks in reducing SSI risk.<sup>328,332-338</sup>

Nevertheless, wearing a mask can be beneficial since it protects the wearer's nose and mouth from inadvertent exposures (i.e., splashes) to blood and other body fluids.

OSHA regulations require that masks in combination with protective eyewear, such as goggles or glasses with solid shields, or chin-length face shields be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated.<sup>315</sup> In addition, a respirator certified by the National Institute for Occupational Safety and Health with protection factor N95 or higher is required when the patient has or is suspected of having infectious tuberculosis.<sup>339</sup>

#### (3) Surgical caps/hoods and shoe covers

Surgical caps/hoods are inexpensive and reduce contamination of the surgical field by organisms shed from the hair and scalp.

SSI outbreaks have occasionally been traced to organisms isolated from the hair or scalp (*S. aureus* and group A *Streptococcus*),<sup>75,76</sup> even when caps were worn by personnel during the operation and in the operating suites.

The use of shoe covers has never been shown to decrease SSI risk or to decrease bacteria counts on the operating room floor.<sup>340,341</sup>

Shoe covers may, however, protect surgical team members from exposure to blood and other body fluids during an operation. OSHA regulations require that surgical caps or hoods and shoe covers or boots be worn in situations when gross contamination can reasonably be anticipated (e.g., orthopedic operations, penetrating trauma cases).<sup>315</sup>

#### (4) Sterile gloves

Sterile gloves are put on after donning sterile gowns.

A strong theoretical rationale supports the wearing of sterile gloves by all scrubbed members of the surgical team.

Sterile gloves are worn to minimize transmission of microorganisms from the hands of team members to patients and to prevent contamination of team members' hands with patients' blood and body fluids.

If the integrity of a glove is compromised (e.g., punctured), it should be changed as promptly as safety permits.<sup>315,342,343</sup>

Wearing two pairs of gloves (double-gloving) has been shown to reduce hand contact with patients' blood and body fluids when compared to wearing only

a single pair.<sup>344,345</sup>

#### (5) Gowns and drapes

Sterile surgical gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Gowns are worn by all scrubbed surgical team members and drapes are placed over the patient.

There are limited data that can be used to understand the relationship of gown or drape characteristics with SSI risk.

The wide variation in the products and study designs make interpretation of the literature difficult.<sup>329,346-350</sup>

Gowns and drapes are classified as disposable (single use) or reusable (multiple use).

Regardless of the material used to manufacture gowns and drapes, these items should be impermeable to liquids and viruses.<sup>351,352</sup>

In general, only gowns reinforced with films, coatings, or membranes appear to meet standards developed by the American Society for Testing and Materials.<sup>351-353</sup>

However, such "liquid-proof" gowns may be uncomfortable because they also inhibit heat loss and the evaporation of sweat from the wearer's body.

These factors should be considered when selecting gowns.<sup>353,354</sup>

A discussion of the role of gowns and drapes in preventing the transmission of bloodborne pathogens is beyond the scope of this document.<sup>355</sup>

### c. Asepsis and surgical technique

#### (1) Asepsis

Rigorous adherence to the principles of asepsis by all scrubbed personnel is the foundation of surgical site infection prevention.

Others who work in close proximity to the sterile surgical field, such as anesthesia personnel who are separated from the field only by a drape barrier, also must abide by these principles.

SSIs have occurred in which anesthesia personnel were implicated as the source of the pathogen.<sup>34,231,234,356-358</sup>

Anesthesiologists and nurse anesthetists perform a variety of invasive procedures such as placement of intravascular devices and endotracheal tubes, and administration of intravenous drugs and solutions.

Lack of adherence to the principles of asepsis during such procedures,<sup>359</sup> including use of common syringes<sup>360,361</sup> and contaminated infusion pumps,<sup>359,362-364</sup> and the assembly of equipment and solutions in advance of procedures,<sup>316,360</sup> have been associated with outbreaks of postoperative infections, including SSI.

Recommendations for infection control practices in anesthesiology have been published.<sup>212,365-367</sup>

#### (2) Surgical technique

Excellent surgical technique is widely believed to reduce the risk of SSI.<sup>26,49,179,180,368,369</sup>

Such techniques include maintaining effective hemostasis while preserving adequate blood supply, preventing hypothermia, gently handling tissues, avoiding inadvertent entries into a hollow viscus,

removing devitalized (e.g., necrotic or charred) tissues, using drains and suture material appropriately, eradicating dead space, and appropriately managing the postoperative incision.

Any foreign body, including suture material, a prosthesis, or drain, may promote inflammation at the surgical site<sup>94</sup> and may increase the probability of SSI after otherwise benign levels of tissue contamination.

Extensive research compares different types of suture material and their presumed relationships to SSI risk.<sup>370-379</sup>

In general, monofilament sutures appear to have the lowest infection-promoting effects.<sup>3,94,179,180</sup>

A discussion of appropriate surgical drain use and details of drain placement exceed the scope of this document, but general points should be briefly noted. Drains placed through an operative incision increase incisional SSI risk.<sup>380</sup>

Many authorities suggest placing drains through a separate incision distant from the operative incision.<sup>283,381</sup> It appears that SSI risk also decreases when closed suction drains are used rather than open drains.<sup>174</sup>

Closed suction drains can effectively evacuate postoperative hematomas or seromas, but timing of drain removal is important.

Bacterial colonization of initially sterile drain tracts increases with the duration of time the drain is left in place.<sup>382</sup>

Hypothermia in surgical patients, defined as a core body temperature below 36°C, may result from general anesthesia, exposure to cold, or intentional coolingsuch as is done to protect the myocardium and central nervous system during cardiac operations.<sup>302,383,384</sup>

In one study of patients undergoing colorectal operations, hypothermia was associated with an increased SSI risk.<sup>385</sup> Mild hypothermia appears to increase incisional SSI risk by causing vasoconstriction, decreased delivery of oxygen to the wound space, and subsequent impairment of function of phagocytic leukocytes (i.e., neutrophils).<sup>386-390</sup>

In animal models, supplemental oxygen administration has been shown to reverse the dysfunction of phagocytes in fresh incisions.<sup>391</sup>

In recent human experiments, controlled local heating of incisions with an electrically powered bandage has been shown to improve tissue oxygenation.<sup>392</sup>

Randomized clinical trials are needed to establish that measures which improve wound space oxygenation can reduce SSI risk.

### 4. Operative characteristics: Postoperative issues

#### a. Incision care

The type of postoperative incision care is determined by whether the incision is closed primarily (i.e., the skin edges are re-approximated at the end of the operation), left open to be closed later, or left open to heal by second intention.

When a surgical incision is closed primarily, as most are, the incision is usually covered with a sterile dressing for 24 to 48 hours.<sup>393,394</sup>

Beyond 48 hours, it is unclear whether an incision must be covered by a dressing or

whether showering or bathing is detrimental to healing.

When a surgical incision is left open at the skin level for a few days before it is closed (delayed primary closure), a surgeon has determined that it is likely to be contaminated or that the patient's condition prevents primary closure (e.g., edema at the site).

When such is the case, the incision is packed with a sterile dressing.

When a surgical incision is left open to heal by second intention, it is also packed with sterile moist gauze and covered with a sterile dressing.

The American College of Surgeons, CDC, and others have recommended using sterile gloves and equipment (sterile technique) when changing dressings on any type of surgical incision.<sup>180,395-397</sup>

#### b. Discharge planning

In current practice, many patients are discharged very soon after their operation, before surgical incisions have fully healed.<sup>398</sup>

The lack of optimum protocols for home incision care dictates that much of what is done at home by the patient, family, or home care agency practitioners must be individualized.

The intent of discharge planning is to maintain integrity of the healing incision, educate the patient about the signs and symptoms of infection, and advise the patient about whom to contact to report any problems.

### F. SSI SURVEILLANCE

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.<sup>16,399,400</sup>

A successful surveillance program includes the use of epidemiologically sound infection definitions (Tables 1 and 2) and effective surveillance methods,

stratification of SSI rates according to risk factors associated with SSI development, and data feedback.<sup>25</sup>

#### 1. SSI risk stratification

##### a. Concepts

Three categories of variables have proven to be reliable predictors of SSI risk: (1) those that estimate the intrinsic degree of microbial contamination of the surgical site, (2) those that measure the duration of an operation, and (3) those that serve as markers for host susceptibility.<sup>25</sup>

A widely accepted scheme for classifying the degree of intrinsic microbial contamination of a surgical site was developed by the 1964 NAS/NRC Cooperative Research Study and modified in 1982 by CDC for use in SSI surveillance (Table 7).<sup>2,94</sup>

In this scheme, a member of the surgical team classifies the patient's wound at the completion of the operation.

Because of its ease of use and wide availability, the surgical wound classification has been used to predict SSI risk.<sup>16,94,126,401-405</sup>

Some researchers have suggested that surgeons compare clean wound SSI rates with those of other surgeons.<sup>16,399</sup>

However, two CDC efforts (the SENIC Project and the NNIS system) incorporated other predictor variables into SSI risk indices.

These showed that even within the category of clean wounds, the SSI risk varied by risk category from 1.1% to 15.8% (SENIC) and from 1.0% to 5.4% (NNIS).<sup>125,126</sup>

In addition, sometimes an incision is incorrectly classified by a surgical team member or not classified at all, calling into question the reliability of the classification.

Therefore, reporting SSI rates stratified by wound class alone is not recommended.

Data on 10 variables collected in the SENIC Project were analyzed by using logistic regression modeling to develop a simple additive SSI risk index.<sup>125</sup>

Four of these were found to be independently associated with SSI risk: (1) an abdominal operation, (2) an operation lasting >2 hours, (3) a surgical site with a wound classification of either contaminated or dirty/infected, and 4) an operation performed on a patient having 3 discharge diagnoses.

Each of these equally weighted factors contributes a point when present, such that the risk index values range from 0 to 4.

By using these factors, the SENIC index predicted SSI risk twice as well as the traditional wound classification scheme alone.

The NNIS risk index is operation-specific and applied to prospectively collected surveillance data.

The index values range from 0 to 3 points and are defined by three independent and equally weighted variables.

One point is scored for each of the following when present: (1) American Society of Anesthesiologists (ASA) Physical Status Classification of >2 (Table 10), (2) either contaminated or dirty/infected wound classification (Table 7), and (3) length of operation >T hours, where T is the approximate 75th percentile of the duration of the specific operation being performed.<sup>126</sup>

#### able 10. Physical Status Classification.

American Society of Anesthesiologists\*  
Society of Anesthesiologists has revised their classification system; the most recent version is available at <http://www.asahq.org/profinfo/physicalstatus.html>.

The ASA class replaced discharge diagnoses of the SENIC risk index as a surrogate for the patient's underlying severity of illness (host susceptibility).<sup>406,407</sup> and has the advantage of being readily available in the chart during the patient's hospital stay.

Unlike SENIC's constant 2-hour cut-point for duration of operation, the operation-specific cut-points used in the NNIS risk index increase its discriminatory power compared to the SENIC index.<sup>126</sup>

#### b. Issues

Adjustment for variables known to confound rate estimates is critical if valid comparisons of SSI rates are to be made between surgeons or hospitals.<sup>408</sup>

Risk stratification, as described above, has proven useful for this purpose, but relies on the ability of surveillance personnel to find and record data consistently and correctly.

For the three variables used in the NNIS risk index, only one study has focused on how accurately any of them are recorded. Cardo et al. found that surgical team members' accuracy in assessing wound classification for general and trauma surgery was 88% (95% CI: 82%-94%).<sup>409</sup> However, there are sufficient ambiguities in the wound class definitions themselves to warrant concern about the reproducibility of Cardo's results.

The accuracy of recording the duration of operation (i.e., time from skin incision to skin closure) and the ASA class has not been studied.

In an unpublished report from the NNIS system, there was evidence that overreporting of high ASA class existed in some hospitals.

Further validation of the reliability of the recorded risk index variables is needed.

Additionally, the NNIS risk index does not adequately discriminate the SSI risk for all types of operations.<sup>27,410</sup>

It seems likely that a combination of risk factors specific to patients undergoing an operation will be more predictive.

A few studies have been performed to develop procedure-specific risk indices.<sup>218,411-414</sup> and research in this area continues within CDC's NNIS system.

#### 2. SSI surveillance methods

SSI surveillance methods used in both the SENIC Project and the NNIS system were designed for monitoring inpatients at acute-care hospitals.

Over the past decade, the shift from inpatient to outpatient surgical care (also called ambulatory or day surgery) has been dramatic.

It has been estimated that 75% of all operations in the United States will be performed in outpatient settings by the year 2000.<sup>4</sup>

While it may be appropriate to use common definitions of SSI for inpatients and outpatients,<sup>415</sup> the types of operations monitored, the risk factors assessed, and the case-finding methods used may differ. New predictor variables may emerge from analyses of SSIs among outpatient surgery patients, which may lead to different ways of estimating SSI risk in this population.

The choice of which operations to monitor should be made jointly by surgeons and infection control personnel.

Most hospitals do not have the resources to monitor all surgical patients all the time, nor is it likely that the same intensity of surveillance is necessary for certain low-risk procedures.

Instead, hospitals should target surveillance efforts toward high-risk procedures.<sup>416</sup>

#### a. Inpatient SSI surveillance

Two methods, alone or together, have been used to identify inpatients with SSIs: (1) direct observation of the surgical site by the surgeon, trained nurse surveyor, or infection control personnel<sup>16,97,399,402,409,417-420</sup> and (2) indirect detection by infection control personnel through review of laboratory reports, patient records, and discussions with primary care providers.<sup>15,84,399,402,404,409,418,421-427</sup>

The surgical literature suggests that direct observation of surgical sites is the most

accurate method to detect SSIs, although sensitivity data are lacking.16,399,402,417,418

Much of the SSI data reported in the infection control literature has been generated by indirect case-finding methods,125,126,422,425,426,428-430 but some studies of direct methods also have been conducted.97,409 Some studies use both methods of detection.84,409,424,427,431

A study that focused solely on the sensitivity and specificity of SSIs detected by indirect methods found a sensitivity of 83.8% (95% CI: 75.7%-91.9%) and a specificity of 99.8% (95% CI: 99%-100%).409

Another study showed that chart review triggered by a computer-generated report of antibiotic orders for post-cesarean section patients had a sensitivity of 89% for detecting endometritis.432

Indirect SSI detection can readily be performed by infection control personnel during surveillance rounds.

The work includes gathering demographic, infection, surgical, and laboratory data on patients who have undergone operations of interest.433

These data can be obtained from patients' medical records, including microbiology, histopathology, laboratory, and pharmacy data; radiology reports; and records from the operating room. Additionally, inpatient admissions, emergency room, and clinic visit records are sources of data for those postdischarge surgical patients who are readmitted or seek follow-up care.

The optimum frequency of SSI case-finding by either method is unknown and varies from daily to 3 times per week, continuing until the patient is discharged from the hospital. Because duration of hospitalization is often very short, postdischarge SSI surveillance has become increasingly important to obtain accurate SSI rates (refer to "Postdischarge SSI Surveillance" section).

To calculate meaningful SSI rates, data must be collected on all patients undergoing the operations of interest (i.e., the population at risk).

Because one of its purposes is to develop strategies for risk stratification, the NNIS system collects the following data on all surgical patients surveyed: operation date; NNIS operative procedure category;434 surgeon identifier; patient identifier; age and sex; duration of operation; wound class; use of general anesthesia; ASA class; emergency; trauma; multiple procedures; endoscopic approach; and discharge date.433 With the exception of discharge date, these data can be obtained manually from operating room logs or be electronically downloaded into surveillance software, thereby substantially reducing manual transcription and data entry errors.433

Depending on the needs for risk-stratified SSI rates by personnel in infection control, surgery, and quality assurance, not all data elements may be pertinent for every type of operation.

At minimum, however, variables found to be predictive of increased SSI risk should be collected (refer to "SSI Risk Stratification" section).

#### b. Postdischarge SSI surveillance

Between 12% and 84% of SSIs are detected after patients are discharged from the hospital.98,337,402,428,435-454

At least two studies have shown that most SSIs become evident within 21 days after operation.446,447

Since the length of postoperative hospitalization continues to decrease, many SSIs may not be detected for several weeks after discharge and may not require readmission to the operating hospital.

Dependence solely on inpatient case-finding will result in underestimates of SSI rates for some operations (e.g., coronary artery bypass graft) (CDC/NNIS system, unpublished data, 1998).

Any comparison of SSI rates must take into account whether case-finding included SSIs detected after discharge.

For comparisons to be valid, even in the same institution over time, the postdischarge surveillance methods must be the same.

Postdischarge surveillance methods have been used with varying degrees of success for different procedures and among hospitals and include (1) direct examination of patients' wounds during follow-up visits to either surgery clinics or physicians' offices,150,399,402,404,430,436,440,441,447,452,455 (2) review of medical records of surgery clinic patients,404,430,439 (3) patient surveys by mail or telephone,435,437,438,441,442,444,445,448,449,455-457 or (4) surgeon surveys by mail or telephone.98,428,430,437,439,443,444,446,448,450,451,455

One study found that patients have difficulty assessing their own wounds for infection (52% specificity, 26% positive predictive value),458 suggesting that data obtained by patient questionnaire may inaccurately represent actual SSI rates.

Recently, Sands et al. performed a computerized search of three databases to determine which best identified SSIs: ambulatory encounter records for diagnostic, testing, and treatment codes; pharmacy records for specific antimicrobial prescriptions; and administrative records for rehospitalizations and emergency room visits.446 This study found that pharmacy records indicating a patient had received antimicrobial agents commonly used to treat soft tissue infections had the highest sensitivity (50%) and positive predictive value (19%), although even this approach alone was not very effective.

As integrated health information systems expand, tracking surgical patients through the entire course of care may become more feasible, practical, and effective.

At this time, no consensus exists on which postdischarge surveillance methods are the most sensitive, specific, and practical.

Methods chosen will necessarily reflect the hospital's unique mix of operations, personnel resources, and data needs.

#### c. Outpatient SSI surveillance

Both direct and indirect methods have been used to detect SSIs that complicate outpatient operations.

One 8-year study of operations for hernia and varicose veins used home visits by district health nurses combined with a survey completed by the surgeon at the patient's 2-week postoperative clinic

visit to identify SSIs.459

While ascertainment was essentially 100%, this method is impractical for widespread implementation.

High response rates have been obtained from questionnaires mailed to surgeons (72% → 90%).443,444,446,455,459-461

Response rates from telephone questionnaires administered to patients were more variable (38%,444 81%,457 and 85%455), and response rates from questionnaires mailed to patients were quite low (15%455 and 33%446).

At this time, no single detection method can be recommended. Available resources and data needs determine which method(s) should be used and which operations should be monitored.

Regardless of which detection method is used, it is recommended that the CDC NNIS definitions of SSI (Tables 1 and 2) be used without modification in the outpatient setting.

## G. GUIDELINE EVALUATION PROCESS

The value of the HICPAC guidelines is determined by those who use them.

To help assess that value, HICPAC is developing an evaluation tool to learn how guidelines meet user expectations, and how and when these guidelines are disseminated and implemented.

## II. Recommendations for prevention of surgical site infection

### A. RATIONALE

The Guideline for Prevention of Surgical Site Infection, 1999, provides recommendations concerning reduction of surgical site infection risk.

Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability.

However, the previous CDC system for categorizing recommendations has been modified slightly.

Category I recommendations, including IA and IB, are those recommendations that are viewed as effective by HICPAC and experts in the fields of surgery, infectious diseases, and infection control.

Both Category IA and IB recommendations are applicable for, and should be adopted by, all healthcare facilities; IA and IB recommendations differ only in the strength of the supporting scientific evidence.

Category II recommendations are supported by less scientific data than Category I recommendations; such recommendations may be appropriate for addressing specific nosocomial problems or specific patient populations.

No recommendation is offered for some practices, either because there is a lack of consensus regarding their efficacy or because the available scientific evidence is insufficient to support their adoption.

For such unresolved issues, practitioners should use judgement to determine a policy regarding these practices within their organization.

Recommendations that are based on federal regulation are denoted with an asterisk.

### B. RANKINGS

Category IA. Strongly recommended for implementation and supported by well-



designed experimental, clinical, or epidemiological studies.

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale.

No recommendation; unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

Practices required by federal regulation are denoted with an asterisk (\*).

## C. RECOMMENDATIONS

### 1. Preoperative

#### a. Preparation of the patient

1. Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the infection has resolved. Category IA

2. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. Category IA

3. If hair is removed, remove immediately before the operation, preferably with electric clippers. Category IA

4. Adequately control serum blood glucose levels in all diabetic patients and particularly avoid hyperglycemia perioperatively. Category IB

5. Encourage tobacco cessation. At minimum, instruct patients to abstain for at least 30 days before elective operation from smoking cigarettes, cigars, pipes, or any other form of tobacco consumption (e.g., chewing/dipping). Category IB

6. Do not withhold necessary blood products from surgical patients as a means to prevent SSI. Category IB

7. Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day. Category IB

8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. Category IB

9. Use an appropriate antiseptic agent for skin preparation (Table 6). Category IB

10. Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. Category II

11. Keep preoperative hospital stay as short as possible while allowing for adequate preoperative preparation of the patient. Category II

12. No recommendation to taper or discontinue systemic steroid use (when medically permissible) before elective operation. Unresolved issue

13. No recommendation to enhance nutritional support for surgical patients solely as a means to prevent SSI. Unresolved issue

14. No recommendation to preoperatively apply mupirocin to nares to prevent SSI. Unresolved issue

15. No recommendation to provide measures that enhance wound space oxygenation to prevent SSI. Unresolved issue

b. Hand/forearm antiseptics for surgical team members

1. Keep nails short and do not wear artificial nails. Category IB

2. Perform a preoperative surgical scrub for at least 2 to 5 minutes using an appropriate antiseptic (Table 6). Scrub the hands and forearms up to the elbows. Category IB

3. After performing the surgical scrub, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows.

Dry hands with a sterile towel and don a sterile gown and gloves. Category IB

4. Clean underneath each fingernail prior to performing the first surgical scrub of the day. Category II

5. Do not wear hand or arm jewelry. Category II

6. No recommendation on wearing nail polish. Unresolved Issue

c. Management of infected or colonized surgical personnel

1. Educate and encourage surgical personnel who have signs and symptoms of a transmissible infectious illness to report conditions promptly to their supervisory and occupational health service personnel. Category IB

2. Develop well-defined policies concerning patient-care responsibilities when personnel have potentially transmissible infectious conditions. These policies

should govern (a) personnel responsibility in using the health service and reporting illness, (b) work restrictions, and (c) clearance to resume work after an illness that required work restriction.

The policies also should identify persons who have the authority to remove personnel from duty. Category IB

3. Obtain appropriate cultures from, and exclude from duty, surgical personnel who have draining skin lesions until infection has been ruled out or personnel have received adequate therapy and infection has resolved. Category IB

4. Do not routinely exclude surgical personnel who are colonized with organisms such as *S. aureus* (nose, hands, or other body site) or group A *Streptococcus*,

unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting. Category IB

d. Antimicrobial prophylaxis

1. Administer a prophylactic antimicrobial agent only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation (Table 4) and published recommendations. 266, 268, 269, 282-284 Category IA

2. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made.

Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. Category IA

3. Before elective colorectal operations in addition to d2 above, mechanically pre-

pare the colon by use of enemas and cathartic agents.

Administer nonabsorbable oral antimicrobial agents in divided doses on the day before the operation. Category IA

4. For high-risk cesarean section, administer the prophylactic antimicrobial agent immediately after the umbilical cord is clamped. Category IA

5. Do not routinely use vancomycin for antimicrobial prophylaxis. Category IB

### 2. Intraoperative

#### a. Ventilation

1. Maintain positive-pressure ventilation in the operating room with respect to the corridors and adjacent areas. Category IB

2. Maintain a minimum of 15 air changes per hour, of which at least 3 should be fresh air. Category IB

3. Filter all air, recirculated and fresh, through the appropriate filters per the American Institute of Architects' recommendations. 299 Category IB

4. Introduce all air at the ceiling, and exhaust near the floor. Category IB

5. Do not use UV radiation in the operating room to prevent SSI. Category IB

6. Keep operating room doors closed except as needed for passage of equipment, personnel, and the patient. Category IB

7. Consider performing orthopedic implant operations in operating rooms supplied with ultraclean air. Category II

8. Limit the number of personnel entering the operating room to necessary personnel. Category II

b. Cleaning and disinfection of environmental surfaces

1. When visible soiling or contamination with blood or other body fluids of surfaces or equipment occurs during an operation, use an EPA-approved hospital disinfectant to clean the affected areas before the next operation. Category IB\*

2. Do not perform special cleaning or closing of operating rooms after contaminated or dirty operations. Category IB

3. Do not use tacky mats at the entrance to the operating room suite or individual operating rooms for infection control. Category IB

4. Wet vacuum the operating room floor after the last operation of the day or night with an EPA-approved hospital disinfectant. Category II

5. No recommendation on disinfecting environmental surfaces or equipment used in operating rooms between operations in the absence of visible soiling. Unresolved issue

c. Microbiologic sampling

1. Do not perform routine environmental sampling of the operating room. Perform microbiologic sampling of operating room environmental surfaces or air only as part of an epidemiologic investigation. Category IB

d. Sterilization of surgical instruments

1. Sterilize all surgical instruments according to published guidelines. 212, 299, 314, 321 Category IB

2. Perform flash sterilization only for patient care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument).

Do not use flash sterilization for reasons

of convenience, as an alternative to purchasing additional instrument sets, or to save time. Category IB

#### e. Surgical attire and drapes

1. Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way, or if sterile instruments are exposed.

Wear the mask throughout the operation. Category IB\*

2. Wear a cap or hood to fully cover hair on the head and face when entering the operating room. Category IB\*

3. Do not wear shoe covers for the prevention of SSI. Category IB\*

4. Wear sterile gloves if a scrubbed surgical team member. Put on gloves after donning a sterile gown. Category IB\*

5. Use surgical gowns and drapes that are effective barriers when wet (i.e., materials that resist liquid penetration). Category IB

6. Change scrub suits that are visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials. Category IB\*

7. No recommendations on how or where to launder scrub suits, on restricting use of scrub suits to the operating suite, or for covering scrub suits when out of the operating suite. Unresolved issue

#### f. Asepsis and surgical technique

1. Adhere to principles of asepsis when placing intravascular devices (e.g., central venous catheters), spinal or epidural anesthesia catheters, or when dispensing and administering intravenous drugs. Category IA

2. Assemble sterile equipment and solutions immediately prior to use. Category II

3. Handle tissue gently, maintain effective hemostasis, minimize devitalized tissue and foreign bodies (i.e., sutures, charred tissues, necrotic debris), and eradicate dead space at the surgical site. Category IB

4. Use delayed primary skin closure or leave an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated (e.g., Class III and Class IV). Category IB

5. If drainage is necessary, use a closed suction drain.

Place a drain through a separate incision distant from the operative incision.

Remove the drain as soon as possible. Category IB

#### 3. Postoperative incision care

a. Protect with a sterile dressing for 24 to 48 hours postoperatively an incision that has been closed primarily. Category IB

b. Wash hands before and after dressing changes and any contact with the surgical site. Category IB

c. When an incision dressing must be changed, use sterile technique. Category II

d. Educate the patient and family regarding proper incision care, symptoms of SSI, and the need to report such symptoms. Category II

e. No recommendation to cover an incision closed primarily beyond 48 hours, nor on the appropriate time to shower or bathe with an uncovered incision. Unre-

solved Issue

#### 4. Surveillance

a. Use CDC definitions of SSI (Table 1) without modification for identifying SSI among surgical inpatients and outpatients. Category IB

b. For inpatient case-finding (including readmissions), use direct prospective observation, indirect prospective detection, or a combination of both direct and indirect methods for the duration of the patient's hospitalization. Category IB

c. When postdischarge surveillance is performed for detecting SSI following certain operations (e.g., coronary artery bypass graft), use a method that accommodates available resources and data needs. Category II

d. For outpatient case-finding, use a method that accommodates available resources and data needs. Category IB

e. Assign the surgical wound classification upon completion of an operation.

A surgical team member should make the assignment. Category II

f. For each patient undergoing an operation chosen for surveillance, record those variables shown to be associated with increased SSI risk (e.g., surgical wound class, ASA class, and duration of operation). Category IB

g. Periodically calculate operation-specific SSI rates stratified by variables shown to be associated with increased SSI risk (e.g., NNIS risk index). Category IB

h. Report appropriately stratified, operation-specific SSI rates to surgical team members.

The optimum frequency and format for such rate computations will be determined by stratified case-load sizes (denominators) and the objectives of local, continuous quality improvement initiatives. Category IB

i. No recommendation to make available to the infection control committee coded surgeon-specific data. Unresolved issue

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