行政院及所屬各機關出國報告書
(出國類別 考察)

奧洲醫療品質管理制度考察報告

行政院研考會/省(市)研考會編號欄

服務機關 行政院衛生署
出國人 職稱 處長
姓名 譚開元
出國地區 奧洲
出國期間 90年9月18日至9月26日
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澳洲醫療品質管理制度考察

主辦機關

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出國地區 澳大利亞

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關鍵詞 醫療品質 醫療體系 醫院評鑑制度

內容摘要 澳洲主辦的「第一屆亞大地區醫療品質論壇」 主要目的在針對醫療照護品質的議題 提供國際間相互交流機會與相關訓練 並提供與會者及醫療品質界領袖 進行深度討論與經驗之分享 研習主題有四 一 改善醫療品質 到目前爲止 我們學到什麼？二 消費者如何觀看醫療體系？三 如何才是安全的醫療品質？四 跨越品質的斷層 將來怎麼做？ 從會中的報告與經驗交流 我們體認建立兼具醫療『品質』與『安全』雙管齊下的全國性政策之必要性 爰建議參採澳洲作法 研擬適用我國的安全照護標準 除出席國際會議外 並考察澳洲醫療品質推行概況與醫院評鑑制度 其建立醫療品質與評鑑資訊資料庫 建立評鑑委員證照與教育訓練制度 與推動評鑑委員參與醫療品質輔導制度等 均值得我國借鏡

本文電子檔已上傳至出國報告資訊網

行政院及所屬各機關出國報告書
(出國類別 考察)

澳洲醫療品質管理制度考察報告

服務機關　行政院衛生署
出國人　職稱　處長
　　　　姓名　譚開元

出國地區　澳洲
出國期間　90 年 9 月 18 日至 9 月 26 日
報告日期　90 年 11 月 15 日

摘　　要

澳洲主辦的「第一屆亞太地區醫療品質論壇」，主要目的在針對醫療照護品質的議題，提供國際間相互交流機會與相關訓練，並提供與會者及醫療品質界領袖，進行深度討論與經驗之分享。

研習主題有四

一、改善醫療品質　到目前為止，我們學到什麼？

二、消費者如何觀看醫療體系？

三、如何才是安全的醫療品質？

四、跨越品質的斷層　將來怎麼做？

從會中的報告與經驗交流，我們體認建立兼具醫療『品質』與『安全』雙管齊下的全國性政策之必要性，爰建議參採澳洲作法，研擬適用我國的安全照護標準。

除出席國際會議外，並考察澳洲醫療品質推行概況與醫院評鑑制度，其建立醫療品質與評鑑資訊資料庫、建立評鑑委員證照與教育訓練制度，與推動評鑑委員參與醫療品質輔導制度等，均值得我國借鏡。

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壹、目的

赴澳洲參加『第一屆亞太醫療品質論壇』，並考察澳洲醫療品質工作推行概況與醫院評鑑制度。

本次澳洲醫療品質管理制度考察行程如下

行程	日期	星期	時間	地點	主要活動
第一天	9/18	二	晚上	桃園中正國際機場	桃園中正國際機場啟程飛往澳洲雪梨市，於 9/19 清晨抵達
第二天	9/19	三	全日	雪梨市	參加『第一屆亞太醫療品質論壇』第一天活動
第三天	9/20	四	全日	雪梨市	參加『第一屆亞太醫療品質論壇』第二天活動
第四天	9/21	五	全日	雪梨市	參加『第一屆亞太醫療品質論壇』第三天活動
第五天	9/22	六	全日	雪梨市	雪梨市地區觀光旅遊
第六天	9/23	日	全日	雪梨市	雪梨市地區觀光旅遊
第七天	9/24	一	上午	雪梨市	參訪協和總醫院(榮民總醫院)
			下午		參訪澳洲醫療照護標準委員會
第八天	9/25	二	上午	雪梨市	參訪雪梨兒童醫院
第九天	9/26	三	上午	雪梨市	由雪梨搭機啟程，返回台灣
			晚上	桃園中正國際機場	抵達桃園中正國際機場歸賦

貳、過程

一、第一屆亞太醫療品質論壇

本論壇是由澳洲醫療安全與品質審議會（Australia Council for Safety and Quality in Health Care）和舉辦過歐洲醫療品質論壇之 IHI（Institute for healthcare Improvement）及 BMJ（British Medical Journal）等機構所共同籌辦，主要目的在於提供亞太地區一個機會與管道，針對醫療品質改善、醫療品質之實證研究與醫療品質管理未來展望等議題進行討論，對於醫療專業人員、醫院管理者、學術研究人員及品質政策制訂者，都是一個很好的觀摩與學習機會。

本次論壇多達 800 人報名，但由於雪梨希爾頓飯店場地限制，實際參加者分別來自 澳洲(地主國 258 人)、紐西蘭(59 人)、美國(23 人)、英國(32 人)、瑞典(4 人)、新加坡(38 人)、巴基斯坦(1 人)、葡萄牙(1 人)、沙烏地阿拉伯(1 人)、挪威(1 人)、荷蘭(1 人)、尼泊爾(1 人)、馬來西亞(1 人)、日本(9 人)、印尼(4 人)、印度(5 人)、香港(8 人)、德國(2 人)、芬蘭(1 人)、庫克島(1 人)、加拿大(3 人)、孟加拉(1 人)、巴林(1 人)、中華民國(3 人)，共 25 國計 674 人出席，盛況空前。

本次論壇的主要目的

1 針對持續改善醫療照護品質的議題，提供相關教育訓練。

2 針對持續改善醫療照護品質的議題，提供國際間相互交流的機會。

3 提供與會者與醫療品質界領袖，進行深度討論與經驗分享之機會。

本次研習主題

1 改善醫療品質　我們到目前為止，已經學到了什麼？

2 消費者如何觀看醫療體系？

3 如何才是安全的醫療體系？

4 跨越品質的斷層　將來怎麼做？

（一）改善醫療品質　我們到目前為止，已經學到了什麼？

Ross Wilson 醫師，引述 1933 年 Ray Liman Wilbur 醫師的名言，『醫療品質是一個文明的指標』。美國醫療品質含義如下

1 品質是可以測量的。

2 醫療品質有相當大的差異性。

3 改善醫療品質是困難的事。

4 提供財務誘因很少會對品質帶來多大的影響。

5 目前還缺少大眾測量品質的工具。

一項澳洲醫療品質研究結果發現

1 16 6%的住院病人都與不良事件(Adverse Event)有關。

2　51%的 AE 都是可以預防的。

3　46 6%的 AE 會導致輕微的殘障。

4　13 7%的 AE 會導致永久殘障。

5　4 9%的 AE 會導致死亡。

我們學到了什麼？

1　資料就是力量。

2　問題越挖越深，成本也就越貴。

3　明確釐訂醫療體系管理責任是必要的。

4　由上而下與由下而上的策略，兩者間應有互動關係。

5　測量是以「裁判」或「改善」為目標。

6　堅持是有必要的。

（二）消費者如何觀看醫療體系？

本主題是採消費者的立場，觀看醫療照護服務體系。研討會的目的，分別為

1 傾聽病患的就醫故事。

2 從故事中，獲取追求品質的教訓。

3 由與會專家的討論，直接深入瞭解品質課題。

主持人 Julie McCrossin 女士係澳洲國家廣播電台的主持人，也是澳洲新南威爾斯州的衛生消費者與社區參與小組副主席。會中提出四位消費者的就醫故事

1 澳洲 Thredbo 土石流山崩災難事件，生還者 Stuart Diver

先生，從建築工地倒塌，歷時 11 個小時才被救出災難現場，歷經急救技術員、一般科醫師的診治，以及到達醫院後接受各項醫療檢查與治療的故事。

2 Emma Sayers 小姐說明自己罹患癌症，接受醫療照顧的心路歷程。

3 Andrew Marich 醫師講述罹患白血病，自己被專業人員治病的過程。當事人覺得醫療照護體系中，少了點人性的關懷。尤其在化療期間，便秘之苦，苦不堪言。感覺到醫療精細分科，卻不易整合之弊。此外，病人權益與隱私的維護，更是需要醫療團隊的努力。

4 Michelle Kosky 則說明其在西澳的醫療消費者委員會，扮演病患角色的親身經歷。

從消費者學習到的重要訊息

1 病人與醫療照護提供者，對安全與品質的要求，都應做出貢獻。

2 醫師與醫療團隊成員，是幫助病患產生信心的重要關鍵，包括資訊充份分享在內。

3 病患與醫師共同承擔治療責任，醫師要學習尊重病人個別價值觀與需要。

4 主動邀請病患參與治療，遠超過只是幫忙病患治病。

（三）如何才是安全的醫療體系？

來自英囯的 James Reason 教授，對建立安全的醫療，從診斷到治療，提出下列重要的觀念與經驗

1　错誤的危險性

美囯每年约有 44,000-98,000 名病患死於醫療處置失誤。其中 3-4%是醫療人員造成的。誤失造成的成本損失，一年约 290 億美元。在英囯，每年约有 10,000 名病人不良事件發生，　其中约有 400 名病患死亡，此外英囯並有 28,000 個書面的病患抱怨事件，每年 4 億元英鎊係用於醫療事故案件。澳州的研究則指出　48%是手術不良事件，14%是制度不佳，13%診斷错誤，10%給藥错誤，8%處置不當，2%麻醉错誤。意外事件肇因於個人因素與组織因素。

错誤的定義係指無法達成規劃的行動，並且無法完成想要的结果。

错誤有三種型態　知識型的错誤、規則性的错誤與技術性的错誤。

意外事件會一再重演，不同的人會一再發生同樣的错誤，則意味著問題是發生於组織因素上。

2　擊敗怪罪式的循環

常見的组織糸统有三種核心表徵　怪罪、否認與追求卓越。

其實错誤是人們會產生的一種狀況，我們無法改變人，卻可以改變狀況，讓人可以在安全的環境中工作。應該設法

建立一種可以容忍錯誤的制度，並營造一種追求安全的文化。

（四）跨越品質的斷層　將來怎麼做？

Dr Don Berwick 是美國 Institute of Healthcare Improvement 的總裁與執行長，同時也是哈佛大學教授，提出如何跨越品質斷層的專論，認為錯誤可以分成三種類型

1 使用過當

例如抗生素過量使用，非必要的手術， 不必要的放射檢查等。

2 使用不足

例如老年人口半數沒有接受流感疫苗接種，五成急性心臟梗塞病患沒有適時接受適當的對症藥物治療。

3 使用錯誤

例如接近一成的醫院病患會有嚴重給藥錯誤，五萬美國人每年死於醫療處置錯誤。

研究指出　醫療界確實有嚴重的品質問題存在，起因於制度設計不良，問題將可以逐步解決，但需要作出有效改變。全國性改進目標應函蓋　安全、有效、平等，並且要以病人為中心去構想。

改變要分四個層面

1 明訂全國性目標。

2 改變照護的本質。

3 改變醫療照護組織。

4 改變政治影響等大因素。

新世紀的醫療照護服務規則

1 醫療照護要能提供連續不中斷的全程治療和復健。

2 醫療照護要由病患的需要和價值觀主導。

3 病患要能充份分享醫療資訊。

4 個別病人醫療方針要以實證醫學為依據。

5 病人的安全要以組織系統的制度化來維護。

6 病歷資訊務必對病人完全透明化。

7 醫療服務要不斷的減少浪費。

8 臨床醫師間的資料照會必須密切整合。

二、深度參訪

（一）澳洲概況

1 澳洲簡介

澳洲自 1770 年被英國的庫克船長發現，經過多年的努力，已從落後的農村，發展成世界知名的國度，2000 年更得到奧林匹克舉辦權，其成就有目共睹。

澳洲面積約七百六十八萬平方公里，人口一千九百

萬人。

澳洲是採聯邦政府，除首都領地、北領地外，下設新南威爾斯、維多利亞、昆士蘭、南澳、西澳與塔斯馬尼亞等六個州。

65 歲以上老年人口占 12%，原住民人口占 2 1%，平均餘命約為 74 歲，全國失業率為 7 3%。

澳洲總衛生支出， 1999-2000 為 537 億澳元，平均每人為 2,817 澳元，占 GDP 的 8 6%，每年約有 4 0%的成長率。

2 雪梨新貌

雪梨坐落於澳洲東南沿岸，是新南威爾斯州的首都，擁有 400 萬人口，失業率為 5 5%，占地面積 4,810 平方公里，是全澳第一大城市，也是一個天然港口形成的國際都會，曾經連續兩年被國際旅遊與休閒雜誌評定為全世界最好的城市。其海港景緻是雪梨一項重要資產，擁有 5 個碼頭區可前往 28 個不同的目的地。雪梨橋下的岩石區、雪梨塔、港灣大橋、歌劇院等最能引人注目。

雪梨亦曾被評為世界上最宜人居住的十大都市之一，觀察其優點如下

（1）市容規劃完善，環境清潔寧靜，居住品質優良。400 個生活圈井然有序，住宅區、商業區與工業區規劃健

全，居民住宅多為獨門獨戶並附有前庭後院之花園住宅。

（2）整個雪梨市，水、陸交通極為便捷，市區的鐵、公路可與機場接駁，並採離峰票價優惠措施，且能提供單日、一週及月票等多種方便選擇。

（3）兒童與老年福利政策與措施完善。兒童的教育與津貼，確能減輕家長經濟負擔。而老年退休年金制度健全，休憩設施完善，更是令人羨慕。

（二）協和總醫院

協和總醫院(Concord Hospital)是雪梨大學的教學醫院。長久以來，主要以服務榮民為主。1993 年始併入新南威爾斯醫療照護體系，具有 555 張病床，是第一家連續五年獲評特優獎的醫院，負責培訓住院醫師，提供多元化綜合性醫療照護服務。

為繼續提供榮民服務，該院特別開設了關節病變、柏金遜氏症、前列腺、中風等次專科門診以應需要。

（三）澳洲醫療照護評鑑委員會

Australia Council on Healthcare Standards（簡稱 ACHS)，為一獨立非營利性機構，該組織最初於 1974 年由澳洲醫學會與澳洲醫院協會聯合設立，致力推動澳洲全

國醫院評鑑工作，時至1989年已經建立一套醫療照護評估計畫，發展出客觀的臨床指標，1994年更將評鑑制度和持續品質改善與測量的觀念加以整合，發展出『醫療照護評估與品質持續改善計畫』(Evaluation and Quality Improvement Program，簡稱EQuIP)。

（四）雪梨兒童醫院

雪梨兒童醫院(The Children's Hospital at Westmead) 擁有350張病床，員工1,881人，是新南威爾斯境內最大的兒童醫院，也是國際著名的兒童醫院，占床92 1%，平均住院日僅3 18天，去年住院人數26,151人，手術13,647人次。

參、心得與建議事項

一、心得事項

本次論壇期間適逢美國遭受恐怖份子攻擊一週後，導致部分美國與會者缺席。大會主席帶領全體與會人員向美國死難者致哀。我國與澳洲的國際機場也都加強安檢措施，確保旅客安全。

本次首屆亞太醫療品質論壇，我國僅由國家衛生研究院石主任曜堂，和彰化基督教醫院陶阿倫主任與本人等三人參

加。而大會主辦人Dr　Ross Wilson 曾主動詢問我國何時願意承辦此一論壇。

澳洲醫療安全與品質審議會已有豐富經驗，成功推動下列事項

（一）建立兼具醫療『品質』與『安全』雙管齊下的全國性政策。

（二）建立讓消費者參與醫療照護過程的新醫療模式。

（三）整合醫療照護體系與健康保險制度，提供必要的資源，定出幾項重要的醫療品質行動專案(Action Plan)。

我國財團法人醫院評鑑暨醫療品質策進會在醫院評鑑標準制定與評鑑實務工作，值得參考借鏡澳洲經驗之處如下

（一）建立醫療品質與評鑑資訊資料庫，開放給一般大眾就醫參考。

（二）評鑑標準宜參酌先進國家『以病患為中心』的方向，融入我國醫療文化，發展出我國特有的醫院評鑑模式。

（三）建立醫院評鑑委員的證照與持續教育訓練制度。

（四）推動醫院評鑑委員參與醫療品質輔導的制度。

二、建議事項

（一）2001 年首屆「亞太醫療品質論壇」已於雪梨召開，2002 年第二屆論壇則已決定在新加坡舉辦，這次會期中我國曾被詢及何時願意主辦，當時答以請給予三年時間，以便妥為準備，此類大型國際會議，政府相關部會經費補助、分攤亦有待協商，而我國「醫療品質委員會」及「醫策會」推動之多項國家品質工作，屆時應已有初步具體成果，可向國際友人展示。是否積極爭取 2005 或 2006 年「亞太醫療品質論壇」主辦權，尚需獲得政策性裁示後辦理。

（二）澳洲新南威爾斯州擁有三萬名醫師，該州亦有類似我國「倫理委員會」的組織，接受各界申訴，如醫院同儕舉發或病人指證醫師缺失。經該委員會初步查證確有可議之處時，即行輪派三位委員組成約談小組，約談該位醫師，目前每週訂有一天，上午約談三位，下午約談三位，即一年平均約有 1%的醫師（300 人）會被約談，據告效果相當良好，受邀醫師均極重視委員建議及指示事項，如戒絕藥癮，每週報到自費驗尿，小心改善與病家溝通技巧等。此一方式我國「倫理委員會」應可參採，或可收端正風氣之宏效。

（三）澳洲醫療安全與品質審議會自成立以來，致力改善全國健康照護的安全與品質，並每年向衛生部長建言。

今年（請參閱附錄）的報告特別提及一套核心安全標準，作為監督改善安全照護的工具，該計畫廣徵學者專家及消費者意見後，以實證醫學為基礎，依安全優先順序（如院內感染、跌倒）、基本安全要求，研訂出此項核心安全標準。我國近年雖不斷推動醫療品質提升，但較輕忽照護安全部分，財團法人醫院評鑑暨醫療品質策進會今年十一月舉辦之台灣醫療品質指標計畫(TQIP)二週年研討會中，已開始探討住院病患跌倒與術後傷口感染等專題，我國或可參採澳洲作法，由本署「醫療品質委員會」以委外研究方式，研擬出一套適用我國的安全照護標準，以符兼顧醫療品質與照護安全的世界潮流。

（四）第二次世界大戰結束已逾半個世紀，澳洲戰後榮民醫院已因老兵逐漸凋零而紛紛融入一般醫療體系，有朝一日我國退除役官兵輔導委員會也可能併入厚生部，屆時榮民醫院與本署醫院，可能都會改隸於厚生部，當然台北榮民總醫院也可能成為陽明大學的直屬教學醫院，與台大、成大同屬教育部。

（五）本次會議，大會備有網際網路服務專區，供與會者使用，會期間經常大排長龍，可見網際網路無遠弗屆，經由上網迅速傳遞訊息，已是一種普遍性的大眾需求。我國既為資訊產業大國，日後在我國召開大型國

際會議時，亦應廣設網際網路服務專區，一方面方便國際友人，另方面亦足以展示我國資訊科技之強大實力。

AUSTRALIAN COUNCIL FOR SAFETY AND QUALITY IN HEALTH CARE

CORE STANDARDS FOR HEALTH CARE SAFETY

Consultation Paper

August 2001

Core Standards for Health Care Safety

Consultation Paper

August 2001

The Australian Council for Safety and Quality in Health Care was established in January 2000 by all Australian Health Ministers to lead national efforts to improve the safety and quality of health care, with a particular focus on minimising the likelihood and effects of error Council reports annually to Health Ministers

This document is an attachment to Council s second report to Health Ministers *Safety in Practice — Making Health Care Safer Second Report to the Australian Health Ministers Conference 1 August 2001*

Further information on the work of the Council can be found at www safetyandquality org or from Council Secretariat tel 02 6289 4244, fax 02 6289 8470 or email safetyandquality@health gov au

Acknowledgments

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RECOMMENDATIONS

That Health Ministers note the intention of the Australian Council on Safety and Quality in Health Care to

1. develop a set of core safety standards for health care facilities and services for which
   - a) there is evidence that demonstrates to an acceptable level of confidence that failure to meet a defined threshold of performance will increase the risk of serious patient harm,
   - b) implementation may be mandatory or voluntary,
   - c) achievement of is able to be verified,
   - d) a description of structure or process, represents conditions under which desired outcomes are likely to be achieved, and
   - e) a description of outcomes, represents results that are known to be achievable and can reasonably be expected to be achieved under acceptable conditions of practice
2. develop an implementation strategy and mechanisms to support uptake and compliance,
3. consult broadly within and beyond the health care sector during the progression of this work, and
4. report to Health Ministers on progress with this initiative including any recommendations regarding mandatory requirements

1 INTRODUCTION

The Australian Council for Safety and Quality in Health Care (the Council) has identified safety as the leading edge of health care quality and as the main focus for its activities Much discussion by Council has focused on the potential utility of standards or guidelines as tools to monitor and improve the safety of care

Standards to improve the safety of care can be used across the health care system from standards that relate to the roles of those who fund and purchase health care services through to those who directly provide services While Council is interested in the development of standards in all these areas the topic of this paper is on standard setting at the organisational provider level that is hospitals and other health care facilities rather than individual practitioners themselves

The paper first outlines some of the current standard setting and monitoring arrangements in place in health care and refers to approaches that have been adopted in other high risk high reliability industries The paper outlines a rationale for and proposes the development of core safety standards for use in the external assessment of health care provider organisations

Council intends to use this paper as a starting point for broad consultations on the development and processes for implementation of these core standards and to make recommendations to Health Ministers regarding mandatory requirements

2 THE RATIONALE FOR CORE SAFETY STANDARDS IN HEALTH

There is little doubt that all stakeholders in the health care system accept the edict first, do no harm Consumers, providers and purchasers can all be assumed to be motivated by a desire to provide safe high quality care

In recent years interest in standard setting and monitoring for safety in health care has been growing This is partly in response to well publicised incidents of iatrogenic injury (examples include the transmission of the AIDS virus between patients in a doctor s rooms, the administration of the wrong drug , missed diagnosis of breast cancer) and partly due to the recognition that as health care is becoming more complex, (with an ever increasing range of new life saving and life enhancing treatments and procedures available) and as the population ages the risks associated with health care are increasing

In this context there are increasing demands for assurances that a health care facility meets an acceptable level of safety See Attachment 1 for a summary of the expectations of accreditation

However many people who do understand the concept of accreditation believe almost certainly incorrectly, that when they see that a facility has been accredited that it equates with an assurance that health care is provided safely or that the service has implemented an acceptable quality improvement system It is questionable whether the continuous quality improvement focus of some of the existing accreditation processes is well understood It is equally questionable whether such processes meet the legitimate expectations of health care consumers or the broader community that health care systems are meeting acceptable standards of safety in health care delivery

This is not to devalue the contribution that the accreditation movement has made to the Australian health care system The culture of the health care industry our understanding of safety and quality issues and the community s expectations of the health care system have all changed substantially since health care accreditation first became available The rate of incidence cost and cause of system failures have not been well recognised nor were techniques to improve performance readily available Accreditation of health care facilities has contributed a great deal to quality practices and system wide awareness of quality issues in health care

However the issues raised above need to be addressed if community confidence in the health system is to be maintained and if costs (both social and economic) of poor quality or unsafe care are to be contained Council believes the development and implementation of a set of core safety standards would be a step in the right direction for addressing these concerns

2 1 Standard setting in other high risk industries

We can, and should be doing better to identify and manage risks and systemic failures in the health care system There is much we can learn from industries such as aviation, mining and road safety and from human factors engineers and cognitive psychologists about how to shift to a system that although inevitably high risk, has high reliability These industries have made measurable improvements in safety Health care needs to recognise that safety concerns are real, that the system is prone to error and failure, and that we need to work to reduce the risk in areas that are inherently risky

In industries where there is a risk of harm to the public or to workers as a result of the activities of those industries, there are usually strong regulatory mechanisms in place The use of mandatory standards is common Compliance with those standards is usually assessed by bodies which are independent of those which set the standards Both the standard setting and the compliance assessment processes are usually transparent and open to public scrutiny Failure by a business or a service to comply with the standards can lead to withdrawal of a licence to operate

As well as consulting within the health care industry Council intends consult more broadly to determine what lessons may be learned from approaches that have been taken in other high risk industries

3 STANDARD SETTING AND ASSESSMENT CURRENT ARRANGEMENTS

As mentioned above, existing approaches to accreditation have contributed substantially to the achievements that have been made in improving the quality of health care services and to raising awareness of this most important of issues

There is a wide and complex range of legislative requirements, standards and regulations which govern the way health care is provided and which consequently have an impact on the safety of health care Examples include building standards standards which relate to the environmental conditions in which health care is delivered and standards about equipment that can be used and the drugs that can be administered (Council is currently considering a project to scope existing legislation and regulation with the purpose of identifying barriers to and opportunities for improving safety that are presented by the current regulatory regime)

The development of standards and the practice of assessing hospitals and other health facilities against these standards is generally known as accreditation and has been undertaken in Australia at least since the 1970s Activity has increased considerably in recent years The most widely known health care accreditation agency in Australia is the Australian Council on Healthcare Standards which is the major player in hospital accreditation Other standard setting and accreditation bodies in health care include Standards Australia which has become more active in the area of hospital accreditation in recent years and the Quality Improvement Council Limited which promotes develops and co ordinates national standards and accreditation particularly in the primary and community health care sectors In addition accreditation services exist for other areas in health including general practice and specialist medical and diagnostic services

The most prevalent approach to accreditation in health care has been one of promoting and supporting approaches to continuous quality improvement This means emphasis has been on participation education and support rather than insisting on compliance with standards This approach is consistent with what has generally been expected of health care accreditation but the question is whether this approach alone is sufficient to ensure that acceptable levels of safety in care are being maintained

4 THE PROPOSAL FOR CORE SAFETY STANDARDS ISSUES FOR CONSULTATION

The first step in progressing this work will be to consult broadly both within and outside the health care industry The issues outlined below are designed to stimulate further discussion and generate suggestions for taking work forward on core safety standards

A set of core safety standards would address those elements of a health care services *structures* or *processes* that are considered critical to ensuring an acceptable level of patient safety Core safety standards may also incorporate *outcome* standards for specific clinical interventions or functions

For the purpose of this paper, the term 'standard' is used to represent a quantitative or qualitative description of structures, processes and/or outcomes in health care

- **which is based on evidence that demonstrates to an acceptable level of confidence that failure to meet a defined threshold of performance will increase the risk of serious patient harm,**
- **implementation of which may be mandatory or voluntary,**
- **the achievement of which is able to be verified,**
- **which, for a description of structure or process, represents conditions under which desired outcomes are likely to be achieved,**
- **which, for a description of outcomes, represents results that are known to be achievable and can reasonably be expected to be achieved under acceptable conditions of practice**

A set of core safety standards would establish a benchmark against which suitability to continue service provision could be assessed At a practical level definition of a set of core safety standards would be meaningless unless appropriate support for implementation and sanctions were available in the event of failure to comply

4 1 In which priority areas should core safety standards be developed?

Core safety standards should be targeted to areas where

- there is a recognised and significant health care safety problem (for example hospital acquired infection, falls medication management management of blood products)
- there is an established evidence basis for a standard
- there are established, risk adjusted outcome standards for health care interventions (for example, organ transplantation) and
- the consequences of failure to achieve the standard are serious either for individual patients or the system as a whole

4 2 Who should develop core safety standards?

Standards development has been, to a large extent a cooperative industry effort with considerable voluntary support from the professional colleges and other institutions and individuals

To ensure an appropriate evidence base and a clear link with safety, the development of core safety standards should be led by professionals qualified and experienced in the evaluation of clinical research, evidence based medicine and standards development The National Institute of Clinical Studies or the National Health and Medical Research Council may be in a position to contribute to this endeavour

Standards development should be undertaken in close collaboration with health care professionals, and should reflect the complexity of health care and the needs of diverse stakeholders including consumers

There may be a conflict of interest where the responsibility for developing standards is undertaken by the same body which has responsibility for assessing compliance This could be particularly so where there is increasing competition between providers of accreditation services The Council recommends that there be a clear separation of these roles

4 3 Who should bear the cost of standards development and assessment?

Costs of Standards Development

While all stakeholders have an interest in the effective development of core safety standards the obvious source of funding for this endeavour is government History suggests that contributions from other stakeholders will be difficult to obtain particularly in the developmental phase, and the legitimacy of requesting stakeholder contribution for the development of enforceable standards is questionable

Costs of Assessment

In some circumstances the introduction of a requirement that hospitals achieve accreditation status (for example by the Victorian Department of Human Services) has been accompanied by the provision of a grant to facilitate compliance

Increasingly third party purchasers such as private health insurers are requiring providers to be accredited While there is usually no direct financial support provided a commercial relationship exists between the parties which presumably allows for the whole contractual costs including the costs of accreditation

Introduction of a rigorous and transparent system of assessment is likely to increase direct costs significantly

Outside health care there is significant precedent for

- safety standards development funded by government (for example occupational health and safety standards)

- regulatory enforcement by government or by third parties acting on government s behalf and funded by government and

- responsibility for costs of compliance resting with the subject of the regulation

This may be a suitable model for health care Ultimately purchasers of health care including government should realise economic benefits from objective improvement in the safety of the health care system

4 4 How and by whom should compliance with standards be assessed?

Surveyors/auditors and the organisations they represent will need to be professional independent highly trained and motivated and capable of undertaking reliable, valid and reproducible assessments of compliance

Compliance assessment should be structured to assure stakeholders that compliance is continuous Random audits combined with regular assessment should be considered

Monopoly of service provision is undesirable In most industries a range of organisations is accredited to undertake similar surveys and audits in compliance with strict auditing standards A similar market could be developed in health care

4 5 How would compliance be supported and assured?

In order to support the take up and implementation of core safety standards mechanisms would need to be in place to support those who have difficulty meeting the standards and to appropriately acknowledge those who achieve them This might involve education advice on how to change processes or structures peer support and bringing the failure to comply to the attention of appropriate authorities

In terms of making compliance mandatory the tension between safety of and access to health care needs to be acknowledged Australian consumers and communities place a high value on both If services are unable to meet mandatory safety standards and as a result their activities are restricted or the services are closed the ultimate outcome will be a reduction in access This is likely to have serious social and political consequences particularly for rural and remote communities

However it is generally held that sanctions must be applied where minimum standards of safety are not met and that sanctions should be spelt out in regulation or via contracts or agreements if change is to be achieved

These issues will be further explored during consultation

4 6 Who should have access to information about compliance?

The public benefit will be well served by transparency of process and outcome The objectives of reform can only be achieved if all stakeholders have access to information about compliance

5 CONCLUSIONS AND NEXT STEPS

Accreditation of health care services has made an important contribution to system wide understanding of and commitment to health care quality improvement Historically the aim of accreditation was to stimulate quality assurance and continuous improvement efforts in the health care system Its origins within the industry and its commitment to assessment by peers have been important in gaining acceptance and cooperation from a range of stakeholders

A rising awareness of significant safety issues in the health care system has caused critical review of the continuous quality improvement focus of accreditation, with many stakeholders identifying compliance with core safety standards as an essential component of a continuous improvement process

Increasingly consumers and third parties are relying on the accreditation status of a health care service as an indicator of the safety and quality of the care provided by it This reliance is raising questions about the validity of accreditation standards as indicators of safety and quality and the rigour of the accreditation process in assessing compliance with those standards While existing approaches to accreditation provide an invaluable service to the health care industry, Council believes these can be effectively complemented and underpinned by a set of core safety standards

The concept of core safety standards, with which universal compliance would be required has been raised by the Council for consideration as a technique for addressing known serious deficiencies in health care safety While this concept is likely to attract considerable support from consumers and third party purchasers its further development is not without risk The potential impact on consumers and governments of the imposition of sanctions consequent to health services failing to meet core standards is likely to be significant

If this concept is progressed development of core safety standards should be undertaken in a rigorous, evidence based framework with a focus on high priority safety issues

The first step in progressing this work will be to consult broadly both within and outside the health care sector

APPENDIX 1

EXPECTATIONS OF ACCREDITATION

Consumers

There is an increasingly explicit recognition of the consumer as the central reference point for assessing the adequacy of our health care safety systems

Although consumers often gain confidence from the fact that a hospital has accreditation status it is not clear that consumers understand what this status confers

Accreditation status is variously interpreted as meaning

- that a service is safe
- that a service provides high quality care
- that a service has implemented an acceptable quality improvement system

> ***"Consumers aren't interested in your journey to quality They want safe hospitals They don't want to meet you at the beginning of your journey "***
>
> Consumer Advocate

There is concern amongst those consumers who do have a better understanding of the meaning of accreditation status that continuous quality improvement approaches to accreditation can overlook the possible inadequacy of the starting point from which improvement is being encouraged

Providers

Accreditation has been widely embraced by providers who may have a variety of objectives

- to access a management tool that will assist in education and the development of a quality culture
- to access industry specific techniques for safety and quality improvement
- to reassure the board management and health care professionals that their facility is providing care of an acceptable standard of safety and/or quality
- to assist with benchmarking performance
- to respond to requests demands or the imposition of financial incentives by purchasers
- to reassure their communities and consumers of the safety and quality of their care

Funders / Purchasers

Funders and purchasers of health care include governments consumers and third parties such as private health insurers Accreditation is generally sought as an assurance to their communities of interest (for example the general public or contributors to a private health fund) that the service that is being purchased on their behalf meets an acceptable standard of safety and quality

With recognition of the likely direct relationship between breaches of safety and increased cost of care funders and purchasers may increasingly, seek firm assurances that safe care is being provided