出國報告（出國類別：研究）

研習美國院內感染監視通報及感染控制與流行病學

服務機關：行政院衛生署疾病管制局
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摘要

2003 年發生了嚴重的 SARS 風暴，造成嚴重的院內感染事件，喪失了許多寶貴的生命。世界衛生組織(WHO)於 2006 年出版 SARS：How a global epidemic was stopped 一書指出，不當的醫院感染控制措施加上病例的延遲辨識，爲台灣爆發流行之主要原因，凸顯出有效的院內感染控制及預防，是當前政策單位的重要議題，也是醫院管理上必要之課責。

此行赴美國疾病管制中心健康照護品質促進組(Division of Healthcare Quality Promotion, DHQP)，研習美國院內感染政策之制定與執行、美國院內感染監視系統(National Healthcare Safety Network, NHSN)及美國感染控制諮詢委員會(Healthcare Infection Control Practices Advisory Committee, HICPAC)之運作，希望藉由實地參與及學習，作爲本局院內感染監視系統(Taiwan Nosocomial Infections Surveillance System, TNIS)規劃、資料分析及院內感染政策之制定與執行之參考。此行並參加美國感染控制及流行病學專業人員學會(Association for Professionals in Infection Control and Epidemiology, APIC)第 35 屆年會(APIC 35th Annual Educational Conference and International Meeting)，實際參與美國感控相關人員年度重大教育訓練課程及國際會議，並研習院內感染控制相關措施及流行病學。

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研習美國院內感染監視通報及感染控制、流行病學是本次出國計畫之主要目的。院內感染是反映醫療品質及病人安全的一個重要指標，美國醫療機構評鑑聯合會(Joint Commission on Accreditation of Healthcare Organizations，JCAHO)藉由訂立病人安全年度目標，作爲所有醫療機構努力促進病人安全之方向，而「減少健康照護相關的感染風險」爲 2008 年之重點目標之一，顯示院內感染控制已備受重視。

院內感染監視在院內感染控制中，扮演著相當重要的角色，因爲定期的院感監測資料分析有助於管理院內感染異常事件發生，以採取有效感染控制措施，並可作爲防治措施執行成效的評估依據，亦能藉由院際間的同儕比較(inter-hospital comparison)，提升院內感染控制品質。爲了有效監視院內感染情形，美國於 1970 年代建置了統一定義與格式的院內感染監視通報系統(National Nosocomial Infections Surveillance System, NNIS)，並於 2005 年將此系統與其他監視系統整合，建置美國國家健康照護安全網路(National Healthcare Safety Network, NHSN)，這套系統經由標準化的作業程序收集了全國志願參與通報之醫院院內感染資料，並透過這套系統協助醫院掌握該院之院內感染情形，更藉由全國資料之院際間的同儕比較，提升院內感染控制品質。

反觀台灣的院內感染監視系統發展歷程，1994 年行政院衛生署防疫處邀請美國疾病管制中心的院內感染控制專家，來台進行 2 天半介紹美國院內感染監視系統(NNIS)的演講，會後即仿效美國之 NNIS，開始推行台灣本土之重點監視計畫「加強加護病房院內感染監測」試辦計畫，並於 1996 年研發「院內感染疫情監視系統」電腦軟體提供各醫院使用，然而該軟體卻於 2000 年時因 Y2K 之問題及經評估效用有限而停止，改以書面方式進行通報。本局於 2000 年接管院內感染業務後，瞭解到建置一套統一定義與格式的院內感染監視通報系統之重要性，便積極開發建置台灣本土之院內感染監視系統(National Nosocomial

Infections System, NNIS)，自 2001 年起分階段推廣至醫療院所。後續爲強化通報系統各項功能及實用性，於 2005 年再行規劃建置台灣院內感染監視系統（Taiwan Nosocomial Infections Surveillance System, TNIS)，並於 2007 年正式啓用。

爲了院內感染政策之制定與執行，評估及瞭解台灣院內感染發生情形是首要條件，因經由正確的現況評估，方能制定有效的院感政策。故此行之目的是瞭解美國如何規劃及維護院內感染監視系統，以及如何經由監視結果及感染控制諮詢委員會(Healthcare Infection Control Practices Advisory Committee, HICPAC)之運作，形成院內感染政策。另外此行並參加美國感染控制及流行病學專業人員學會(Association for Professionals in Infection Control and Epidemiology, APIC) 第 35 屆年會(APIC 35th Annual Educational Conference and International Meeting)，以研習院內感染控制及流行病學相關實務工作及教育訓練。

貳、過程

此次出國計畫共計 15 天，主要分爲 3 大部分。第 1 部分爲 6/9-6/11 於美國疾病管制中心負責醫院感染控制業務的健康照護品質促進組(Division of Healthcare Quality Promotion, DHQP)，學習院內感染監視系統(NHSN)之規劃及維護，以作爲本局院內感染監視系統(TNIS)之參考。第 2 部分爲 6/12-6/13 參加美國疾病管制中心召開之感染控制諮詢委員會，研習院內感染政策之制定與委員會運作方式。第 3 部分爲 6/14-6/19 參加美國感染控制及流行病學專業人員學會第 35 屆年會，以研習美國醫院實務感控人員院內感染控制實行現況及醫院實務感染控制流行病學。

一、美國疾病管制中心健康照護品質促進組

第一天抵達美國疾病管制中心，經由 Global Communication Center 嚴密的安全檢查後，首次進入位於喬治亞州亞特蘭大的美國疾病管制中心。美國疾病管制中心園區內有 20 餘棟建築物，我們此行主要學習的對象是位於園區內第 16 號建築物負責醫院感染控制業務的健康照護品質促進組(DHQP)，其隸屬於美國疾病管制中心傳染病協調中心(Coordinating Center for Infectious Diseases, CCID)下之國家傳染病整備、偵測與控制中心(National Center for Preparedness, Detection, and Control of Infectious Diseases, NCPDCID) 。DHQP 下分 3 個分組：監測分組(Surveillance Branch, SB)、預防與應變分組(Prevention and Response Branch, PRB)及臨床與環境實驗室分組(Clinical and Environmental Laboratory Branch, CELB)。NHSN 爲監測分組之主要業務，其小組長(NHSN development team leader) Teresa C. Horan 是我們於疾病管制中心期間主要負責安排和接待的人。Teresa 爲我們此行安排了豐富且廣泛的院內感染控制議題，且經由業務主辦人一一地和我們進行深入的小組討論，使我們能藉由討論瞭解院感政策的制定、監測目的和方法及有效執行策略。

位於美國喬治亞州亞特蘭大的 CDC 總部

出國人員合影

1．台灣院感政策及監視系統現況簡介

美國疾病管制中心 DHQP 爲了瞭解台灣院感政策及監視系統現況，以便進一步協助和建議我們未來的發展及執行方向，議程的一開始就是由曾副組長淑慧報告台灣院感政策及監視系統現況。台灣疾病管制局於 2007 年啓用台灣院內感染監視系統(TNIS)，期望透過監視系統的設置，瞭解國內各層級醫院院內感染發生情形，進而達到院內感染控制之目的。藉由定期分析系統資料回饋的方式，與通報醫院溝通互動，同時提供監測數據，作爲各醫院院內感控措施制定與執行之參考。截至目前，全國醫學中心及區域醫院 96 家中，已有 55%的醫院加入 TNIS 系統正式通報，其餘 40%的醫院也已陸續進入本局防疫資訊交換中心院感模組測試階段。簡報中與會人員約有 15 人，對於院感查核政策和院內感染監測通報結果及台灣特有之醫院商店街文化等，提出熱烈討論。

由曾副組長淑慧報告「台灣院感政策和監視系統現況」

2. 美國院內感染監視系統簡介

美國於 1970 年代建置了統一定義與格式的院內感染監視通報系統(National Nosocomial Infections Surveillance System, NNIS)，爲了提升效率、增進功能，於 2005 年整合院內感染通報系統(NNIS)、洗腎透析監視系統(Dialysis Surveillance Network, DSN)及醫院工作者監視系統(National Surveillance of Healthcare Workers, NaSH)，並更名爲美國國家健康照護安全網路(NHSN)，NHSN 包含 4 個部分(component)：病人安全(Patient Safety)、健康照護人員安全(Healthcare Personnel Safety)、研究與發展(Research & Development)及生物性警戒(Biovigilance，目前仍發展中)，各部分又分別包含數個模組(module)，其中病人安全部分主要爲院內感染之通報，相當於本局之 TNIS 系統，爲本次研習之重點，其架構如下表：

模組	項目
侵入性醫療裝置相關(Device-associated, DA)	● 中心導管相關血流感染(Central Line-Associated Bloodstream Infection, CLABSI) ● 導尿管相關泌尿道感染(Catheter-Associated Urinary Tract Infection, CAUTI) ● 呼吸器相關肺炎(Ventilator-Associated Pneumonia, VAP) ● 中心導管置入實務遵從性監測 Central Line

	Insertion Practices (CLIP) Adherence Monitoring ● 洗腎透析事件(Dialysis Incident, DE)
手術相關 (Procedure-associated, PA)	● 外科部位感染(Surgical Site Infection, SSI) ● 術後肺炎(Post-Procedure Pneumonia, PPP)
抗生素相關 (Medication-associated, MA)	● 抗微生物製劑使用與抗藥性(Antimicrobial Use and Resistance, AUR)
多重抗藥性菌株/困難腸梭菌相關疾病 (MDRO/CDAD)	● 多重抗藥性菌株/困難腸梭菌相關疾病感染(MDRO/CDAD infection)
病人流感疫苗接種(Patient Influenza Immunization)	● 方法 A ● 方法 B

NHSN 的目的爲藉由收集醫院資料，建立美國院內感染之流行病學資料庫(例如院內感染發生事件及相關危險因子)及院內感染控制介入措施(例如實行侵入性裝置是否依據指引操作技術)，進而評估院內感染之發生情形及年代趨勢，且經由院內的自我監控及風險校正因子之資料進行院際間的同儕比較，提升院內感染控制品質；並協助醫院發展適當監測機制及流行病學研究調查，以及早發現院內感染的異常情形。

NHSN 開放參與對象爲美國醫院協會(American Hospital Association, AHA)、醫療保險與醫療補助服務中心(Centers for Medicare and Medicaid Services, CMS)及榮民醫院(Veteran Affairs)之合約醫院。參與醫院必須經過一個較爲複雜的申請程序，以確保相關通報資料之資訊安全。初次申請的醫院必須於了解和接受 NHSN 通報規範後，登錄醫院基本資料，之後便會收到 NHSN 電子郵件通知該院之數位認證(Digital Certificate)申請方法，醫院則需依據說明至資訊安全網(Secure Data Network)申請加入通報 NHSN 之數位認證。當完成前揭申請後，會再收到資訊安全網電子郵件通知該院下載 NHSN 軟體方法和安裝程序，完成安裝後於 NHSN 填寫啓用單後送出，會收到 NHSN 確認申請通知回復，醫院申請者需再列印出並簽名及回覆使用同意書，NHSN 於收到同意書後始啓用醫

院之帳號。經過上述這些複雜的程序後，醫院才能真正開始參與通報。DHQP 同仁說明以上這些過程雖然較爲繁複，且常被醫院申請者抱怨，但是這樣的過程卻可以確保資訊安全的問題，所以 NHSN 仍堅持實行這樣的申請程序。

NHSN 有 1 項特色是「In Plan」的設計，也就是參與醫院於進行通報前，必須先於 NHSN 的月通報計畫(Patient Safety Monthly Reporting Plan)中勾選哪一些項目是該院預計要通報的，只有在計畫單中勾選通報的項目，才會納入 NHSN 資料分析，且於該院輸入資料時，會依據醫院設定要通報之項目出現相關欄位及提示通報之訊息。因 NHSN 通報項目繁多，多數醫院不一定會全數進行監測及通報，而這樣的設計因不要求醫院必需通報所有的項目，故醫院可著重於要通報的項目，因而能提升醫院通報資料的完整性和正確性。這種設計是目前台灣院內感染監視系統中沒有的功能。

另 1 項 NHSN 的特色是客製化欄位的設計，醫院可以自行增列他們需要的資料收集欄位，而不侷限於 NHSN 既定的通報項目，例如醫院特有的院內感染危險因子，醫院可自行增列該變項，以便進行資料收集和後續資料分析，以符合醫院個別需求。因 NHSN 大多爲醫院自願通報，這樣的設計，可以增加醫院通報之意願。

與 DHQP 之 Teresa C. Horan(NHSN 小組長, 左)及 Ben Kupronis(系統資訊人員,右)合影

3.抗微生物製劑及抗藥性政策及監視

抗微生物製劑及抗藥性政策及監視是目前美國院感政策中重要的項目，監測項目抗微生物製劑使用與抗藥性(Antimicrobial Use and Resistance, AUR)中，抗生素的使用量分爲口服和注射，由醫院藥局(Pharmacy)按月依照通報之抗生素類別項目加總彙算使用總量(克)；對於分離菌株抗藥性監測的部份，由醫院檢驗室(Microbiology Laboratory)按月依照通報之菌株及其對應之抗生素感受性結果，分別通報菌株總數。所以抗微生物製劑及抗藥性監視是由藥局和檢驗室完成（此部分不限於院內感染個案），而侵入性醫療裝置相關模組則由感控部門完成，因此院內感染控制監視必須由院內的各個部門通力合作，包括感控部門、檢驗部門及藥局等。相對於台灣院內感染通報系統，通報項目以感染個案資料及住院人日數等月維護資料爲主，多數的通報項目資料來源侷限於感控部門，如何結合其他部門的共同合作力量，將醫院感染管制監視適當發揮，是我們下一步需要加以思索的。

另外，因爲台灣對 Methicillin 產生抗藥性之金黃色葡萄球菌(Methicillin-resistant *Staphylococcus aureus*, MRSA)現況較爲嚴峻，我們也於會中討論 MRSA 監視及防治作爲。DHQP 經由 NHSN 監視系統發現近年來不論是實驗室分離菌株或院內感染個案分離菌株，其抗藥性百分比有明顯的增加，面對這樣的趨勢 DHQP 也推出多項介入措施，包括推行抗生素合理使用及加強抗藥性監視，但是仍無法阻擋抗藥性增加的情形。DHQP 提出澄清說明雖然金黃色葡萄球菌分離菌株中 MRSA 的比例有明顯增加，但是實際上 MRSA 院內感染發生率並無增加的情形。不過，雖然 MRSA 院內感染發生率並無增加，但是個案一旦遭受金黃色葡萄球菌感染，其爲 MRSA 之比例增加，而相較於感染無抗藥性金黃色葡萄球菌之個案，感染 MRSA 個案之預後較差，故 MRSA 仍爲不可忽視之議題，而有效的感染控制介入措施仍是非常重要的。

與 DHQP 之 L. Clifford McDonald(預防與應變分組小組長)合影

4. 院內感染資料分析

美國 NHSN 系統除了可提供醫院直接通報資料外，也可於系統中直接製作圖表分析，圖表的格式和分析的變項可以由醫院使用者自訂，而非一律是統一格式的圖表。每一個醫院基本特性不同，需求也會不同，對於圖表的分析變項和呈現格式也會不同。對於醫院使用者而言，參與 NHSN 不僅是爲了通報，也可以利用 NHSN 中的分析功能，進行醫院內部比較(intra-hospital comparison)，並即時獲得與全國通報醫院感染率之比較情形，以進行外部比較，如此可提高醫院參與通報之意願，並達到資料分享及品質改善之目的。DHQP 也會不定期將通報資料進行分析，投稿至美國感染控制期刊(American Journal of Infection Control, AJIC)之中，因 DHQP 認爲許多的資訊、警訊或公告，都需要經過具公信力的公開發表嚴格審核機制，以確保資料分析的正確性和推論的邏輯性，凡經過這些程序發表的結果，才能讓一般大眾信服，而非只是官方一言堂的言論發表和政策推廣，而沒有足夠的實證基礎來支持。

與 DHQP 之 Arjun Srinivasan(疫情調查員)合影

5．不同系統資料與 NHSN 整合

許多大型醫院有自己的院內感染系統資料庫，醫院的感染控制人員會將資料輸入於醫院端的系統中，因爲 NHSN 是屬於自願通報的性質，所以已有院內感染系統的醫院並不會有意願於 NHSN 重複輸入資料通報。但是隨著院內感染控制於醫療品質和病人安全的議題逐漸被重視之際，部分州政府已將通報 NHSN 列爲法定通報項目，因此醫院系統對 NHSN 系統的連結的需求與日俱增，經由院內感染系統的橋接，感染控制人員可免於重複的資料輸入工作，也可將節省下的時間進行更多的感染控制措施。面對這樣的需求，NHSN 正發展系統橋接之方法，但目前仍處於初步進行的階段，並未有成功橋接的醫院。台灣 CDC 的院內感染通報系統與醫院端院內感染系統的橋接，於 2007 年開始推廣和辦理，截至目前已有 13 家醫院完成系統橋接工作，順利的將醫院端資料自動上傳通報，以免重複輸入資料造成人力和時間的浪費。

6．院內感染研究計畫執行進度報告

此次前往 DHQP 適逢其委託院內感染研究計畫(Prevention Epicenter Program)執行進度報告，該計畫自 1997 開辦，爲美國疾病管制中心與學術單位

合作，致力於有關院內感染、抗生素抗藥性及其他醫療不良事件預防之重大議題研究，每 5 年會更新合作之研究團隊，最新的研究團隊開始於 2006 年，包含 University of Utah、Ohio State University、Washington University in St. Louis、Rush University Medical Center 及 Harvard Pilgrim Health Care 等 5 支研究團隊，代表數十家的醫院。據悉因美國幅員廣大，多數的執行進度報告是以視訊連線的方式進行，部分計畫執行多年，計畫人員與業務單位之間卻鮮少進行面對面溝通，本次會議非常難得地聚集各計畫人員於同一會議室進行。與會人員都是帶著大型行李箱前往，因爲參與會議的人須於前一日抵達當地，隔日參與會議，之後一日再參與美國感染控制諮詢委員會之執行進度報告。執行計畫內容是針對院內感染控制相關議題，包括評估例行性收集住院期間抗生素使用及出院診斷碼資料是否可作爲敏感及有效率之偵測外科部位感染之方法、利用健保(Medicare)申報資料之外科部位感染風險因子對醫院排序、評估 e 化之規則可否取代傳統以感控人員監測中心導管相關血流感染率、評估每日使用 chlorhexidine 擦澡以降低感染之介入措施等。另外會中也針對院內感染困難腸梭菌(*Clostridium difficile*)、抗生素使用和管制、血流感染於院內之現況和防治進行詳盡之討論。會中除針對計畫之執行進度作討論外，業務單位也針對業務需求提出說明，以使計畫結果能有效提供政策之參考。在計畫逐一進度報告和討論後，也進行分組討論，藉此與會者可以針對研究中的細節部份作進一步討論和說明。

7．行程表

Agenda

Monday, June 9, 2008
Bldg 16, Rm 3128/3136

9:00	Arrive CDC and clear security	Ms. Monroe
9:30	Introductions	Ms. Horan, Ms. Andrus
10:00	TNIS presentation to DHQP	Dr. Tseng, Ms. Su, Ms. Chou
11:30	Lunch	Ms. Horan
12:30	NHSN Overview	
-	Authority, Eligibility, Requirements	Ms. Horan, Ms. Andrus
-	Component Protocols	
-	Demo	
3:00	IT aspects of NHSN	Ms. Horan, Ms. Albitz
4:30	Adjourn	

Tuesday, June 10, 2008
Bldg 16, Rm 3128/3136

9:00	Arrive CDC and clear security	Ms. Monroe
9:30	Training	Ms. Horan, Ms. Dudeck
11:30	Policies and monitoring of antimicrobial resistance and use	Dr. Fridkin, Ms. Sievert
12:15	Lunch	Ms. Horan
1:00	Analysis	Mr. Edwards
2:30	Break and move rooms	

Bldg 16, Rm 3220

3:00	Incorporating data from other systems into NHSN	Ms. Albitz, Mr. Kupronis, Mr. Edwards
4:30	Adjourn	

Wednesday, June 11, 2008
Bldg 19, Auditorium B1

7:30	Arrive CDC and clear security	Ms. Horan
8:00	Attend Prevention Epicenter investigator presentations	
12:15	Lunch; return to Bldg 16	Ms. Horan

Bldg 16, Rm 3220

1:30	Outbreak investigation and prevention and control of antimicrobial resistance	Dr. Srinivasan
2:30	Wrap up	Ms. Horan
3:30	Adjourn	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

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二、 美國感染控制諮詢委員會

美國感染控制諮詢委員會(HICPAC)設置目的爲制定全國院內感染預防與控制指引、提供有關醫院感染管制之政策規劃及實務諮詢、編審醫院感染管制研究報告及相關計畫資料等。每年開會 3 次，必要時得召開臨時會議。

目前感染控制諮詢委員會之委員有 14 位，成員主要包括具實務經驗之醫院感染控制專家、負責感染控制醫學人員(含內科、外科及兒科醫師等)、醫療品質及病人安全專家、流行病學專家、微生物學家及衛生行政人員。HICPAC 的主席爲美國疾病管制中心外聘醫院專家 Patrick J. Brennan，P.J.主席爲賓州(Pennsylvania)大學醫學院附設醫院之感染控制部門部長，也是該院之副院長。HICPAC 主任秘書則由美國疾病管制中心的 DHQP 副組長 Michael R. Bell 擔任。

相較於台灣之感染控制諮詢委員會，HICPAC 特別的是會議中除了邀集感染控制專家擔任諮詢委員外，也會藉由這個平台固定邀集相關人員與會，以期達成溝通協調之目的。HICPAC 之當然成員(ex-officio members)包括有美國健康照護研究與品質機構(Agency for Healthcare Research and Quality, AHRQ)、醫療保險與醫療補助服務中心(Center for Medicare & Medicaid Services, CMS)、退伍軍人事務部(Department of Veterans Affairs, VA)、食品及藥物管理局(Food and Drug Administration, FDA)、健康資源和服務管理局(Health Resources and Services Administration, HRSA) 、國家衛生院(National Institute of Health, NIH)。除此之外，也邀請相關非政府機構列席參加，包括美國職業與環境醫學院(American College of Occupational and Environmental Medicine)、美國健康照護協會(American Health Care Association, AHCA)、美國醫院協會(American Hospital Association, AHA)、感染控制及流行病學專業人員學會(Association of Professionals of Infection Control and Epidemiology, APIC)、消費者聯盟(Consumer Union)、美國醫療機構評鑑聯合會(Joint Commission, JCAHO)、美國健康照護流行病學會(Society for Healthcare Epidemiology of America, SHEA)等。HICPAC 藉

由諮詢委員、當然成員及相關單位統合組織機制，整合美國感染控制業務與公共健康服務體系之量能，提升感染控制品質。當然成員及相關單位人員的工作重點在支援 HICPAC 的指引及政策產生，以組織方式的努力，強化整體公眾健康系統。

美國 HICPAC 會議，是一個為期 1.5 天的會議，多數與會的委員由幅員廣闊的美國各地前來現場參加會議，會中也開放視訊連線方式給無法現場參加的人員。另外現場也開放給有興趣的人員事前申請參加，而我們即屬於此類參加人員；資訊的公開及透明化是 HICPAC 的另一特色。此次會議主要討論的內容包括有院內感染研究計畫執行進度報告、DHQP 業務報告、院內感控指引內容更新及 NHSN 執行現況報告等。會議紀錄如附件。

出國人員參加美國感染控制諮詢委員會

與美國感染控制諮詢委員會主席 Patrick J. Brennan 合影

與美國感染控制諮詢委員會主任秘書(DHQP 部門副組長)Michael R. Bell 合影

1．院內感染研究計畫執行進度報告

院內感染研究計畫執行進度報告爲 HICPAC 委員進行審查 Epicenter 的研究計畫報告，由 DHQP 科技計畫負責人將各子計畫執行情形統合爲整合型研究計畫執行進度，於會中進行報告，而各子計畫主持人及相關研究人員則列席參加。當執行進度簡報完成後，委員會提問並給予相關審查意見，計畫主持人則需針對較爲細節的計畫內容回復意見。

2．DHQP 業務報告

DHQP 業務報告包含預防與應變分組近來田野疫情調查及其他進行中的活動、困難腸梭菌相關疾病(*C. difficile*-associated disease, CDAD)及門診照護、注射安全和基本感染控制等主題，以及實驗室分組之業務報告。

其中較爲特別的是 CDAD 流行病學報告，由 DHQP 人員針對美國院內感染監測結果及防治措施現況進行評估及報告。困難腸梭菌目前引發多則的疫情報導；研究指出近年在美國感染困難腸梭菌流行株(NAP1/B1/027)的發生率有增加的情形，此一流行株因會產生較大量的毒素導致感染個案疾病嚴重度增加，且其以常用抗生素 metronidazole 治療失效的比例也較高，這項警訊引發了國際間高度的關注。根據研究調查，CDAD 是造成院內感染腹瀉最常見的原因之一，在美國每年約造成超過 30 萬人的感染，而且近年來有越來越多困難腸梭菌引發院內感染

和聚集事件的發生，估計每 1,000 住院的人中有 20 人遭受感染。防制措施部份，發現監測資料在成功控制 CDAD 的過程中，扮演著相當重要的角色。因爲回饋監測數據可以提供機構作爲防治措施執行成效的評估依據，所以 DHQP 目前除了針對日益增高的需要提出 CDAD 監測指引建議，也已經開始在 NHSN 中，規劃建置 CDAD 通報模組。簡報結果引起許多委員的重視和討論。

3．院內感控指引內容更新

制定全國院內感染控制指引爲 HICPAC 重點任務之一，會議中除了例行的指引制定外，定期的檢視和依據現有研究證據更新既有的指引，也是其重要的目標。HICPAC 截至目前共計完成了 13 個指引(guideline)和 1200 多個院內感染控制建議(recommendation)。此次 HICPAC 會議爲制定最常見之院內感染部位之泌尿道感染防治等指引。HICPAC 會中委員也提出了因爲有太多的院內感染指引和建議，故決議要列出最重要的 10 項指引建議，以利醫院可將重點放在最重要的指引建議上；此外，因各項指引建議內容繁多，第一線醫院感染控制人員可能無法立即掌握其主要重點所在，故需要將所有指引建議列出最重要的 3 項資訊，以便使用者遵循。

4．NHSN 執行現況報告

NHSN 執行現況爲 DHQP 之 NHSN 小組長針對美國院內感染監測結果及系統現況進行評估及報告，是屬於業務報告的範圍。院內感染資料的監測在成功降低院內感染的過程中，扮演著相當重要的角色，因爲回饋監測數據可以提供機構作爲防治措施執行成效的評估依據。過去美國許多研究也發現及時回饋醫院全國代表性監測結果與該院之比較，可以降低院內感染率。

5．議程

MEETING OF THE HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
Centers for Disease Control and Prevention
1600 Clifton Road Atlanta, GA Building 19, Auditorium B3

Thursday June 12, 2008

9:00	**Welcome and Introductions** Administrative issues: Meeting logistics and planning for November and February Dates for 2009 Liaison report format revision Conflicts of interest declarations	Patrick J. Brennan
9:30	**DHQP Updates:** Prevention and Response Branch Epi-Centers update and discussion	John Jernigan
10:45	Break	
11:00	Prevention and Response Branch Updates, continued: Outbreak investigations *C.difficile*-associated disease Ambulatory care, injection safety and basic infection control	Cliff McDonald
11:45	Laboratory Branch	Roberta Carey
12:00	Lunch	
13:15	Charge to the Committee NCPDCID Director, Dr. Rima Khabbaz HHS Principal Deputy Assistant Secretary for Health , Dr. Don Wright: Implications of GAO report Prioritization of recommendations Collaboration across HHS	
14:00	**Guideline Updates :** Norovirus Guideline Disinfection Guideline HCW vaccination Guideline (with ACIP)	Kurt Stevenson, Tara MacCannell, Craig Umsheid Michael Bell Steve Gordon, Joe Perz
14:30	UTI Guideline draft review and discussion	David A. Pegues, Carolyn Gould Craig Umsheid
15:45	Break	
16:00	**Working Groups:** • Preventability • Model Legislation • Response to JC Nat'l Patient Safety Goals • Methods paper for guideline production • Ambulatory care guidelines	Patrick J. Brennan, Craig Umsheid Tammy Lundstrom Tammy Lundstrom Craig Umsheid TBD

17:30	**Liaison Reports:**	
	Advisory Committee on Elimination of Tuberculosis	Jeffrey P. Engel Rachel L. Stricof
	Agency for Healthcare Research and Quality	William B. Baine
	American College of Occupational and Environmental Medicine	Mark Russi
	American Hospital Association	Roslyne Schulman
	Association of peri-Operative Registered Nurses	Joan C. Blanchard
	Association for Professionals in Infection Control and Epidemiology	Nancy Bjerke
	Board of Scientific Counselors	Nalini Singh
	Center for Medicare and Medicaid Services	TBD
	Consumers Union	Lisa McGiffert
	Council of State and Territorial Epidemiologists	Marion Kainer
	Food and Drug Administration	Sheila A. Murphey
	The Joint Commission	Robert Wise, Louise Kuhny
	National Institutes of Health	David Henderson
	Society for Healthcare Epidemiology of America	Lisa Maragakis
	Veteran's Administration	Stephen Kralovic

Friday June 13, 2008

9:00	**Recognition of departing members** **New items:** Surveillance Branch NHSN – participation, new modules, recent data Results of peer review Process measures for new guidelines Surveillance guideline / risk-assessment template	Patrick J. Brennan Scott Fridkin Russ Olmsted
11:15	**HICPAC actions** in follow-up to Charge from HHS	Patrick J. Brennan HICPAC members
12:15	Voting for issues to be decided	Patrick J. Brennan HICPAC members
12:45	Summary and Wrap Up	Patrick J. Brennan

三、感染控制及流行病學專業人員學會第 35 屆年會

美國感染控制及流行病學專業人員學會(APIC)是美國最主要感染控制推展機構，主要發展感染管制專業，及加強感染管制工作與學術研究之推展，並提高醫療院所感染防治之觀念。該學會願景爲以預防和促進院內感染事件或其他不良事件之零容忍(zero tolerance)觀念爲首，以及經由專家學者、付費者、病人等全方位感染管制之醫學面向，達到適當的感染預防和控制措施之標準化和測量方式正確化，並定期舉辦感染管制學術研討會、推動感染管制學術之研究與發展，以提升參與學會會員之專業知能。該學會擁有上萬名的會員，主要以美國籍會員爲主，目前也擁有不少的國際會員。我們此行參加 APIC 第 35 屆年會爲其每年例行舉辦之年會，爲期大約一週，包括會前教育訓練研討會(pre-conference workshop)及國際研討會(international meeting)2 部分，前者包括風險管理、考照課程、NHSN、監測、職業衛生等教育訓練課程，後者包括許多目前最熱門的議題，例如院內感染強制通報、院內感染不給付政策及侵入性導管相關院內感染等議題。研討會中除了安排精彩的議題和演說外，也同時安排了許多優良的論文海報展示和口頭報告；另有約 200 個感染控制相關單位及廠商參展，如美國疾病管制中心亦於展覽會場展示手部衛生之宣導品，與會者也可藉此獲得諸多感染控制相關資訊。該研討會有一特色，即於同一時段安排多項議題和演說，使研討會內容更加豐富，而與會者亦可依個人之偏好，選擇參與不同的活動。

感染控制及流行病學專業人員學會第 35 屆年會於美國科羅拉多州丹佛市之國際會議廳舉行

1．院內感染監視系統教育訓練

美國疾病管制中心的 DHQP 部門當然不會錯過這一年一度的感染控制界盛事，更藉此機會辦理教育訓練，推廣 NHSN 系統的優點給尚未參與的醫院，同時將已參與醫院的收案一致性或相關通報的疑義，一併說明清楚。NHSN 教育訓練爲期半天，參與的人多數爲已參加 NHSN 的醫院，因教育訓練對象爲醫院感控人員，所以介紹 NHSN 的部份也以病人安全(Patient Safety)的通報項目爲主，其中包含侵入性醫療裝置相關(Device-associated)和手術相關 (Procedure-associated)之院內感染通報定義和操作說明，並針對部分很細節但卻又是重大的影響因素，如侵入性醫療裝置使用人日數之計算，進行詳細之說明。教育訓練中也針對感控人員常見問題及疑義進行釐清，並進行充分的雙向溝通。此外，DHQP 也預告及介紹 NHSN 即將啓用之新模組，如 CDAD 模組及 MDRO 模組。

於 APIC 年會中與 NHSN 團隊成員合影

2．院內感染強制通報

病人安全(patient safety)是近年來倍受重視的議題之一，因爲對於院內感染的零容忍(zero tolerance)觀念逐漸的被接受，有越來越多的州政府規定院內感染爲法定通報項目(圖 1~3)，甚至有的州政府規範轄下的醫院指定通報至 NHSN 系統中。因爲依據美國 Institute Of Medicine (IOM)的報告指出，每年因爲醫療不良事件造成約有 44,000 至 98,000 人死亡及 1 百萬人傷害，高於同年乳癌、交通事故或愛滋病死亡的人數，居十大死因的第 8 位，所造成的醫療成本損失更

高達 170 至 290 億美元。而院內感染是反映醫療品質及病人安全的一個重要指標，美國醫療機構評鑑聯合會(Joint Commission on Accreditation of Healthcare Organizations，JCAHO)訂立病人安全年度目標，作爲所有醫療機構努力促進病人安全之方向，「減少健康照護相關的感染風險」爲 2008 年之工作目標，更凸顯了院內感染控制已受到極大之重視。其實院內感染的通報，最主要的目的是希望能藉由持續有效的監測，來降低院內感染事件的發生。

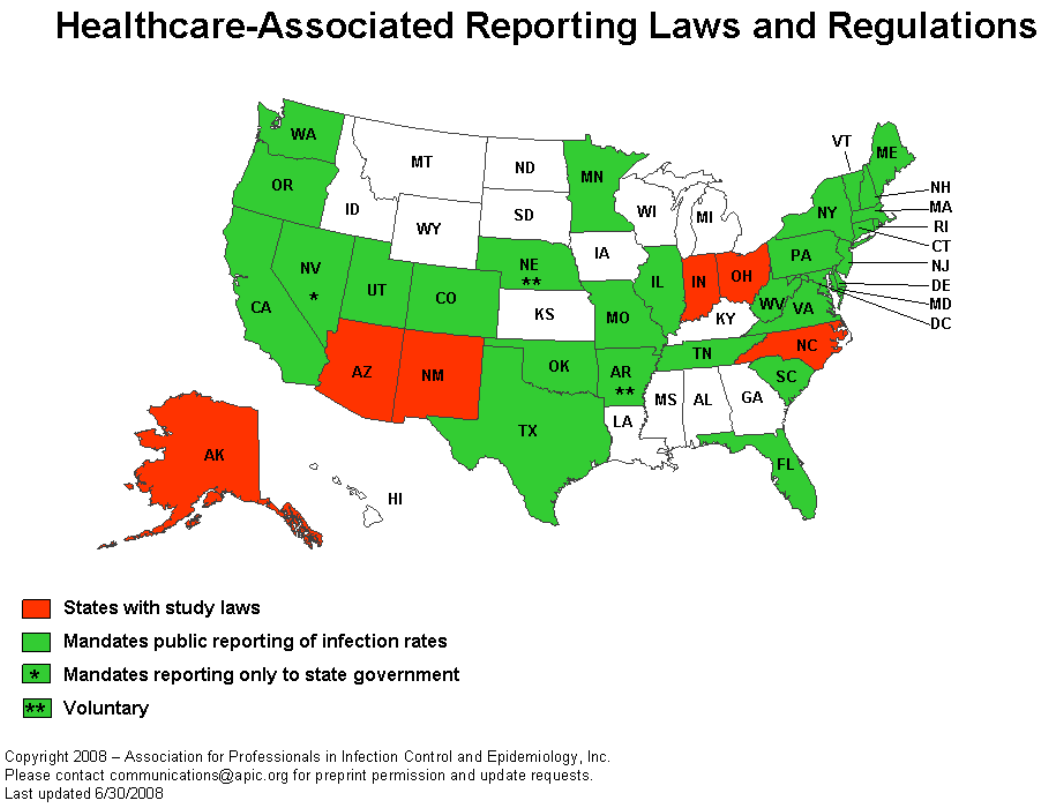


圖 1 美國各州院內感染強制通報之法制化情形

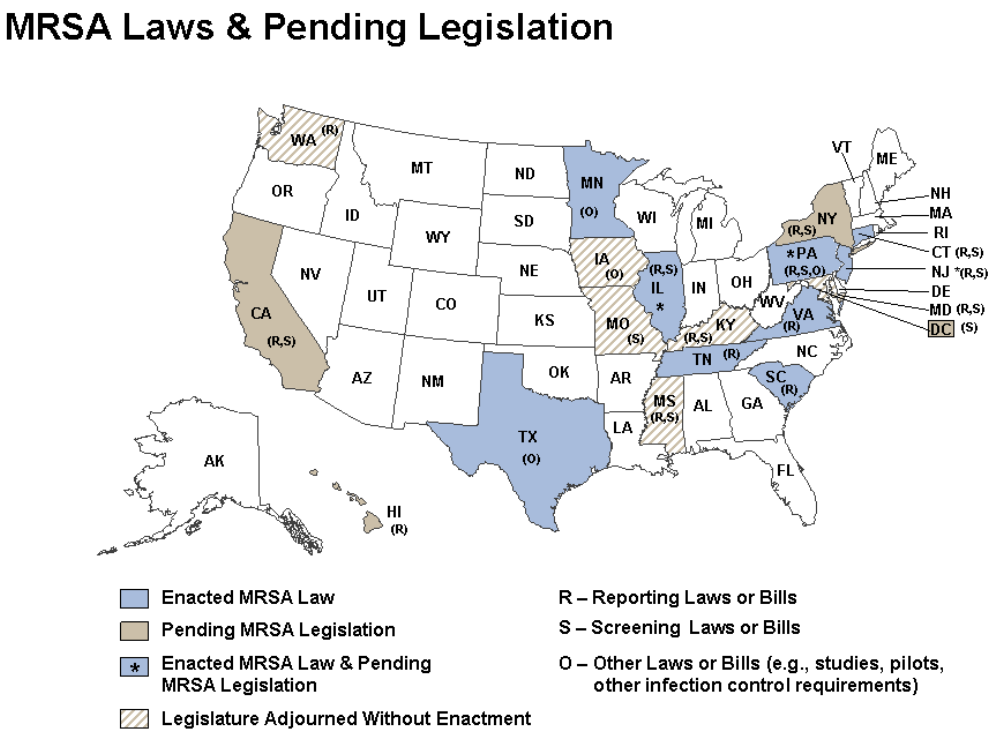


圖 2 美國各州 MRSA 強制通報之法制化情形

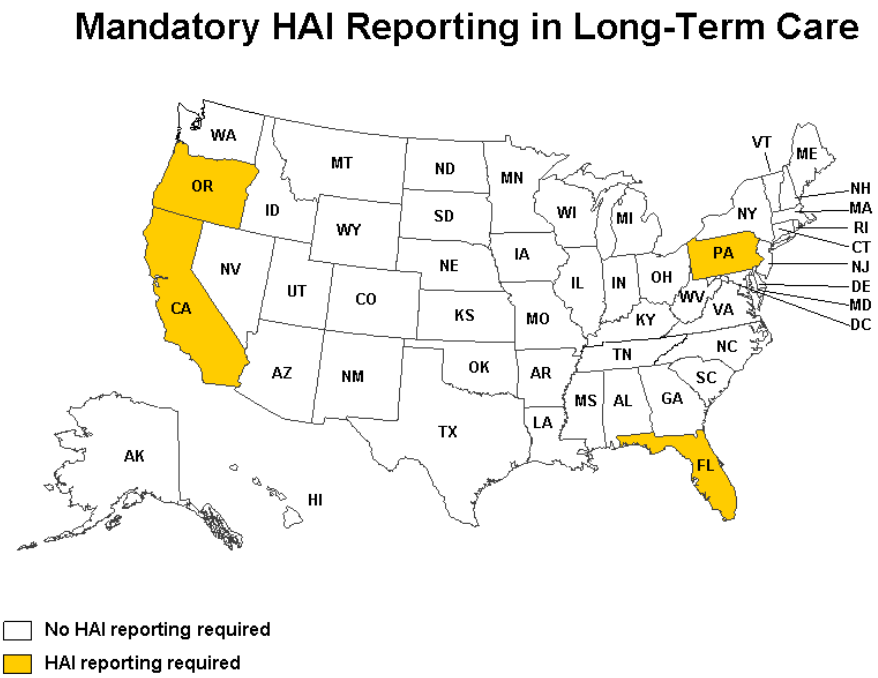


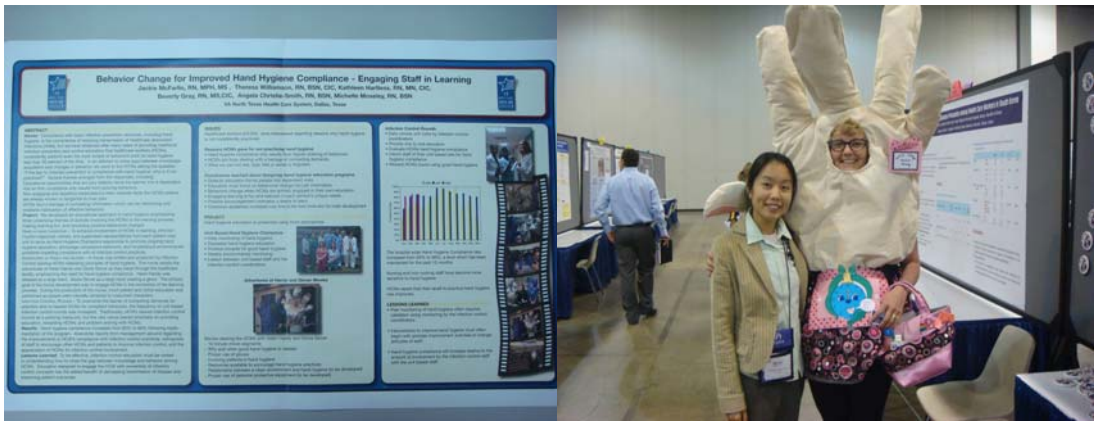
圖 3 美國各州長期照護機構院內感染強制通報情形

3.院內感染不給付政策

部份研究證實有效的感染控制措施，能達到院內感染事件的零發生。基於這樣的實證基礎，CMS 爲了增進醫療品質及避免不必要之醫療費用(cost)，認爲如果醫院的院內感染作的不好，造成院內感染事件的發生，這樣的後果並不應由全民買單，而應由醫院負起責任、自行吸收成本，也就是 pay for performance (P4P)。美國預計自 2008 年 10 月開始，CMS 採用的 DRG（Diagnosis Related Group，住院診斷關聯群）支付制度，將不再支付因院內感染造成之住院費用，也就是除病人入院診斷外，因特定院內感染造成之額外醫療費用，將不再由保險支付，例如導尿管相關泌尿道感染、中心導管相關血流感染等，2009 年更預計擴大不支付範圍爲特定手術之外科部位感染、呼吸器相關呼吸道感染。這樣的政策受到許多醫院的反彈，因爲並不是所有的院內感染都是外源性的，也有部份是病人本身的因素所造成。全由醫院買單，也可能會造成醫院爲了保護自己的利益，而拒絕收治嚴重度較高或院內感染風險較高的病人，因此，此項保險政策的重大改變，其後續發展將值得我們觀察與研究。

4．海報展示及口頭報告

研討會的其中 3 天開放海報展示，海報展示將相關院內感染議題分成幾個主題，包括抗生素抗藥性、消毒滅菌措施、生物恐怖災難緊急準備、院內感染成本效益分析、侵入性醫療裝置相關院內感染及部位別院內感染、新興及再浮現傳染病、感染預防和控制計畫、強制通報、疫情調查、病人安全、品質管理系統等。海報展示區裡有許多則關於加強洗手措施以降低院內感染的海報，因醫院裡比較難纏的就是「抗藥性病菌」，當醫院感染管制與防護措施不良，就容易造成交互傳染，而良好的衛生防護及洗手策略，是降低感染風險重要之一環。手部衛生被認爲是一個成本效益高的介入措施，只要好好洗手即能有效降低感染的風險，其成本效益和介入措施結果評估都是會場中熱門的議題。海報展示的作者也會在會場中，與觀展的人作進一步的討論，也很樂意回答相關的問題。



研討會現場手部衛生之海報展示(左)及與展示作者合影(右)

5．課程表

Sessions-at-a-Glance (as of 3/12/08)

SLC Located at the Satellite Learning Center (SLC)

◤ Call for Presentations Selections

★ Back by Popular Demand

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Saturday, June 14

8:00 AM - 12:00 PM **Pre-conference Workshop**
- Risk Management

8:00 AM - 5:00 PM **Pre-conference Workshops**
- Certification Review Course
- Take the Leadership Challenge: Crucial Conversations

Sunday, June 15

8:00 AM - 12:00 PM **Pre-conference Workshops**
- NHSN: Implementation Update
- Surveillance

8:00 AM - 5:00 PM **Pre-conference Workshops**
- Certification Review Course *(continued)*
- Take the Leadership Challenge: Crucial Conversations *(continued)*

1:00 PM - 5:00 PM **Pre-conference Workshops**
- Occupational Health

3:30 PM - 4:30 PM **Orientation Programs**
- Conference Survival Skills
- International Attendees Conference Orientation

5:00 PM - 8:00 PM **Opening Reception** *(Exhibit Hall Opens)* Baxter

Monday, June 16

7:00 AM - 4:00 PM **Posters on Display All Day**

8:15 AM - 9:15 AM **General Session**
- Opening Ceremonies, President's Address and Carole DeMille Award Presentation

9:15 AM - 10:15 AM **General Session**
- Keynote Address

10:15 AM - 1:30 PM **Exhibit Hall Open** *(Silent Auction)*

1:30 PM - 2:30 PM **Concurrent Sessions**
- Adenovirus and Respiratory Synctial Virus in the Health Care Setting
- (SLC) Catheter-Related Bloodstream Infection (CR-BSI)
- (SLC) CBIC: Linking Certification to Positive Best Practice Outcomes
- Construction Terminology for the ICP
- Disclosure of Adverse Events
- (◤SLC) How to Keep Score and Achieve Winning Outcomes
- (◤SLC) Passionate Leaders for Surgical Conscience: A Powerful Collaboration
- Top Ten Publications of the Year

1:30 PM - 4:00 PM **Professional Development Workshop:**
- Study Design

2:30 PM - 2:45 PM **Break**

2:45 PM - 3:45 PM **Concurrent Sessions**
- (★) AORN Recommended Practices
- (◤SLC) Environmental Services: Challenges Toward Coping with Reality and Fostering Collaboration
- (SLC ★) How to Develop an Outstanding Presentation
- International Exchange Program enturia
- Logistics and Business Case for MRSA Screening BD
- (◤SLC) Managing Loaner Instrumentation and Implants
- (SLC) Strategies for Infection Prevention in Long-Term Care (LTC)
- Update on Legislative Issues
- (★) Update: CDC Outbreaks

3:45 PM - 4:00 PM **Break**

4:00 PM - 5:30 PM **APIC ANNUAL BUSINESS MEETING** *(members only)*

Sessions-at-a-Glance (as of 3/12/08)

Tuesday, June 17

7:00 AM - 5:00 PM	**Posters on Display All Day**
8:00 AM - 9:00 AM	**General Session** • **Elaine Larson Lectureship:** Who Will Be in the Health Care Workforce of the Future?
9:00 AM - 9:15 AM	**Break**
9:15 AM - 10:15 AM	**General Session** • Mandatory Reporting Five Years Later
10:15 AM - 1:30 PM	**Exhibit Hall Open** *(Silent Auction)*
10:30 AM - 11:30 AM	**Poster Rounds with Professors** *(ticket holders only)*
11:30 AM - 12:30 PM	**Poster Sessions** *(with presenters - open to all)*
1:30 PM - 2:30 PM	**Oral Abstract Presentation Sessions**
2:30 PM - 2:45 PM	**Break**
2:45 PM - 3:45 PM	**Late-Breaker Session** • Outbreak of Chronic Inflammatory Neuropathy
2:45 PM - 3:45 PM	**Concurrent Sessions** • (SLC) Collaboration with Public Health Partners - The Fight against MRSA BD • Functioning in the Black and Using Scarce Resources • (SLC) IFIC: Infection Control in Limited Resource Settings around the World • Infection Related Recalls I: Devices/Allografts • The Changing Epidemiology of *Clostridium difficile* • (SLC) USP Standard <797>: Update • Ventilator-Associated Pneumonia (VAP) Surveillance: Point-Counter Point BAIRD
2:45 PM - 5:00 PM	**Professional Development Workshop** • Statistics Workshop: The Mini Masters of Public Health (MPH)
3:45 PM - 4:00 PM	**Break**
4:00 PM - 5:00 PM	**Concurrent Sessions** • (SLC) Cultural Diversity and Infection Prevention • (SLC) Department of Veterans Affairs' Administration (VA's) National MRSA Prevention Initiative: Rising to the Challenge BD • Drug-Resistant Malaria, Dengue Fever BD • Infection Prevention System of the Future: Update 2008 • Law and Order: The Changing Legal Landscape of Healthcare-Associated Infections (HAIs) • Surgical Site Infections (SSI) Technologies and Infection Prevention • (SLC) Tools You Can Use: The APIC HAI Cost Calculator • When to Discontinue Isolation: A Guide for the ICP BD

Wednesday, June 18

6:45 AM - 7:45 AM	**Meet-the-Expert Sessions** • Challenges for ICPs • Construction Challenges • (★) Creating Infection Prevention Networks • Preventing Surgical Site Infections
7:45 AM - 8:00 AM	**Break**
8:00 AM - 3:00 PM	**Posters on Display**
8:00 AM - 9:00 AM	**General Session** • HICPAC Today
9:00 AM - 9:15 AM	**Break**
9:15 AM - 10:15 AM	**General Session** • Surveillance: CDC Infection Definitions - Interactive
10:15 AM - 10:30 AM	**Break**
10:30 AM - 11:30 AM	**General Session** • Disinfection and Sterilization, Current Issues and New Technologies
11:30 AM - 1:30 PM	**Lunch Break**

FEATURED SPEAKERS

Mary Andrus, BA, RN, CIC
Kathleen Arias, MS, CIC
Bonnie Barnard, MPH, CIC
Trish Barrett, BSN, MBA, CIC
Judene Bartley, MS, MPH, CIC
Brenda A. Battle
Oralia V. Bazaldua, PharmD, BCPS
Robert Belknap
Mike Bell, MD
Gail Bennett, MSN, RN, CIC
Joan Blanchard, RN, BSN, MSS, CNOR, CIC
Michael Borg, MD, MSc(Lond), DLSHTM, FMCPath, DipHIC
Suzanne Bradley, MD
PJ Brennan, MD
Vickie Brown, RN, MPH, CIC
Chip Chambers, MD
Libby Chinnes, RN, BSN, CIC
Barbara Citarella, RN, MSN, CHCE
Sara Cosgrove, MD
Nizam Damani, MBBS, MSc, (Lond), FRCPI, FRCPath, CIC
Jeanette Daniel, RN, CIC
E. Patchen Dellinger, MD
Louise Dembry, MD
Jonathan Edwards, MS
Roger Faix, MD
Rosie Fardo, RN, BSN, CHSP, CIC
Janet Frain, RN, CPHQ, CPHRM, CIC
Scott Fridkin, MD
John P. Furuno, PhD
Teresa Garrison, RN, MSN, CNLCP, CIC
Randy Gauvin, MHS, PA-C
Susan Gerber
Rachel Gorwitz, MD, MPH
Carolyn Gould, MD, MSc
Denise Graham
Patti Grant, RN, BSN, MS, CIC
Donna Haiduven, PhD, RN, CIC
Gail Harris, RN, MS, MA, CPHRM, CIC
Loreen Herwaldt, MD
John Hick, MD
Gerald Hickson, MD
Linda Homan, BSN, CIC, CWCN
Diane Hopkins-Broyles, RN, MSN, CIC
Teresa Horan, MPH
Marguerite Jackson, RN, PhD, FAAN, CIC
Marilyn Jones, RN, MPH, CIC
Tobi Karchmer, MD, MS
Doug Keeley
Stephen Kralovic, MD, MPH
Deanie Lancaster, RN, BSN, MHSA, CPHRM, CIC
Terrie Lee, RN, MS, MPH, CIC
Tammy Lundstrom, MD, JD
L. Clifford McDonald, MD
Patricia Metcalf, RN, BSN, CIC
Ona Montgomery, MSHA, RN, CIC
Denise Murphy, RN, MPH, BSN, CIC
Cathryn Murphy, RN, MPH, PhD, CIC
Stacy D. Nelson, EdD
Glen Nowak, PhD
Christine Nutty, RN, MSN, CIC
Carol O'Boyle, RN, PhD
Charles Palenik, MS, PhD, MBA
Marcia Patrick, RN, MSN, CIC
Jeanne Pfeiffer, RN, MPH, CIC
Gregory Poland, MD
Angela Recktenwald, MPH
Deoine Reed, PhD
Kathleen Roye-Horn, RN, CIC
Lole Ruhl, RN, BS
William Rutala, PhD, MPH
Rose Seavey, RN, MBA, CNOR, ACSP
Sue Sebazco, RN, BS, CIC
Emily Sickbert-Bennett, MS, CIC
Barbara Soule, RN, MPA, CIC
Maureen Spencer, RN, M.Ed., CIC
Stephen A. Streed, MS, CIC
Thomas Talbot, MD MPH
Lisa Tomlinson
Akeau Unahalekhaka, PhD (Epidemiology)
Gertie van Knippenberg-Gordebeke
Robert M. Wachter, MD
Ian Williams, PhD, MS
Vicky Zelenka, RN, CIC

Sessions-at-a-Glance (as of 3/12/08)

SLC Located at the Satellite Learning Center (SLC)

◤ Call for Presentations Selections

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Wednesday, June 18 *(continued)*

12:00 PM - 1:00 PM **Meet-the-Experts Sessions**
- Challenges for ICPs
- Construction Challenges
- (★) Creating Infection Prevention Networks
- Preventing Surgical Site Infections

1:30 PM - 2:30 PM **Concurrent Sessions**
- (◤ SLC) Creative Hand Hygiene Programs to Motivate Staff and Visitors
- (◤ SLC) Getting to Zero: The ICP as a Change Agent
- (SLC) Home Health Preparedness
- Health Literacy and What We Teach Patients
- Media Training
- Multi-drug Resistant (MDR) *Acinetobacter* and Gram Negative (GNR) Bacteria BD
- Pandemic Flu Planning in a Rural Community Setting
- Potpourri of Surveillance Definitions

1:30 PM - 4:00 PM **Professional Development Workshop:**
- Risk Assessment for Infection Control Programs

1:30 PM - 5:00 PM **Professional Development Workshop:**
- You Too, Can Write an Abstract

2:30 PM - 2:45 PM **Break**

2:45 PM - 3:45 PM **Concurrent Sessions**
- Elimination of MRSA: The Netherlands Story BD
- Emergency Preparedness
- (◤ SLC) From the Bedside to the Bench: The Evolution of ICP to Researcher
- Got Milk? Infection Prevention Implications for Human Milk and Powdered Formula
- (◤ SLC) Infection Prevention Programs: Prioritize + Organize = Maximize
- MDR/XDR — Tuberculosis BD
- (SLC) Treatment of MRSA Infections and Role for Decolonization BD
- Using Systems Thinking: From Action to Outcome
- (SLC) Weeding Through the Evidence: How to Assess the Medical Literature

3:45 PM - 4:00 PM **Break**

4:00 PM - 5:00 PM **Concurrent Sessions**
- (◤ SLC) "I'm About to Blow a Gasket!" Coping With the Stress of Infection Prevention Program Management
- Infection Related Recalls II: Foodborne Outbreaks
- New HICPAC Guidance on Preventing Catheter-Associated BARD Urinary Tract Infections
- (SLC) Neonatal ICU
- Recommendations for Measurement of Multi-drug Resistant Organisms (MDROs) in Health Care Settings BD
- (◤ SLC) Rivers, Rocks, and Realities: A Fresh Look at Time and Change in our Profession
- Role of Environment in Transmission of Infection
- (SLC) The Future ICP
- The Public Health Epidemiologist: The Bridge Between Public Health and the Hospital

Thursday, June 19

8:00 AM - 9:00 AM **General Session**
- TBD

9:00 AM - 9:15 AM **Break**

9:15 AM - 10:15 AM **General Session**
- (★) Influenza Immunization for Health Care Workers: A Patient Safety Imperative

10:15 AM - 10:30 AM **Break**

10:30 AM - 11:30 AM **General Session**
- The Mark of a Leader

參、心得及建議

此行印象最深刻的事情有三點:國內第一線執行醫院感染管制之工作人員的訓練和管理必須紮實和完整、台灣院內感染監視系統應更強化和發展、院內感染政策之重大變化，以朝向院內感染事件發生「零容忍」之目標。

一、國內第一線執行醫院感染管制之工作人員的訓練和管理必須紮實和完整

唯有完整且紮實的訓練,才能使醫院內感染控制人員成爲醫院其他工作者之角色模範,引領其他工作者遵循感染控制措施。因爲感染控制並非由感染部門獨立完成，而是醫院內各部門之合作和配合，才能達成有效之感染管制。但是如果感控部門的訓練和管理不夠完整和紮實,可能會引領醫院作出錯誤的感染控制措施或使感染控制部門形同虛設。爲推行醫院感染管制和公共衛生政策，感染管制工作需要法制的後援，有完整的法源作爲管制工作的後援外，從條列分明的隔離措施指引及明確的院內感染收案操作型定義可知,所有工作執行皆有可遵循的指引和建議。在美國看到的醫院感控人員非常專業，雖然他們知道院內感染事件發生「零容忍」之目標是一個超凡的遠景，但是他們都願意嘗試且將此當作自己的目標。同時美國也相當注重這些感控人員的訓練，從我們參加他們的研討會和要求他們每年固定在職教育訓練時數來看，國內相關專業和訓練顯仍略顯不足。

二、台灣院內感染監視系統應更強化和發展

美國於 1970 年代開始建置院內感染監視通報系統(NNIS)，至今系統發展已逾 30 年，在這樣久遠的發展歷史下，他們不斷地檢討和進步，造就院內感染系統爲各國公認成功監測的典範。此行 NHSN 的小組長 Teresa 也爲我們安排了豐富且廣泛的院內感染控制議題，且經由業務主辦人一一的和我們進行深入的討論，使我們能藉由討論瞭解院感政策的制定、監測目的和方法及有效執行策略。這樣縝密的分工和合作，也使我瞭解 NHSN 的專業和團隊合作的力量。反觀國內之院內感染系統之推展，本局於 2000 年接管院內感染業務後，積極建置台灣本土之

監視系統，於 2001 年開始推展 NNIS 系統，後於 2007 年啓用台灣院內感染監視系統（TNIS）。台灣的院內感染監視系統起步較慢，而且目前因初步開放使用，有許多設計和欄位也需要進一步的檢討和改進，良好的系統開發應能達到監視和使用者需求兼具的目的，但是這樣的目標需要持續的系統發展和維護，NHSN 強大完整的功能及客製化欄位、圖表分析之設計，都是 TNIS 未來系統發展可以參考的方向。

三、院內感染政策之重大變化

院內感染政策的重大變化可能包含了院內感染的強制通報議題和保險的不給付政策。依據美國 Institute Of Medicine (IOM)的報告指出，每年因爲醫療不良事件造成約有 44,000 至 98,000 人死亡及 1 百萬人傷害，高於同年乳癌、交通事故或愛滋病死亡的人數，居十大死因的第八位，所造成的醫療成本損失更高達 170 至 290 億美元。院內感染事件的發生究竟是否該完全究責於醫院感染控制措施的失效，以消費者的角度觀之，醫院應盡其所能加強院內感染控制，以維護就醫者之權益；以醫院經營者的角度觀之，爲了達成零容忍的院內感染控制，所需付出的代價可能超過其所能負擔的經費；以公共衛生的角度觀之，爲了維護大眾之健康，有效的感染控制措施的必需的。因此美國目前越來越多的州政府開始著手院內感染的法定強制通報，以期達成降低醫療不良事件的發生。而且 CMS 的不予給付政策實施後，也可能連帶影響美國多數的私人保險公司的給付方式，這都是值得國內深入思考的重大政策變化。

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Preparedness, Detection and Control of Infectious Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee
June 12-13, 2008
Atlanta, Georgia

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ATTACHMENT 1

List of Participants

HICPAC Members
Dr. Patrick Brennan, Chair
Dr. Steven Gordon
Dr. Tammy Lundstrom
Dr. Yvette McCarter
Mr. Russell Olmsted
Dr. David Pegues
Dr. Keith Ramsey
Dr. William Schecter
Dr. Nalini Singh
Ms. Barbara Soule [via conference call]
Dr. Kurt Stevenson

Designated Federal Official
Dr. Michael Bell, Executive Secretary

***Ex-Officio* and Liaison Members**
Dr. William Baine (Agency for Healthcare Research and Quality)
Ms. Nancy Bjerke (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Dr. David Henderson (National Institutes of Health)
Ms. Lorine Jay (Health Resources and Services Administration)
Ms. Marion Kainer (Council of State and Territorial Epidemiologists) [via conference call]
Dr. Stephen Kralovic (Veterans Administration)
Dr. Lisa Maragakis (Society for (Healthcare Epidemiology of America)
Ms. Lisa McGiffert (Consumer's Union)
Dr. Sheila Murphey (Food and Drug Administration)
Dr. Mark Russi (American College of Occupational and Environmental Medicine)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)
Dr. Robert Wise (Joint Commission)

CDC Representatives
Dr. Rima Khabbaz, NCPDCID Director
Dr. Denise Cardo, DHQP Director
Mary Andrus
Elise Beltrami
Elizabeth Bolyard
Sandra Bulens
Blake Caldwell
Roberta Carey
Amy Collins
Joanne Cono
Cecilia Curry
Maggie Dudeck
Jonathan Edwards
Scott Fridkin
Carolyn Gould
Jeff Hageman
Rita Helfand
Teresa Horan
John Jernigan
Valerie Johnson
Melanie King
Alexandra Levitt
Tara MacCannell
Clifford McDonald
Marty Monroe
Robin Moseley
John O'Connor
Adelisa Panlilio
Christine Pearson
Joseph Perz
Cathy Rebmann
Kristin Rainisch
Chesley Richards
Lynne Sehulster
Arjun Srinivasan
Wendy Vance
Joni Young

Guest Presenters and Members of the Public
Su Chin-Hsia (Taiwan CDC)
Wei-Hui Chou (Taiwan CDC)

Beth Feldpush
(American Hospital Association)
[via conference call]
James Heilman (3M Health Care)
Tom Keaty (Sage Products)
Nicole Larsen (Medline Industries)
Grace Lee (Eastern Massachusetts
Prevention EpiCenter)
[via conference call]
Hollie Lewis (Cepheid)
James Liddell (Becton Dickinson
Microbiology Systems)
Michele Marill (Hospital Employee Health)
Richard Platt
(Harvard Pilgrim Healthcare)
Jaime Ritter (CR Bard, Inc.)
Matthew Samore
(University of Utah)
Tsag Shu (Taiwan CDC)
Wade Tetsuka (AirlnSpace)
Craig Umscheid (University of
Pennsylvania Health System
Center for Evidence-Based Practice)
Robert Weinstein
(Rush University Medical Center)
Don Wright (Principal Deputy Assistant
Secretary for Health, HHS)

EXECUTIVE SUMMARY

During the opening session of the Healthcare Infection Control Practices Advisory Committee (HICPAC) meeting on June 12-13, 2008, no members declared any new conflicts of interest for the record that were pertinent to the current agenda.

The Division of Healthcare Quality Promotion (DHQP) highlighted results from four Prevention EpiCenters projects: (1) methods to enhance inpatient surgical site infection (SSI) surveillance; (2) the use of Medicare claims data to rank hospitals by SSI risk; (3) a multi-center comparison of electronic algorithms for central line-associated bloodstream infection (CLABSI) surveillance in intensive care units (ICUs); and (4) interventions to reduce infections by daily chlorhexidine bathing. A new EpiCenter project was proposed to prioritize recommended infection control and prevention practices in the United States.

HICPAC agreed to have further discussion on formulating guidance to advance electronic surveillance, piloting EpiCenter algorithms in National Healthcare Safety Network (NHSN) hospitals, and supporting the proposed EpiCenter project to prioritize infection control and prevention recommendations in the United States.

A panel of DHQP staff provided extensive updates on recent field investigations and community outreach campaigns conducted by the Prevention and Research Branch; ongoing efforts to address *C. difficile*-associated disease (CDAD); activities to improve ambulatory care, injection safety and basic infection control practices; and laboratory research projects conducted by the Clinical and Environmental Microbiology Branch.

HICPAC agreed to listen to additional presentations and have more substantive discussions during future meetings before taking formal action to address injection safety and basic infection control practices in outpatient facilities.

The Principal Deputy Assistant Secretary for Health at the Department of Health and Human Services (HHS) described a five-point strategy for HHS to respond to the Government Accountability Office report on healthcare-associated infections (HAIs). HICPAC was given a formal charge to assist HHS in reducing HAI rates.

HICPAC was asked to prioritize the list of recommended clinical practices and develop a global top 10 list across the entire gamut of HAIs. HICPAC was also asked to develop criteria for its guidance to be considered for inclusion in the Centers for Medicare and Medicaid *Conditions of Participation* as either “high-priority prevention interventions” or “high-priority HAIs.”

The HICPAC Chair proposed an approach to respond to the charge from HHS, including initial prioritization of the SSI, catheter-associated urinary tract infection (CA-UTI), and bloodstream infection guidelines. **None of the HICPAC members opposed the approach and all of the members made a commitment to meet HHS’s fall 2008 deadline.**

Updates were provided to describe progress that has been made since the previous meeting on HICPAC’s norovirus, disinfection, healthcare worker vaccination and CA-UTI guidelines. The updates also included a proposed concept for a new ambulatory care guideline; a description of HICPAC’s updated guideline methodology; and preliminary recommendations and grades for the

CA-UTI guideline. HICPAC made a number of suggestions for consideration in revising the preliminary recommendations for the CA-UTI guidelines.

The HICPAC workgroups reported on their respective activities since the previous meeting. The HAI Preventability Workgroup presented the "Mortality from Reasonably Preventable HAIs" document. The workgroup agreed to revise the document based on HICPAC's comments and suggestions. The Guideline Methods Workgroup described key sections of a companion paper that would be released with the CA-UTI guideline to summarize HICPAC's updated guideline methodology.

The Model Legislation Workgroup outlined its continued efforts to compile existing HAI legislation in each state and begin drafting a document to assist groups in writing new or adapting existing legislation. The National Patient Safety Goal (NPSG) Workgroup reviewed its letter that was sent to the Joint Commission in June 2008 to outline HICPAC's concerns with the NPSGs proposed for 2009.

HICPAC's liaison and e*x-officio* members submitted written reports on recently completed, ongoing and upcoming activities of their respective organizations and agencies.

The DHQP Surveillance Branch provided a comprehensive update on its ongoing research, particularly a study to (1) determine differences between the percentage of methicillin-resistant *Staphylococcus aureus* (MRSA) and MRSA incidence using CLABSIs as a candidate infection among ICU patients and (2) characterize actual trends and incidence of MRSA and methicillin-sensitive *Staphylococcus aureus* CLABSI rates by different ICU types.

DHQP's summarized its other activities, including a MRSA surveillance project through the Emerging Infections Network; efforts to respond to the tremendous growth of NHSN over the past year; and a new CDAD and multidrug-resistant organism module for facilities to report proxy measures that can be populated by electronic data sources.

HICPAC agreed to take several actions to respond to recommendations that were specifically directed to HICPAC during the External Peer Review of the DHQP Surveillance Branch in May 2008. HICPAC would develop a new surveillance guidance document in collaboration with a broad range of partners and stakeholders. HICPAC would create a risk assessment template for facility- and setting-based application.

The HICPAC Chair would draft a letter to express HICPAC's formal support for additional technical and financial resources for DHQP to respond to the tremendous growth of NHSN. HICPAC would explicitly endorse NHSN as the standard for HAI surveillance in the new surveillance guidance document.

Business items that were raised over the course of the meeting were reviewed, including HICPAC's future discussion on the evidence base for flash sterilization.

The next HICPAC meeting would be held on November 13-14, 2008 at the Georgetown Marriott Hotel in Washington, DC.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Preparedness, Detection and Control of Infectious Diseases
Division of Healthcare Quality Promotion

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
June 12-13, 2008
Atlanta, Georgia

Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on June 12-13, 2008 at CDC's Global Communications Center, Building 19, Auditorium B3, in Atlanta, Georgia.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:07 a.m. on June 12, 2008. He welcomed the attendees to the proceedings and opened the floor for introductions. No members declared any new conflicts of interest for the record that were pertinent to the June 12-13, 2008 HICPAC agenda. The list of participants is appended to the minutes as Attachment 1.

Dr. Brennan announced that due to the volume of HICPAC's agendas, the meeting format would be revised to streamline oral reports by the liaison and *ex-officio* members. However, he confirmed that written reports submitted by the liaison and *ex-officio* members would continue to be a part of HICPAC's official record in their entirety.

Dr. Michael Bell, Designated Federal Official of HICPAC, was pleased to announce that Ms. Wendy Vance was recently appointed to serve as HICPAC's Committee Management Specialist on a full-time basis.

Update on the Prevention Epicenter Program

Dr. John Jernigan, of DHQP, explained that funding for the current EpiCenters was awarded in February 2006 to investigators at the University of Utah, Ohio State University, Washington University in St. Louis, Rush University Medical Center, and Harvard Pilgrim Health Care. He highlighted results of four EpiCenter projects.

Project 1 examined methods to enhance inpatient surgical site infection (SSI) surveillance. The premise of the study was that routinely collected inpatient pharmacy and discharge diagnosis codes could be used as a more sensitive and efficient method for detecting SSIs than traditional surveillance. The study focused on Surgical Care Improvement Project (SCIP) procedures.

The study design included the identification of all procedures with SSIs by routine surveillance and a random sample of 200 other procedures with no known SSI at each hospital. Medical records were retrospectively re-reviewed for antibiotic exposure and ICD-9 codes. National Healthcare Safety Network (NHSN) criteria were used to reassess SSI classifications.

Antibiotic duration during index hospital stay, discharge diagnosis codes, and readmission with antibiotics during 30 days were used as markers to identify SSIs in seven procedures: coronary artery bypass graft (CABG), craniotomy, hysterectomy, hip replacement, Caesarian section, knee replacement and breast surgery.

The study showed that routine surveillance failed to detect some SSIs. Enhanced surveillance in the smaller group of hospitals that met antibiotic exposure or discharge code criteria was more sensitive in detecting SSIs than routine surveillance. Enhanced surveillance most likely would require less effort than routine surveillance of all patients in many hospitals because fewer charts would need to be reviewed and more infections would be detected. Enhanced surveillance also would provide hospitals with a standardized approach to case finding.

Project 2 ranked hospitals by SSI risk using Medicare claims data. The study was conducted because traditional identification of SSIs is hospital-dependent, incomplete and non-uniform. Two key hypotheses guided the study. Medicare claims data can be used to standardize identification of possible SSIs following CABG surgery. Hospital-specific SSI rates based on Medicare claims can be used to rank hospitals. The EpiCenters developed claims-based indicators of SSIs to distinguish between hospitals with high and low SSI rates.

The study goals were to use selected claims codes and apply an algorithm to 2005 Medicare claims data to identify SSIs; identify hospital outliers with high SSI risk post-CABG; refine codes using EpiCenters as the test bed; and validate this approach in a national sample of U.S. hospitals. The Centers for Medicare and Medicaid Services (CMS) database showed that in 2005, 671 U.S. hospitals performed ≥80 CABGs in Medicare patients. Preliminary data showed that interventions could be beneficial because infection rates were higher in the 671 hospitals.

In the national validation phase of the study, CMS will request records from flagged patients in a sample of the 671 hospitals in both the top and bottom deciles. NHSN criteria will be used to

review and assess records to validate SSIs that were identified. The records also will be evaluated to determine differences between the percentage of validated SSIs in the top and bottom deciles. The review of 2,500 charts will begin in the summer of 2008.

Project 3 was a multi-center comparison of electronic algorithms for central line-associated bloodstream infection (CLABSI) surveillance in intensive care units (ICUs). The aim of the study was to determine whether electronic algorithms could be an acceptable surrogate for manual surveillance by infection control practitioners (ICPs) in measuring CLABSI rates.

During the 2004-2006 project period, 20 ICUs at four medical centers submitted data for 47 unit periods that included 311,602 patient-days and 210,684 central-line days. All units conducted prospective determinations of BSI rates using standard NHSN methods and ICPs. Electronic algorithms and definitions were applied retrospectively to identify BSIs.

Phase II of the BSI algorithm project will be launched because the electronic detection method appeared to identify more SSIs than ICPs. Three primary and secondary objectives have been established for Phase II of the study. Sources of variability between ICP and algorithmic CLABSI determinations will be assessed. A determination will be made on whether the second ICP review more often agreed with electronic or prior manual determinations. Results from the second ICP review will be extrapolated to the entire sample and unit-specific BSI rates will be calculated and compared to those determined by primary manual and electronic determinations.

To further analyze the tremendous variability between ICP and algorithmic determinations, a computer simulation was performed of hospitalized ICU patients who had catheters placed and removed, developed infections and had cultures drawn. Moreover, surveillance performance characteristics of individual ICPs were simulated. The model also used two methods to perform surveillance with simulated data after patient discharge: traditional or subjective criteria applied by simulated ICPs and automated or objective criteria.

The simulated approach to CLABSI surveillance generated a number of benefits. Each surveillance method can be compared with a true gold standard rather than each other. The tradeoff between validity and reliability of the two methods can be examined. Performance in estimating true CLABSI rates can be analyzed and actual hospital rank order can be estimated. The preservation of rank order can be assessed using Kendall's Tau rank correlation method.

Overall, results of the simulated model suggested that objective criteria were less accurate than subjective criteria in estimating the true BSI rate of an individual facility. However, objective criteria appeared to provide more accurate estimates of true differences in BSI rates between institutions.

Project 4 analyzed interventions to reduce infections by daily chlorhexidine (CHG) bathing. The ICU-based intervention included daily skin cleansing with 2% CHG-impregnated cloths, no rinse and avoidance of CHG-incompatible lotions. The study outcomes included multidrug-resistant organism (MDRO) incidence, vancomycin-resistant *Enterococcus* (VRE) transmission and BSIs. Three trials were implemented in two hospitals with the following time series: pre-intervention

using soap and water, the actual intervention using CHG cloths, post-intervention using cloths without CHG, and post-intervention using soap and water.

The results showed major reductions in primary bacteremia, central venous catheter-associated bacteremia, and contaminated BSIs in medical ICUs. Decreases also were observed in VRE cross-transmission as well as clinical incidence of MDRO from VRE and methicillin-resistant *Staphylococcus aureus* (MRSA) clinical cultures in medical ICUs. No emergence of CHG resistance was detected in any of the trials.

In addition to the four projects Dr. Jernigan highlighted, he also described other EpiCenter studies that are underway: (1) a statewide *Clostridium difficile* (*C. difficile*) infection prevention collaborative in Ohio; (2) electronic alerts of MRSA carriage and unnecessary urinary catheter use; and (3) use of electronic data to measure *C. difficile* infection, quantify antimicrobial use, and measure ventilator-associated pneumonia (VAP) and other ventilator-associated morbidity.

Dr. Grace Lee, of the Eastern Massachusetts Prevention EpiCenter, described a potential EpiCenter project to prioritize recommended infection control and prevention practices in the United States. The EpiCenters are proposing this effort because CDC has released 13 guidelines and 1,200 recommended practices for hospitals on infection control and prevention.

CDC's guidelines focus on the strength of the evidence for each recommendation and strongly encourage 500 practices. However, prioritization is implicit in the guidelines and no further guidance is given on strategies to prioritize these practices. The lack of prioritization may hinder efforts to promote implementation of the guidelines. The goal of the proposed EpiCenter project is to provide decision-makers with a framework for prioritizing infection control and prevention recommendations in the United States.

A decision analysis framework would be the basis of one potential approach to the proposed project. A policy decision would be made to implement either "strategy A" with the status quo or "strategy B" with a new intervention. An HAI would have a more likely chance of occurring in strategy A compared to strategy B. However, potentially negative consequences would need to be considered in implementing both of the strategies.

A cost-effectiveness analysis (CEA) that is built on the field of decision analysis would be the basis of another potential approach. This strategy would incorporate probabilities, costs and utilities and also would measure the cost per case prevented and the cost per quality-adjusted life year (QALY) saved as outcomes. On the one hand, a strategy would not be adopted if health outcomes are worse with a new intervention. On the other hand, a strategy would be adopted if health outcomes are improved by a new intervention and cost less than current practices.

A CEA framework generates a number of benefits. Transparency can be promoted by explicitly stating assumptions that would be included in a model. Outcomes or health benefits associated with each strategy can be quantified. Hospitals can be advised on approaches to invest limited resources to maximize the health impact of their patient populations. Tradeoffs can be clarified when one strategy is implemented versus another.

A CEA framework also has several limitations. The quality of data that are used to inform model input will affect outcomes. A common metric is needed because all QALYs are not equal. Equity and value judgments are an important part of the decision-making process, but are not included in a CEA framework.

Institute of Medicine (IOM) Committees published two reports in 1985 and 2000 in an effort to prioritize infection control and prevention recommendations: (1) *New Vaccine Development: Establishing Priorities in the United States and Developing Countries* and (2) *Vaccines for the 21st Century: A Tool for Decision-Making*. Both reports used a quantitative model to prioritize vaccine development, but the 2000 report also used a CEA framework to prioritize vaccines that would warrant future investments to maximize the health of the U.S. population. Another IOM Committee is currently reviewing priorities in the HHS National Vaccine Plan.

In the EpiCenters proposed project, current guidance would be reviewed with an expert panel to particularly focus on the 500 practices that CDC strongly recommends. Evidence for the guidance would be assessed and the feasibility of using a CEA framework would be evaluated. Based on the quality and quantity of data, a core model would be developed to estimate the net health benefits and costs of each recommended intervention.

Probabilities, costs and utilities included in the model would be based on the published literature, empiric data to supplement unavailable published estimates and expert panel opinion. EpiCenter hospitals could serve as a potential source to fill data gaps in cost estimates, probability estimates or utilities.

The outcomes of the proposed project would include costs, health benefits, cost per case prevention, and cost per QALY saved. Sensitivity analyses would be performed to better understand changes in results of the model as key assumptions varied over plausible ranges. The project also could be designed to identify potential areas of future research.

Dr. Denise Cardo, Director of DHQP, made several remarks for HICPAC to consider in its discussion. The overarching goal of the EpiCenters is to improve and enhance the specificity of methods for detecting BSIs, SSIs and other healthcare-associated infections (HAIs). The application of EpiCenter data is a critical need at this time to minimize confusion in the field, avoid competition between ICPs and electronic algorithms, and address other unintended consequences or barriers.

Dr. Cardo asked HICPAC to provide formal recommendations or develop a new guideline to assist DHQP in applying current EpiCenter data to actual practice on a larger scale. HICPAC's advice could help DHQP to identify gaps to guide the development of future EpiCenter projects. She also requested HICPAC's leadership and expertise to support additional resources DHQP would need to meet the growing demand that is placed on NHSN. Most notably, the nation expects NHSN to improve surveillance through enhanced case detection, stronger data validation, and increased use of electronic algorithms.

HICPAC thanked the Prevention EpiCenter Principal Investigators for joining the meeting to answer questions and provide clarification on their innovative projects. Several HICPAC

members made comments and suggestions to advance the research projects of the Prevention EpiCenter Program.

- EpiCenter algorithms and other methods should be piloted in a sample of NHSN hospitals due to the history of these institutions in collaborating with CDC and collecting HAI data. HICPAC could use outcomes from the pilot to determine whether EpiCenter methods could be applied nationally.
- The EpiCenter pilot should include institutions with solid experience in using electronic tools and data and should not be limited to NHSN hospitals. This strategy could address the disconnect between institutions that use electronic data and the broader infection control community. For example, ICPs in some states do not use discharge or coded data as a tool to assess hospital quality, ranking or comparisons. Other ICPs at the state level have limited knowledge or are unfamiliar with the role and function of NHSN.
- The EpiCenters should expedite the timeline to publish data from their studies in the peer-reviewed literature. This approach would assist HICPAC in providing evidence-based guidance to DHQP.
- The EpiCenters should explore the possibility of developing electronic or non-electronic algorithms for detection of catheter-associated urinary tract infections (CA-UTIs) as a future project. This effort would be extremely useful to HICPAC's development of the CA-UTI Guideline.
- The EpiCenters should strengthen their focus on children in future projects because the prevention of BSIs would result in enormous cost of life-years saved in the pediatric population.
- The EpiCenters should consider the possibility of incorporating a "value stream analysis" in a CEA framework. This approach ranks interventions based on those in which clinicians are most or least willing to fund.
- The EpiCenters should address issues that typically have not been the focus of CEAs. For example, the non-linearity of effects of infection control interventions have not been adequately addressed, such as the indirect impact on patients who do not receive interventions due to transmission of infectious diseases. Simulated models would play a significant role in better understanding non-linear dynamics and effects. Moreover, problems with estimating the cost-effectiveness of preventing infections have not been resolved to date due to tremendous flaws in traditional methods. The EpiCenters should attempt to address this issue in the proposed project to prioritize infection control and prevention recommendations in the United States.
- The EpiCenters should promote a stronger research agenda to implement guidance for the infection control and healthcare community.

Dr. Brennan confirmed that HICPAC would have further discussion on the suggestions for HICPAC to formulate recommendations to advance electronic surveillance, pilot EpiCenter algorithms in NHSN hospitals, and support the proposed EpiCenter project to prioritize infection control and prevention recommendations in the United States.

Update on DHQP Activities

Dr. Arjun Srinivasan, of DHQP, described recent field investigations and other ongoing activities conducted by the Prevention and Research Branch (PRB). PRB is evaluating infection control practices at ambulatory surgical centers (ASCs) in Oklahoma and also is investigating an outbreak *of Group A Streptococcus* infections in a long-term care facility (LTCF) in Nevada.

PRB investigated transmission of lymphocytic choriomeningitis virus to two recipients in Massachusetts from an organ donor that had neurologic abnormalities pre-mortem. The investigation resulted in discussions with the organ transplant community about developing guidelines for evaluating neurologic abnormalities in organ donors.

PRB investigated the sudden increase in cardiac arrests and severe adverse events at a dialysis center in Texas. Because the investigation raised the possibility of intentional wrongdoing by an employee, a criminal investigation is ongoing. PRB reviewed infection control practices at ASCs in Nevada.

PRB recently led a field investigation of bleeding deaths among dialysis patients in the District of Columbia, Maryland and Virginia. The investigation indicated issues with access failure and preceding access complications in some patients. PRB is attempting to determine potential risk factors to identify the types of patients who might be at risk for bleeding events.

PRB investigated anaphylactic reactions at a pediatric dialysis center in Missouri. The investigation found an association between adverse reactions and receipt of heparin; led to a national investigation by CDC and the Food and Drug Administration (FDA) that identified oversulphated chondroitin sulphate (OSCS) in multiple heparin products; and resulted in the development of a new screening test for OSCS. The contaminated heparin products have since been recalled.

PRB's investigation of a *Burkholderia cepacia* outbreak that was associated with contaminated mouthwash led to an initial national recall of one lot of product and subsequent market withdrawal of mouthwash made by the company. The investigation increased PRB's knowledge of a common misunderstanding in healthcare facilities about "voluntary recalls." PRB and FDA are collaborating to educate and better inform medical providers about voluntary recalls.

PRB is continuing to receive telephone calls and requests for assistance on investigations of outbreaks of multidrug-resistant *Acinetobacter*, cases and outbreaks of *Klebsiella pneumoniae* carbapenemase (KPC)-producing organisms, and cases of *C. difficile* and MRSA.

At the division level, DHQP is partnering with an advertising company to develop a community MRSA educational initiative to educate patients and providers on the recognition and management of MRSA skin and soft tissue infections (SSTIs). The national campaign will be targeted to mothers with lower socioeconomic status as the patient audience and primary care and emergency department physicians as the provider audience.

Two key messages will be delivered to the patient audience in the MRSA campaign. MRSA SSTIs are preventable and treatable. Patients should know the signs of an SSTI and obtain help

early. Providers will be encouraged to consider MRSA as an important cause of SSTIs and appropriately diagnose and treat these infections. At this time, educational and advertising materials are being market tested and finalized. DHQP intends to launch the MRSA campaign nationally in the fall of 2008.

DHQP is leading the effort to revitalize a previous campaign that was designed to prevent antimicrobial resistance in healthcare settings. In the updated campaign, emphasis will be placed on four major strategies rather than 12 steps. The website will be revamped with descriptions of activities that have been successful in curtailing antimicrobial resistance. DHQP is increasing its efforts to improve antimicrobial use and is also closely collaborating with the "Get Smart" Program to coordinate activities. DHQP welcomes input from HICPAC on both the MRSA and antimicrobial resistance campaigns.

Dr. Clifford McDonald, of DHQP, described DHQP's continued efforts to address *C. difficile*-associated disease (CDAD). The Agency for Healthcare Research and Quality (AHRQ) recently published a national inpatient sample of hospital discharges that showed a marked increase in the total number of hospital discharge diagnoses of *C. difficile* since 2000. Data collected in 2006 showed that *C. difficile* is continuing to increase.

At the state level, Ohio mandated public reporting of all *C. difficile* cases in hospitals and nursing home in 2006. Of 14,000 cases reported in the state since that time, >50% occurred in nursing home settings. A review of death certificates in Ohio showed a sharp increase in the number of deaths with *C. difficile* listed as the primary cause of death.

DHQP extrapolated Ohio data to the U.S. population and estimated the national burden of *C. difficile* to be 475,000 cases and 23,000 deaths in hospitals or nursing homes after adjusting for missing data. However, DHQP recognizes that the onset of *C. difficile* in hospitals and nursing homes most likely accounts for only 50% of the total burden.

DHQP also acknowledges that better data are needed on the actual costs and outcomes of *C. difficile* to prioritize recommendations for this infection. To support this effort, the St. Louis Prevention EpiCenter analyzed *C. difficile* in a hospital-based endemic setting over one year. Based on index hospitalization or 180 days as markers, the study showed excess costs of $5,000 per case or a total of >$1 billion in excess healthcare costs from *C. difficile* alone. The study also found that *C. difficile* accounted for ~6% of attributable mortality in an endemic setting and 15,000-30,000 excess deaths.

DHQP recently investigated a *C. difficile* outbreak in a Baltimore hospital. Because traditional infection control measures were not effective, the hospital consulted with DHQP and removed all fluoroquinolones from its formulary. This approach led to a decrease in *C. difficile* cases. The investigation indicated unnecessary antimicrobial use in many hospitals because antibiotic usage is one of the most important drivers for *C. difficile* in healthcare settings.

In addition to healthcare settings, *C. difficile* is also causing problems in unique populations. DHQP recently reported on ten cases in pregnant women of which six were hospitalized in ICUs for toxic megacolon, five required colectomies, three died, and three lost their babies.

To address the burden of *C. difficile*, DHQP published recommendations in 2008 on conducting surveillance of this infection. Data from six hospitals that applied the *C. difficile* guidance showed 50%-60% of all cases were healthcare-onset and 44% were community-onset. Connecticut published data in April 2008 on statewide community-associated cases and found that ~30% of cases had no previous antibiotic use in the three months preceding symptom onset and ~30% of cases had no underlying conditions.

Data from DHQP, Connecticut and hospitals confirmed that community-associated disease represents a small proportion of the total burden. The most critical control point for the majority of *C. difficile* cases continues to be the interruption of transmission and control of antibiotic use in healthcare settings.

DHQP is partnering with veterinary researchers to analyze the incidence of *C. difficile* in food-producing animals. An epidemic strain that was commonly found in pigs and cattle is now increasingly being detected in humans in the community. Typing data suggested possible migration of *C. difficile* from food-producing animals to humans. A survey that was administered to collect and characterize 92 isolates from nine states showed a larger variation in community strains then hospital strains.

Overall, the continued increase in *C. difficile* rates, mortality and costs is primarily associated with a human epidemic strain. The increase is more notable in previously low-risk populations, such as community residents and pregnant women. Ecological evidence indicates the potential for transmission of virulent strains of *C. difficile* from food-producing animals to humans, but this migration accounts for an extremely small proportion of all human *C. difficile* disease. Human-to-human transmission still accounts for the vast majority of *C. difficile* disease in humans.

Dr. Joseph Perz, of DHQP, reported on DHQP's activities to improve ambulatory care, injection safety and basic infection control practices. Outpatient care has grown to ~1.2 billion outpatient visits per year in the United States. In 2005, 4,755 dialysis centers and 4,445 ASCs were operating in the United States. These numbers represent increases of 65% and 210%, respectively, in the growth of these facilities since 1996. Outpatient facilities account for significant infection-related morbidity and mortality and serve as important settings in terms of the emergence of antibiotic-resistant patterns.

Healthcare delivery has shifted from acute care settings to ambulatory care, long-term care and free-sanding specialty care sites. However, these settings often lack infection control oversight and present an emerging threat to patient safety. Outbreaks associated with unsafe injection practices and breakdowns in basic control practices are increasing in outpatient facilities.

In January 2008, a cluster of three acute hepatitis C virus (HCV) cases was identified in an endoscopy clinic in Las Vegas. All three patients underwent procedures at the same clinic during the incubation period. The clinic performed 50-60 upper and lower endoscopies per day. A review of surveillance records, laboratory records and a physician report identified three additional cases associated with the clinic.

The investigation showed that unsafe injection practices most likely led to HCV transmission in the endoscopy clinic. Some providers used old syringes with new needles to draw more anesthesia and also used medication remaining in the vial to sedate the next patient. This practice was a major breach in infection control because the vials were labeled for single rather than multiple use. The endoscopy clinic was immediately advised to stop unsafe injection practice, but the clinic was eventually closed after its license was revoked.

The investigation also found that some clinic staff had commonly used unsafe practices for at least four years. Due to this period of time, the local health department began notifying ~40,000 patients and recommending HCV, HIV and hepatitis B virus (HBV) screening. CDC and its partners assisted Nevada in performing rapid assessments of infection control practices at all licensed ASCs in the state.

In 2007-2008, three incidents of syringe reuse that occurred in a variety of outpatient settings in New York City, Michigan and Long Island, New York resulted in notification to and testing of patients for HBV, HCV and HIV. Administration of anesthesia during outpatient procedures was the common factor in all of the outbreaks. Additional incidents included syringe reuse during influenza vaccination and kidney failure in three patients subjected to unsafe cosmetic injections. All of the outbreaks have received intense press coverage and legislative interest.

In the *2007 Isolation Precaution Guideline*, CDC acknowledged the transition of healthcare delivery from primarily acute care hospitals to outpatient settings. CDC also reaffirmed its 1996 standard precautions as the foundation for preventing transmission of infectious agents in all healthcare settings. CDC cited HBV and HCV outbreaks in ambulatory settings as a strong evidence base for the need to reiterate safe injection practice recommendations as part of standard precautions.

At this time, CDC is making stronger efforts to disseminate its previous guidance to assure that all healthcare workers consistently adhere to and implement basic infection control practices. For example, CDC is collaborating with CMS and state licensing and certification agencies. CDC's tool that was used to administer special surveys to ASCs in Nevada will be replicated in three other states to more heavily focus on injection safety and other basic infection control practices.

CDC is continuing its dialogue on this issue with FDA and professional groups, developing and disseminating educational materials, and conducting outreach. CDC is also participating in a pilot campaign targeted to patients and providers on injection safety and basic infection control practices.

Dr. Roberta Carey, of DHQP, provided an update on ongoing laboratory activities conducted by the Clinical and Environmental Microbiology Branch (CEMB). From 2007-2008, CEMB has played an integral role in >41 outbreaks involving >1,900 specimens. Intrinsic contamination of healthcare items has contributed to transmission of infection through heparin pre-filled syringes, alcohol-free mouthwash, fentanyl chloride, packed red cells, pooled platelets and infant formula.

Contaminated healthcare items have resulted in transmission of *Serratia marcescens*, *Group C Streptococcus*, *Burkholderia vanimaris*, *Sphingomonas paucimobilis*, *Yersinia enterocolitica*, and

Enterobacter sakazakii. Reuse of syringes, needles, multi-dose vials of drug products and other lapses in infection control practices during healthcare delivery have contributed to transmission of infection from extrinsic contamination.

CEMB develops and evaluates sampling and processing methods for recovery of emerging pathogens from environmental surfaces. This effort has led to CEMB detecting environmental infection, including *C. difficile* and *Acinetobacter baumannii* transmission from contaminated portable x-ray machines, intravenous poles, bedrails, sinks and counters.

CEMB developed genetic typing databases to characterize emerging pathogens, such as *Burkholderia* in mouthwash. CEMB is currently developing and evaluating disinfection protocols to enhance intervention strategies, including disinfection of healthcare environmental surfaces and chlorine and mono-chloramine disinfection of nontuberculous mycobacteria biofilms.

CEMB is continuing to address KPC. KPC is a class A β-lactamase that confers resistance to all β-lactams, such as extended-spectrum cephalosporins and carbapenems. KPC is most common in *Klebsiella pneumoniae*, but has also been reported in *Klebsiella oxytoca*, *Serratia*, *Citrobacter freundii*, *Enterobacter*, *Salmonella*, *Escherichia coli*, and Pseudomonas aeruginosa in Colombia and Puerto Rico.

KPC isolates most frequently have been detected in Delaware, Long Island, New Jersey and Pennsylvania, but sporadic isolates have been observed in other parts of the country and sent to CEMB for characterization and validation. Risks for an infection with KPC include hospitalized patients with an increased number of co-morbid conditions, frequent or prolonged hospitalization, invasive devices or antimicrobial exposure. Carbapenemase-producers are most frequently isolated from urine or blood.

CEMB's methods focus on sensitivity and specificity to detect KPC in the laboratory and inform clinicians and ICPs of a problem. With imipenem, sensitivity ranges from 42%-94% and specificity ranges from 93%-28%. With meropenem, sensitivity ranges from 48%-94% and specificity ranges from 96%-100%. With ertapenem, sensitivity ranges from 90%-100% and specificity ranges from 81%-93%.

KPC should be considered with *Enterobacteriaceae*, particularly *Klebsiella pneumoniae* that are resistant to extended-spectrum cephalosporins. However, a more detailed examination should be performed with a carbapenem minimum inhibitory concentration of 2 or 4 µg/mL. A disk diffusion also can be performed with ertapenem or meropenem to determine whether the zone of inhibition range decreases to $\leq$22 mm. Although imipenem is most commonly tested, the drug is a poor predictor of KPC.

After KPC is detected, molecular testing should be performed to confirm the presence of the organism. Because CEMB is not equipped to handle the numerous flood of requests for molecular testing across the country, clinical laboratories should confirm KPC with a modified Hodge test.

CEMB is also focusing on nine vancomycin-resistant *Staphylococcus aureus* (VRSA) cases. Of these nine cases, seven unique VRSA isolates were detected in Michigan. The outcomes of the Michigan VRSA cases were that *S. aureus* maintained VRE *vanA* plasmid and TN*1546*-like elements integrated into *S. aureus* plasmid. CEMB also found that a unique Inc18-like *vanA* plasmid was associated with five of the seven Michigan VRSA isolates, more often found in the Michigan VRE cases than other geographical locations, and more frequently observed in *Enterococcus faecalis* than other VRE species.

CEMB analyzed 1,034 isolates from the Active Bacterial Core Surveillance System that were found in invasive disease to examine pulse field types. USA100 and USA500 strains are most common in HAIs. The analysis showed that >91% of these infections occurred in healthcare settings or community settings with a healthcare background. The majority of USA300 strains occurred in community settings, but 11% occurred in hospitals. Only three USA300 pulse field types accounted for 84% of all USA300 patterns, while multiple USA100 pulse field types caused infections in hospital settings.

CEMB is partnering with Emory University to conduct a MRSA carriage study in an HIV-positive population. The study design includes nares and groin screening of methicillin-sensitive *Staphylococcus Aureus* (MSSA) among 601 patients enrolled at their routine clinic visits as the baseline; follow-up screening at six- and 12-month intervals; and a comparison of the sensitivity between direct plating and broth enrichment.

Preliminary results showed that 31% of patients had MSSA with nares of 27% and groin positivity of 18%. These findings were similar to nasal carriage data from the National Health and Nutrition Examination Survey (NHANES). The study also showed that 13.5% of patients had MRSA with nares of 11% and groin-positivity of 8%. These findings were nearly ten times higher in the study population of HIV patients than healthy adults in NHANES. The inclusion of groin cultures in the study led to the detection of an additional 3% of positive patients. The inclusion of enrichment broth led to the detection of an additional 15% of positive nasal cultures and an additional 29% of positive groin cultures.

HICPAC thanked the panel of presenters for providing comprehensive updates on DHQP's ongoing field investigations, community outreach activities, research projects and laboratory studies. Several members suggested next steps that HICPAC and CDC should consider to improve healthcare infection control practices.

- HICPAC should formulate guidance to emphasize the critical need for outpatient facilities to designate a staff member to oversee injection safety and basic infection control practices on a full-time basis.
- CDC should partner with the Joint Commission, American College of Surgeons and other organizations to use the recent syringe reuse incidents as an opportunity to create a professional organizational structure and culture for outpatient facilities. This strategy could promote more effective implementation of policies in these settings.
- HICPAC should engage and solicit input from outpatient facilities in the development of future guidelines. For example, ASCs and other outpatient settings do not believe that HICPAC guidelines apply to their facilities.

- HICPAC should recommend the development of training and education initiatives to assure competencies in safe injection practices for physicians, physician assistants and mid-level practitioners. HICPAC's guidance in this area also should emphasize the need to incorporate basic infection control practices into medical school curricula.
- CDC should attempt to link to ongoing efforts in some states that require ASCs to report infections.

Dr. Brennan explained that HICPAC would take no formal action at this time on injection safety and basic infection control practices in outpatient facilities due to the tremendous magnitude and scope of the problem. He advised HICPAC to carefully review and consider the information that was presented during the meeting. He confirmed that additional presentations and more substantive discussions would be placed on future agendas. Dr. Brennan also pointed out that during its business session on the following day, HICPAC would discuss the development of a new ambulatory care guideline.

Dr. Bell agreed with Dr. Brennan's approach for HICPAC to address this complex issue in a step-wise process over time. Most notably, HICPAC would need to engage a number of interest groups and stakeholders in its discussions, including organizations representing surgeons, nurse anesthetists, gastroenterologists, peri-operative registered nurses, epidemiologists and ICPs. Dr. Bell also noted that HICPAC's guidance would need to address flaws in professional education at all levels, retention of institutional accreditation and professional requirements.

Overview of HHS's Role in Reducing HAI Rates

Dr. Don Wright is the Principal Deputy Assistant Secretary for Health at HHS. He reminded HICPAC that the Government Accountability Office (GAO) issued its report on HAIs in March 2008 with a focus on three key areas: (1) CDC's preventive guidelines and activities supported by HHS to promote implementation of the recommendations; (2) accreditation efforts to reduce HAIs; and (3) identification, integration and interoperability of HHS's data collection systems.

GAO made a number of recommendations to HHS based on its in-depth study of HAIs. CDC's recommended clinical practices should be prioritized to promote implementation of high-priority practices and assure compliance in hospitals. The prioritized recommendations should be considered for inclusion in CMS's *Conditions for Participation*. Consistency, compatibility and interoperability of data collected across HHS should be enhanced to increase the reliability and robustness of national estimates of HAIs.

In April 2008, Dr. Wright provided HHS's formal response to the GAO report during testimony before the House Oversight and Reform Committee. He focused his remarks on four major areas: (1) HHS's successful efforts in the prevention of HAIs, including the development of outstanding guidelines by HICPAC and CDC; (2) improved quality and robustness of monitoring and surveillance through HAI reporting to NHSN by nearly 1,500 hospitals; (3) value-based purchasing to create incentives and pay for healthcare quality rather than quantity; and (4) regulatory approaches to facilitate quality improvement research.

After the Congressional testimony, the Deputy Secretary of HHS charged Dr. Wright with developing a plan to address flaws and areas of improvement outlined in the GAO report. In response to this directive, Dr. Wright created a five-point strategy that will be implemented over the next few months.

Strategy 1 is the establishment of a new "HHS Steering Committee on HAI Reduction." The membership of the Steering Committee will be limited to representatives of HHS agencies with no outside participation. The Steering Committee will be charged with developing national goals for reducing HAIs, such as "decreasing HAIs by 60% in five years." The national goals and strategies will be transparent to CDC, AHRQ, CMS, FDA and other HHS operating divisions.

The Steering Committee will be responsible for creating benchmarks, tracking progress and measuring success in reducing HAIs at three intervals: 1-2 years for short-term goals, 3-5 years for mid-term goals, and 5-10 years for long-term goals. For example, interoperability of information technology, computer systems and data sets across HHS agencies most likely would be a long-term goal. The Steering Committee also will develop approaches to coordinate and leverage HHS resources to accelerate and maximize impact.

Strategy 2 is the prioritization of recommended clinical practices and will be implemented in partnership with HICPAC. HICPAC will be charged with prioritizing the existing 1,200 recommended infection control and prevention practices and developing two top 10 lists. The "global" top 10 list will cover the entire gamut of HAIs rather than a single class of HAIs and will serve as the platform for a National Prevention Campaign to raise awareness throughout the country of the importance of lowering HAI rates.

The global list will also help to guide the administration of CMS hospital surveys; incorporate an infection control perspective into the hospital accreditation process; and assist CDC and AHRQ in translating recommendations into practice programs. The "secondary" top 10 list will prioritize and bundle individual classes or anatomic locations of HAIs, such as catheter-induced BSIs. This list will be distributed to hospitals to assist in decreasing the incidence of HAIs.

The top 10 lists will not be intended to minimize the importance of the other recommended clinical practices. Instead, the top ten lists will serve as a mechanism for hospitals to focus on the most critical recommendations. Moreover, the top 10 lists might change as new data emerge and research gaps are filled over time.

Strategy 3 is the improvement of hospital regulatory oversight and compliance and will be implemented in partnership with CMS, the Joint Commission and the American Osteopathic Association. The partners will administer infection control practice surveys as a part of their routine surveillance processes. Trade associations, professional societies and other groups with similar missions will be engaged as needed.

The possibility of including recommended infection control practices in the *Conditions for Participation* will be explored with CMS. DHQP will be asked to collaborate with its partners to

provide technical assistance to hospitals with deficient infection control programs to assist in lowering HAI rates in these institutions.

Strategy 4 is the improvement and expansion of HAI surveillance. Alignment of definitions across HHS data systems will be assured. Standardized measures will be developed to enhance compatibility and comparability of HAI rates across HHS agencies. Reporting of HAIs through NHSN will be encouraged. At this time, 25% of U.S. hospitals participate in NHSN.

Strategy 5 is the direct link between value-driven healthcare and reduced HAI rates. The HHS Secretary believes that public reporting of HAIs and other patient measures empower consumers to make informed choices and result in improved overall quality of care. Studies have demonstrated that provider feedback plays an effective role in reducing HAIs. Incentives for prevention may increase prevention efforts.

Dr. Wright outlined HICPAC's formal charge to assist HHS in reducing HAI rates. First, HICPAC would prioritize the list of recommended clinical practices and develop a global top 10 list across the entire gamut of HAIs to help focus rapid implementation efforts. The global top 10 list would serve as a platform for a National Prevention Campaign. HICPAC would develop a secondary top 10 list of other major classes of HAIs, such as catheter-induced BSIs and VAP, that would be distributed to hospitals and accrediting bodies.

Second, HICPAC would develop criteria for its recommendations to be considered for inclusion in CMS's Medicare *Conditions of Participation* as either "high-priority prevention interventions" or "high-priority HAIs." HICPAC would create the criteria with input from CMS and AHRQ *ex-officios*. The criteria would reflect affected populations, the magnitude of the problem, strength of evidence, economic impact and feasibility.

Dr. Wright announced that he recently obtained support and endorsement from CMS leadership for HICPAC to undertake this effort. However, CMS expressed an interest in HICPAC creating HAI criteria for its other tools and resources beyond the *Conditions of Participation*, such as pay-for-performance for reporting SSIs.

Dr. Wright explained that the majority of tasks for HHS's strategy to reduce HAIs would be completed by the Steering Committee during monthly meetings and by five workgroups during meetings twice per month. The five workgroups would be charged with addressing the following issues: (1) prevention guidelines and implementation, (2) regulatory oversight and incentives, (3) outreach and messaging, (4) research gaps and future directions, and (5) the role of information technology in reducing HAI rates.

HICPAC would provide ongoing input to the Steering Committee, but its primary focus and involvement would be in the Prevention Guidelines and Implementation Workgroup and the Regulatory Oversight Workgroup. However, HICPAC's charge would be directly linked to activities of all five workgroups.

Dr. Wright emphasized that a short timeline has been established for this initiative because the Deputy Secretary of HHS has expressed a strong interest in finalizing HHS's HAI plan by the end

of the current Administration. HHS hopes to receive an initial draft report in the fall of 2008 and present the preliminary "National Policy on Lowering HAIs" to HICPAC during its next meeting for review and comment. The National Policy will serve as HHS's strategic plan for reducing HAIs over the next ten years.

The initial draft will be revised based on input from HICPAC and other internal sources and then published in the *Federal Register* for public comment. HHS will also solicit feedback from the Association of Professionals of Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA) and other professional societies.

Dr. Wright clarified that no additional resources have been allocated to date to support the planning phase of the National Policy. However, he realized that HHS would need to closely examine and prioritize resources in the future, particularly to implement recommendations from the Research Gaps and Future Directions Workgroup.

Dr. Wright concluded his overview by informing HICPAC that he is a career employee and not a political appointee. As a result, he would continue to serve as the Principal Deputy Assistant Secretary for Health regardless of the changes in the new Administration. He planned to provide consistent leadership in implementing the National Policy over time.

Dr. Brennan emphasized that attention to HICPAC's guidelines at Dr. Wright's level is extremely gratifying. His position was that HHS's leadership and support would elevate HICPAC's previous efforts of collaborating with the Joint Commission, CMS and professional organizations to translate HICPAC recommendations into accreditation processes and *Conditions of Participation*.

On behalf of HICPAC, Dr. Brennan accepted the charge as outlined by Dr. Wright. He confirmed that HICPAC welcomed the opportunity to partner with HHS in developing the National Policy. He noted that HICPAC would discuss its charge in more detail during the business session on the following day. He concluded that the National Policy is tremendous in its potential impact and would serve as a major opportunity for HHS, DHQP, HICPAC and the public to reduce HAIs across the nation.

Based on HICPAC's acceptance of the charge, Dr. Cardo conveyed that CDC would continue to explore options to provide personnel, resources and outside experts to support HICPAC's participation in developing HHS's National Policy.

Update on the HICPAC Guidelines

Dr. Kurt Stevenson provided an update on the *Guideline for the Prevention and Management of Norovirus in Healthcare Settings*. He reminded HICPAC that five key questions the workgroup developed to inform the development of the norovirus guideline were presented during the November 2007 and February 2008 meetings and have not changed.

The workgroup also created an analytic framework to answer research questions for the norovirus guideline based on evaluating patients at baseline, identifying sporadic infections and outbreaks, preventing transmission of an outbreak, and focusing on environmental cleaning.

From September 2007-February 2008, the workgroup reviewed existing guidelines, developed the five key questions and conducted a literature search. Screening of titles and abstracts and a review of full-text studies are underway to determine papers that will be used to support the evidence of the norovirus guideline.

Searches of Medline and other databases led to the workgroup identifying 3,702 studies to include in the title and abstract screening process. This process also excluded 3,323 studies based on the following criteria. The study was not in English. The study contained a meeting abstract only with no publication of full text. The study was not relevant to one of the five key questions.

The study could not be characterized as "primary analytic research," such as systematic reviews of analytic research; economic and meta-analyses; interventional studies; and prospective and retrospective observational studies, *i.e.*, cohort, case-control or analytic cross-sectional studies. The full text of the study was published, but was not available for review. Of 379 studies that were considered for the full-text review, 129 were not included based on the exclusion criteria.

The workgroup has now identified 250 full-text studies to be included in the data extraction process. By the November 2008 HICPAC meeting, the workgroup expects to extract data from the 250 studies into evidence tables, assess the quality of each study, apply the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) system to weigh the strength of the evidence, and formulate draft recommendations.

The workgroup will address four major issues before drafting the preliminary recommendations: (1) the level of sensitivity and specificity of the norovirus search, such as combining viral gastroenteritis terms with more specific terms; (2) use of basic science and *in vitro* studies, particularly for key questions 3 and 5; (3) use of uncontrolled studies; and (4) use of non-systematic reviews.

Dr. Bell informed HICPAC that the *Disinfection Guideline* was submitted to the *Morbidity and Mortality Weekly Report* (*MMWR*) and is in the queue to receive editorial input. Issues regarding inactivation of prion-contaminated material were removed from the disinfection guideline because a decision was made that this topic could be addressed in separate publications. The original authors of the prion section are currently exploring the possibility of revisiting this issue in a

separate APIC/SHEA document. After the *MMWR* editorial process is complete, Dr. Bell would circulate the publication date to HICPAC.

Dr. Brennan confirmed that HICPAC and CDC would take Ms. Stricof's suggestion under advisement to make the disinfection guideline available electronically since the infection control community is eagerly anticipating the release of the document.

Dr. Robert Wise, HICPAC's liaison to the Joint Commission, announced that an organization's sole use of flash sterilization for outpatient eye surgery was rather controversial. The Joint Commission cited HICPAC's disinfection guideline to make strong case against the use of flash sterilization for eye surgery. Because the guideline was developed in 1999, several large outpatient surgical centers emphasized that the recommendations were outdated and inconsistent with current industry practice throughout the country.

Dr. Wise pointed out that the Joint Commission heavily relies on HICPAC's evidence-based guidelines to support its accreditation process, but the recommendations must be up-to-date due to the magnitude and scope of the infection control industry. He asked HICPAC to review, update and release the disinfection guideline and other outdated recommendations as quickly as possible to inform the field and reflect current practice.

Dr. Steven Gordon provided an update on the *Healthcare Worker (HCW) Vaccination Guideline* that HICPAC and the CDC Advisory Committee on Immunization Practices (ACIP) are jointly developing. The guideline is targeted to occupational health personnel and HCWs. The workgroup is continuing its review of BCG and other vaccines to inform the development of the recommendations. The workgroup hopes to present the draft HCW vaccination guideline to HICPAC in the first quarter of 2009 for review, comment and a formal vote.

The overarching purpose of the guideline is to update the joint ACIP/HICPAC HCW vaccination recommendations that were developed ~10 years ago; address previously unresolved issues; and present the recommendations in a more streamlined and user-friendlier format. Because no new vaccines will be recommended, the updated guideline is not expected to result in any controversy.

During the presentation of the updated guideline in 2009, the authors will ask HICPAC to pay particular attention to new recommendations on the evidence of immunity in HCWs with the measles, mumps and rubella vaccine (MMR). Updated guidance for the MMR vaccine will exclude year of birth and self-reported history of disease.

Dr. Bell provided an overview on the concept for a new *Ambulatory Care Guideline for Infection Prevention*. The guideline should be modeled on the streamlined format of the norovirus and CA-UTI guidelines and should not be developed as a voluminous document on ambulatory care practices.

The guideline potentially could focus on the following areas: (1) injection safety and basic infection control practices due to current legislative interest in these issues; (2) strategies to

examine ASCs; (3) requirements to update continuing medical education or related educational activities; and (4) prevention of transmission of respiratory infections in ASCs.

The fourth area of focus would compliment national attention to pandemic influenza prevention and resources that are allocated to DHQP in this area. This set of recommendations could address architectural innovations, displacement ventilation, the organization of patients in waiting areas, environmental controls for frequently touched surfaces, and other approaches to decrease the risk of exposure to respiratory infections in healthcare facilities. Dr. Bell asked HICPAC to consider the concept of the new ambulatory care guideline overnight in preparation for a discussion of this issue during the business session on the following day.

Dr. Craig Umscheid described guideline methods that were used to develop the *CA-UTI Prevention Guideline*. The goal of this process was to conduct a targeted systematic review based on the best available evidence with explicit links between the literature reviewed and the final recommendations. The workgroup achieved this goal in a multi-step process.

A search was conducted of national and international guidelines to develop key questions and design search strategies. A literature search was performed to answer the key questions. An abstract and full-text screening process was implemented for studies that were identified during the literature search. Data were extracted into evidence tables to evaluate the quality of each study. GRADE tables were created to weigh the strength of the evidence. Outcomes from the GRADE tables were used as the basis to formulate preliminary recommendations.

A comparison of condom versus indwelling urethral catheters is one example of applying the guideline methods. The critical outcomes in this model would include symptomatic UTI, bacteriuria, bacteremia and patient satisfaction. The quantity and type of evidence would include randomized controlled trials (RCTs) and observational studies. The findings would include decreased risk, no difference or increased patient satisfaction.

To grade the evidence, an RCT would be initially graded as “high.” However, the RCT grade could be decreased to “moderate” or “low” based on the quality and consistency of data, directness and precision of the evidence, and publication bias. An observational study would be initially graded as “low,” but could be increased to “moderate” or “high” if the data demonstrated a strong association. The overall grade of condom versus indwelling urethral catheters would be “moderate” after applying the GRADE System because the lowest and highest quality evidence would be compared to the most critical outcomes.

The overall evidence grades are divided into four categories. A “high” grade means that further research is very unlikely to change confidence in the estimate of effect. A “moderate” grade means that further research is likely to impact confidence in the estimate of effect and may change the estimate. A “low” grade means that further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate. A “very low” grade means that any estimate of effect is very uncertain.

Three factors must be considered in applying overall evidence grades and formulating recommendations: (1) values and preferences used to determine critical outcomes; (2) net

benefits, net harms or tradeoffs from weighing critical outcomes; and (3) the overall GRADE of the evidence for critical outcomes.

Category I recommendations are strong. For example, most patients would desire the recommended course of action and only a small proportion would not. Patients should request discussion if the physician does not offer an intervention. Clinicians should provide most patients with the recommended course of action. For policymakers, recommendations can be adopted as policy in most situations.

Category II recommendations are weak. For example, most patients would desire the recommended course of action, but many would not. Clinicians should recognize that different choices would be appropriate for various patients. Patients would need help to arrive at management decisions consistent with their values and preferences. For policymakers, policymaking would require substantial debate and involvement of many stakeholders.

A "strong" GRADE recommendation would be equivalent to HICPAC's Category IA, IB and IC recommendations in which the net benefits and net harms would be weighed. A "weak" GRADE recommendation would be equivalent to HICPAC's Category II recommendations in which tradeoffs would be weighed. A GRADE recommendation of "further research" would be equivalent to HICPAC's "no recommendation" in which tradeoffs would be uncertain. The workgroup will clarify in the CA-UTI guideline that Category IA, IB and IC recommendations are equally strong and should be "implemented" rather than "considered."

Dr. Carolyn Gould explained that the workgroup formulated three key questions and multiple sub-questions to inform the development of the *CA-UTI Prevention Guideline*. The workgroup also defined "symptomatic UTI," "bacteriuria" and "bacteriuria/unspecified UTI" as CA-UTI outcome categories in the GRADE tables. The workgroup's preliminary recommendations and grades for the key questions and sub-questions of the CA-UTI guideline are outlined below.

QUESTION 1 focused on populations that should receive urinary catheters. Sub-question 1A: Is urinary catheterization necessary in certain populations? Urinary catheters in operative patients should be used only as necessary rather than routinely. The risks of infection, risks of urinary retention, and the need for intraoperative catheterization should be weighed. (Category II) Urinary catheterization of patients and nursing home residents should be avoided for management of incontinence. (Category II)

Further study is needed on periodic use of condom catheters in this population and the use of catheters to prevent skin breakdown. (No recommendation/unresolved issue) Further study is needed on the benefit of using a urethral stent as an alternative to an indewelling catheter in selecting patients with bladder outlet obstruction. (No recommendation/unresolved issue)

Alternative urinary drainage strategies for chronic indwelling urinary catheters should be used in spinal cord injury patients whenever possible. (Category II) Clean intermittent catheterization should be used in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration. (Category II)

Question 1B: What are the risk factors for CA-UTI? A sterile and continuously closed drainage system should be maintained. (Category IA) The catheter and urinary drainage system should not be disconnected unless the catheter must be irrigated. (Category IA) Catheters should be left in place only as long as needed for appropriate indications. (Category IA)

Urinary catheter use and duration of use should be minimized in patients at higher risk for CA-UTI, such as women, elderly persons, and patients with impaired immunity, higher severity of illness, diabetes, renal dysfunction and incontinence. (Category II) Only properly trained personnel should insert urinary catheters using correct aseptic techniques. (Category II)

Question 1C: What populations are at highest risk of mortality from catheters? Urinary catheter use and duration of use should be minimized in patients who might be at higher risk for mortality due to catheterization, such as elderly persons and patients with higher severity of illness. (Category II)

QUESTION 2 focused on the best practices to decrease the risk of infection for persons who might require urinary catheters. Sub-question 2A: What are the risks and benefits associated with different approaches to catheterization? Condom catheter drainage is preferable to an indwelling urethral catheter in cooperative male patients without urinary retention or bladder outlet obstruction. (Category IB)

Intermittent catheterization is preferable to an indwelling urethral or suprapubic catheter in selected patients with bladder emptying dysfunction. (Category II) Intermittent catheterization should be performed at regular intervals to prevent urinary retention. (Category II) For operative patients who have an indication for an indwelling catheter, the catheter should be removed as soon as possible post-operatively, preferably within 24 hours. (Category II)

Further study is needed on the risks and benefits of suprapubic catheters as an alternative to indwelling urethral catheters in selected patients requiring short- or long-term catheterization, particularly with respect to patient preference and complications related to catheter insertion or the catheter site. (No recommendation/unresolved issue) Clean intermittent catheterization is an acceptable and more practical alternative to sterile intermittent catheterization for patients requiring chronic intermittent catheterization. (Category IB)

Question 2B: What are the risk and benefits associated with different catheters or collecting systems? Further study is needed on the benefit of antimicrobial silver alloy or antibiotic-coated catheters compared to standard silicone-based catheters in reducing the risk of clinically significant CA-UTI events. (No recommendation/unresolved issue) Hydrophilic catheters are preferable to standard catheters for patients requiring intermittent catheterization. (Category II) A sterile and continuously closed drainage system should be maintained. (Category IA)

Complex urinary drainage systems are not needed as a routine prevention measure for CA-UTI. (Category II) The use of urinary catheters with pre-connected sealed junctions is a useful adjunct measure to reduce the risk of disconnection of the sterile and closed drainage system. (Category II) Further study is needed to clarify the benefit of catheter valves in reducing the risk of CA-UTI

and other urinary complications and also to identify the appropriate patient population for this device. (No recommendation/unresolved issue)

Question 2C: What are the risks and benefits associated with different catheter management techniques? The workgroup is continuing to review the evidence to answer this question for the following techniques: antibiotic prophylaxis, bladder irrigation, antiseptic instillation in drainage bags, local skin care, frequency of catheter or bag change, catheter lubricants, secured devices, bacterial interference, clamping versus free drainage, duration of catheterization for short-term drainage, portable ultrasound to assess bladder volume, and catheter cleansing procedures.

Question 2D: What are the risks and benefits associated with different systems changes? The workgroup is continuing to review the evidence to answer this question in the following areas: reminders, bacteriologic monitoring, mixed infection control and quality improvement programs, hand hygiene, isolation, catheter teams, feedback, and nurse-directed catheter removal.

For QUESTION 3, the workgroup is continuing to review the evidence to determine whether management of an obstructed urinary catheter is the best method to manage urinary catheter-associated complications. The other sections of the CA-UTI guideline the workgroup is still developing focus on implementation and audit and recommendations for further research. In the final draft, the workgroup plans to list all the recommendations at the beginning of the document and also in each of the relevant sections.

HICPAC commended all of the workgroups for their tremendous progress in refining the guidelines since the previous meeting. Several members made suggestions for the CA-UTI workgroup to consider in revising its preliminary recommendations.

- The language of "increased risk of urinary retention or **re-catheterization** in patients not receiving catheters" should be changed to **catheterization** because these patients never received catheters for surgery.
- Caution should be taken in providing too much detail in the recommendations. For example, a description of surgical indications for catheters in the recommendations might lead to confusion.
- A list of indications for catheterization should be developed for clinicians and included in the guideline.
- The recommendation should be changed to "minimize urinary catheter use and duration of use in all patients at higher risk for CA-UTI, particularly women, elderly persons, and patients with impaired immunity, higher severity of illness, diabetes, renal dysfunction and incontinence."
- A footnote should be added to the recommendation to "ensure that only properly trained personnel insert urinary catheters using correct aseptic techniques." Because the recommendation is graded as Category II or "suggested" for implementation, untrained personnel could be used.
- The guideline should emphasize that Category IA, IB and IC recommendations are all strong and should be equally implemented. The guideline should further clarify that the only difference among the three categories is the quality of the evidence.

- The language of "in operative patients, there was low-quality evidence to suggest a benefit of **not using urinary catheters routinely**" should be changed to "**avoiding urinary catheterization when possible**."
- New text should be included to provide guidance on appropriate times to perform urine culturing. The guideline focuses on prevention and not treatment, but this language would be important in the current era of pay-for-performance.
- New text should be included on the use of antimicrobial catheters. This language should be supported by primary studies.
- Innovation, surgical intervention at earlier stages and evaluation of incontinence in certain populations should be described in the "further research" section to highlight gaps in knowledge, opportunities for improvement and the need for funded studies in the future.

HICPAC Workgroup Reports

HAI Preventability Workgroup. Dr. Brennan reported that the "Mortality from Reasonably Preventable HAIs" document was distributed to HICPAC for review. SHEA drafted the document in response to a Congressional request in March 2008 to make estimates on the extent to which mortality from HAIs is preventable. The document was circulated during the hearing of the House Oversight and Reform Committee in April 2008.

Dr. Umscheid explained that the purpose of the document was to estimate the number of annual deaths in U.S. hospitals from reasonably-preventable cases of HAIs. To estimate the number of HAIs and resulting mortality, the best available evidence was gathered from the National Nosocomial Infections Surveillance System (NNIS), National Hospital Discharge Summary, and American Hospital Association (AHA). To estimate the proportion of HAIs that could be prevented, HAI risk reduction data resulting from quality improvement strategies were extracted from a recent AHRQ report.

Of ~1.7 million HAIs that occurred in 2002, 98,987 resulted in deaths and accounted for 5.7% of fatal infections. UTI prevention studies reviewed by AHRQ suggested a 17%-69% reduction in UTIs depending on the intervention and population examined. Five studies of good or moderate quality conducted over the past ten years were included in the review.

Based on these data sources, the following estimates were made on the number of preventable infections: (1) 44,762-203,916 from BSIs; (2) 95,078-177,646 from VAP; (3) 95,483-387,550 from UTIs; and (4) 75,526-156-862 from SSIs. The following estimates were made on the number of preventable deaths: (1) 5,520-25,145 from BSIs; (2) 13,667-25,537 from VAP; (3) 2,225-9,031 from UTIs; and (4) 2,133-4,431 from SSIs.

Because the estimates will be used to inform policy discussions regarding the reduction of HAIs in hospitals, the uncertainty and limitations of the analysis are explicitly outlined in the document. Survey data on the number of deaths caused by HAIs were collected more than five years ago and do not reflect improvements in infection control practice since that time. A method has not been developed to date to definitively attribute deaths to HAIs.

The quality of available HAI reduction studies is limited, none of the studies are randomized, and only a few studies are controlled. Some published studies were conducted ten years ago. The validity of reported risk reductions is uncertain and might be exaggerated due to limitations of the data sources. Preventable deaths were not estimated from studies that directly measured death as an outcome. An assumption was made that rates of preventable deaths and infections were the same.

An appendix is included in the document that estimated the cost of reasonably-preventable HAIs to be $1.8-$9.4 billon. Four cost studies on catheter-related BSIs in the United States conducted in 1999-2006 were used as data sources to develop the cost estimates.

The HICPAC members made a number of comments and suggestions on the HAI preventability document.

- The public might view the document as broad "guesstimates" with flawed data and a waste of resources. Consumer advocates most likely would rank the implementation of proven infection control practices for hospitals to reduce HAIs and save lives as a much higher priority than studies to estimate the number of preventable HAIs.
- The summary of the document should include more information on the decline of HAIs based on improvements in infection control practice.
- Billing code data should be gathered to correlate HAIs to the diagnosis-related group of septicemia.
- The term of "attributable to and mortality from HAIs" should be clarified because this language is inconsistent with NHSN definitions.
- The additional focus of the document on preventable deaths from HAIs should be reconsidered due to the ongoing effort to develop a National HAI Elimination Plan.
- Pediatric studies should be included in the document to estimate the number of preventable HAIs in children.

Dr. Brennan asked HICPAC to submit additional comments on the HAI preventability document in writing to Dr. Umscheid. The document would be revised and redistributed to HICPAC for further review and comment. He hoped to publish the paper as a joint document by SHEA, HICPAC, APIC and other groups to address language in the CMS regulations about the extent to which HAIs are reasonably preventable.

Guideline Methods Workgroup. Dr. Umscheid reported that a companion paper would be released with the CA-UTI guideline to summarize HICPAC's updated guideline methodology. Key sections of the companion paper are outlined as follows. HICPAC's role and function in producing evidence-based guidelines on healthcare infection control practices will be described.

Details will be provided on methods and processes that were used to develop HICPAC's recent guidelines. Organizational changes that were made to update HICPAC's guideline methodology will be specified. For example, DHQP staff and HICPAC members were assigned to develop key questions for guidelines, screen abstracts and full-text studies for inclusion in the guidelines, write

or review evidence summaries and recommendations, and share bibliographies and draft guidelines with outside experts.

Dr. Umscheid and other methodology consultants at the University of Pennsylvania Health System Center for Evidence-Based Practice were engaged to develop and maintain methods for the guidelines, establish timelines, build evidence and GRADE tables, design search strategies, manage references, and review and integrate all aspects of the development process.

Challenges in producing HICPAC guidelines will be highlighted in the companion document, such as the rapidly growing evidence base, increased attention on HAIs, emerging infectious diseases, and prioritization and communication of guidelines to providers.

Other issues will be noted as challenges or future opportunities, such as continued development of clinically-relevant and targeted key questions; judgments of studies to include in guidelines; the complexity of systematic reviews; use of meta-analyses in light of the heterogeneity of the evidence; adaptation of the GRADE System to the HICPAC ranking scheme; the role of cost analyses in HICPAC guidelines; the need to sufficiently balance content and method expertise; and opportunities to direct future research.

To support HICPAC's updated guideline methodology, the workgroup acknowledged that capacity will be needed to (1) rapidly develop and update guidelines; (2) rapidly respond to emerging needs; (3) address key clinical questions of infection control providers and personnel; (4) use available evidence to answer questions; and (5) provide unbiased and transparent guidance.

The workgroup will take several actions to achieve these goals. Emerging methods and evidence-based medicine will be used in developing guidelines. A targeted systematic review process will be developed based on the best available evidence with explicit links between the evidence and HICPAC's recommendations. A rapid, unbiased, transparent and evidence-based review process will be implemented and efficiently updated to address key questions of providers.

The HICPAC members made two key suggestions on the companion paper to the CA-UTI guideline. First, the identification of gaps in current knowledge is an important outcome of the document and should serve as a foundation to develop a hospital epidemiology research agenda for the next ten years. Second, the companion paper should be consistent with the National Quality Forum process because this effort led to the identification of infection reporting research that should be conducted.

Dr. Brennan asked HICPAC to submit additional comments on the companion paper in writing to Dr. Umscheid. He noted that the document would need to be vetted, cleared and released in parallel with the CA-UTI guideline to inform the professional community of HICPAC's updated methodology.

Model Legislation Workgroup. Dr. Bell reported that the workgroup is currently developing a table to capture existing HAI legislation in each state. The workgroup will also draft an outline to describe the rationale, potential benefits and unintended consequences of HAI legislation. The

workgroup will use the draft outline as the basis to develop a concise and succinct document with no more than 2.5 pages.

The document will contain language in bullet form to help groups in writing new or adapting existing legislation to address local needs. Cautionary language on the potential consequences of misinterpreting HAI legislation will be included in the document as well. The workgroup will convene a conference call after the outline is drafted.

National Patient Safety Goal (NPSG) Workgroup. Mr. Russell Olmsted reported that on June 4, 2008, the workgroup sent HICPAC's comprehensive letter to the Joint Commission on the proposed 2009 NPSGs. The letter outlined HICPAC's concerns in several general areas. A number of the proposed NPSGs were based on draft documents that were unpublished, not vetted and had untested measures. HICPAC emphasized the need to validate these measures before their establishment as NPSGs.

The proposed NPSGs were prescriptive and appeared to negate the current Joint Commission standard that requires each facility to perform an annual risk assessment. Pathogen-specific goals related to MRSA and *C. difficile* were narrow and appeared to divert attention from other emerging problems in hospitals. The term "best practices" in the proposed NPSGs appeared to be subjective and might not be effective across the spectrum of acute care delivery. The workgroup also made comments that were specific to individual NPSGs.

Although the workgroup did not receive a formal response to the letter, Dr. Brennan announced that the Joint Commission gave serious consideration to comments and input by HICPAC and SHEA.

Liaison and *Ex-Officio* Reports

Ms. Rachel Stricof submitted a written report on key outcomes of the meeting of the Advisory Council for the Elimination of Tuberculosis that was held in March 2008. The presentations focused on the budget of the Surveillance, Epidemiology and Outbreak Evaluation Branch; TB public health laws; nucleic acid amplification testing guidelines; and the 2007 technical instructions for overseas screening of TB. Ms. Stricof also submitted a copy of a presentation that was given during the meeting on the role of BCG vaccine in the prevention of TB for HCWs in high-risk situations overseas.

Dr. William Baine submitted a written report on AHRQ's $5 million MRSA initiative. AHRQ is partnering with CDC and CMS to fund six projects under the special initiative.

Dr. Mark Russi submitted a written report on recent activities by the American College of Occupational and Environmental Medicine, including key outcomes from its annual spring meeting in April 2008; an updated online guidance document for delivery of occupational health services in medical center settings; an extensive update of its evidence-based practice guidelines;

and revisions and updates to its position statements on influenza vaccination and HIV in the workplace.

Dr. Brennan conveyed that AHA's written report covered its comments on the FY'09 Medicare Inpatient Prospective Payment System; case studies focusing on the reduction of HAIs as part of an AHA quality improvement initiative; and continued communications with policymakers to focus resources and efforts on decreasing HAIs.

Ms. Joan Blanchard submitted a written report on recent activities by the Association of periOperative Registered Nurses (AORN), including development of its electronic standardized peri-operative record; the Executive Symposium that will be held in July 2008 in Colorado; the "Smoke Evacuation Toolkit" to assist peri-operative teams in implementing the AORN *Position Statement on Surgical Smoke and Bioaerosols*; the successful 2008 AORN Congress in California; and the 13th Conference on Infectious Disease.

Ms. Nancy Bjerke submitted a written report on APIC's recent activities, including the release of the *APIC/HICPAC Surveillance Definitions for Home Health Care and Home Hospice Infections* on the APIC web site; the Annual APIC International Conference in June 2008 in Colorado; the first "National U.S. Inpatient Healthcare Facility *Clostridium difficile* Prevalence Study; the premiere of the quarterly *Prevention Strategist* publication in April 2008 to replace *APIC News*; APIC's testimony before Congress on HAIs; and the "Mastering the New CMS Regulations: Implications for Infection Prevention Control Conference" in September 2008 in Virginia.

Dr. Nalini Singh submitted PowerPoint slides with key outcomes of the most recent NCPDCID Board of Scientific Workgroup meeting. The workgroup discussed and provided input to NCPDCID on NHSN, the Epidemiology and Laboratory Capacity Grant Program, the GeoSentinel Surveillance System, and the Early Aberration Reporting System.

Ms. Lisa McGiffert submitted a written report of hospital infection stories that the Consumer's Union has compiled. The stories were accompanied by photographs of affected patients across the country.

Ms. Marion Kainer submitted a written report of recent activities by the Council of State and Territorial Epidemiologists (CSTE), including its annual conference in June 2008 in Denver; feedback on the Durbin Bill; position statement on NHSN; input on AHRQ's proposed patient safety organizations; and HAI Workgroup.

Dr. Sheila Murphey submitted a written report on FDA's recent activities, including the release of its *Sentinel Initiative: A National Strategy for Monitoring Medical Product Safety* white paper; redesign of its web site; publication of draft guidance on *Certifications to Accompany Drug, Biological Product and Device Applications and Submissions*; web link to CMS's final rule on the Medicare Part D Claims Data Rule; and release of recommendations to manufacturers seeking to develop plasmodium species antigen detection assays.

Dr. Brennan conveyed that the Joint Commission's written report described its Standards Improvement Initiative; continued participation on the HAI Allied Task Force; and ongoing efforts to gather data on major clinical issues related to flash sterilization.

Dr. David Henderson submitted a written report describing the National Institute of Health's continued focus and activities related to emergency preparedness; multidrug-resistant *Acinetobacter baumannii* infections; influenza immunization of healthcare providers; and an outbreak of nosocomial pneumonia due to a *Legionella pneumophila* serogroup 1 case cluster.

Dr. Lisa Maragakis submitted a written report on SHEA's recent activities, including its successful 18th Annual Scientific Meeting in April 2008 in Orlando; HAI guidelines that were developed in partnership with the Infectious Disease Society of America and approved for publication; educational initiatives; a briefing to Senate staffers on HAIs in the context of NHSN and public reporting; and public policy responses to a number of documents and issues.

Dr. Stephen Kralovic submitted a written report on the Veterans Administration's (VA) MRSA Prevention Initiative that directs all VA acute care facilities in the United States to initiate a MRSA prevention program. The VA is continuing its performance-based management process to achieve quality healthcare outcomes as well as its award-winning "Infection: Don't Pass It On" public health campaign. The VA will hire and deploy a high-level epidemiologist to DHQP to explore strategies to link NHSN and the VA surveillance system.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:47 p.m. on June 12, 2008.

Update by the DHQP Surveillance Branch

Dr. Brennan reconvened the HICPAC meeting at 9:12 a.m. on June 13, 2008 and yielded the floor to the first presenter.

Dr. Scott Fridkin, Deputy Chief of the Surveillance Branch, explained that DHQP made a number of changes in transforming NNIS to NHSN. Surveillance data are collected from non-ICU units and smaller hospitals. Pathogen and susceptibility data are gathered. Hospital areas are categorized differently to collect information from bone marrow transplant wards and other specialty care areas.

NNIS allowed data on any nosocomial infection from an ICU, but NHSN's data on pathogens are limited to device-associated and post-procedure infections. An influx of NHSN facilities was observed in 2007 due to open enrollment and state-based mandates. Due to these differences, comparisons between NNIS and NHSN are difficult without a specialized evaluation or analysis.

Data submitted to infection control and hospital epidemiology departments as part of the first *NHSN Antibiotic Resistance Report* showed that 28,000 HAIs were reported. Of reported HAIs, CLABSIs accounted for 35% and post-procedure infections accounted for 19%. Of 23,000

device-associated infections, 13% were from non-ICU areas. The proportion of smaller hospitals that reported ≥1 HAI to NHSN increased to 32%.

Of 33,000 pathogens that were associated with the 28,000 HAIs reported to NHSN, gram-positive organisms accounted for the majority of BSIs and gram-negative organisms accounted for the majority of VAP. An analysis of the percentage of pooled mean resistance of all organisms tested in a particular species showed that SSI resistance was 50% and CA-UTI resistance was 65%.

Data collected from NNIS in 2003 showed that 29% of any type of *Enterococci* was vancomycin-resistant and ~60% of *S. aureus* was methicillin-resistant. Because data collected from NHSN in 2006 showed a slight increase in VRE and a slight decrease in MRSA, DHQP conducted a study to (1) determine differences between the percentage of MRSA and MRSA incidence using CLABSIs as a candidate infection among ICU patients and (2) characterize actual trends and incidence of MRSA and MSSA CLABSI rates by different ICU types.

Over the past 10 years, 1,600 units have reported ~2,500 MSRA CLABSIs and ~1,600 MSSA CLABSIs to NNIS or NHSN. The study showed a significant increase in the percentage of MRSA from ~50% to ~65% over the past 10 years. An increase in the incidence of MRSA CLABSIs per 1,000 central-line days was observed in the first part of the study period, but a significant decrease was seen in this rate in 2000-2001. An overall reduction of ~50% was seen in the MRSA CLABSI rate at the end of the study period compared to the beginning. A steady decrease of ~70% was seen in the MSSA CLABSI rate over the entire study period.

DHQP performed the same analysis for each major ICU type, including surgical ICUs (SICUs), medical ICUs, and medical/surgical units in both major and non-major teaching facilities. In SICUs, for example, no significant trends in the percentage of MRSA were seen. An impressive increase of ~102% that was seen in the incidence of MRSA in SICUs in the first few years of the study period was followed by a marked decline of ~62% throughout the remainder of the study period. A steady decrease in MSSA CLABSIs was observed in all ICU types.

DHQP made a number of conclusions based on results of the study. MRSA provides an incomplete picture of the changes in the magnitude of the MRSA problem over time. MRSA incidence might be a better metric of MRSA burden, but is dependent on specific issues that are addressed, such as the impact of prevention efforts or guidance for empiric therapy. MRSA CLABSI rates are declining in some, but not all ICU types. Additional studies are needed to understand the influence and cause of inflection points in ICUs, such as MRSA-specific efforts or the impact of CLABSI infection prevention practices.

DHQP is collaborating with state health departments to conduct another MRSA surveillance project through the Emerging Infections Network (EIN). The number of invasive MRSA cases classified as "nosocomial" reported to EIN was ~1,500 in 2005 and ~1,400 in 2006. DHQP will use EIN to launch a *C. difficile* surveillance system in 2009.

In addition to surveillance of HAIs, DHQP is also focusing on the tremendous growth of NHSN over the past year. Of ~491 facilities enrolled in NHSN in April 2007, 24% were moderate size with 200-500 beds, 80% were general acute care hospitals, and 40% were non-major teaching

hospitals. Of 1,470 facilities enrolled in NHSN in May 2008, 56% had <200 beds, 91% were general acute care hospitals, and 61% were non-major teaching hospitals.

At this time, >1,000 hospitals actively report data to NHSN and 17 states now use or plan to use NHSN for mandatory reporting. DHQP's recent analysis showed that mandatory reporting only accounted for ~50% of NHSN's growth, while voluntary reporting accounted for the remainder of the growth. Most states with reporting requirements are focusing on CLABSIs, but four states are considering the use of the MDRO and CDAD module.

DHQP plans to launch a new MDRO and CDAD module in August 2008 for facilities to report proxy measures that can be populated by electronic data sources. DHQP will use laboratory identification event reporting to calculate the number of hospital-onset MRSA cases, BSI isolates or nosocomial cultures per 1,000 patient days. Proxy measures in the MDRO and CDAD module will be consistent with the HICPAC/SHEA position paper on evaluating and measuring MDROs in the context of prevention efforts.

Although the proxy measures in the MDRO and CDAD module will be based on the approved HICPAC/SHEA MDRO metric document, Dr. Brennan pointed out that HICPAC would need to take a formal vote to officially agree on editorial changes. A conference call would be convened within the next 10 days for HICPAC to vote on the revised MDRO metric paper.

Mr. Olmsted served as the chair and represented HICPAC on the External Peer Review of the Surveillance Branch that was convened in May 2008. The Panel was charged with evaluating NHSN in the context of its other capabilities and initiatives. The Panel was also asked to assess DHQP's other surveillance activities, including electronic HAI surveillance, adverse drug event surveillance; population-based surveillance of MRSA and CDAD; and use of the National Hospital Discharge Survey or National Inpatient Sample.

DHQP described the purpose of NHSN to guide the Panel's discussion. NHSN provide facilities with risk-adjusted data that can be used for inter-facility comparisons and local quality improvement activities. NHSN is based on the NNIS paradigm in which voluntary confidential data reporters provide high-quality data if the data are useful to them and no penalties are imposed for reporting the truth.

DHQP presented detailed information to the Panel on all aspects of NHSN, including the Patient Safety Component; a new Biovigilance Component, eSurveillance Initiative and Special Pathogens Module; device-associated procedures; tremendous growth over the past year; and the recent influx of smaller hospitals.

DHQP informed the Panel of the three categories of the current landscape of HAI surveillance. The "scientific" landscape covers MDROs, CDAD, HAIs in non-hospital settings, algorithmic detection of HAIs, surrogate measures of HAIs, and adherence to HAI prevention guidelines in clinical practice.

The "technical" landscape covers technical solutions that capitalize on the availability of healthcare data in an electronic format and reduce or obviate the need for manual data collection

and data entry. The "policy" landscape covers mandatory reporting by providers to public health agencies; public reporting of hospital-specific rates; and renewed interest in validating HAI reporting, linking federal data systems, and estimating the national scope and cost of HAIs.

The Panel discussed the strong business case for conducting HAI surveillance, including the need to protect patients and hospital personnel in the most cost-effective manner, increased scrutiny on HAIs, demands for transparency and disclosure of HAIs for patients to make informed decisions, value-based purchasing, assurance of effective prevention practices, and solid surveillance programs and infrastructures to manage data.

The Panel agreed with a study that concluded NHSN's methods for expression of infection rates and risk adjustment have become a national and international standard for categorizing and benchmarking HAI rates. The Panel also noted that many other countries have adopted NNIS or NHSN principles and methodologies for HAI surveillance. The Panel's overall impression was that NHSN is CDC's "crown jewel" in terms of surveillance.

The Panel reviewed results of a survey that was recently administered to ~800 ICPs throughout the country. The survey showed that surveillance was one of the greatest challenges for ICPs. ICPs expressed an interest in a better, timelier and more efficient system to track HAIs in the entire hospital population in both acute care facilities and non-hospital settings. ICPs also cited MDROs, hand hygiene and state-based mandates as significant challenges.

The Panel formulated recommendations in response to three key questions posed by DHQP. One, did the Surveillance Branch's presentations omit important scientific, technical or policy features of the current landscape of HAI surveillance in the United States, including antimicrobial resistance?

- The Surveillance Branch provided an excellent discussion on the scientific, technical and public policy landscape of HAI surveillance.
- NHSN should broaden its focus beyond acute care hospitals to more accurately reflect the direction of care delivery outside of this traditional setting.
- HICPAC and DHQP should jointly develop a risk assessment template for facility- and setting-based application. HICPAC also should create a surveillance guideline to assist providers in the field in identifying key areas to measure. The risk assessment template and surveillance guideline should be linked. APIC's recently published *Recommended Practices for Surveillance* should be reviewed and expanded in this effort.

Two, are the Surveillance Branch's current capacity, priorities and plans for NHSN adequate with respect to the current landscape of HAI surveillance?

- The Surveillance Branch's activities and plans for NHSN are appropriate, but its technical and financial capacity is not sufficient at this time to implement these plans. Most notably, NHSN is entirely supported by discretionary funds and has no dedicated line item. The potential loss of the NHSN infrastructure would compromise capacity in the field to advance and expand prevention. HICPAC should make a recommendation on the critical need to allocate additional resources to DHQP for NHSN.

- CDC should view NHSN as a pivotal area and a priority to address patient safety and provide necessary data to control and prevent HAIs. An appropriate level of resources should be allocated to DHQP to ensure data and other aspects of NHSN are not compromised as the demand on the system continues to increase.
- CDC should fully embrace partnerships with other HHS agencies, particularly AHRQ and CMS, to meet the growing demand for NHSN services. Collaborations with CSTE and the Joint Commission should be strengthened in this effort as well.
- HAIs should be viewed as a public health problem beyond hospitals.

Three, what directions, strategies and steps are most important for the Surveillance Branch to meet new opportunities and challenges in HAI surveillance?

- HICPAC should explicitly endorse NHSN as the standard for HAI surveillance and reinforce its endorsement in all relevant guidelines and other communications that are developed in the future.
- HICPAC should assist DHQP and the HHS Secretary by playing a proactive role in determining appropriate actions to take when existing surveillance data are inconsistent or conflicting. For example, HICPAC should establish a position on the value and efficacy of active surveillance and detection of MDROs.
- HICPAC and DHQP should jointly establish linkages between NHSN and evidence-based guidelines, new contributions to the literature, and information generated by other parts of CDC and other HHS agencies.
- CDC should build a constituency of partners to support the aims and goals of NHSN as the premiere source of data on epidemiologic trends, new findings and other aspects of HAIs.
- CDC should encourage and promote the use of NHSN data by outside researchers, but sound policies should be developed on the use of these data.
- CDC should launch a marketing campaign to broadly share success stories that showcase the efficacy and value of NHSN.
- CDC should take a multifaceted approach to improve the communication and timely output of NHSN data while increasing the visibility of NHSN analytic products. CDC should use innovative communication mechanisms to disseminate data to the public, such as developing and releasing a consumer version of NHSN and posting user-friendly information on web sites.

HICPAC commended Mr. Olmsted and the other Panel members for conducting an excellent and comprehensive peer review of the DHQP Surveillance Branch. Several HICPAC members made suggestions to advance the Panel's recommendations.

- The recommendation for HICPAC and DHQP to jointly develop a risk assessment template for facility- and setting-based application should take advantage of the current opportunity to create a risk adjustment tool to prospectively collect data on SSIs. HICPAC and DHQP should link their epidemiological expertise to the wound and SSI expertise in the Surgical Infection Society to develop and apply a clinically-relevant tool. This effort could be tested in NHSN's research and development component.

- A cost analysis should be performed to determine resources that DHQP would need to implement the Panel's recommendations.
- HICPAC should not wait until DHQP develops a strategic plan for national surveillance before creating a surveillance guideline. These efforts can be conducted in parallel to ensure that both activities inform each other.

Dr. Bell's position was that HICPAC should develop a new surveillance guidance document rather than a guideline. He explained that a "guideline" involves an extensive evidence review and a transparent assessment of the quality of evidence using the updated methodology for the norovirus and CA-UTI guidelines. A "guidance document" captures the experience, wisdom and expert opinion of a broad group of constituents upfront rather than using these consultants as reviewers after a document is developed. Concise guidance documents are also developed more rapidly than guidelines.

Dr. Brennan reviewed next steps for HICPAC to begin developing the new surveillance guidance document. A conference call would be convened to identify the membership of the new workgroup, such as APIC, SHEA, the Joint Commission, Prevention EpiCenters and health departments. Due to the broad range of partners and stakeholders that would be engaged upfront, subgroups might need to be established as well. The workgroup also would develop the risk assessment template in parallel with the surveillance guidance document.

Dr. Brennan turned to the Panel's recommendation for HICPAC to endorse additional technical and financial resources DHQP would need to respond to the tremendous growth of NHSN. He would draft a letter on this issue and circulate the document to HICPAC for review and comment. In terms of the Panel's recommendation for HICPAC to explicitly endorse NHSN as the standard for HAI surveillance, a formal statement would be embedded in the new surveillance guidance document.

HICPAC Business Session

Dr. Brennan announced that the terms of Drs. Steven Gordon and Nalini Singh would expire after the current meeting. He emphasized that both of the outgoing members have made significant contributions to HICPAC, particularly the leadership of Dr. Gordon in developing the electronic health records white paper and the expertise and strong advocacy of Dr. Singh for the pediatric population.

Dr. Brennan presented plaques and certificates of appreciation to Drs. Gordon and Singh. The participants applauded the outstanding service of the two outgoing members.

Dr. Wright reviewed next steps for HICPAC to respond to its charge from HHS. HICPAC would identify four or five guidelines that should be prioritized and provide HHS with a timeline for this deliverable. HICPAC would use the prioritized guidelines to develop a top 10 list for HHS's National Policy on Lowering HAIs.

The top 10 list primarily would be targeted to healthcare providers, but the Joint Commission and other accrediting bodies also would use the list during their routine hospital surveys. The HHS Steering Committee would establish short-, mid- and long-term benchmarks to track progress with the top 10 list.

Dr. Wright emphasized that the development of the National Policy over the next six to eight months should not be overly comprehensive and delay the process. Instead, the National Policy would be an ongoing process over time with evaluations at specific intervals similar to HHS's *Healthy People* initiatives.

Dr. Wright reiterated that HICPAC would also develop a global top 10 list as the foundation for HHS's National Prevention Campaign. This list would be targeted to the general public with important strategies to lower the incidence of HAIs in healthcare settings.

The HICPAC members made a number of suggestions in response to the charge from HHS.

- The hand hygiene, SSI, CLABSI, CA-UTI, VAP, MDRO, isolation, and disinfection and sterilization guidelines should be prioritized.
- HICPAC's disease- or procedure-specific guidelines should serve as the basis for developing the top 10 list for healthcare providers in the National Policy.
- HICPAC should create an "Infection Control Bill of Rights for Patients" as the top 10 list for the public in the National Prevention Campaign. The Consumer's Union should serve as a key liaison in this effort.
- The "universal precautions" section should be extracted from the isolation guideline and used as the basis for developing the global top 10 list of HAIs.
- A new ambulatory and office-based surgery guideline should be created and prioritized. The guideline could provide advice and education on implementing important infection control practices to address the growing shift in care from acute care settings to outpatient facilities.
- HICPAC should create a short checklist for each guideline of the five most important infection control practices that should be implemented.

Dr. Chesley Richards, Deputy Director of DHQP, noted that the new Medicare policy on non-payment or reduced payment for HAIs should be considered as an additional factor in prioritizing HICPAC's guidelines. He explained that CA-UTIs, a specific SSI and BSIs will be implemented under the new Medicare policy beginning in October 2008. He also pointed out that MRSA, *C. difficile* and VAP have been released for public comment and are being considered for possible implementation in 2009.

Drs. Brennan and Cardo conveyed that DHQP could develop a new tool for facilities to report process measures to NHSN on the prioritized HAIs. For example, SCIP process measures could be incorporated into NHSN to efficiently collect both process and outcome data. This strategy also would respond to the GAO recommendation for data systems to be aligned across HHS agencies. CMS would capture process-related HAIs and CDC would capture present-on-admission (POA) indicators through NHSN.

Based on the comments and suggestions by HICPAC and DHQP leadership, Dr. Brennan proposed the following process for HICPAC to respond to its charge from HHS. HICPAC would convene a conference call by the end of June 2008 to begin formalizing action steps. The CA-UTI, SSI and BSI guidelines would be initially prioritized because these three infections will be implemented under the new Medicare policy in October 2008.

This approach would ensure that HICPAC's efforts are aligned with CMS's POA indicators to avoid the perception of competing interests within HHS. However, HICPAC would re-review the prioritization of the initial three guidelines in the future since CMS is considering implementation of different HAIs in 2009. Workgroups with current and former HICPAC members, DHQP staff and external subject matter experts would conduct activities over the summer to meet HHS's deadline of developing the global top 10 list of priorities by the fall of 2008.

None of the HICPAC members opposed Dr. Brennan's proposed approach and all of the members made a commitment to meet HHS's fall 2008 deadline.

Dr. Bell returned to the new ambulatory care guideline and suggested the development of a top 10 list for this document. Because no new data have been generated on outpatient infection control, information on basic practices could be extracted from other guidelines and repackaged for ASCs. This short-term activity could be rapidly conducted and embedded into HICPAC's response to its charge from HHS.

Dr. Bell noted that HICPAC's development of a guideline on the prevention of acute respiratory infections in ASCs obviously would require much more time. As a result, he proposed tabling discussions to plan this effort until the November 2008 meeting.

Dr. Bell pointed out that HICPAC's examination of the evidence base for flash sterilization to determine the advantages and disadvantages of this procedure also would need to be discussed during the November 2008 meeting. HICPAC would submit the outcomes of its analysis to the Joint Commission.

Dr. Brennan led HICPAC in a review of business items that were raised over the course of the meeting.

- Dr. Bell will distribute the proposed dates for the 2009 and 2010 meetings to ensure that HICPAC members have no scheduling conflicts with other events.

- Drs. Bell and Brennan will identify a CMS representative to serve on HICPAC's new "HHS Prioritization Workgroup."

- Drs. Bell and Brennan will convene a conference call by the end of June 2008 for HICPAC to discuss four major topics: (1) the response to HICPAC's specific questions during the May 2008 conference call regarding the MDRO metrics paper; (2) the framework to develop the HHS priorities for HAIs and the "Infection Control Bill of Rights for Patients;" (3) the membership of the new Surveillance Guidance Workgroup; and (4) next steps on the ambulatory care guideline.

- The HICPAC members and liaisons will participate in the following ongoing or new activities:
  - Further revisions to finalize the joint ACIP/HICPAC HCW vaccination, CA-UTI, MDRO and norovirus guidelines.
  - Participation on the new HHS Prioritization Workgroup.
  - Participation on the new Surveillance Guidance Workgroup, including the development of a new risk assessment tool for SSIs.
  - Completion of the MDRO metrics paper.

Closing Session

The next HICPAC meeting would be held on November 13-14, 2008 at the Georgetown Marriott Hotel in Washington, DC. With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 11:28 a.m. on June 13, 2008.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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Patrick J. Brennan, M.D.
Chair, Healthcare Infection Control
Practices Advisory Committee