行政院及所屬各機關出國報告
（出國類別：考察）

中央健康保險局
「加拿大英屬哥倫比亞省科技評估制度考察」

出 國 人：中央健康保險局副總經理江宏哲
中央健康保險局醫審小組組長龐一鳴
中央健康保險局醫務管理處藥品特材科科長黃肇明
中央健康保險局醫務管理處支付標準科四等專員劉媛媛
行政院衛生署企劃處第一科科長陳穎慧

出國地區：加拿大維多利亞、溫哥華

出國期間：(1)江副總經理為 90 年 6 月 13 日至 6 月 30 日
(2)龐組長為 90 年 6 月 13 日至 7 月 1 日
(3)黃、劉及陳等三員為 90 年 6 月 17 日至 7 月 1 日

報告日期：90 年 7 月 27 日初稿第一稿完成，90 年 8 月 16 日完稿

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報告名稱:

科技評估制度考察

主辦機關:

行政院衛生署中央健康保險局

聯絡人／電話:

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出國人員:

江宏哲　行政院衛生署中央健康保險局　副總經理
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龐一鳴　行政院衛生署中央健康保險局　台北分局　組長
黃肇明　行政院衛生署中央健康保險局　醫審小組　組長
劉媛媛　行政院衛生署中央健康保險局　醫務管理處　四等專員

出國類別: 考察

出國地區: 加拿大

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分類號/目: J0／綜合（醫藥類）　J0／綜合（醫藥類）

關鍵詞:　健康科技評估, 實證醫學, 系統評估

內容摘要: 本考察團期望本次的取經行動，能紮實地效法加拿大英屬哥倫比亞省的經驗，以實證醫學（evidence-based medicine）爲本，運用系統評估（systematic review）的方法，將健康科技評估組織建造起來，將健康科技評估的原理原則散播開來，更希冀在以社會觀點凝聚所有參與者共識的前提之下，來建立本土的模式，也希望不久的將來，於實際的健康科技議題之中，如藥品、特殊材料、儀器、處置、檢驗、介入、專案、臨床執業準則、以及健康相關之行政、服務與企劃等等領域，政府、學術單位及醫療決策精英都能責無旁貸，共同以健康科技評估爲本進行決策，讓決策的過程趨於理性、合理、系統化，也爲健保注入另一波新的改造。

本文電子檔已上傳至出國報告資訊網

考察報告摘要

廣義而言，健康科技評估（Health Technology Assessment, HTA）為一種政策研究，係檢驗單一健康照護技術的短期及長期結果。加拿大自 1989 年由中央政府草創該國的健康科技評估制度，在現今的國際社會享有美譽，英屬哥倫比亞省（British Columbia, BC）健康科技評估執行的能力亦是該國的翹楚，為瞭解加拿大健康科技評估制度之機構、運作及各機構間合作與整合之現況，本局特與行政院衛生署、國立臺灣大學、國防醫學院等學者專家組成考察團，赴加拿大英屬哥倫比亞省進行深度訪問，除了瞭解該省健康科技評估之內容及方法，也以個案、雙向討論的方式與專家交流意見。

本考察團期望本次的取經行動，能紮實地效法加拿大英屬哥倫比亞省的經驗，以實證醫學（evidence-based medicine）為本，運用系統評估（systematic review）的方法，將健康科技評估組織建造起來，將健康科技評估的原理原則散播開來，更希冀在以社會觀點凝聚所有參與者共識的前提之下，來建立本土的模式，也希望不久的將來，於實際的健康科技議題之中，如藥品、特殊材料、儀器、處置、檢驗、介入、專案、臨床執業準則、以及健康相關之行政、服務與企劃等等領域，政府、學術單位及醫療決策精英都能責無旁貸，共同以健康科技評估為本進行決策，讓決策的過程趨於理性、合理、系統化，也為健保注入另一波新的改造。

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中央健康保險局

「加拿大英屬哥倫比亞省科技評估制度考察」

一、背景說明

健康科技評估（Health Technology Assessment, HTA）是保險制度中相當重要的一環。基於醫事人員掌握的資訊往往比病人大得多的狀況，保險人加入健康服務提供者與保險對象的交易關係，這種保險制度可運用來確保健康服務能符合最低、可接受的標準，保障保險對象有效利用醫療資源，減少保險對象接受「非屬醫療必需之診療服務及藥品」及「未經實證與潛在有害之治療」，並有效控制醫療費用。基於整體保險對象需求之考量，實務上需架構在科技評估系統之下，發展一套符合科學原則的科技評估執行模式，審慎決定是否列入「支付標準」、「藥價基準」及訂定相關規範，並儘可能以健康科技評估制度來早期監測保險對象所接受的健康服務項目、藥品、特殊材料及儀器，使其能有合於時代進步、具經濟學上的成本效益，更希望可進一步以預防措施來保障保險對象，讓他們受到侵害的可能性到最小（如財務與健康上的損失）。

以保險運作著眼，健康保險第三者付費的方式，常引發兩大議題：部分保險對象無法珍惜醫療資源的道德危機及部分醫事服務者誘發保險對象的需求，倘若上述兩大現象事態擴大，可能會危害健保財務並影響到健保永續經營的機會、降低健康服務之適當性及品質，也就是可能危及全體保險對象的公共利益。以德國社會法典第五部為例，明文規定不符經濟效益的項目，保險疾病基金會並不給付。

再就科技發展的特性說明，新發展的健康科技並不一定是「科技發展之最先進（state of the art）」，也有可能是「理論發展之最先進（state of the theory）」。一項健康科技研發成功後，經動物實驗、進入臨床人體試驗，須具高度安全性、效能、適當性及廣為醫界主流所接受後，保險人方審慎評估是否納入「全民健康保險醫療費用支付標準」或「全民健康保險藥價基準」，基於全民健保財源有特定範圍，不符經濟效益的項目，自應不在給付範圍。

如何界定及評估或再評估不符經濟效益的服務項目呢？依據司法院大法官會議九十年四月二十日釋字第五二四號針對全民健康保險所生權利義務之解釋，保險所生之權利義務應有明確之規範，若法律就保險關係之內容授權以命令為補充規定者，其授權應具體明確，且須為被保險人所能預見*。就目前全民健保規範體系中內部事項之行政規則，雖在總額支付制度及非總額支付制度會有不同的思維，惟基本上，方法學上仍須考量了新舊醫療處置的優缺點、安全性、效益、成本、醫界技術純熟度、醫院設備、醫療輔助人力等等狀況，再由決策主體權衡保險對象付費能力及健康需要來設定合理之給付項目，現制以儘量能納入「全民健康保險醫療費用支付標準」及「全民健康保險藥價基準」的原則，唯與先進國家科學化、系統化的科技評估模式相較，仍有一段距離，如本國尚未有保險對象所能預見的「保險服務項目科技評估準則」，也尚未將經濟學評估藥物或治療模式的科學實證(evidence based)手法運用至健保決策。

加拿大自 1989 年由中央政府草創該國的健康科技評估(Health Technology Assessment, HTA)制度，在現今的國際社會享有美譽，英屬哥倫比亞省(British Columbia, BC) 係該國的十省及三個特區中，繼 Quebec 省之後執行健康科技評估的省份（以英語為主的省份為第一個開辦的），該省除了擁有較多的人口及預算外，健康科技評估執行的能力亦是該國的翹楚，故本局特與行政院衛生署、國立臺灣大學、國防醫學院等學者專家組成考察團，除了出發前在國內以讀書會的形式進行多次經驗與資料交流之外，再以深入訪問的方式造訪英屬哥倫比亞省省會維多利亞市及溫哥華市，期盼這次向加拿大 BC 省學習制定「健康科技評估」章法的取經行動，能為健保注入另一波新的改造。

***按司法院大法官會議九十年四月二十日釋字第五二四號解釋文略以：「全民健康保險為強制性之社會保險，攸關全體國民之福祉至鉅，故對於因保險所生之權利義務應有明確之規範，並有法律保留原則之適用。」同文之解釋理由書略以：「若法律就保險關係之內容授權以命令為補充規定者，其授權應具體明確，且須為被保險人所能預見。」

二、目的

(一) 瞭解加拿大健康科技評估制度之機構、運作及各機構間合作與整合之現況。

(二) 瞭解加拿大英屬哥倫比亞省健康科技評估之內容及方法，並以個案、雙向討論的方式與專家意見交流。

(三) 嘗試以加拿大英屬哥倫比亞省的經驗凝聚參加人員之共識，以建立本土之模式。

三、過程：

本團為考察加拿大健康科技評估制度之部分，於90年6月17日至90年7月1日共十五天，除了來回飛機飛行時數各十五小時餘之外，在英屬哥倫比亞省省會維多利亞停留七天，在溫哥華停留五天，考察團名單、行程、拜會機構與專家名單，以及考察過程經綜合整理，分為BC省的醫療服務體系、健康科技評估制度的基本方法和與醫療服務體系的關係、加拿大及BC省健康科技評估制度之組織架構、BC省健康科技評估制度之實務運作等四項議題，說明如下：

(一) 加拿大英屬哥倫比亞省科技評估考察團名單

1. 行政院衛生署
   - ◆ 陳穎慧　行政院衛生署企劃處第一科科長
2. 中央健康保險局
   - ◆ 江宏哲　中央健康保險局副總經理
   - ◆ 龐一鳴　中央健康保險局醫審小組組長
   - ◆ 黃肇明　中央健康保險局醫務管理處藥品特材科科長
   - ◆ 劉媛媛　中央健康保險局醫務管理處支付標準科四等專員
3. 國立台灣大學
   - ◆ 侯勝茂　國立台灣大學醫學院教授
   - ◆ 賴美淑　國立台灣大學公共衛生學院教授
   - ◆ 張啟仁　國立台灣大學醫學院附設醫院副研究員兼任副教授
   - ◆ 王貞棣　國立台灣大學醫學院附設醫院主治醫師
4. 國立國防醫學院
   - ◆ 譚延輝　國立國防醫學院藥學系副教授

(二) 每日考察行程

詳如下列表一：

表一　考察行程(90 年 6 月 17 日至 7 月 1 日)

***6 月 17 日(星期日): 啟程，由台北搭 AC018 出發，於 Vancouver 轉 AC8363 抵維多利亞(Victoria)**

	Monday June 18	Tuesday June 19	Wednesday June 20	Thursday June 21	Friday June 22
AM 9:00 to 12:00	Session 1 *1. Welcome & Review of Schedule* *2. Overview of BC Healthcare System* 主持人: Steve Kenny 地點: 加拿大俾詩省衛生處(BC Ministry of Health)	Session 3 *1. Current Status of Health Technology Assessment in Canada: organizations and mandates* *2. Role of HTA in Utilization Management* 主持人: Steve Kenny 地點: 加拿大 維多利亞大學(University of Victoria)	Session 5 *Introduction to Health Technology Assessment (II):* *1. Systematic Reviews & Other Sources of Unbiased Information* *2. Vendor Information* *3. HTA as a tool for evidence-based management* 主持人: Rebecca Warburton 地點: 加拿大 維多利亞大學(University of Victoria)	Session 7 *Medical Services Plan Clinical Practices Guidelines and Protocols: history, organization and process.* 主持人: Mary Baker 地點: 加拿大俾詩省衛生處(BC Ministry of Health)	Session 9 *Health Technology Assessment: Hospital Perspective* (Capital Health Region Office) 主持人: Barbara Poole 地點: Eric Martin Pavilion, Royal Jubilee Hospital
	Lunch (BCHIDO)	Working Lunch	Lunch	Lunch	Lunch
PM 1:30 to 4:30	Session 2 *Orientation to Victoria* 主持人: Steve Kenny 地點: 加拿大俾詩省衛生處(BC Ministry of Health)	Session 4 *Introduction to Health Technology Assessment (I):* *1. definition & terminology* *2. Assessment & Technology Life Cycle* *3. Economic Evaluation* 主持人: Rebecca Warburton 地點: 加拿大 維多利亞大學(University of Victoria)	Session 6 *Introduction to Health Technology Assessment:* *Case Study* 主持人: Malcolm MacLure 地點: 加拿大 維多利亞大學(University of Victoria)	Session 8 *1. British Columbia Pharmacare Program* *2. Drug Benefits Committee* *3. Facility Tour: BC Pharmanet* 主持人: Nerys Hughes 地點: 加拿大俾詩省藥物照護執行方案辦公室(BC Pharmacare Office)	Session 10 *Roundtable Discussion:* *End of Week Review and Discussion* 主持人: Steve Kenny Rebecca Warburton Malcolm MacLure 地點: Eric Martin Pavilion, Royal Jubilee Hospital
	dinner	dinner	dinner	dinner	dinner
PM 5:00 to 6:30		*經驗與心得分享* 主持人: 侯勝茂教授 地點: 旅館 (Queen Victoria Inn)		*經驗與心得分享* 主持人: 江宏哲副總經理 地點: 旅館 (Queen Victoria Inn)	

***6 月 23 日(星期六):　於旅館整理資料(in Victoria)。**

***6 月 24 日(星期日):　由維多利亞(Victoria)行至溫哥華 (Vancouver) 。**

	Monday June 25	Tuesday June 26	Wednesday June 27	Thursday June 28	Friday June 29
AM 9:00 to 12:00	Session 11 ***Introduction to British Columbia (and Canadian) Pharmaceutical Policies*** 主持人: Bob Nakagawa 地點: 加拿大英屬哥倫比亞大學 (University of British Columbia, UBC)	Session 13 ***British Columbia Therapeutic Initiative (II):*** ***Case Studies and Discussions*** 主持人: Jim Wright 地點: 加拿大英屬哥倫比亞大學(UBC)	Session 15 ***Meeting the Experts on Pharmaceutical Issues:*** 1. ***Review of BNHI/NTU initiative*** 2. ***Review of NTU Sample Assessment Case*** 3. ***Roundtable discussion*** 主持人: Jim Wright 地點: 加拿大英屬哥倫比亞大學(UBC)	Session 17 ***Overview of British Columbia Office of Health Technology Assessment (I):*** ***1. Overview & /Organization*** ***2. Case study*** 主持人: Ken Bassett Arminee Kazanjian 地點: 加拿大英屬哥倫比亞大學(UBC)	Session 19 ***Summary Roundtable Discussion:*** ***What is next for HTA in Taiwan?*** 主持人: Ken Bassett Arminee Kazanjian Isabelle Savoie 地點: 加拿大英屬哥倫比亞大學(UBC)
	Lunch	Lunch	Lunch	Lunch	Lunch
PM 1:30 to 4:30	Session 12 ***British Columbia Therapeutic Initiative (I):*** 1. ***Program overview*** 2. ***Organization*** 3. ***Policy and Procedure*** 4. ***Case Study*** 主持人: Jim Wright 地點: 加拿大英屬哥倫比亞大學(UBC)	Session 14 ***British Columbia Pharmacoeconomic Initiative (I):*** 1. ***Program overview*** 2. ***Organization*** 3. ***Policy and Procedure*** 4. ***Case Study*** 主持人: Aslam Anis 地點: ***St. Paul's Hospital***	Session 16 ***Individual Research Time*** 地點: 旅館(Rosedale on Robson)	Session 18 ***Overview of British Columbia Office of Health Technology Assessment (II):*** ***Case Study*** 主持人: Isabelle Savoie 地點: 加拿大英屬哥倫比亞大學(UBC)	Session 20 ***Preparation for returning to Taiwan (整理資料、打包行李)*** 地點: 旅館(Rosedale on Robson)
	dinner	dinner	dinner	dinner	dinner
PM 5:30 to 7:00	***經驗與心得分享*** 主持人: 侯勝茂教授 地點: 旅館 (Rosedale on Robson)			***經驗與心得分享*** 主持人: 江宏哲副總經理 地點: 旅館 (Rosedale on Robson)	

*6 月 30 日(星期六): 返程，於溫哥華(Vancouver)搭 AC9801 飛回台北(7 月 1 日抵達)

(三) 加拿大 BC 省科技評估相關機構及網址(website)

本考察團共於十個工作天的行程中，拜會英屬哥倫比亞省維多利亞、溫哥華各類科技評估之機構共 11 處，相關機構及網址羅列如附件一。

(四) 加拿大英屬哥倫比亞省科技評估專家之拜會

專家拜會方面，有省方衛生單位、區域或社區內之醫院及二所大學等單位，共有 19 位專家向本團團員詳細解說與互相交流，該省專家們態度相當親切與細心，傳遞本團不少資料及經驗，相關名單如附件二。

(五) BC 省的醫療服務體系

加拿大政府衛生體系之層級分為中央政府(Federal) 、省政府(Provincial)及區域或社區(Region/community)等三級；加拿大健康法案(Canada Health Act)之特點為 Universality、Comprehensiveness、Accessibility、Portability、Public Administration 等五項，故健康照護體系提供民眾的服務，大多由公家機關長遠規劃與管控，範圍涵蓋包括預防保健、急性照護、繼續照護（即長期照護）、復健、安寧照護及心理健康等，無論衛生政策及健康保險的決策，皆由各省衛生處執行與規劃，例如所有醫院均為公立，基層保健醫療大多由開業醫師執行，繼續照護機構大多為私立等，其餘有關健康照護體系、健康保險系統及 Pharmacare 的介紹，請見附錄一、二、三的資料。

(六) 健康科技評估制度的基本方法和與醫療服務體系的關係

1. 健康科技評估（Health Technology Assessment）之定義：

(1) 狹義：評估或檢定一項技術的安全性、效能及效益（the evaluation or testing of a technology for safety, efficacy, and effectiveness.）。

(2) 廣義：為一種政策研究，係檢驗單一健康照護技術的短期及長期結果（a process for policy research examining short- and long-term consequences of individual health-care technologies.）。

2. 健康科技評估制度的基本方法及相關工具

健康科技評估是一種混合實證醫學與以實證為本做決策的方法。

(1) 實證醫學（Evidence-based medicine, EBM）

是種憑良心、明確、明智的過程，用在照護個別病人時，利用現有最好的實證來下決定，在已有的、最好的、外在的臨床實證之中做系統性研究，整合個別臨床專家的見解。重要五項步驟：一個特定且能回答的臨床問題、搜尋相關實證（Evidence）、對實證進行 critically appraise 以求其重要性與效度、運用實證來治療病人、評估實證醫學本身的成果。

(2) 系統評估（Systematic Review）

為健康科技評估常用的方法。根據 Cochrane 組織的說明，系統評估為

相當重要的健康研究方法，發展於 1980 年代，該研究方法是種批判性的審核（critical review），為合成某一特定主題已存在的實證，使用系統性方法來進行研究設計，以使偏頗減至最小。其重點在：強調一個清晰的問題、包括所有相關的臨床試驗結果（也含"gray"文獻）、使用 critically appraise 及合成研究結果的方法與工具（如 critical appraisal、meta-analysis、並不一定要所包含的研究結果都是實證等級達最高等的）。

(3)相關工具之參考資料：本考察團拜會相關機構及專家後，搜集到的資料相當豐富，其中有多個網址(website)，包含健康科技評估關聯之機關、健康科技評估常見之方法、藥物治療資訊等參考資料，可做為推展健康科技評估的資料來源。經綜合整理可供運用的網址(website)共 92 個，分成十四大類如下（詳如附件一）：

A. Health Technology Assessment
B. Regulatory Status
C. Clinical Practice and Practice Guidelines
D. Meta-analysis
E. Quality of Life Measurement
F. Systematic Reviews
G. Sources of Evidence
H. Hospital HTA
I. Journals online
J. Social Sciences
K. HTA: Case studies
L. Health Policy Research

M. Drug Therapy Information

N. Canada Government Links

3. 健康科技評估制度與醫療服務體系的關係

關於健康科技評估（Health Technology Assessment, HTA），加拿大中央政府制定有國家模式，由各省依各地之需求及環境等因素，決定是否執行與規劃；英屬哥倫比亞省健康科技評估系統是以官方資助、由大學學術獨立研究機構為主體的模式執行，並整合成為政府衛生體系決策系統之重要智庫，除擔任政府制定執業指引或準則(guideline and protocol) 、評估業界對新藥之分析報告等等衛生政策之諮詢角色外，健康科技評估的手法已廣為英屬哥倫比亞省（BC 省）省政府(Provincial)及區域或社區(region/community) 決策時必要之方法，如以系統評估(systematic review)的方式比較新藥、新特材及技術是否符合成本效益，提供 Pharmacare、Medical Services Plan、Hospital 是否支付或引進的決策依據。

(七) 加拿大及 BC 省健康科技評估制度之組織架構

1. 加拿大健康科技評估的國家級模式

(1)於 1989 年 12 月加拿大聯邦政府、各省或特區政府聯手共同創立加國健康科技評估聯合辦公室（Canadian Coordinating Office for Health Technology Assessment，CCOHTA），其組織經立法為非營利組織，位於 Ottawa 的辦公室於 1990 年 8 月正式運作。該組織建立之初為三年的實驗計畫，於 1993 年 4 月經外部的評估，建議 CCOHTA 應強化

並成為永久的組織。於1999年12月經Conference of Deputy Ministers of Health通過的五年計畫，其經費成長超過二倍，更加肯定CCOHTA。

(2)因為加拿大關於健康科技的引進（acquisition）、擴散及利用之事項係為省政府的職責，聯邦政府的責任在於科技的法規及許可（如規範藥物符合安全性(safety)及效能(efficacy)之標準），CCOHTA則是由這兩個層次的政府所聯合草創，其原因是：(A)健康科技的重要性、好好瞭解其費用的需要與健康科技對人類健康帶來的衝擊；(B)來自生醫研究的技術發明產量多且快速，造成對資源分配的壓力；(C)體認缺乏科技資訊散播與利用的合理性；(D)評估資料可做為衛生政策的重要決策依據；(E)可用來聯邦政府與地方政府間健康科技之管理；(F)可用來改革健康體系時實驗的需要等。

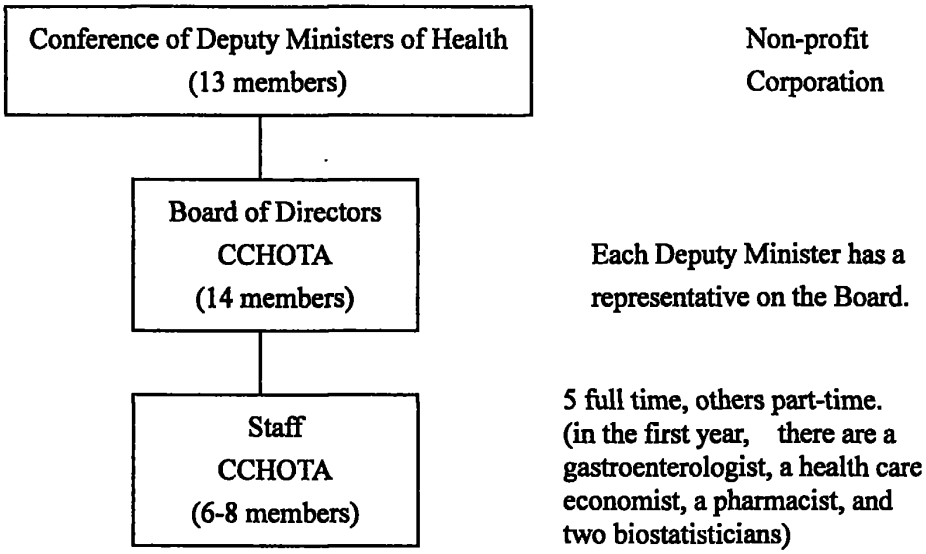
(3)CCOHTA在1990/91年度的預算約54萬加幣，30%來自聯邦政府，70%來自地方政府，費用依人口數來計算，大約是每人頭2分加幣。

(4)宗旨（mandate）：CCOHTA的任務是藉由影響決策者採用科技成本與效益以及科技對健康的衝擊等資料做決策，這些資料是經由資料搜集、分析、創造和資訊傳播等過程，以鼓勵能合宜使用健康科技。身為國家組織的CCOHTA，以促進資訊交換、資源共享、使健康科技評估依優先順序的各項工作井然有序為目標。

(5)CCOHTA評估的過程如附錄四。

(6)組織：CCOHTA 開辦初期之組織如圖一所示。

圖一　Organization Chart in 1992



目前的理事會及諮詢委員會，其簡要說明如下：

A. Board of Directors：理事有 14 位，由聯邦政府、10 省及 2 個特區的衛生部副部長指定。理事會擔負 CCOHTA 的統籌、製定政策與優先順序、管理基金等責任。理事中互選出執行委員會（Executive Committee），產生主席、副主席及 Member-at-Large 等各一位。代表聯邦政府的理事可參加所有執行委員會的會議。

B. Scientific Advisory Panel (SAP)：委員有 15 位。提供可靠、獨立及專家的科學性意見給 CCOHTA 理事會。委員係由理事會指定著名研究者組成，代表的領域有臨床方法學者、經濟學家、統計學者、人口健

康學者、藥物流行病學者、臨床各領域的專家等，任期二年，得連任一次。SAP 下由三位委員再組成各次委員會，來審議專案。另 SAP 與 Pharmaceutical Advisory Committee 共同對藥物相關的評估專案提供意見，以及設定評估的優先順序。

C. Pharmaceutical Advisory Committee (PAC)：委員有 14 位。提供關於藥物評估與相關議題的意見給 CCOHTA 理事會。委員係由理事會指定，代表各省、特區的藥品部門以及聯邦政府衛生部與 Patented Medicine Prices Review Board。

D. Devices and Systems Advisory Committee (DSAC)：委員有 14 位。關於醫療器材與健康體系或服務的健康科技評估議題，提供意見給加拿大各衛生部，CCOHTA 理事會及研究員。委員係由理事會指定，代表各省、特區及聯邦政府衛生部。

(7)一般功能

A. Coordination：建立與維持加拿大連結相關機構參與研究發展或健康科技評估、同時蒐集科技技術與政策上的資料、設立圖書館、使加拿大整個國家的資訊分享井然有序、促進聯邦與地方政府在健康科技評估的領域採聯合行動、儘可能使加拿大新技術發展的評估井然有序。

B. Anticipation the Future：監測科技的研究與發展、確定浮上檯面技術的趨勢、確定評估的優先順序。

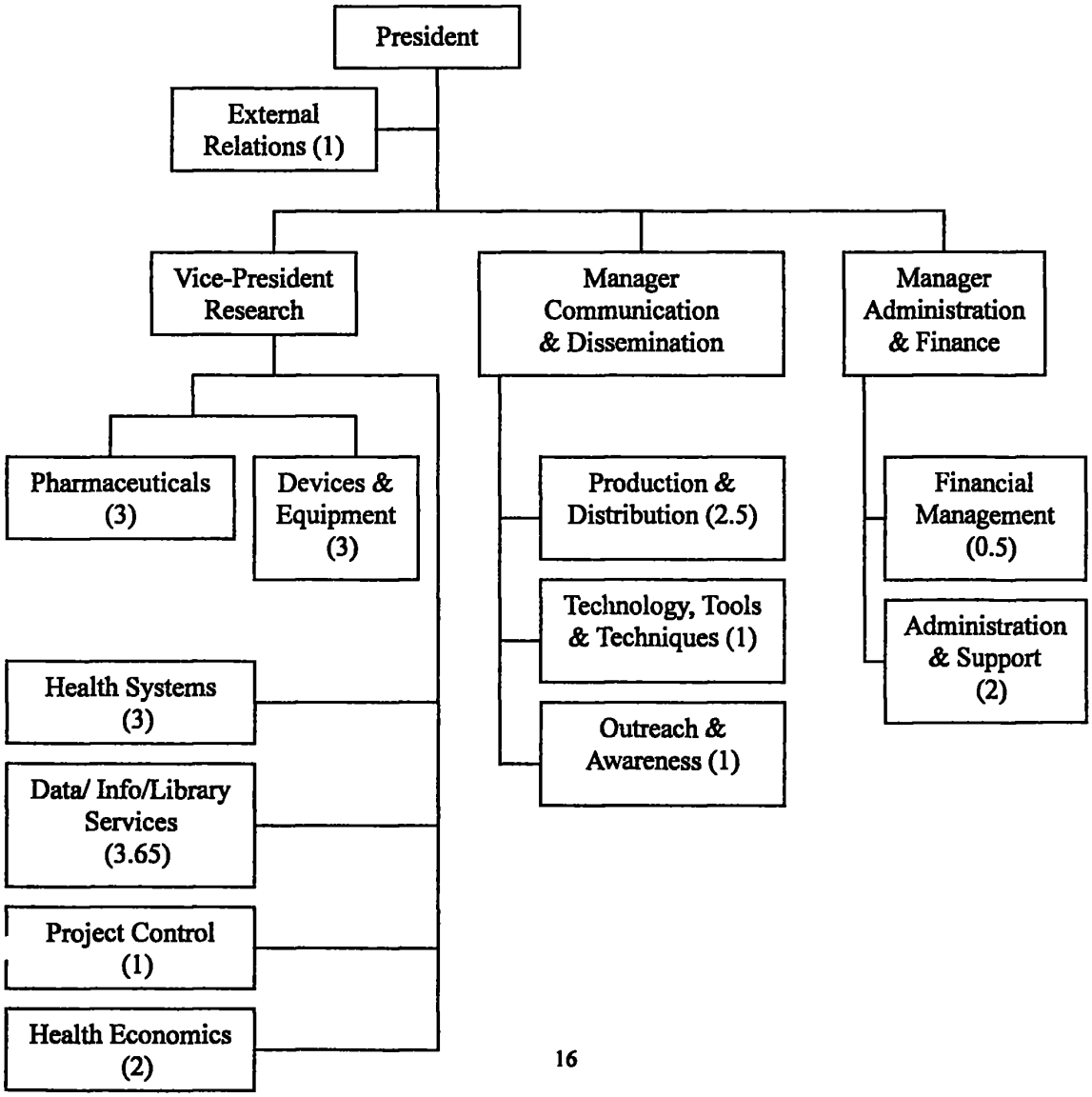
C. Knowledge Development：確定科技評估研究的優先順序、促進評估技術的發展與使用、發表健康科技評估資訊。

D. CCOHTA 並不做成建議案，僅提供 critical analyses，各省政府的任務則基於這些分析發展成建議。

E. 各項報告一般是在組織內完成草稿，每份報告皆由 3 到 5 位專家審查。

(8)現行 CCOHTA 之組織如圖二所示：

圖二　CCOHTA Organization (Now)



(9)該單位已發表及進行中之研究詳見其網址（網址如附件一）。其中出版的藥物經濟評估準則（現行版本為"Guidelines of Economic Evaluation of Pharmaceuticals Canada", CCOHTA 2nd Ed., 1997）是加拿大各省或其他國家奉行的圭臬。

(其他參考資料：Technology Assessment: National and International Perspectives on Research and Practice (a Satellite Symposium of ISTAHC 8) June 13, 1992, pp3-6)

2. 英屬哥倫比亞大學(University of British Columbia, UBC)在加拿大英屬哥倫比亞省健康科技評估體系的角色與功能

加拿大英屬哥倫比亞省的健康科技評估組織，主要以英屬哥倫比亞大學內設BC省健康科技評估辦公室（British Columbia Office of Health Technology Assessment，BCOHTA），創辦於1990年，其功能在促進與鼓勵政府部門、實業、臨床等三個層次能使用健康科技評估的研究成果，以合宜地施行政策、企劃與醫療利用，所使用的研究方法是標榜針對目前與發展中的健康科技進行效益（effectiveness）方面的科學實證（scientific evidence）檢驗。研究經費全部來自省政府。因應歷史的淵源，各相關機構分述如下：

(1) Center for Health Services and Policy Research, CHSPR

於1990年秋天由英屬哥倫比亞大學the Board of Governors and

Senate 創立，並由英屬哥倫比亞省衛生處開幕之，主要任務在於刺激科學方式探索人口群層面之健康議題，以及健康服務之方式。該中心以五年一次合約接受英屬哥倫比亞省衛生處的資助，三年共 9 億加幣預算。BC 省健康科技評估辦公室（BCOHTA）即設置在 CHSPR 之內。

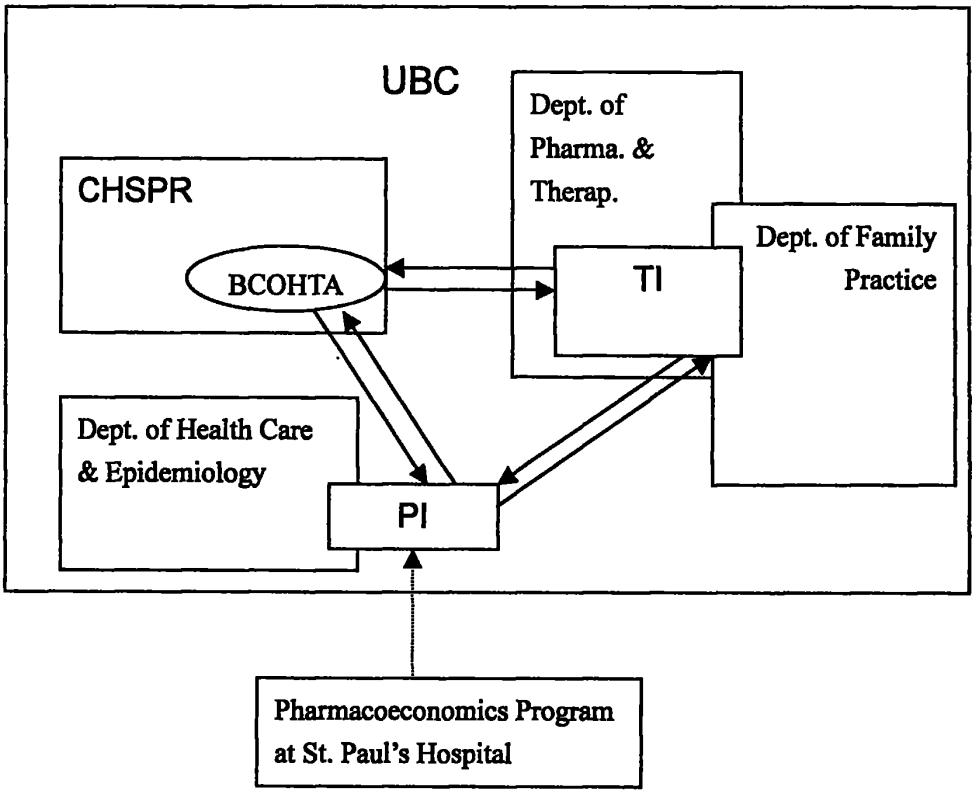
A. CHSPR 與內外組織的關係詳如附錄五。

B. 該單位已發表及進行中之研究詳見其網址（網址如附件一）。

(2) BC 省健康科技評估辦公室（British Columbia Office of Health Technology Assessment, BCOHTA）

於 1990 年 12 月設立，屬英屬哥倫比亞大學 Center for Health Services and Policy Research 之部分單位，全部經費均來自英屬哥倫比亞省衛生暨老人照護處，並不接受私人公司的資助，以維護超然、獨立、學術的立場，該辦公室之運作主要是依據該國中央層級--加國健康科技評估聯合辦公室（Canadian Coordinating Office for Health Technology Assessment， CCOHTA）的組織架構設立，因藥物治療的評估有其個別特性及案件量較多的需要，後來另組專家成立 Therapeutics Initiative（TI）及 Pharmacoeconomics Initiative（PI）。UBC、CHSPR、BCOHTA、TI、PI 的關係圖如圖三：

圖三　The Relationship among BCOHTA, TI & PI



A. 宗旨（Mandate）：促進及鼓勵去利用健康科技評估的研究，用於臨床運作及政府部門層次之政策、企劃案、技術引進、醫療利用的決定等等。

B. 優先順利的標準：衝擊的廣範性、費用的高低、可能影響下決定、資訊及技術的準備度等。

C. 評估主題：(a)藥品、特殊材料及儀器；(b)介入措施、施行方案、處置及檢驗；(c)臨床執業準則；(d)衛生行政、健康服務之提供、健康政策企劃。

D. 該單位已發表及進行中之研究詳見其網址（網址如附件一）

E. 主要方法：(a) Comprehensive framework：Population impact、Population at risk、Social Context、Effectiveness evidence、Economic Concerns；(b) Systematic reviews：Systematic Search、Critical Appraisal、Synthesis。

F. 該單位運用 evidence-based medicine 來協助發展系統評估、臨床執業準則及健康科技評估的相關工具詳如附錄六。

(3) Therapeutics Initiative, TI

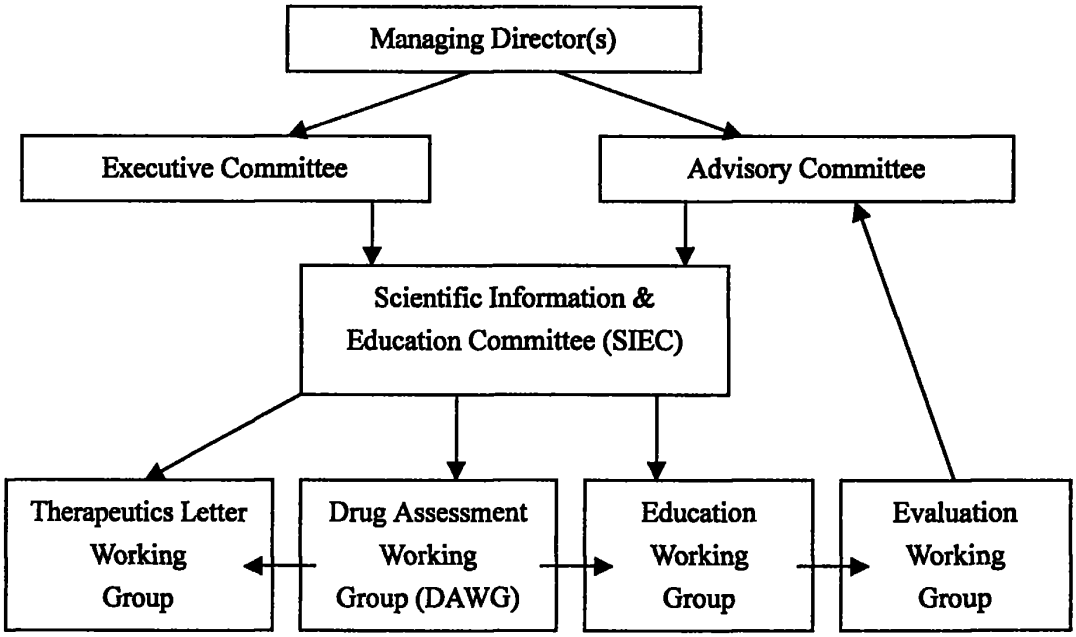
是由英屬哥倫比亞大學 Department of Pharmacology and Therapeutics 與 Department of Family Practice 共同合作的獨立單位，進行無偏頗、以實證為本之藥物評估與教育，於 1994 年創立，以提供醫師及藥師最新（up-to-date）的臨床藥物治療資訊。經費的來源是五年一期、來自英屬哥倫比亞省衛生暨老人照護處撥付給英屬哥倫比亞大學的基金。

A. TI 的目標：(a)依科學文獻關於臨床效益最好實證的標準，評估新的及現有的藥物治療；(b)利用上述之評估建立第一選擇的藥物與最佳臨床使用的建議；(c)為醫師與藥師提供實證及相關建議，來設計及執行各類教育性策略；(d)使用 Pharmacare/Pharmanet 資料庫及質性的評估方法學，評估教育活動對醫師開藥型態的衝擊；(e)協調其

他國家及國際組織參與藥物評估與教育(f)出版經同儕審查後相關衝擊的評估結果；(g)利用回饋系統得到加強及改善醫師與藥師的教育；(h)提供 Pharmacare、BC 省藥品支付方案之專家資源。

B. TI 的組織圖如圖四：

圖四　Therapeutics Initiative Organization



C. Education Working Group 的資訊擴散與教育活動範例如附錄七。

D. 該單位之道德倫理規範詳如附錄八。

E. 該單位已發表及進行中之研究成果詳見其網址（網址如附件一）。

(4) Pharmacoeconomics Initiative, PI

是由英屬哥倫比亞大學為基礎的獨立單位，針對藥商所送之成本效益分析進行標準化的審查，協助 BC 省藥物照護方案(Pharmacare)以實證為本進行決策。PI 於 1995 年創立，其目標為促使 BC 省以有限的省政府預算支付最多的健康給付。經費的來源是五年一期、來自英屬哥倫比亞省衛生暨老人照護處撥付給英屬哥倫比亞大學的基金。

A. 藥品納入 Pharmacare、BC's provincial formulary 的二階段過程

BC 省藥物照護方案(Pharmacare) Drug Benefits Committee 審核新品項是否納入時，採二階段的評估過程，所有來自藥廠申請保險支付的案件，由二個獨立的科學性審核委員會進行 critically appraise，也就是前述的 TI 及 PI。

(a) 第一階段： TI 補足 PI 的工作，TI 是 critically appraise 新藥的治療價值（含所有共存的治療），及評估藥廠申報的 efficacy 及 toxicity 檔案，其評估結果直接加入 PI 的成本效益與 efficacy 評估，其中包括 health-related quality-of-life 及 compliance 與 tolerability 等議題。

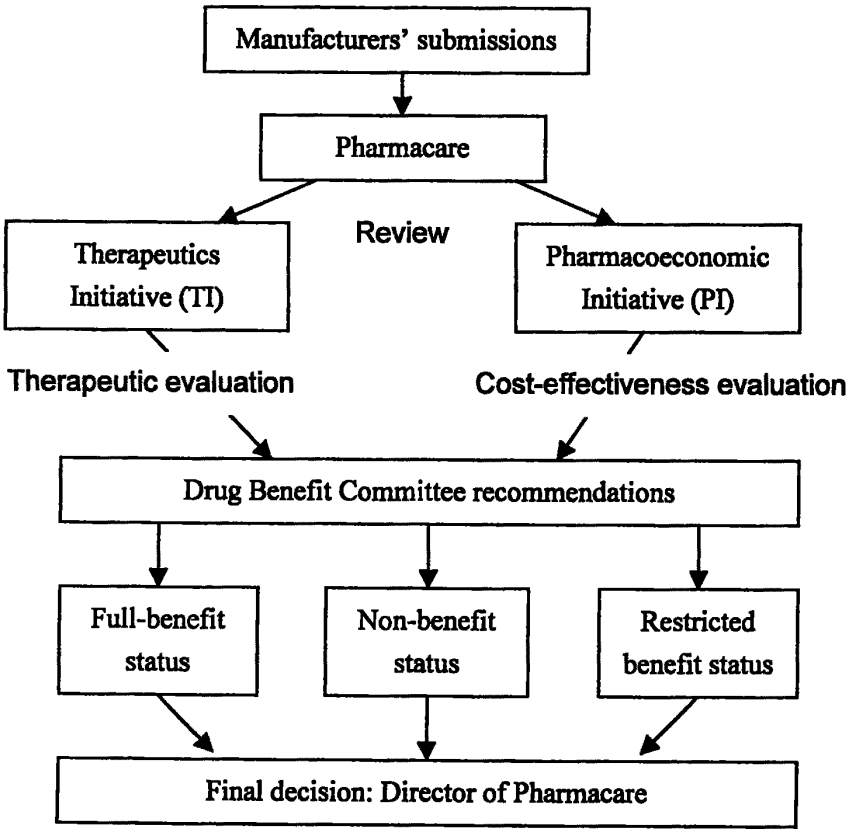
(b) 第二階段：TI 及 PI 的評估結果一併送入 BC 省的 Drug Benefit Committee (DBC，在該委員會中 PI、TI 及 Pharmacare 各有一位代表在內)，由 DBC 負責合併 TI 及 PI 的意見，並確立 Pharmacare 新藥的合宜支付狀態：完全支付、不支付及限制支付，惟最後的核

定權在 Pharmacare 的主管。

(c) 加拿大目前只有 BC 省及 Ontario 省要求藥廠所有新藥申請納入 provincial formulary approval 時，須一併提出藥物經濟學評估資料。

(d) 藥品納入 Pharmacare、BC's provincial formulary 二階段審核過程之圖五所示：

圖五 BC's two-stage drug approval process



B. PI 健康科技評估之 PI Drug Submission Form（用來標準化評估的程序）及 Feedback Form（用來透明化評估的過程及標準，提供良好的回饋給藥廠）如附錄九。

C. 該單位已發表及進行中之研究成果詳見其網址（網址如附件一）。

(八) BC 省健康科技評估制度之實務運作

1. 運用健康科技評估在醫療利用管理（Utilization Management）所扮演的角色：英屬哥倫比亞省衛生暨老人照護處(Ministry of Health and Ministry Responsible for Seniors, British Columbia, Canada)之醫療利用管理（Utilization Management）係以實證為本設計嚴謹的管理措施，其資料分析單位到達個別醫師、機構及地區等，可依設立的指標做比較性分析，並定期回饋給個別醫師，做為教育之用，可用來導引醫師的醫療行為。目前有五個執行方案：Across Canada (CIHI-CHAP)、Rates per 1000 BC Comparison（以上是外部比較的部分）、3-LOS Trend、Physician Specific: LOS Comparison、Cost Comparison （以上是內部比較的部分）。

2. 訂定 Guidelines & protocols 的發展：BC 省 Medical Services Plan (MSP) 治療指引及準則諮詢委員會(Guidelines and Protocols Advisory Committee)於 1995 年設立，由政府及專業學會合作發展以實證為本的 Guidelines & protocols，protocols 並與保險支付結合(如附錄十)。

3. BC 省健康藥物照護保險支付之重要依據：以藥物為例，BC 省藥物照護方案(Pharmacare) Drug Benefits Committee 審核新品項是否納入時，採二階段的評估過程，由 TI 及 PI 提供以實證為本的審查意見，相關說明如前有關 TI 及 PI 的部分。這種評估方式目前漸漸推展至暨有的品項，例如整合 PI 及申報資料庫，以進行各項藥品費用之排序及 time-series 的分析，可做到預測藥物的利用情形。

4. 區域醫療網運用健康科技評估的決策模式：BC 省首都健康區域辦公室 (Capital Health Region Office) 運用健康科技評估，發展一系列行政架構，來確保能搜集與提供有效的資料，以便相關委員會針對藥品、醫療器材的採購或引進某項技術等議題時，能依據可信賴的資訊做出明智的決策(相關表格如附錄十一)。

5. 健康科技評估之學術研究結果納入經常性健康政策與業務：維多利亞大學(University of Victoria)進行的相關個案，如以 delayed policy trial 與 BC 省 MSP 的政策結合，以 evidence-based 方法，針對 protocol 之改變（限縮特定藥品之使用，改以其他治療替代），研究設計是以「如期施行」及「延期施行」兩組、採 independent 的步驟與方法進行之，即隨機選出為數為少部份的「延期施行」組（10%醫師）做研究對象，進行相關的分析與研究。

(九) 以加拿大英屬哥倫比亞省經驗為基礎，探討如何設置台灣健康科技評估辦公室及其制度時，下列問題需由我們進一步釐清及展開：

To set up

1. Establish where?
2. Funding from where?
   (1)Reporting
   (2)Contract
3. What mandate?
4. Steering committee?
5. Champions
6. Staffing
   (1)Full time
   (2)Confidence
   (3)Attitude
7. Priorities
8. Dissemination
9. Success factors

幾經本考察團開會討論及參照加拿大專家提供的醒思，相關建議詳見本報告第五部分「建議」乙節（第 32 頁）。

四、心得

就 BC 省的醫療服務體系、健康科技評估制度的基本方法和與醫療服務體系的關係、加拿大及 BC 省健康科技評估制度之組織架構、BC 省健康科技評估制度之實務運作等四個方面闡述。

(一)BC 省的醫療服務體系

1. 對於衛生政策或健康保險的支付，民意代表通常不會干預，有少數個案有民意代表的干涉，也是必先經過部長。
2. 總額預算於一定範圍內可以流用，但其原則是不流到急性照護。
3. Pharmacare 使用 PharmaNet 來管理，利用資訊系統 online 且 real time 的技術進行審查，雖然審查的點並不多，卻可將重復用藥減少很多。

(二)健康科技評估制度的基本方法和與醫療服務體系的關係

1. Clinical path 已經差不多了，應該走到 evidence-based medicine，而 systematic review 是重要的方法。
2. Systematic review 目前只有國衛院及台北榮總圖書館使用或推廣，可以透過榮陽網站瞭解。
3. Systematic review 的推廣很重要，應推到醫學會層面，唯 article review 和 systematic review 是兩個層次，故研究方法需先推廣之。
4. 學識的推廣及其路徑在台灣是沒問題，問題在行為不足，未實際運用。
5. 新加坡推廣健康科技評估的方法之一，是新加坡大學請英國的學者採

密集上課的方式，其種子人員的課程是從最基本至常用之方法學皆教授之，並有個案研究的課程。

6. 我們可以也辦一個針對學術界推廣健康科技評估的研討會，由各醫學大學（院）校長指派種子人員參加，預計於九月舉行，上午可以講理論、方法，下午報告案例及討論，先從重要性開始學習，其次是學習方法學，再來實際執行；可先用一、二項東西去推方法學；邀請的聽眾不必太多。

7. 醫療院所也應學習及採用 systematic review，原因在於總額預算下追求醫院最高的營運效率，往往是最重要的考量，systematic review 可協助找出最有成本效益的科技。

8. 全民健保 review 的方法論也尚未建立，應學習及採用 systematic review。例如在藥事小組會議中，討論的資料常常只看到廠商提供的資料，這項問題需要一段時間來轉換這種做法，有個前提要克服的是，第一是健保核價的時限在三個月之內，第二是國內還沒有 systematic review 這個概念，因而在健保六、七年運作的結果，已在藥事小組形成一種決策的文化或默契，新委員的加入會開始挑戰這種文化或默契，新加入的藥學界委員可以當成一個種子開始形成新的文化。

9. 對照台大科技評估工作小組，我們的方法論並不差，但架構有些問題，即太重視量化的方法，惟接受質化的方法是要由共識而來，大家要有

shared vision 的觀念。例如 BCOHTA 的 TI 並不全然使用 meta-analysis，而視研究目的、資料的性質，再決定採用合適的量化或質化的方法。

(三)加拿大及 BC 省健康科技評估制度之組織架構

1. BCOHTA 的組織有二大部分，一是上層的指導及監督，下層的運作執行，值得學習。
2. 由 BCOHTA 的組織我們可得到的借鏡，是「independent」這個字很重要，也就是說不能球員兼裁判。
3. TCOHTA 的總部已在台大形成，其他各校可以各自運用其特色與專長，進行相關事項的合作與競爭，例如總部可依設定的優先順序選取一些題目，再將這些題目協調分配給各校執行。
4. BCOHTA 身為政府諮詢的角色，相當有制度，如以固定的專家來 review。
5. 為避免球員兼裁判的問題，有如加拿大 BC 省的模式，臺灣科技評估的組織最好建立在中央健康保險局之外。

(四)BC 省健康科技評估制度之實務運作

1. 加拿大 BC 省將健康科技評估運用到政策或方案的實際案例中，delayed policy trial 令人印象深刻，把 policy 的範圍定義得很廣，也就是說採 evidence-based 去面對。該研究計畫經費不多就能有不錯的結果，其研究步驟與方法是 independent，只隨機選出少部分人（10%醫

師）做研究對象，對緊縮的政策實施很有助益，因為限縮既得利益的工作比較困難，加拿大 BC 省由 restriction 著手 delayed policy trial，值得學習，不過我們要運用於 delisting 時不一定好做，建議現階段和衛生署企劃處（陳穎慧科長）繼續討論。

2. 加拿大 BC 省之 protocol 係將 guideline 與支付制度結合，內容只撰寫要管理（二八原則）的部分，且其規定相當嚴格；guideline 則詳實、清楚，主要提供臨床參考。在訂定 guideline 之前，需先有 guideline for guidelines。

3. 加拿大 BC 省 clinical guideline 的推行，由於 medical service plan 中主要由 general practitioner 擔任照顧居民的角色，故 guideline 主要是提供給 general practitioner 使用。因 guideline 大部分都用在 general practitioner，國內若要在專科醫師間推行，應該不會有問題。我們要做的西醫基層總額，如果將基層醫師當 general practitioner，健保局應找些經費請公會的人來決定那些 guideline 要先做。如果用提昇品質的角度來要求做 guideline，西醫基層的醫師可能不會去實際落實，建議經由健保資料庫檔案分析及專家意見分析後，由易濫用的項目開始著手。

4. 加拿大 BC 省推行 protocol 之初，並不成功，幾乎停滯數年，可能是由疾病切入太大太複雜，也可能是後來找對人來領導這項專案，使得 protocol 順利進行。台灣可先嘗試推展 protocol（與支付制度結合），其

資料之分析非為研究，而是協助實際業務的推行，資料分析結果須回饋給健保局。

5. 醫院關心的還是如何進用藥物，在總額預算下，這種方法就可以用來選用最有成本效益的藥品，如果各醫院想成立藥委會的話，健康科技評估的這套方法是值得各醫院廣於運用。仿效加拿大 BC 省的做法，因應實務上的需求，最好不只是個別醫院來做，而是形成醫療區域。

6. TCOHTA 當挺身幫西醫基層總額預算，針對臨床執業準則（clinical practice guideline）及保險醫療服務審查準則（protocol）設定優先順序，健保局可先分析健保資料，其準備工作要細緻且以長期為主，惟行動需快，TCOHTA 工作小組可以參加但不接下來。

7. BCOHTA 分析資料的單位已到臨床的層次，令人印象深刻，以往健保太重視管理的資料，理當努力轉型。國內對新藥廣告已經管得很好，應該繼續。

8. BC 省健康科技評估制度所發展的 TI letter，是 dissemination 好方法的範例。

五、建議

為勾勒高度可行性的台灣健康科技評估制度，綜合整理加拿大專家意見及本考察團討論後之初步計畫，茲就建立我國健康科技評估體系、落實實證醫學（evidence-based medicine）、健康科技評估資訊的普及化、國際合作、以及全民健保可以採用的具體作法等五項議題分述如下：

(一)建立我國健康科技評估體系

建議參照加拿大模式，在醫療體系中建立健康科技評估之組織及其本身內部之單位，可分為政府、學術單及醫療決策精英等三方面進行。

1. 確認健康科技評估體系之 objective、mandate、general principle：建立我國健康科技評估體系的首要任務就是 objective、mandate、general principle 的確認，建請本局科技評估制度推動小組（龐一鳴組長及黃肇明組長）起草後提供專家討論。
2. 政策之配合：為確保台灣健康科技評估組織之公正公平的角色，以及需考慮台灣健康科技評估體系之位階應放在何處？是比照經濟部支持資策會的開辦模式？或比照衛生署設立國家衛生研究院的模式？或仿效衛生署支援醫療品質策進會的成立？還是放在公私立醫學院校校長會議之下，純由十大醫學院校支持或加入行政部門的資源？無論該組織位階落於何處，基本上健康科技評估組織是種非營利的學術機構，依其設立的宗旨與任務獨立運作。

3. 經費來源之籌措：經費來源之籌措以能保持台灣健康科技評估組織超然、獨立的立場為原則，經費額度的多寡則是決定任務範圍及工作量的重要因素。經費來源之籌措與政策的配合密不可分。從多元機關籌款？亦是從單一機關編預算籌組？與資助機構的關係採長期合約的方式？還是成為附屬機構或其他形式？

4. 組織人力及強力支持的群體：機構內的全職職員可容納多少？初期草創所任用的人才相當重要，其工作態度是否投入、自信心是否充份，也是台灣健康科技評估體系成功與否的影響因素之一。此外，學術界、政府部門、產業界及社會各方人士，強力支持的力量也是成功的因素，例如李國鼎先生對科技發展的支持（像 B 型肝炎疫苗）往往就成為成功的案例。

5. 各組織間的關係：

(1)建議 TCOHTA 的總部設立在台灣大學，其他各校可以各自運用其特色與專長進行相關事項的合作與競爭，例如總部可依設定的優先順序選取一些題目，再將這些題目協調分配至各校執行。若採取本形式時，尚需建立各校分享資訊的機制。另政府部門是否能採用 TCOHTA 的分析角度與結果，也需建立機制使之能合作。

(2)因為健康科技評估組織兼具政府諮詢的角色，以及協助提供具完整性的決策資料，其人力、作業內容需制度化，建議由各領域專家組

合的工作小組（working group）中，要有固定的專家主持各項評估計畫，其研究計畫及成果皆須經過內部及外部的專家審查，此外，須正式組成指導委員會（steering committee）或諮詢委員會（advisory committee）擔任監督與驗收工作小組成員工作成果的角色，另可定期與外面專家合作或進行調查。

6. 台灣健康科技評估之工作成果採分階段逐漸展開：為紮實推動台灣健康科技評估，建議科技評估制度除採分階段建立外，其工作成果或產品宜採逐步推出的方式，並能同時傳布（dissemination）給專業人士及普羅大眾。

7. 出版臺灣健康科技評估年度報告（annual report）：為有效推展健康科技評估制度及確保經驗傳承，應籌劃年度報告之出刊，臺灣健康科技評估辦公室籌備完竣前，請本局科技評估制度推動小組（黃肇明組長）及早籌備。

8. 設定健康科技評估的優先順序：

(1) 宜在健康科技評估制度之組織架構確認後再進行。設定健康科技評估優先順序時，因科技日新又新，尤其是近年來新藥的產出相當多，有必要設計具系統化的執行方案，以協助設定健康科技評估的優先順序，方能跟上市場的腳步。例如荷蘭就是全世界率先在健康科技評估系統之下，為審慎管理「健康需求」與花費健康保險費用

「優先順序」的空隙(gap)（避免扭曲），須設立一個系統來確認健康科技的潛在效用（potential benefits），企圖早期偵測已上市的新技術（含藥品、器材、處置及創新的健康服務方式等），尤其是施行總額預算的國家，面對正在行銷的新科技，即早期監測其運用及散佈的情形，可協助決策者、健康專業人員、保險人能有合理化與適當控制的決定。常見的方法採多元式，通常是四種方法並行：系統評估、電話調查、Delphi 專家意見調查以及個案研究（註：個案研究通常是對業界重要人士及專業人員進行深度訪談，資料來自書籍、專業雜誌、文章、已出版及未出版文獻）。

(2)由於出發點是以成本效益的實證醫學為本，以及健康保險總額預算下新科技對費用的衝擊，宜由確認嶄新的健康科技、監測其散佈（diffusion）與採用的評估結果，來設定健康科技評估優先順序，有四項機制需考量：(A)在新的及浮上檯面的健康科技廣泛擴散在健康體體系前，先確認與監測之，其工作有：建立已存在科技之詳實目錄（inventory），以數量、單價及實證基礎等標準搜錄；(B)選取最重要的主題評估之，其進行評估的主題數量、範圍，往往取決於研究團隊的能力及容量、經費來源等；(C)在最合宜的時機，以最適合的研究方法進行；(D)透過運作一個體系來執行知識的散布以及實際執行的工作。

(二)落實實證醫學（evidence-based medicine，EBM）

1. 積極推廣系統評估（systematic review）及實證醫學（evidence-based medicine）的研究方法：學術機構當積極提供系統評估（systematic review）及實證醫學（evidence-based medicine）的教育訓練，事涉臺灣健康科技評估之學術教育訓練，建議由學者專家（台灣大學醫學院侯勝茂教授、賴美淑教授、張啟仁副教授、國防醫學院譚延輝副教授）主導。

2. 促使醫療決策精英習於以健康科技評估為本的資料做決策：建議醫療決策精英仰賴的決策資料，其準備工作係架構在健康科技評估制度之下，醫療決策精英的工作小組，其蒐集、分析資料及報告之撰寫，皆採健康科技評估制度所強調的系統評估及實證醫學等方法，唯這項建議的落實，可能需細水長流的方式推動，現階段的建議是，除了執行針對醫療決策精英概念傳布（dissemination）的工作外，台灣健康科技評估制度建立後，政府單位有如中央健康保險局及行政院衛生署之決策者，應儘速學習及建立運用健康科技評估之結果做決策、要求醫事服務機構及醫療產業提送之文件符合健康科技評估原則、與醫事服務機構協商的資料也符合健康科技評估原則等等，同時學術機構也適時適所來提供教育訓練，以便帶動醫療院所、藥界或醫療儀器產業之決策精英也能儘速採用。

(三)使健康科技評估資訊的普及化：建構健康科技評估之同時，建議同時針對專業人員及普羅大眾進行概念傳布（dissemination）的工作，以收相輔相成的功效。

1. 健保局部分：江副總經理宏哲在健保局晨會分享西醫基層總額推動健康科技評估的願景。

2. 台大科技評估小組：讀書會中安排張啟仁教授報告健康科技評估「學術」部分（如方法學），由黃肇明組長報告「政府」或「行政」部分（如政策、各組織間關係、經費來源之籌措等）。

3. 學術界部分：

(1) 本考察團返國後，由健保局及台大科技評估小組（聯絡窗口為劉媛媛專員，王貞棣醫師、台大科技評估小組黃靖惠助理、林佳美助理協助之）合辦一場一整天的研討會，預定於九月底或十月初舉行，參與者採邀請式，其對象為各醫學院校長及專家、台北市政府衛生局醫療品質小組等等（暫不邀請業者），主軸是介紹 HTA 及其願景、各項原則及圓桌討論。該研討會主題預訂如下：

- ◆ 健康科技評估的介紹
- ◆ 健保總額預算與健康科技評估
- ◆ 加拿大健康科技評估的組織架構與 PI、TI 的經驗

◆ 健康科技評估下方法學的介紹

◆ 台灣運用健康科技評估的案例報告

◆ 圓桌討論

(2) 為將此行所學的觀念擴散出去，除了寫下來供學術界的瞭解（如投稿至台灣醫界、健康世界、當代醫學等）之外，還要到處講。

(3) 在報章雜誌發表文章，對普羅大眾傳播健康科技評估的概念。

(四)國際合作

由於歐美國家已有十餘年的經驗，不少國家（除加拿大之外，如美國、瑞典、澳洲、法國、英國、荷蘭等）已建立本身的模式，也組成國際組織進行國際合作，台灣不妨參考已存在的健康科技體系之研究成果與經驗，以確保我們的運作能涵蓋所有型態的科技，因此，建議與國外先進機構交流時，除健康科技評估推動小組積極推動參與國際學（協）會或組織外，建議行政院衛生署與加拿大 BC 省簽署合作備忘錄，台灣大學與英屬哥倫比亞大學（UBC）建立正式的合作關係。

(五)全民健保可以採用的具體作法

1. 本局八十八年下半年及八十九年度委託台灣大學辦理「台灣醫療科技評估之建立與執行」研究計畫後續試辦方向：

(1) 進行中的藥材 review，其結果建議比照加拿大 TI 或 PI，於 review 成果產出後，再送入專家委員會（類似 Scientific Information and

Education Committee 或 Pharmacoeconomic Initiative Scientific Committee）審查，以增進研究成果信效度。

(2) 由加拿大BC省模式對照台灣的科技評估小組，目前成員已有 content expert，無論採正式延攬至工作小組或委員會，或者是定期對外向專家諮詢或調查，建議再依國內現況，適時適地增添 method expert、圖書館專家等。

(3) 因為健康科技評估的工作具有延續性，短期（0 至 5 年）與長期（5 年以上）的議題皆需兼顧，無論健康科技評的正式組織設置在何處，該研究計畫的研究成果當儘量納入健保實際業務，以協助目前業務能順利與司法院大法官會議九十年四月二十日釋字第五二四號的要求接軌，也可運用到國民醫療利用的衛生教育、減少專業人員偏重廠商提供新科技專業知識的偏頗、防範對美貿易遭受動用 301 或超級 301 條款等等的工作準則，可說是運用廣泛、受益良多。綜合上述的理由，本委託研究計畫最好能在健保局進行幾年，直到健康科技評的正式、永久組織能籌措到足夠開辦的經費與能正式運作為宜。

2. 健康科技評估的具體運用：

(1)建議健保局運用 co-management 的模式，先在西醫基層總額預算下推展健康科技評估制度。加拿大 BC 省的運作、決策方式，值得一學，若將 HTA、guideline、protocol、TI letter 等項目一次推出，可能會

消化不良，應採分階段逐步推出。健康科技評估方面，我們可以試著用雅節的分析結果做一次推廣。

(2)健康科技評估制度的引進，期望產出的系統化資料能提供全民健保醫療給付協議會議、藥事小組、特殊材料專家小組等委員會研議相關事項所用，可提高審核新品項納入支付標準及藥價基準的效率。

(3) 將健康科技評估運用到臨床執業準則（practice guidelines）與保險醫療服務審查準則（protocol）：可仿效加拿大 BC 省，由學術及專業團體，將健康科技評估運用到健康服務提供者所需之 guidelines & protocol，建議需先行製定 guideline for guidelines，再依設定之優先順序，由易浪費的項目，如檢驗、24 小時攜帶式心電圖、影像檢查等項目開始，結合各專業團體的力量著手各項 guidelines 的製定，並由保險單位藉由保險支付制度之結合來推展 protocol，較能有效發展之。

(4) 將健康科技評估運用到政策或方案之施行：可仿效加拿大 BC 省嘗試 delayed policy trial，建議以健保需緊縮的項目優先著手。

(5) 運用健康科技評估到醫療利用管理（Utilization Management）的層次，以強化全民健康保險醫療服務審查的合理性與有效性。

附件一

加拿大 BC 省科技評估相關機構及網址(website)

一、機構

Ministry of Health and Ministry Responsible for Seniors, British Columbia, Canada
1515 Blanshard Street
Victoria, British Columbia
Canada V8W 3C8
URL: http://www.hlth.gov.bc.ca/

British Columbia Health Industry Development Office
2170 Mt. Newton X Road
Saanichton. British Columbia
Canada V8M 2B2
Tel: +1-250-544-2554
Fax: +1-250-544-2506
URL: http://www.hinetbc.org/ http://www.bchido.org/

Guidelines and Protocols Advisory Committee, MSP, BC
1515 Blanshard Street 1-2
Victoria, British Columbia
Canada V8W 3C8
Tel: +1-250-952-1347
Fax: +1-250-952-1417
E-mail: guidelines.protocols@moh.hnet.bc.ca
URL: http://www.hlth.gov.bc.ca/msp/protoguides/

Pharmacare
Ministry of Health
P. O. Box 9655 Stn Prov Govt
Victoria, British Columbia
Canada V8W 9P2
Tel:
Greater Victoria: +1-250-952-2866
Lower Mainland: +1-604-682-6849
Elsewhere in British Columbia: 1-800-554-0250
URL: http://www.hlth.gov.bc.ca/pharme/index.html/

Capital Health Region Office, BC
2334 Trent Street
Eric Martin Pavilion, Royal Jubilee Hospital
Victoria, British Columbia
Canada

Center for Health Services and Policy Research of BC
429-2194 Health Sciences Mall
Dept. of Pharmacology & Therapeutics
The University of British Columbia
Vancouver, British Columbia
Canada V6T 1Z3
Tel: +1-604-822-4969
Fax: +1-604-822-5690
URL: http://www.chspr.ubc.ca/

British Columbia Office of Health Technology Assessment (BCOHTA)
429-2194 Health Sciences Mall
Center for Health Services and Policy Research
The University of British Columbia
Vancouver, British Columbia
Canada V6T 1Z3
Tel: +1-604-822-7049
Fax: +1-604-822-7975c
E-mail: bcohta@chspr.ubc.ca
URL: http://www.chspr.ubc.ca/bcohta/

Therapeutics Initiative of BC
2176 Health Sciences Mall
Dept. of Pharmacology & Therapeutics
The University of British Columbia
Vancouver, British Columbia
Canada V6T 1Z3
Tel: +1-604-822-0700
Fax: +1-604-822-0701
E-mail: info@ti.ubc.ca
URL: http://www.ti.ubc.ca/

Pharmacoeconomics Initiative of BC
620-1081 Burrard Street
Vancouver, British Columbia
Canada V6Z 1Y6
Tel: +1-604-806-8712
Fax: +1-604-806-8778
E-mail: pi@hivnet.ubc.ca
URL: http://www.pharmacoeconomics.ubc.ca/PI/

University of British Columbia
URL: http://www.ubc.ca/
Office of the Coordinator of Health Sciences (OCHS) & the Council of Health & Human Service Programs
http://www.health-sciences.ubc.ca/index.html/

Department of Pharmacology & Therapeutics
http://www.pharmacology.ubc.ca/

University of Victoria
URL: http://www.uvic.ca/

二、其他可供參考之網址(website)

Health Technology Assessment

Canadian Coordinating Office for Health Technology Assessment, CCOHTA
http://www.ccohta.ca/
Albert Heritage Foundation for Medical Research, AHFMR
http://www.ahfmr.ab.ca/
International Network of Agencies for Health Technology Assessment, INAHTA
http://www.inahta.org/
International Society of Technology Assessment in Health Care, ISTAHC
http://www.istahc.org/
WHO Program on Health Technology
Clinical Technology
http://www.who.int/pht/clinical_technology/index.htm
Technology assessment and quality assurance
http://www.who.int/pht/technology_assessment/index.html/
U. S. Food and Drug Administration: Center for Drug Evaluation and Research
http://www.fda.gov/cder/
Agency for Health Care Research and Quality, US
http://www.ahcpr.gov/
National Information Center on Health Services Research and Health Care Technology, NICHSR, US
http://www.nlm.nih.gov/pubs/factsheets/nichsr_fs.html/
Office of Technology Assessment. OTA, US
http://www.wws.princeton.edu/~ota/
RAND Corporation
http://www.rand.org/
Medical Technology and Practice Patterns Institute, MTPPI, USA
(WHO Collaborating Center for Health Technology Assessment)
http://www.mtppi.org/
NSW Therapeutic Assessment Group
http://www.clininfo.health.nsw.gov.au/nswtag/about/index.html/
Medicare Service Advisory Committee, MSAC, Australia
http://www.health.gov.au/haf/msac/
Health Technology Board for Scotland
http://www.htbs.org.uk/

Scottish Health Purchasing Information Center, SHPIC, closed in 1998
http://www.nhsconfed.net/Scotland/index.html/
National Coordinating Center for Health Technology Assessment, UK
http://www.hta.nhsweb.nhs.uk/
University of York NHS Center for Reviews and Dissemination
http://nhscrd.york.ac.uk/
New Zealand Health Technology Assessment – Clearing House for Health Outcomes and Health Technology Assessment, NZHTA, New Zealand
http://nzhta.chmeds.ac.nz/
Catalan Agency for Health Technology Assessment and Research, CAHTA, Catalonia (WHO Collaborating Center for Health Technology Assessment)
http://www.aatm.es/ang/ang.html/
Swedish Council on Technology Assessment in Health Care, SBU
http://www.sbu.se/admin/index.asp/
TNO Prevention and Health
http://www.tno.nl/homepage.html/

Regulatory Status

Health Canada
Notices of Compliance –Drugs
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/noc_drugs.html/
Medical Device Licence Issued
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/md_lic.html/
Patent Register
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/patents.html/
U. S.
U. S. Food and Drug Administration: Center for Drug Evaluation and Research
http://www.fda.gov/cder/

Clinical Practice and Practice Guidelines

Agency for Healthcare Research and Quality, US (formerly AHCPR: Agency for Health Care Policy and Research)
http://www.ahrp.gov/news/gdluser.htm/
National Guideline Clearinghouse
http://www.guideline.gov/
U. S. National Library of Medicine, NLM
http://text.nlm.nih.gov/
Health Services/Technology Assessment Text, National Library of Medicine
http://hstat.nlm.nih.gov/
U. S. CDC Prevention Guidelines Database
http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid/prevguid.shtml/
Oncolink at the University of Pennsylvania
http://oncolink.upeen.edu/

University of Iowa's the Virtual Hospital: Information for Healthcare Providers
http://www.vh.org/Providers/ClinGuide/CGType.html/
University of Iowa's the Virtual Hospital: Family Practice Handbook
http://www.vh.org/Providers/ClinRef/FPHandbook/FPContents.html/
EMBBS Emergency Medicine & Primary Care
http://www.embbs.com/
Ontario Association of Medical Laboratories (OAML) - Guidelines
http://www.oaml.com/guide.html/
British Columbia Office of Health Technology Assessment (BCOHTA): Supporting Clinical Practice Guidelines Development
http://www.chspr.ubc.ca/bookall.htm/
Canadian Medical Association, CMA – Clinical Practice Guidelines Listing
http://www.cma.ca/cpgs/
Centers for Health Evidence, Alberta, Canada
http://www.cche.net/principles/content_all.asp
National Institute of Clinical Excellence, NHS, UK
http://www.nice.org.uk/

Meta-analysis

http://www.cochrane.dk/cochrane/handbook/handbook.htm/
http://www.bmj.com/cgi/content/full/321/7260/540/

Quality of Life Measurement

http://www.hsph.harvard.edu/organizations/hcra/cuadatabase/intro.htm/

Systematic Reviews

http://www.updateusa.com/enter/
http://hiru.mcmaster.ca/cochrane/cochrane/revhb302.htm/
http://www.update-software.com/ccweb/cochrane/revabstr/mainindex.htm/
http://www.update-software.com/Cochrane/order.htm
http://nhscrd.york.ac.uk/welcome.html/
http://www.ingenta.com/

Sources of Evidence

http://cebm.jr2.ox.ac.uk/docs/levels.html/
http://www.acponline.org/catalog/electronic/best_evidence.htm/
http://igm.nlm.nih.gov

http://195.84.253.17/sub-site/reports/abstracts/119e/
http://www-med.standford.edu/medworld/medbot/
http://www.hon.ch/
http://www.inahta.org/
http://hta.uvic.ca/

Hospital HTA

http://www.chspr.ubc.ca/cgi-bin/pub?program-BCOHTA/

Journals online

http://www.il-st-acad-sci.org/health/medjrnls.html/
http://www.bmj.com/
http://jama.ama-assn.org/
http://www.nejm.org/
http://www.thelancet.com/

Social Sciences

http://campbell.gse.upenn.edu

HTA: Case studies

Bone Densitometry
http://www.bmj.com/cgi/content/full/312/7041/1254
http://www.bmj.com/cgi/content/full/318/7187/862
http://cebm.jr2.ox.ac.uk/docs/spPinsnNout.html/

Health Policy Research

Health Services Utilization and Research Commission, Saskatchewan
http://www.sdh.sk.ca/hsurc/index.htm/
Center for Health Economics and Policy Analysis, CHEPA
http://chepa.mcmaster.ca/
Institute for Clinical Evaluation Sciences on Ontario, ICES
http://www.ices.on.ca/
Institute for Work and Health
http://www.iwh.on.ca/
Canadian Institute for Health Information, CIHI
http://www.cihi.ca/index.html/
Manitoba Center for Health Policy & Evaluation, MCHPE
http://www.umanitoba.ca/centres/mchpe/

Health and Prevention Social Research Group, GRASP
http://tornade.ere.umontreal.ca/~marchand/grasp.html/
Population Health Research Unit, Dalhousie University
http://www.mcms.dal.ca/gorgs/phru/
International Health Economics Association, iHEA
http://qhp.queensu.ca/ihea/
Canadian Health Economics Research Association, CHERA
http://www.healtheconomics.org/chera/

Drug Therapy Information

Australian Prescriber
http://www.australianprescriber.com/
Canadian Medical Association (CMA) Infobase (guidelines)
http://cma.ca/cpgs/
Cochrane Library (unbiased systematic reviews of drug therapy evidence)
http://cochranelibrary.com/
Drug and Therapeutics Bulletin (UK)
http://which.net/health/dtb/main.html/
Drug of Choice (published by CMA)
http://cma.ca/catalog/252.htm/
Food and Drug Administration US
http://www.fda.gov/cder/
Goodman and Gilman
http://www.mcgrawhill.ca/medical/hardman.htm/
Iowa drug info service (US)
http://www.uiowa.edu/~idis/idisnews.htm/
Medical Letter (US)
http://www.medletter.com/
Prescrire International
http://www.esculape.com/prescrire/
Therapeutics Letter
http://www.ti.ubc.ca/
Therapeutics Choices (published by Canadian Pharmaceutical Association, CPA)
http://www.cdnpharm.ca/
Worst Pills, Best Pills (US)
http://www.citizen.org/hrg/

Canada Government Links

Health Canada
http://www.hc-sc.gc.ca/
Patented Medicine Prices Review Board
http://www.pmprb-cepmb.gc.ca/

附件二

加拿大英屬哥倫比亞省科技評估專家拜會名單

Ministry of Health and Ministry Responsible for Seniors, British Columbia, Canada

S. R. (Steve) Kenny
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附錄一

加拿大英屬哥倫比亞省(BC)
健康照護體系之簡介

British Columbia Health Industry

The Canadian Health System

INTRODUCTION:

The Canadian Health Care System is a managed care system with participation by the federal and municipal governments but with the primary responsibility for the organization and delivery of care resting with the 10 provinces and 3 territories. Each province has its own health care system but the basic standards and characteristics are common to all provincial programs.

The federal government introduced health insurance for hospital coverage in 1957 with the Hospital and Diagnostic Services Act. In 1968 the Medical Care Services Act extended coverage to include all medically required services of physicians. In 1984 the various pieces of legislation were incorporated into the Canada Health Act which enshrines five basic principles that form the foundation for the Canadian Medicare System. Federal government transfer payments to support the cost of health care are then made to the provinces ensuring that they adhere to the five principles, which are:

- Universality
- Comprehensiveness
- Accessibility
- Portability, and
- Public Administration.

Federal transfer payments to the provinces represent approximately 30% of the cost of medical and hospital care. The total cost of health service expenditures is approximately $2,000 per capita which represents approximately 9% of the Gross National Product. Approximately 75% of health expenditures in Canada is financed through the public sector by various levels of government. This compares to approximately 45% in the United States and almost 90% in the Scandinavian countries.

For the most part, physicians are reimbursed on a fee-for-service basis with some specialties being paid on a salaried basis. Canadian hospitals are all public sector with operational costs usually being funded on a global budget basis. This entails a process of determining the level of appropriate funding a hospital or region should receive based on the population served, age adjusted and taking into account factors such as referral patterns, specialties provided, and sometimes the socioeconomic status of the population. Physicians and hospitals provide medically necessary services without any point of service cost to the patient. Procedures such as cosmetic surgery, when not considered medically necessary, are undertaken on a private basis.

Canada enjoys some of the most favourable health statistics in the world:

Factor	Canada	British Columbia
Population	30 million	3.9 million
Land Area	10 million sq. km	1 million sq. km.
Population Density	2.9 residents/sq. km.	2.9 residents/sq. km.

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For information on the Healthcare Industry visit our website http://www.hinetbc.org

Life Expectancy at Birth	75.7 for males; 82.7 for females
Crude Birth Rate	13.33 births per 1,000 population
Death Rate	7.17 deaths per 1,000 population
Infant Mortality Rate	6.1 per 1,000 population
Fertility Rate	1.81

CONTACT:

The British Columbia Health Industry Development Office mobilizes health care expertise from the public and private sectors to respond to a wide variety of international project opportunities.

FOR FURTHER INFORMATION PLEASE CONTACT

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附錄二

加拿大英屬哥倫比亞省(BC)
健康保險系統之簡介

Health Insurance Systems

DESCRIPTION:

The Province of British Columbia introduced hospital insurance in 1957 along with other parts of Canada. Medical care insurance was introduced by the Province in 1965 in preparation for the Medical Services Insurance Act, passed in 1967 by the Government of Canada.

Hospital care coverage is provided for all legal residents of British Columbia and funding is provided to hospitals on a global budget basis. Budgets are based on the population served, their demographics and the referral pattern of care into and out of the region. This funding model is very well developed as is the system of reporting acute care hospital information.

Medical care by physicians and other health practitioners is reimbursed on a fee for service basis. The on-line systems that supports this reimbursement mechanism features:

Teleplan:

The first on-line, physician/practitioner claims system introduced in Canada. Teleplan has been operational since 1985 and enables the direct entry of claims information by physician/practitioner offices, thus obviating the need for clerical data entry, speeding up the payment process, reducing errors and generally improving the control of claims.

Claims Processing:

The claims process uses thousands of adjudication rules based on artificial intelligence to determine the eligibility of claims submitted. Through this system, only a small number of staff are required to assess individual claims that cannot be assessed by the computerized system.

Registration and Premium Billing:

British Columbia is one of only two provinces in Canada which charges residents medical care insurance premiums. This system is fully integrated into the Client Registry that follows patients/residents through various interactions with the provincial health care system and vital statistics events.

Decision Support System:

While many claims processing systems are built around operational data required to process the claims, the decision support system is designed to provide a full range of information to support government policy and planning functions and minimize expenses in the claims payment budget through use of good information.

Pharmacare and Pharmanet:

British Columbia introduced the Pharmacare program in 1974. This pharmacy program covers the cost of drugs for seniors, the chronically ill and those people on social assistance. In 1995, British Columbia

introduced Pharmanet, possibly the most comprehensive pharmacy network in North America. Delivered over the provincial information network, HealthNet/BC, Pharmanet connects all of the pharmacies in British Columbia to facilitate claims submission, on-line assessment and payment of claims. Connection to hospital emergency rooms and physician offices is in progress. Pharmanet captures prescription information for the whole population and detects any contraindications, automatically alerting the health provider or pharmacist. The system also helps eliminate abuse and fraud. This system is one of the most advanced in the world and has facilitated a number of progressive policy changes, which assist in controlling pharmacy costs.

SERVICES:

The British Columbia health insurance program and associated information systems are very mature enabling us to assist other countries and jurisdictions by providing:

- consultation on health insurance policy and program development, financing and information systems;
- training of staff in the development and use of health insurance programs and information systems;
- definition of requirements, design and development of programs and information systems.

KEY COMPANIES AND ORGANIZATIONS:

Much of the operational policy, financing and systems capacity is situated within the Medical Services Plan and in the Acute Care division of the British Columbia Ministry of Health. Experienced staff are available to participate in projects along with specialized health consultants from the private sector who helped develop these systems.

Information systems development is often undertaken as a collaborative venture with Ministry staff working with an information technology company. This partnership approach is the approach of choice for major systems development work within British Columbia, such as the development of Pharmanet, the provincial pharmacy network.

CONTACT:

The British Columbia Health Industry Development Office mobilizes health care expertise from the public and private sectors to respond to a wide variety of international project opportunities.

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附錄三

英屬哥倫比亞省(BC) 健康保險系統

Pharmacare 之簡介

PHARMACARE INFORMATION SUMMARY

Pharmacare, a Ministry of Health Services program, assists British Columbia residents in paying for eligible prescription medications and designated medical supplies including:

- eligible medications prescribed by a physician, dentist, midwife or licensed podiatrist
- insulin, needles, and syringes for diabetics
- blood glucose monitoring strips for diabetics with a valid *Certificate of Training*
- certain ostomy supplies
- designated, pre-approved permanent prosthetic appliances and children's orthotic devices

Please contact Pharmacare for specific information on eligible benefits.

PHARMACARE PLANS

Plan A—provides coverage for permanent residents of British Columbia who are age 65 or over and who are enrolled in the Medical Service Plan (MSP) of British Columbia. Pharmacare covers 100% of ingredient costs but the patient is responsible for the first $200 in dispensing fees each calendar year.

Plan B—residents of licensed long-term care facilities receive Pharmacare benefits at no charge.

Plan C—provides coverage for recipients of B.C. Benefits (excluding Seniors). Eligibility for Plan C is determined by the Ministry of Social Development and Economic Security.

Plan D—provides coverage for eligible digestive enzymes for patients registered with the province's Cystic Fibrosis clinics. Additional items, such as nutritional supplements and vitamins, are not covered under Plan D but may be covered under other Pharmacare plans for eligible Plan D patients.

Plan E—provides coverage for all British Columbia residents who are not receiving benefits under Plans A, B or C **and** for eligible medications and medical supplies not covered under Plan D or G. Once the annual deductible is exceeded, the family pays only 30% of further eligible drug costs.

Plan F—provides eligible benefits at no charge to children eligible for benefits under the *At Home Program* of the Ministry for Children and Families.

Plan G—provides coverage for certain psychiatric medications to patients registered with a Mental Health Centre.

Home Oxygen Subsidy Program—assists with the cost of oxygen and oxygen equipment for in-home use for patients who require respiratory assistance. A physician must submit an application to Pharmacare for this subsidy. For more information, contact the Pharmacare Burnaby Office at (604) 660-6707.

Palliative Care Drug Plan—on behalf of the *British Columbia Palliative Care Benefits Program*, which is funded as a continuing care service, the drug plan covers the costs of medications listed in the *Palliative Care Drug Formulary* for eligible patients. For information, contact your physician, local health authority, or the British Columbia Palliative Care Association.

Note: Pharmacare does not provide out-of-province coverage and coverage is not retroactive.

Visit the Pharmacare Web site
www.hlth.gov.bc.ca/pharme/

BRITISH COLUMBIA

For further information contact:

Pharmacare
Ministry of Health Services
P.O. Box 9655 Stn Prov Govt
Victoria BC V8W 9P2
Greater Victoria: 952-2866
Lower Mainland: 682-6849
Elsewhere in British Columbia: 1-800-554-0250

~ Please quote your Personal Health Number ~

加拿大英屬哥倫比亞省藥物保險計劃簡介

譚延輝，吳惠美

加拿大之英屬哥倫比亞(BC)省的藥物保險計劃稱為 Pharmacare，在1974年元月開始執行。Pharmacare 為一區域性(BC 省)的藥物保險計劃，主要在確保 BC 省居民能合理地獲得及適當地使用處方藥品、特定的衛材及相關的用藥福利。在 Pharmacare 的藥物保險計劃中，BC 省居民會被納入下列七項保險計劃中的某一項，其享受用藥福利會不同：

A 計劃：有 BC CareCard 的 65 歲以上住民。自付調劑費，但藥品費由 Pharmacare 付(非給付之藥品則須自費)。一年自費所付調劑費若差過$200 元，超出金額由 Pharmacare 付。

B 計劃：住在有執照之長期照護機構的住民。Pharmacare 付所有處方藥品費及一些醫療器材費。每一個長期照護機構都有一家合約藥局來提供服務，而給付是依每日計酬(per diem)的模式。

C 計劃：接受社會發展與經濟保障部門所提供之社會救濟(social assistance)的居民。Pharmacare 直接付全部處方藥品費給藥局。

D 計劃：有囊性纖維瘤之病人在省內診所有登記註冊者，當診所醫師開消化性酵素時，可接受免費之藥品。此酵素由社區藥局提供。也有部份營養補充物可免費獲得，可向診所或經由 PharmaNet 獲得相關資料。

E 計劃：不包括在 A, B, C, F 計畫中的所有居民，適用此計畫。給付是以家庭的藥品總花費為基礎，不以個人為基礎。目前一年的 Pharmacare 扣除額(deductible, 或稱自付額)為$800 元。當您的家庭在處方藥及其他福利上使用之總花費超過$800 元時，超出的部份 Pharmacare 會付 70%(僅限有給付項目)。若一年總花費達$2000 元，則以上部份 Pharmacare 給付全部。

F 計劃：透過兒童及家庭部門的居家、嚴重殘障之兒童，可獲得全額給付處方藥品費及一些醫療衛材費。

G 計劃：經由精神照護中心決定之精神疾病患者，可免費獲得精神科藥物。其目的是避免財物情況不好的患者，因為不服藥而導致的住院或其他嚴重不良後果。有處方集的制定來決定給付項目。

當 BC 省居民接受住院醫療服務時，藥品是屬於醫院系統的花費。在病人出院後，藥品的給付就由 Pharmacare 承接起來。因此為了要使此保險計劃發揮最大的功能，在 Pharmacare 的藥物保險計劃中採取下列管理方法：

1. **管理藥品給付(Management of reimbursement system)**

   對處方藥品及相關福利之服務進行保險給付制度的管理，以避免不合理之計價或使用醫療資源。

2. **藥物使用評估(Drug Use Evaluation program, DUE)**

   經由使用評估來監測藥物治療及處方型態的適當性及成本效益。

3. **低價取代政策(Low Cost Alternative policy, LCA)**

   低價取代政策可提供最有效的處方藥福利計劃，因為低價位的替代藥(low cost alternative drugs)比市面上同成分其他品牌的藥品便宜，所以對消費者、藥品保險計畫及健保局能直接有意義的節省支出。醫師所開處方藥若低於 reference drug 的價位，則以實際進貨價給付；若高於那價位，病人須自付價差。但病人若願意更換廠牌，使用等於或少於 reference drug 之價位的藥品，則仍不須自費。

4. **為最適當地使用醫療資源，確實評估新藥之成本與社會利益的關係**

   在將新藥品項納入健保給付之前，須評估治療優勢並與已存在的品項比較成本效益及對健保財務之經濟衝擊。

5. **經由促進健康之策略，提升適當使用藥品之概念與知識**

6. **發展出治療準則(Therapeutic guidelines)以推廣正確的藥物治療**

7. **發展“網路藥歷檔”(PharmaNet)協助達成上述目標**

一、藥品給付之管理

在 Pharmacare 計劃中，有給付的項目包括：(1)由醫師、牙醫師、助產士(midwife)、足醫師(podiatrist)所開的有給付藥品；(2)糖尿病患者使用之胰島素、針頭、針筒；(3)當血糖監測是絕對需要，又從核准之糖尿病訓練中心獲得有效訓練證書者，這些糖尿病患者使用的監測血糖試紙；(4)部份造口術(ostomy)之衛材；(5)特定之義肢、人工補缺術等衛材及小孩牙齒矯正器材料等(但需要申請核准才給付)。

若是醫療上有需要，一些沒有給付的品項也可申請給付，沒有全額給付的品項可變為全福利，不能用 LCA 的人變為可用。病患的醫師必須填表向 special authority 申請。必須核准使用後才使用，才能得到給付。

在 Pharmacare 計劃中不給付的項目包括：(1)眼鏡，(2)助聽器及其電池，(3)繃帶，(4)人工甜味劑，(5)制酸劑、瀉下劑、及其他 OTC 藥，(6)輪椅、協助步行器具、及其他醫療器具，(7)已被其他健康照護計畫全額給付之藥品費，(8)在 BC 省外買得之藥品與衛材，(9)在 BC 省外的公司所處理之郵寄處方藥品。

在 Pharmacare 計劃中有 30 天給藥政策。對急性病處方箋及慢性病治療的第一張處方箋，規定最多只給付 30 天的藥品費。這急性病的藥物包括抗生素、鎮靜劑、助眠劑及 Barbiturates，有些藥具成癮性或長期使用治療效果會變差。慢性病(如糖尿病、巴金森氏疾病)的第一次維持治療藥物規定在 30 天之目的是避免浪費，因為要在此期間確定藥物之療效。之後的處方用藥可以長達最多 100 天的供應量。住在郊區或偏遠地區之病患，若沒有藥局在附近，可免除上述規定。

二、參考藥計畫(Reference Drug Program)

此計畫是 Pharmacare 比較同治療類別，不同藥廠的不同藥物產品，去取得最好價格又最有效的藥物產品。若有科學證據顯示幾個藥品針對某醫療狀況，都有相類似的治療效果，Pharmacare 給付那成本最低的藥品，這藥就是參考藥(reference drug)。這計畫能降低 Pharmacare 之成本，維持其運轉並持續保障 BC 省居民之用藥與健康福利。

參考藥計畫在 1995 年十月開始執行，一開始是三類藥：(1)H2 antagonists 來治療一些胃部不適狀況；(2)nitrates 來控制心絞痛；及 (3)NSAIDs 來治療關節炎。從 1997 年增加治療高血壓的藥物，包括 diuretics, beta blockers。這些藥是期望使用的優先選擇藥品，因為已證實可以降低突發性心臟病與中風之機率。目前市面上共有約 30 種 diuretics and beta blockers 的藥物產品，Pharmacare 會給付所有這些藥品。新的計畫又增加 ACE inhibitors 及一些 Ca^{++} channel blockers。

ACE Inhibitors。此類藥品的參考藥是 captopril, ramipril, cilazapril and quinapril。若病患是服用這些藥的其中一種，則 Pharmacare 會全額給付。但若使用 benazepril, enalapril, enalapril/HCTZ, fosinopril, lisinopril and lisinopril/HCTZ，則 Pharmacare 只給付參考藥之藥價，而多出去的藥價差，病患須自費。

Calcium channel blockers。針對 dihydropyridine calcium channel blockers 的參考藥是 felodipine，若病患服用此藥，Pharmacare 會全額給付。此類別的其他藥物，如 amlodipine, nicardipine and nifedipine，Pharmacare 只給付參考藥之藥價，而多出去的藥價差，病患須自費。另外，verapamil and diltiazem 仍然全額給付。

通常一般疾病都有許多種藥物可以用來治療，這些藥價格差異很大但可能療效都差不多。Pharmacare 是請獨立的專家們提供建議，看哪一些同一類別的藥物是安全、有療效，而且何者最符合成本效益。這最適當藥物的成本就是參考藥的給付價格，屬於此類別的任一藥物都以此價格為參考。低於此價格就以低價格給付，高於此價格以此價格給付，而病患自付價差。若依據臨床需要，病患需要用到更貴的藥品，其主治醫師可從 Pharmacare 處得到特殊授權，則仍可獲得全額給付。

省政府邀請一群醫師與藥師組成“藥物治療委員會”，依現有科學文獻的證據，來評估並比較新及現有藥品(同一治療類別)在治療某一醫療狀況的有效性。此委員會提供審核資訊給醫師，以協助他們開出最好的藥物；並提供建議給 Pharmacare 決定何藥應列入給付。

參考藥制度與低價取代政策是不同的。低價取代政策是指同一個主成份的不同藥廠製劑，以品質優良的最低成本廠牌藥品作為給付價依據。而參考藥制度是主成份不同的藥品，但屬於相同的藥理類別，可以用來治療相同的醫療狀況，Pharmacare 給付那成本最低的藥品。

三、低價取代政策 (Low Cost Alternative, LCA Policy)

此制度從 1999 年十一月開始執行。低價取代政策是指同一個主成份的不同藥廠製劑，以品質優良的最低成本廠牌藥品作為給付價依據。在 LCA 類別中，Pharmacare 從所有替代藥的申報藥價中，取成本最低之優良製劑廠牌設定一個 LCA 給付價。只有此廠牌的製劑是 full benefit status，病患可獲得全額給付。其他廠牌的同一主成份藥品製劑都屬於 partial benefits status，若價格低於 LCA 價，則全額給付，若高於 LCA 價，則給付 LCA 價而病患需要付價差。這類似台灣將執行之 reference pricing 制度。

若醫師所開處方箋上藥品屬於 partial benefit 類而且價格高於給付價，藥師必須告訴病患此藥不會獲得全額給付，另外有低價替代藥或參考藥的存在，會有相同或類似的療效。若病患仍選擇使用醫師所開的製劑，病患就自付價差。在 E 計畫中的患者，只有低價位替代藥的花費計算在累積的家庭扣除額中。

四、申請新藥列入給付項目

所有新處方藥在藥廠申請列入給付項目時，必須準備下列資料，以備審查。委員會將探討其治療優勢，已給付同類藥品之成本效益特質比較，以及對 Pharmacare 之財務衝擊。

1. 主成份若是新化學物，需提出三份申請資料。
2. 主成份若是俗名藥、新劑型或新單位含量，提出一份申請資料。
3. 由 Health Canada 所核准之證明，包括：Notice of Compliance (NOC), Drug Identification Number, and Product Monograph。
4. Unrestricted letter of consent permitting communication with Health Canada, other Canadian Provinces and Territories, and with the Patented Medicines Prices Review Board with respect to the product under review.
5. 目前之藥價資料，包括所有劑型、單位含量及包裝大小。
6. 製造藥廠之保證、有能力提供所預期的需求量。
7. 由 Health Canada 所核發之藥廠的三位數 alpha code。
8. 已發表或已被接受發表在有同儕審查之雜誌的臨床研究文獻影本。有探討其臨床使用、療效、安全性及副作用。
9. 符合加拿大 CCOHTA 標準或 Ontario 指南之藥物經濟學評估結果。
10. 說明任何專利之議題。
11. 有關新藥來源之資訊。在得到 NOC 之前，是由藥廠提供、由 Special Access program、或臨床試驗的一部份。
12. 製劑之處方組成資料，包括所有主成份、所有賦型劑、色素及充填物。
13. 任何更改此產品資料之書面信件。
14. 若是俗名藥，藥廠需寫出與社會上已存在的哪些產品是相同的。

五、網路藥歷檔

PharmaNet 經由網路提供線上的、即時的 BC 省居民藥歷檔案，以及整合性的藥物資訊資料庫。PharmaNet 每週七天及每天 24 小時開放(即全年無休)，以提供加拿大 BC 省居民合理取得、適當使用處方藥及相關的醫療服務。PharmaNet 是經由與下列各單位的協商而形成的區域性藥學電腦網路，包括內閣／國家財政委員會、醫政處、BC 省藥師學院、BC 省內科與外科醫師學院、BC 省藥學會、法醫廳(coroner's office)等單位。在加拿大 Pharmacare 中，設計此區域性藥學網路是希望能提供下列的服務：

(1)避免因無意的重複用藥或欺騙不實，而過度使用處方藥品。

(2)經由藥物交互作用及劑量審核，避免不適當的藥物治療。

(3)鼓勵使用符合成本效益的藥品及其他替代選擇

(4)提供完整的病人資料及整合的藥物資訊，而改善執業標準

(5)對藥局及社會大眾提供立刻的審核作業，以簡化而有效率地進行申報與給付作業，。

為了提供上述服務，PharmaNet 資料庫所記錄之資料有：(1)病人的藥歷檔，包含所有的調劑藥品、藥品過敏紀錄、臨床病況、病人基本資料如個人健康編號(personal health number)、姓名、住址、性別及出生日期。(2)提供給藥師或病人的藥物資訊，以及藥物交互作用評估。(3)給付資料，包括合乎條件的給付項目及可扣除額。以上資料都需要時時更新及維持。除此之外，PharmaNet 為了提供更有效及精準的功能，需要不斷的更新及加強軟體功能。新版的 PharmaNet 中，加強及改變軟體需經過 Pharmacare Management Advisory Committee 審核，此諮詢委員會由上述機構派代表組成。因為此委員會是諮詢顧問的性質，所以委員會所提出的建議有可能因政府的政策改變或預算重新分配而不被接受。目前 Pharmacare 所使用的是 PharmaNet 第四版，此版本包括許多系統上的改變，如：

(1)執行 *First DataBank's* 藥物過敏檢核的資料庫，此資料庫會報導病人對藥物成分、過敏原及相關結構之藥品是否過敏。

(2)執行執業者用藥限制之更多檢核功能。

(3)當有新藥上市後，有能力檢核增多的藥物交互作用案件

一旦可以藉由區域性的電腦網路提供病人的藥歷檔後，病人及藥物資訊將由 BC 省藥師學院管理；藥品給付資料為給付者(可能為保險公司、雇主等)所有，因此加拿大 Pharmacare 可以取得執行此計劃之給付資料。在建立及傳輸資料時，需考慮到登錄資料的準確性及保障隱私權的問題。為了確保資料準確性，PharmaNet 在接受或登錄任何個人資料前，都需作確認身份的動作；修改檔案與申報數據之動作都有相關限制規定。

在保障隱私權方面，PharmaNet 可以偵測及監控非經授權的瀏覽。當藥師或技術人員使用此網路系統時，必須與藥品調劑、用藥指導或商業交易行為連結起來。因此具有執照的值班藥師須對維持藥歷檔隱私權及安全性負起責任。在 BC 省任何一間藥局，病人可以要求影印儲存在 PharmaNet 中的藥歷檔影本。此要求可透過 PharmaNet 向 BC 省藥師學院提出，然後藥師學院將資料印出並寄發出去。當病人提出要求之前，需與藥師確認藥歷檔案中地址的正確性。PharmaNet 公司提供許多安全措施，預防非經授權經由網路取得病人資料。除了這些安全措施外，病人也可以選擇使用密碼的方式來確保本身的隱私權，密碼的優點及缺點有：

(1) 密碼鎖住病人的藥歷檔，只有知道密碼者才能取得病人的藥歷檔。

(2) 如果取得病人的同意，密碼可以儲存在當地藥局的電腦中。

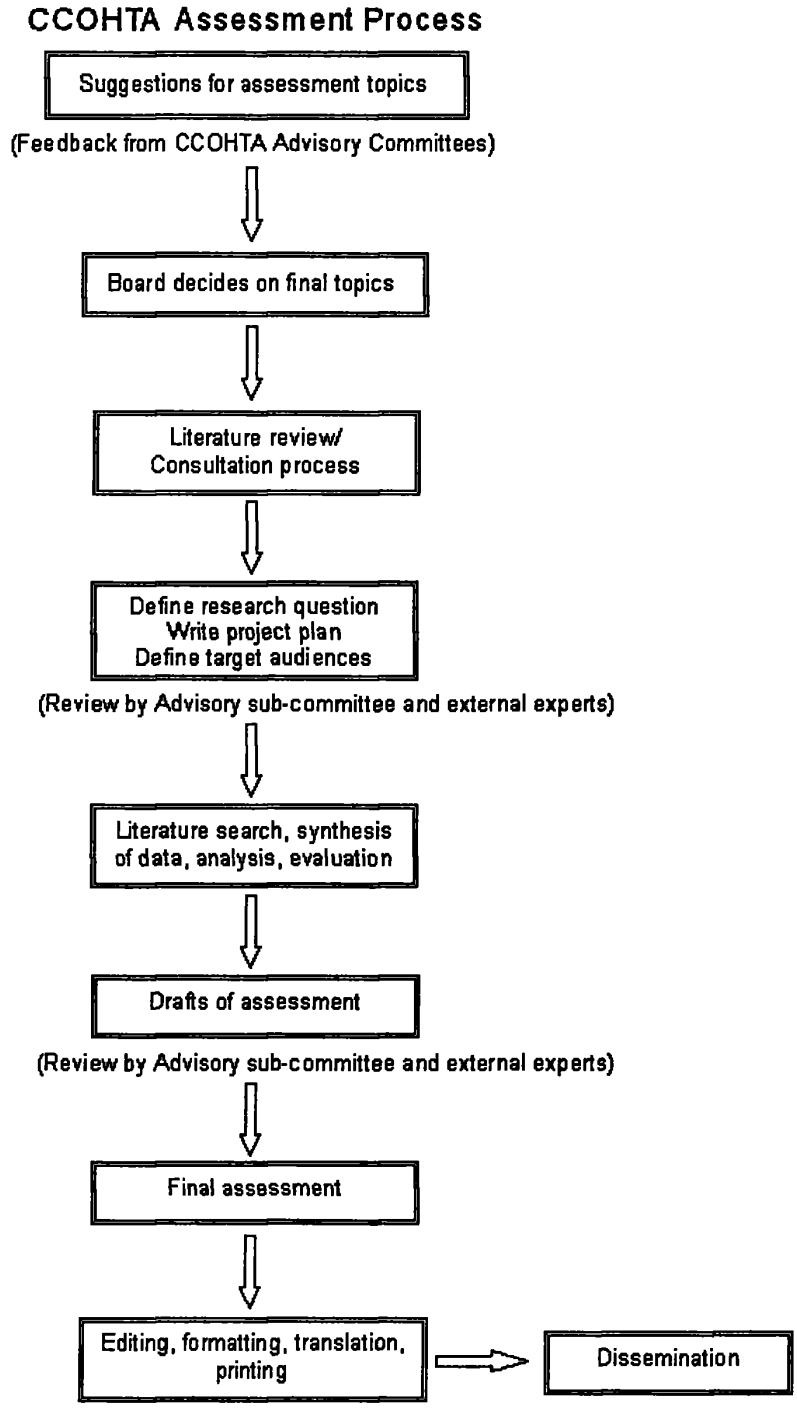
(3) 若病人忘記密碼或不能提供密碼，則會延遲接受到服務。

(4) 當藥師需要使用病人藥歷檔時，必須能得到密碼。如病患親自來調劑時、當要求再調劑處方箋時、當病人醫師電話處方時、當病人或醫師依病患之需要而要求處方藥物資料時。

在BC省區域性的PharmaNet藉由改善藥師執業行為而改善大眾的健康情形；又因為電腦化的申報系統及藥物資訊也改善對民眾的服務；同時也提供加拿大的藥物保險計劃Pharmacare執行上的彈性及成本的節省。

附錄四

加國健康科技評估聯合辦公室 (CCOHTA)的評估過程


CCOHTA Assessment Process
Suggestions for assessment topics
(Feedback from CCOHTA Advisory Committees)
Board decides on final topics
Literature review/
Consultation process
Define research question
Write project plan
Define target audiences
(Review by Advisory sub-committee and external experts)
Literature search, synthesis
of data, analysis, evaluation
Drafts of assessment
(Review by Advisory sub-committee and external experts)
Final assessment
Editing, formatting, translation,
printing
Dissemination

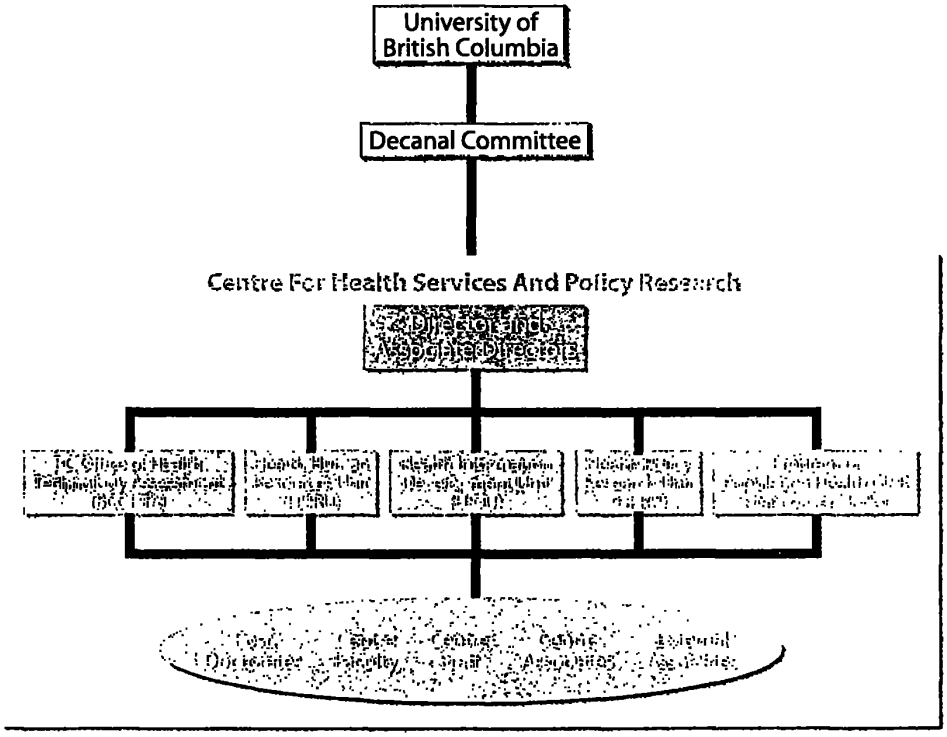
附錄五

英屬哥倫比亞大學(UBC)
Center for Health Services and Policy Research
與內外組織的關係

Appendix II

CENTRE FOR HEALTH SERVICES AND POLICY RESEARCH

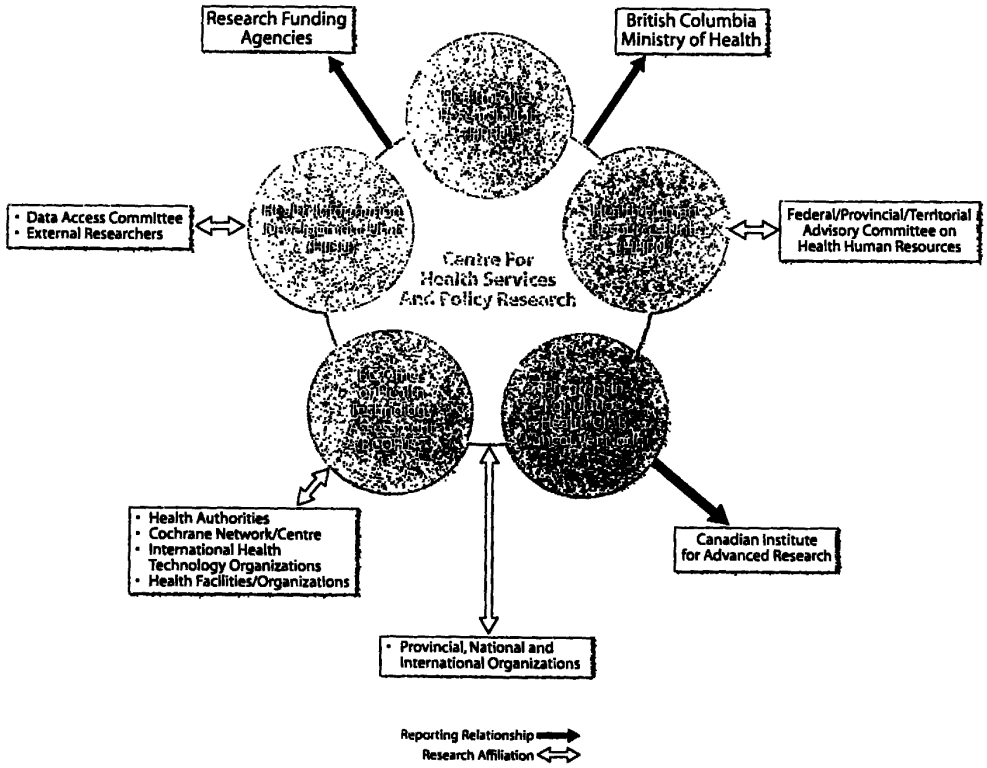
Internal Relationships



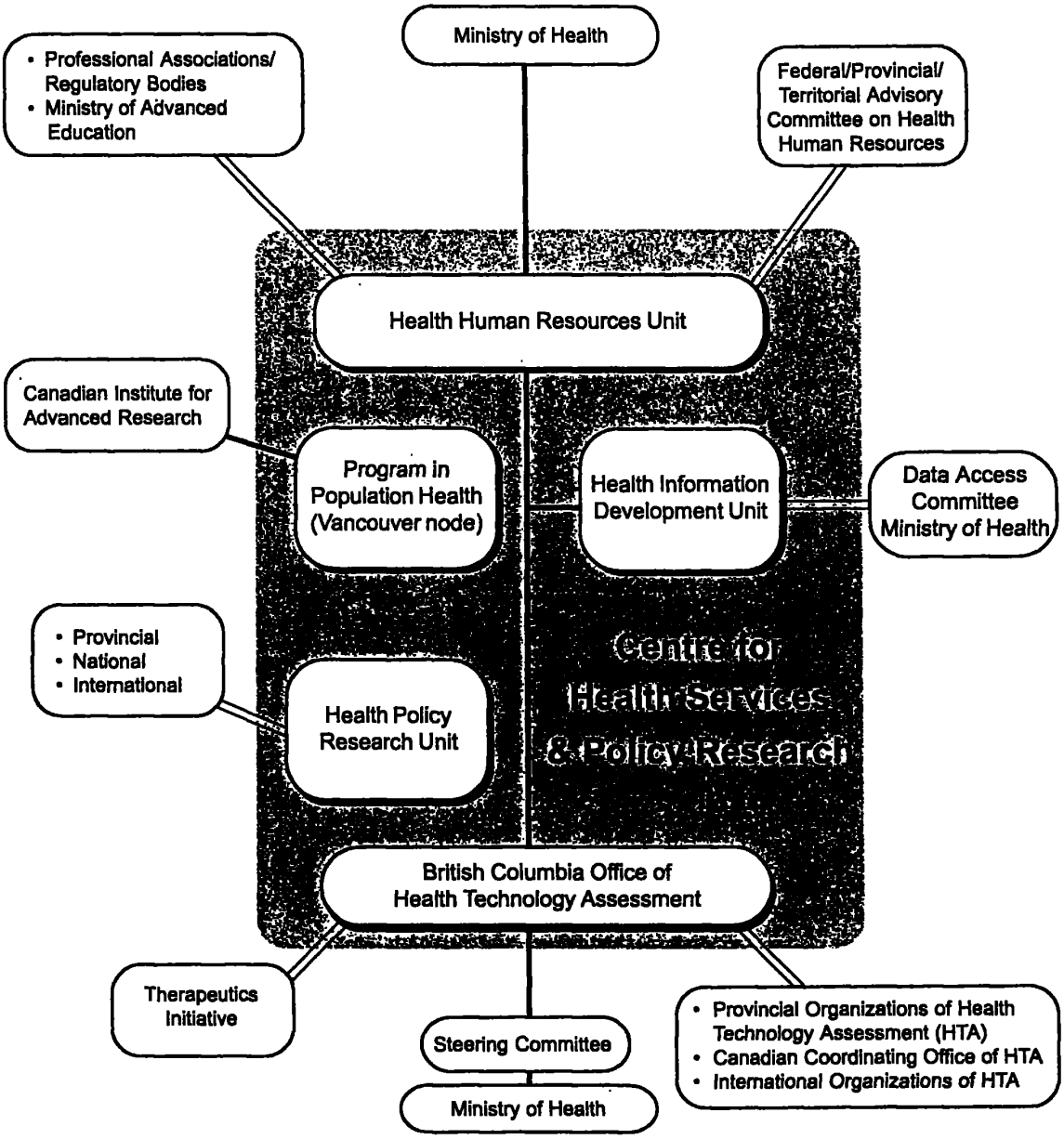
Appendix III

CENTRE FOR HEALTH SERVICES AND POLICY RESEARCH

External Relationships



Centre External Relationships



BCOHTA STEERING COMMITTEE

Terms of Reference

Objectives:

- identify and communicate with external stakeholders with respect to the mission and objectives of the BCOHTA
- set strategic direction for BCOHTA by determining relative importance/allocation of resources to the three areas of focus: research, communication and education.

Research:

- provide advice on areas/projects of concentration as appropriate
- provide assistance with setting project priorities for BCOHTA research staff as necessary
- assist with identification of external expertise for collaboration, consultation and review of documents.

Communication:

- assist with development of communication strategies through identifying potential recipients of assessment information and developing appropriate vehicles/fora
- develop guidelines for allocating BCOHTA resources across competing communication processes/vehicles, and between communication and other areas of responsibility.

Education:

- develop guidelines for allocating BCOHTA resources across competing education roles, and between education, communication and research activities.

Funding

- assist grantholder(s) as appropriate in identifying and/or negotiating with existing and potential new funding sources
- develop guidelines for assigning BCOHTA staff to the development of new funding sources (e.g., grants) for the Office, and providing assistance to other potential investigators in the development of grants.

附錄六

加拿大 BC 省健康科技評估辦公室 (BCOHTA) 協助發展 systematic reviews, clinical practical guideline and health technology assessment 的工具

Quality Evaluation Form Systematic Reviews, CPGs and HTA

Bibliography #: (Table 1 column a)	Title: (Table 1 column a)	Year: (Table 1 column a)
Author: (Table 1 column a)	Reviewer:	Review date:

	Y/N	Description/Details/Comments
Research questions: List RQ		
Types of participants eligible in studies included in the review described? • Adults • Principal diagnosis: • Co-morbidities reported?		Age= How defined and severity
Types of comparisons /interventions reported?		
Outcomes reported? • •		How defined and when measured How defined and when measured How defined and when measured
Types of study designs included? • Randomized controlled • Un-randomized controlled • Uncontrolled • Blinded		
Types of setting reported? • Acute		Inpatient /outpatient/ insurer

• Level • Population-based		University-tertiary/ primary Multi-center/ single-center

Search strategy: sources checked?		
Review Group specialized registers consulted?		Which?
Reference lists checked?		Included / relevant
Personal communication conducted?		
How?		Mail/ email/ fax/ phone
Comprehensive list submitted		
Inclusion criteria sent		
Electronic databases searched?		Which?
The Cochrane Controlled Trials Register		
MEDLINE and EMBASE		
SCISEARCH		
Registers of clinical trials		
Other bibliographic databases (Gale Directory of Online, Portable and Internet databases)		
Hand-searching conducted?		Which journals and how (Uncover Reveal Table of Content?)

Search strategy: key word and specifics reported?		
Search strategy for each database reported?		
Date of the search; temporal constraints reported?		
Language limitations reported?		
Other constraints reported?		
Date that the search was done reported?		
Index terms and text words used reported?		

Selecting studies for inclusion		

Inclusion Criteria		
Exclusion Criteria		
Included studies listed?		
Excluded studies listed?		
Reason for exclusion listed?		
Number of studies considered reported?		
How was double counting avoided?		
More than one reviewer assessed eligibility?		
Content area experts; non-experts, or both?		
Blinded assessment of inclusion?		
Handling of disagreements determined?		
Possibility of publication bias evaluated?		How? (funnel plot?)

Evidence on adverse effects		
• other types of studies searched for?		Types and search methods
Evidence on social impact		
• other types of studies searched for?		Types and search methods
Evidence on ethical impact		
• other types of studies searched for?		Types and search methods
Evidence on legal impact		
• other types of studies searched for?		Types and search methods
Evidence on economic impact		
• other types of studies searched for?		Types and search methods

Assessment of study quality Quality assessment conducted?		
Criteria used reported? Which?		
How was the quality assessment conducted?		
• Number of reviewers reported?		

• Reviewers: methods or content specialists?		
• Handling of disagreement determined?		
• Assessment criteria piloted?		Intra- inter-rater reliability
• Blinded?		
Validity of studies summarized?		How?
Study validity incorporated in review?		
As a threshold for inclusion of studies?		
As a possible explanation for differences in results between studies?		How did the SR take into account the methodological quality of the studies included in their analysis or conclusion?
In sensitivity analyses?		
As weights in statistical analysis of the study results?		
Additional data obtained from investigators as necessary?		

Data extraction form		
Data extraction form used?		Which?
Multiple reviewers used for data extraction?		How many?
Reliability of data extraction measured?		
Handling of disagreements determined?		
Data collected from investigators if needed?		How?

Analyzing and presenting results (meta-analysis)		
Effect across studies summarized?		
• Weight given by variance?		
• Weight based on quality?		
Post hoc analyses identified as such?		

Heterogeneity Investigated?		
Were subgroup analyses conducted?		
Were sensitivity analyses conducted?		IF NO GO TO EFFECT SIZE
IF YES TO ABOVE: By types of study participants, interventions or outcome measures?		
By including or excluding studies where there is some ambiguity as to whether they meet the inclusion criteria?		
By reanalysing the data using a reasonable range of results for studies where there may be some uncertainty about the results?		
By reanalysing the data imputing a reasonable range of values for missing data?		
By reanalyzing the data using different statistical approaches?		
Was effect size data available for all included studies?		
Was the statistical significance of the meta-analysis determined even if the effect size couldn't?		
Is CI, SD or P value reported and what is it?		

Interpreting results		

Was the strength of evidence considered in interpreting results?		
Was the quality of the included trials considered?		
Was the size and significance of the observed effects discussed?		
Were the effects consistent across trials?		
Was there a clear dose-response relationship?		
Was there indirect evidence that supports the inference?		
Have other plausible competing explanations of the observed effects (eg. bias or co-intervention) been ruled out?		
Was the applicability of the findings discussed?		
Were biologic and cultural variation considered?		
Were variations in compliance considered?		
Were variations in baseline risk considered?		
Were variations in the results of the included studies considered?		
• patient features, such as age, sex, biochemical markers		
• intervention features, such as the timing or intensity of the intervention		
• disease features, such as hormone receptor status		
Were adverse effects discussed?		
• Was the strength of the evidence on adverse effects discussed?		
• Were estimates of their seriousness included?		
Were social-ethical-legal-economic issues discussed?		
• Was the strength of the evidence on adverse effects discussed?		

• Were estimates of their seriousness included?		
Trade-offs Were judgments about preferences made explicit?		What were they?

Findings		
Findings, outcomes, recommendations		
Are the conclusions linked to the evidence?		
What was done when research evidence was missing? -concluded to lack of evidence to support use? -expert opinion used? -consensus panel used?		
Is the magnitude of the difference clinically important?		
Is the difference statistically significant?		

3.2 Appraisal of clinical practice guidelines

To review and evaluate the process used in developing clinical practice guidelines, and to determine the extent to which the guidelines were "evidence-based", BCOHTA used a set of 15 appraisal criteria derived from work done by the Institute of Medicine and the Agency for Health Care Policy and Research.[5-6] A comprehensive list of these criteria is presented in Table 1. The list of criteria as presented below was used as an extraction form. The criteria were answered by "Yes/No-Describe" or "Discussed/Not Discussed". To meet the criteria, the information needed to be clearly provided in the documents. No assumptions or inferences were drawn based on the name, status, or reputation of the authors or supporting organizations.

Each guideline was independently appraised by two researchers. The researchers had expertise in critical appraisal, epidemiology, medicine, anthropology, and economics. The researchers were not blinded as to authors or organizations. Differences between the researchers were resolved by obtaining additional information from members of the guidelines development groups.

Participants from various guidelines development groups were asked to review the appraisal of their respective guidelines in order to: i) ensure the accuracy of the appraisal; and, ii) ensure that all relevant background information had been considered. Whenever additional information or corrections were provided *as to the guidelines development process*, the results of the appraisal were based on the additional information or corrections. When comments were made *as to the research evidence* considered, changes to the appraisal were made only if the consideration of this evidence could be substantiated. The appraisal was based on the guidelines documentation and comments available as of January 1996.

Table 1: Criteria for appraising clinical practice guidelines

1. How was the panel constituted?	
a) selected by contracting agency or requesting agency?	Yes/No-Describe
b) nominated by professional or clinical organization?	Yes/No-Describe
c) multi-disciplinary? (>1 health / health-related discipline)	Yes/No-Describe
d) were selection criteria established? Were they assessed by interview of the candidate and nominating organizations? Did they incude:	
-possession of outstanding clinical and academic credentials?	Yes/No-Describe
-willingness to consider alternative opinions?	Yes/No-Describe
-possession of an open mind about clinical guidelines?	Yes/No-Describe
-ability to work well in group (as judged by peers)?	Yes/No-Describe
e) was a balance achieved between:	
-academia vs. clinical-based practice?	Yes/No-Describe
-geography?	Yes/No-Describe
-gender?	Yes/No-Describe
-ethnicity?	Yes/No-Describe
-practice style (those who do and do not refer for cholesterol testing)?	Yes/No-Describe
f) was one chair or 2 co-chairs appointed?	Yes/No-Describe
2. How were the key methods and procedural issues handled?	
a) were the topic and population to be targeted by clinical guidelines delineated? What were they?	Yes/No-Describe
b) were criteria for deciding on what to include as scientific evidence established? What were they?	Yes/No-Describe
c) was a rating scheme adopted to report on the strength of the evidence underlying a recommendation? Which one?	Yes/No-Describe
3. What process was used to conduct the literature search and to identify the research evidence to be included?	
a) was a search conducted? By who?	Yes/No-Describe
b) was a search strategy elaborated? What was it?	Yes/No-Describe
c) were inclusion / exclusion criteria defined? What were they?	Yes/No-Describe
d) was a time frame determined? What was it?	Yes/No-Describe
4. How was the strength of the research evidence assessed?	
a) was an appraisal conducted? By who?	Yes/No-Describe
b) were appraisal criteria used? Which ones?	Yes/No-Describe

...continued

Table 1 (continued)

5. What research evidence was provided or was missing regarding:	
The ability of the lipid tests to discriminate between those who will or will not develop CHD?	
a) prevalence	Discussed/Not Discussed
b) sensitivity	and Describe
c) specificity	"
d) false positive	"
e) false negative	"
f) positive predictive value	"
g) negative predictive value	"
Whether knowledge of cholesterol level will change patient management beyond lifestyle modifications?	Discussed/Not Discussed and Describe
Whether the change in management will improve health outcomes?	
a) incidence of angina and non-fatal MI	Discussed/Not Discussed
b) mortality by CHD	and Describe
c) all-causes mortality	"
6. What was done when research evidence was missing?	
a) were population sub-groups considered? Which ones?	Yes/No-Describe
b) was an expert panel used? How was it composed?	Yes/No-Describe
c) was panel consensus achieved on management or range of management strategies for all sub-groups? How was it achieved?	Yes/No-Describe
7. What was the link between the research evidence and the recommendations? i.e., Were the recommendations supported by research evidence or by the group's conclusion on the research evidence?	Yes/No-Describe
8. Was a clinical algorithm used to present the recommendations?	Yes/No-Describe
9. Were peer reviews to address the scientific validity of the guidelines:	
a) done? When? How often?	Yes/No -Describe
b) done while reviewers maintained strict confidentiality? How?	Yes/No-Describe
c) done first by an "inner circle" of experts? How were the experts nominated?	Yes/No-Describe
d) done second by an "external circle" of experts? How were the experts nominated?	Yes/No-Describe

...continued

Table 1 (continued)

10. Was a pilot review conducted to assess:	
a) the clarity of the guidelines? How was that done?	Yes/No-Describe
b) the feasibility of applying the guidelines in practice? How was that done?	Yes/No-Describe
c) the "user friendliness" of the guidelines? How was that done?	Yes/No-Describe
d) the utility of the guidelines in the clinical setting? How was that done?	Yes/No-Describe
e) whether all the exceptions to the guidelines were mentioned? How was that done?	Yes/No-Describe
11. Was a contracting agency involved in the development of the clinical guidelines? Which one?	Yes/No-Describe
12. How was the labour divided between the requesting and contracting agencies?	Describe
13. Were future updates of the clinical guidelines planned? When?	Yes/No-Describe
14. Was the description of projected health outcomes to be achieved by guidelines included? How were those projections estimated?	Yes/No-Describe
15. Was the description of projected health costs / savings to be achieved by clinical guidelines included? How were those projections estimated?	Yes/No-Describe

4.0 SEARCH RESULTS AND SELECTED GUIDELINES

The search of the published and unpublished literature yielded 17 guidelines produced after 1990 (Table 2). A preliminary examination revealed that only five of these guidelines were "potentially" evidence-based. The other 12 guidelines clearly either were based on expert opinion or consensus or did not include any systematic search or appraisal of the research evidence. Five reviews were also found, none of which were based on a systematic search and appraisal of the research evidence. They were also excluded.

The guidelines developed by the BC Medical Association, though not appearing to be evidence-based, were included as they were the only locally developed guidelines and the starting point for the Cholesterol Panel.[25] The guidelines from the Task Force of the European Society of Cardiology, European Atherosclerosis Society and European Society of Hypertension (1994)[26] and the guidelines from the US Preventive Services Task Force (1994)[27] were also examined. Since the European recommendations were not based on a systematic search and appraisal of the research evidence, and as their assessment would have provided little additional information, a comprehensive appraisal of these guidelines was not undertaken. The 1994 draft of the US Preventive Task Force guidelines was unavailable for citation at the time of this report.

Table 1: Characteristics of Included Studies

Study	Population and setting	Types of studies included	Inclusion/ Exclusion criteria	Outcomes Evaluated (def and when)

Table 2: Study Appraisal

Study	Quality Assessment (y/n)	Quality Criteria (which?)	Search Strategy						Selection inclusion appropriate (y/n)	Data Extraction Appropriate (y/n)
			Major databases (y/n)	Fugitive (y/n)	Textword MeSH (y/n)	Limit English (y/n)	Time frame	Adv Effects (y/n)		

Table 3: Reported Results

Study	Outcomes	Affecting Factors	Incidence		CI or SD or Pvalue	Clinical significance
			Treatment / Exposed (n/d)	Control (n/d)		

Then:

Our analysis of the implication of the methods on the reported results and our conclusion of what can be concluded based on reported results and methods.

附錄七

Therapeutics Initiative 的資訊擴散與教育
— Therapeutics Initiative letter 等

Education Working Group

Therapeutics Initiative

UBC

June 25, 2001

B. EDUCATION WORKING GROUP

Mandate

- To translate evidence-based, unbiased, pharmacotherapeutic information into relevant clinical messages.
- To develop educational strategies and disseminate these messages to physcians and pharmacists in British Columbia.
- To measure (in cooperation with the Evaluation Working Group) the effectiveness of these strategies on changing prescribing patterns of the clinicians.
- To redesign strategies when they have proven to be ineffective.
- To cooperate & collaborate with local, national and international initiatives that deliver evidence-based pharmacotherapeutic information to clinicians.
- To foster research towards improving the dissemination and implementation of evidence based pharmacotherapy into practice.

Strategies

- Annual Drug Therapy Course
- Travelling Road Show for Community Physicians and Pharmacists.
- Teleconferences
- Academic Detailing
- Small Group Problem Based Learning Modules
- Undergraduate & Postgraduate Medical Education
- Community Influentials
- Strategies Aimed at Specialists' prescribing

Evaluation

Evaluation of the effectiveness of a number of the strategies on prescribing patterns is carried out using the Pharmanet/Pharmacare data base in cooperation with the Evaluation Working Group of the TI. Based on a paradigm of a cooperative and collaborative delivery of continuing education this committee is made up of representatives from academic and community-based organizations involved in the education of physicians and pharmacists.

Membership Representation

Members represent:

- Community Based Physicians (Generalists and Specialists)
- Community Based Pharmacists
- BC Chapter College of Family Physicians of Canada
- BCMA
- Community Based CME
- Clinical Competency Program, UBC
- College of Pharmacy
- Dept. of Family Practice UBC
- Dept. of Pharmacology & Therapeutics UBC
- Dept. of Internal Medicine UBC
- Public Education
- Adult Education, UBC
- Evaluation Working Group, TI

Changing Prescribing Behaviour - Using Multiple Interventions

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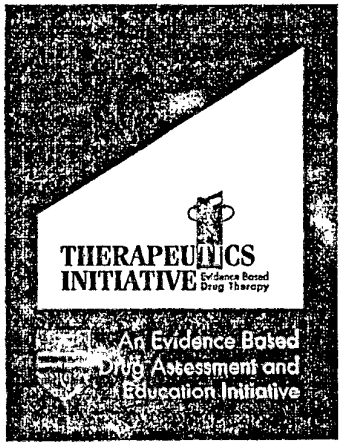


Education Program

Therapeutics Initiative

Focused on delivering and facilitating the incorporation of clinically relevant, unbiased, evidence - based pharmacotherapeutic information into medical practice.

Objective

To demonstrate if multiple evidence - based pharmacotherapeutic educational interventions delivered sequentially to a community of physicians are effective in moving prescribing behaviour towards a defined optimum.[1,2]

Process

1. **Establish the message**
2. **Design the experiment**
3. **Disseminate the message**
4. **Evaluate the effect**
5. **Feedback**

1. Establish the message

- Identification of drug therapy category of interest and concern by community physicians and pharmacists.
- Identify the unbiased evidence related to the drug therapy category.
- Establish an optimal prescribing pattern goal
- Establish how current prescribing in the community differs from that goal.
- Adapt the educational messages and strategies to achieve the goal.

2. Design the experiment

Randomize physician groups to test and control communities

3. Disseminate the message using multiple interventions

Using multiple sequentially delivered educational messages to the test communities:

- **Therapeutics Letter**
- **Community seminars for physicians/pharmacists/public**
- **Academic detailing**
- **Small group practice based learning**
- **Teleconferences**

4. Evaluate the effect

- Evaluate the changes in prescribing by comparing the test and control groups
- Evaluate the impact on prescribing attitudes

5. Feedback

Feedback to reinforce and improve the process

References:

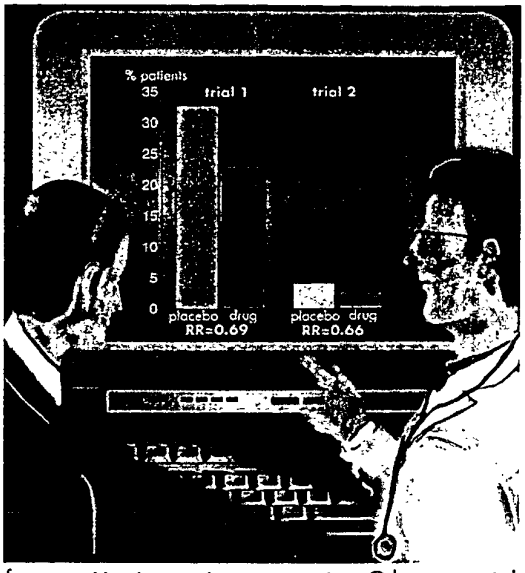
1. Mugford M, Banfield P, and O'Hanlon M, (1991) Effects of feedback of information on clinical practice: a review. *BMJ* 303: 398-402
2. Maciura M, Dormuth C, Naumann T, McCormack J, Rangno R, Whiteside C, Wright JM. Influences of educational interventions and adverse news about calcium-channel blockers on first-line prescribing of antihypertensive drugs to elderly people in British Columbia. *Lancet* 1998; 352: 943-48

therapeutics letter
aug/sep/oct 1996

THERAPEUTICS INITIATIVE Evidence Based Drug Therapy

Evidence Based Drug Therapy

What do the numbers mean?



Imagine you just discovered that you have a risk factor for cardiovascular disease (e.g. high LDL cholesterol). A drug that will reduce this risk factor is available, and it has a low incidence of side effects. Consider the 3 following scenarios. Would you be willing to take this drug daily for the next 5 years if significant results from randomised placebo controlled trials showed that:

1 patients taking this drug for 5 years have 34% fewer heart attacks than patiens taking placebo; **or**

2 2.7% of the patients taking this drug for 5 years had a heart attack, compared to 4.1% taking a placebo, a difference of 1.4%; **or**

3 if 71 patients took this drug for five years the drug would prevent one from having a heart attack. There is no way of knowing in advance which person that might be.

Did you make the same decision for all three scenarios? If not, you were fooled by the numbers, because the three scenarios represent the same data from the same trial presented to you in three different ways[1,2].

• *Why do you and your patients need to know the difference between relative risk (RR), relative risk reduction (RRR) absolute risk reduction (ARR), and number needed to treat (NNT)?*

Benefits in clinical trials are most often presented in trial reports and advertisements as RR (risk ratio) or RRR; these can often be misleading to clinicians and patients. In fact, clinicians and patients make different drug therapy decisions, depending on the way the results are presented; **in the example shown above fewer physicians[1] and patients[2] will choose the therapy when the data is presented as ARR and NNT than if presented as RR or RRR**. Table 1 demonstrates how the different terms are calculated and the practical implications of this concept. In this example the RR and the RRR are similar, yet the overall results are quite different. The ARR and NNT give a much better appreciation of the magnitude of the benefit and of the potential for a positive impact in your practice. Other essential parameters to be considered are the importance of the outcome to the patient and the time required to achieve the benefit (see Table 2). **It is tempting but inappropriate to extrapolate benefits beyond the duration of the trial.**

• *How can you and your patient make the most informed decision?*

For most drug therapy trials ARR and NNT are easily calculated from the data presented in the paper. Risks of a drug therapy can also be calculated as absolute risk increase, or NNT to cause an adverse event. When dealing with individual patients, it is important to realise that patients differ markedly in their attitude toward taking medications. It is therefore essential that the practitioner is able to explain the benefits and risks of a treatment in a form that the patient can understand. Often the NNT to prevent or cause events in a specified period of time are the most meaningful. Once the patient understands the potential benefits and risks of therapy, a joint decision can be made. To help guide the clinician and patient, Table 2 outlines the use of these numbers to present some of the evidence for 7 common clinical scenarios (including the examples in Table 1).

Table 1: An example of similar relative risks but different absolute risk reductions.[4,7]

Placebo # of patients Total	Event	Drug # of patients Total	Event	Relative Risk* RR	Relative Risk Reduction# RRR	Absolute Risk Reduction▪ ARR	Number Needed to Treat▼ NNT
3178	1038	3810	854	854/3810 / 1038/3178 = 0.69	1-0.69 x 100 = 31 %	32.6% - 22.4% = 10.2 %	100 / 10.2 = 10
2030	84	2051	56	56/2051 / 84/2030 = 0.66	1-0.66 x 100 = 34 %	4.1% - 2.7% = 1.4 %	100 / 1.4 = 71

* Relative risk (RR) = Event rate (Drug)/Event rate (Placebo)
▪ % Absolute risk reduction (ARR) = % Event rate (Placebo) - % Event rate (Drug)
% Relative risk reduction (RRR) = 1- relative risk X 100
▼ Number needed to treat (NNT)= 100/% absolute reduction

The Therapeutics Initiative is at arms length from government and other vested interest groups. Our function is unbiased review and dissemination of therapeutic evidence. Assessments apply to most patients; exceptional patients require exceptional approaches. We are committed to evaluate the effectiveness of our educational activities using the Pharmacare database without identifying individual physicians, pharmacies or patients. Please notify us if you do not wish to be part of this evaluation.

Table 2: Examples of Evidence of Benefit of Common Drug Therapies*

Clinical trial (measured outcome events)	Event incidence % Placebo	Drug	RR	RRR %	ARR %	NNT	Trial duration (years)
ACE inhibitors for congestive heart failure[4] (total mortality or hospitalisation for CHF)	32.6	22.4	0.69	31	10.2	10	~0.5
Diuretics and beta blockers in old patients with hypertension[6] (total mortality or cardiovascular event)	22.5	13.7	0.61	39	8.8	11	5
Simvastatin for elevated cholesterol in patients with coronary heart disease[5] (total mortality or coronary event)	31.0	22.6	0.73	27	8.4	12	5
Long-term beta blockers after myocardial infarction[7] (total mortality or non-fatal reinfarction)	17.6	13.7	0.78	22	3.9	26	~0.5
Gemfibrozil in male patients with high cholesterol[8] (total coronary events)*	4.1	2.7	0.66	34	1.4	71	5
Aspirin in healthy male physicians[9] (total myocardial infarctions)*	2.2	1.3	0.56	44	0.9	111	5
Misoprostol in rheumatoid arthritis patients taking NSAIDs[10] (serious gastrointestinal complications)	0.95	0.57	0.60	40	0.38	263	~0.5

RR=Relative Risk RRR = Relative Risk Reduction ARR = Absolute Risk Reduction NNT = Number Needed to Treat
* Inclusion in the table does not necessarily imply endorsement by the Therapeutics Initiative.
* Total mortality not included because not statistically different; if total mortality were added NNT is even greater.

• *What is Evidence Based Drug Therapy?*

Evidence based drug therapy means **integrating the best evidence, the individual characteristics of the patient, and individual clinical expertise, into a decision making process which leads to optimal drug therapy**[3]. This is a complex process that requires a detailed understanding of the evidence, including how the evidence was derived and an appreciation of the magnitude of the benefits and/or risks.

• *How does the Therapeutics Initiative compile the evidence that is presented in the Therapeutics Letter?*

First, a search is done to determine whether other groups around the world have done a recent "systematic review" (meta-analysis) of the subject. We only use systematic reviews that meet rigorous scientific standards (e.g. those done by the Cochrane Collaboration). When other systematic reviews are not available, we do a comprehensive literature search and compile the relevant published trials. We limit ourselves to the best evidence, **the randomised-controlled, double-blind clinical trial, or meta-analysis of randomised controlled trials**, whenever possible. We try to focus on trials that measure the true goal of therapy (e.g. morbidity and mortality) and not surrogate markers (e.g. blood pressure), and exclude trials with major methodological flaws. When this is done the number of trials that need to be extensively critiqued is limited and manageable. Our recommendations are based on the best trials, the most important of which we include in our reference list. Before the Letter is sent out, a draft is reviewed by the members of the Advisory and Scientific Information and Education Committees of the TI, representatives of the B.C. College of Family Practice, and specialists in that particular therapy. All suggestions are considered and included if substantiated by evidence. Once published, we welcome feedback. Drug therapy is a rapidly changing field and we are always open to new evidence or evidence that we may have overlooked.

• *What if the evidence is inconclusive?*

Unfortunately, this situation is frequently the case. The only available evidence may be based on surrogate endpoints, cohort studies, case control studies, or subgroup analyses of randomised controlled trials. Such forms of evidence are interesting and hypothesis generating, but are not conclusive. A good example of this is the evidence for long-term menopausal hormone therapy presented in Letter 14. **In such cases it is important that the proper experiment, a randomised controlled trial, is done, and that the practitioner and patient be aware that the evidence is not conclusive at present.**

References:

1. Bucher, HC, Weinbacher M, Gyr K. *Influence of method of reporting study results on decision of physicians to prescribe drugs to lower cholesterol concentration.* BMJ 1994; 309:761-4.
2. Hux JE, Naylor CD. *Communicating the benefits of chronic preventive therapy: does the format of efficacy data determine patients' acceptance of treatment?* Med Decis Making 1995;15:152-157.
3. Sackett DL, Rosenberg WMC, Gray JAM, et al. *Evidence based medicine: What it is and what it isn't.* BMJ, 1996; 312:71-2.
4. Garg R, Yusuf S. *Overview of randomised trials of angiotensin-converting enzyme inhibitors on mortality and morbidity in patients with heart failure.* JAMA, 1995; 273:1450-1456.
5. The Scandinavian Simvastatin Survival Study Group. *Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease.* Lancet, 1994; 344:1383-9.
6. Dahlöf B, Lindholm LH, Hansson L, et al. *Morbidity and mortality in the Swedish trial in old patients with hypertension (STOP- Hypertension).* Lancet, 1991; 338:1281-85.
7. Yusuf S, Peto R, Lewis J, et al. *Beta blockade during and after myocardial infarction: an overview of the randomised trials.* Progress in Cardiovascular Diseases, vol. XXVII, no. 5 (March/April), 1985; 335-371.
8. Heikki Frick M, Elo O, Haapa K, et al. Helsinki Heart Study: *Primary-prevention trial with gemfibrozil in middle-aged men with dyslipidemia. Safety of treatment, changes in risk factors, and incidence of coronary heart disease.* N Engl J Med, 1987; 317:1237-45.
9. Steering Committee of the Physicians' Health Study Research Group. *Final Report on the aspirin component of the ongoing Physicians' Health Study.* N Engl J Med, 1989; 321:129-35.
10. Silverstein FE, Graham DY, Senior JR, et al. *Misoprostol reduces serious gastrointestinal complications in patients with rheumatoid arthritis receiving non steroidal anti-inflammatory drugs.* Ann Intern Med, 1995; 123:241-249.

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OPTIMAL PRESCRIBING COURSE

May 17, 2001

(DRAFT)

Only one profession has the power to legally prescribe a chemical which when taken will affect every cell of the patients body. We must be absolutely certain of the benefit and harm of what we prescribe and ensure that decision to prescribe is evidence based and made in collaboration with the informed consent of the patient.

CONTENT	PRESENTER	DATE	COMMENT
DRUGS FROM BIRTH TO DEATH • Development • Trials • HC / FDA reviews • To you and your patients • Post surveillance marketing • Beyond			
PRINCIPLES OF PRESCRIBING • Evidence based prescribing • Would you prescribe this to someone you loved? • Low and slow • Generic vs. trade name • Costs • What do the numbers mean? • Efficacy vs. effectiveness • Translating evidence into clinical relevance • Ethics / professionalism / social responsibility			
RECALLING BASIC PHARMACOLOGY • Receptors / agonists / antagonists • Action at the cellular level • Metabolism • Excretion			
ACCESSING THE EVIDENCE • Trusted, evidence based, unbiased resources • Computer based access • Other sources • Palm pilots • Guidelines			

CONTENT	PRESENTER	DATE	COMMENT
WRITING PRESCRIPTIONS • Basics • How to take? (caps / tabs / suppositories) • Compliance data • For how long? • Triplicate prescriptions • Special authority • Tele refills			
ADVERSE DRUG REACTIONS • Identifying • Interactions • Overdoses (intentional and unintentional) • Reporting • The future			
BRING YOUR CASES: Small Group Problem Based Sessions • HBP • CHF • Asthma • Chronic pain management • Musculo-skeletal pain • GERD • ETC			
COLLABORATIVE DECISION MAKING • The patient and the Internet • Informed shared decision making • Implement what the numbers really mean			
MONITORING SESSION • Bring your duplicate prescriptions for review			

CONTENT	PRESENTER	DATE	COMMENT
MARKETING INFLUENCES • On public (illness clubs / DTCA) • On health policy • On the profession (physicians / pharmacists) • Detailers • No Free Lunch / Melam / Bioject • Early adaptors etc. • On costs of drugs • Societal responsibility • Ethics • Dealing with new drugs innovators maintainers and persisters			
FORMULARIES • Developing a personal formulary and knowing the details			
ANTIBIOTICS USE AND ABUSE • Resistance • Appropriate use • Appropriate choice			
PRESCRIBING, CMPA & THE LAW • Interesting cases • Principles of avoiding the Law			
BRING YOUR CASES • • •			
EVALUATION • • •			
REGISTRATION WITH THE POSTGRADUATE DEAN'S OFFICE • • •			

CONTENT	PRESENTER	DATE	COMMENT
ONGOING MONITORING • • •			
MONITORING SESSION • • •			
WEANING TOWARDS INDEPENDENT PRESCRIBING • • •			
PAYMENT FOR TEACHERS • • •			
STRATEGIES • Databases • Case based • Better prescribing project module and profiles • Duplicate prescriptions (monitoring prescribing patterns) • Feedback sessions • Pharmacy examples of mistakes • Palm pilot programs/databases • Practice writing prescriptions • Adverse drug reaction (SPH) • Link to resident research projects • DTC			

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Proposal for Multi-Pronged, Sequentially Delivered Educational Intervention

October 19, 1998

Key Words:
- Evidence Based Prescribing/Clinically Relevant/Clear Messages
- Prescribing Behaviors
- Geographic Surveillance
- Combined International Strategies
- Clear Messages
- Ongoing Reminders
- Ongoing Monitoring
- Disease Based
- Collaboration
- Focused Communities (Community Based)
- NNT/ARR
- Appropriate Surrogate Markers
- Terminal Outcome Evaluations
- Combined Educational Interventions
- Ownership
- Communication Skills
- Public
- Media
- Pharmacist
- Physician

Based on:
- Multiple, combined interventions are more effective than single interventions (Mugford '91 BMJ) etc.
- Clear messages – delivered by a credible source – repeated often and in an attractive way are effective ®
- Changes take time ®

® = *Review of literature as outlined in EDM (Essential Drugs Monitor), Nov. 23/97, Summary of International Conference on Improving Use of Medicine*

Objective

To bring about a change in prescribing patterns as a result of delivering evidence based, clinically relevant, pharmacotherapeutic messages using a combination of education interventions.

Suggestions

That this become the major intervention strategy of the EWGTI. The question would be: Can a combination of educational strategies, delivered over a prolonged period of time to a test community, influence prescribing behaviors in such a way that changes resulting reflect messages delivered through these interventions? The combined strategies would include:

1) Those which would deliver messages from a distance (i.e. teleconference, newsletters);
2) Those which deliver messages to a focused community of physicians and pharmacists (travelling Road Show);
3) Those focused on individual physicians and pharmacists (prescribing advisor).

Details

These strategies would deliver clear, disease oriented, evidence based pharmacotherapeutic messages, in a sequential manner over a prolonged period of time. Messages would be standardized and fit into each specific strategy.

The overall process could be as follows:

	Process	Source
1.	Identify disease/prescribing area to be the basis of message	Prescribing surveillance data
2.	Review the evidence	DAWG
3.	Translate evidence into clinically relevant message	Executive Sc & I Committee
4.	Pass message to EWGTI	EWGTI/Executive
5.	Adapt message to multiple interventions	EWGTI
6.	Choose test and control communities	Drug surveillance data based (PharmaNet)
7.	Review community prescribing patterns for test disease drugs	PharmaNet, drug surveillance
8.	Begin dissemination interventions	EWGTI
9.	Newsletter	Executive/EWGTI
10.	Identify community influentials and educate	EWGTI
11.	TI community intervention "Drug Road Show" focused on physician, pharmacist and public	EWGTI
12.	Teleconference reminder *(ongoing monitoring)*	EWGTI/CME
13.	Revisit community using 1:1 interventions prescribing advisors *(ongoing monitoring)*	EWGTI
14.	Incorporate messages into small group problem solving strategy and deliver *(ongoing monitoring)*	EWGTI/CCFP(BC)
15.	Teleconference reminder *(ongoing monitoring)*	EWGTI/CME
16.	Ongoing surrogate markers which reflect terminal outcomes	EVWGTI/EWGTI
17.	Reduce cost to DTC for participants	EWGTI
18.	Terminal evaluation	EVWGTI/PharmaNet
19.	Ongoing community support	EWGTI

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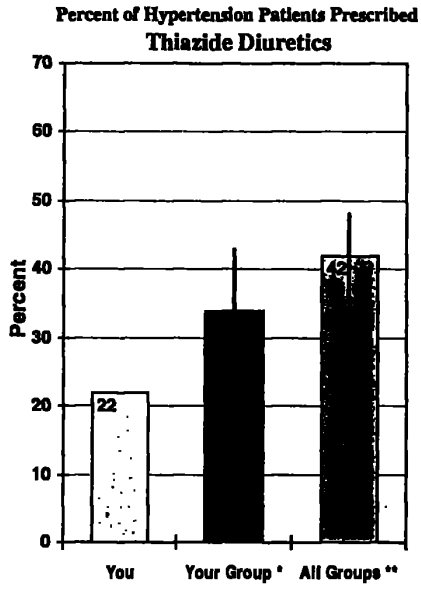
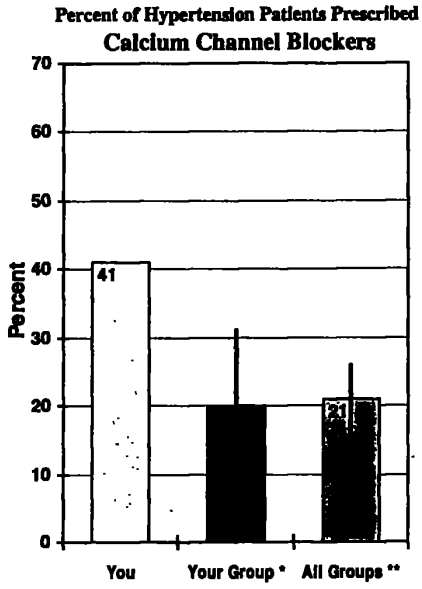
MANAGEMENT OF HIGH BLOOD PRESSURE

How does your prescribing compare?

Group ID: AP
Physician ID: 100





# Patients:	22	212	8047	40	127	4040
Avg. Age:	70	65	66	68	66	68

* Mean of your Problem Based Small Group
** Mean of total physicians in project

EVIDENCE:

Low dose *thiazides* (12.5 - 25mg HCTZ) can be confidently prescribed first-line for hypertension based on substantial evidence that they reduce the risk of stroke, coronary heart disease, and total mortality. The same cannot be said for high dose thiazides or any of the other classes of drugs (therefore most patients, > 70%, should probably be receiving a thiazide).

In contrast, *calcium channel blockers* do not appear to reduce adverse cardiovascular outcomes as well as other classes of drugs based on most available evidence (observational studies, head-to-head RCT's).

Psaty et al. Health outcomes associated with antihypertensive therapies used as first-line agents. A systematic review and meta-analysis. JAMA 1997;277:739-745.
Wright et al. A systematic review of the effectiveness and efficacy of anti-hypertensive therapies: Does the evidence assist in choosing a first-line drug? Can Med Assoc J 1999, in press.

See reverse for explanation of the data

What drugs are included?

Thiazides:
hydrochlorothiazide
chlorthalidone
chlorothiazide
bendrofluazide
indapamide
metolozone
methyclothiazide
polythiazide,
amiloride
spironolactone
triamterene HCL
quinethazone
either alone or in combination

Calcium channel blockers:
verapamil
diltiazem
nifedipine
felodipine
amlodipine
nicardipine

Which patients are included in the percentages?

The graphs represent PharmaNet data (all prescriptions in BC) for the year 1998.
We have defined total hypertension patients as anybody who has received an antihypertensive drug (thiazide, beta-blocker, ACE inhibitor, calcium channel blocker (CCB), alpha-blocker, vasodilator, or sympatholytic). We removed patients who are receiving these drugs for angina or CHF by eliminating patients who had a previous or concurrent prescription for nitrates or furosemide, respectively.

Left graph:
The percentage of total hypertensive patients receiving a thiazide diuretic.

Right graph:
The percentage of total hypertensive patients receiving a CCB.

First bar (You)
Your individual prescribing data.

Second bar (Your group)
The average data for your PBSG.

Third bar (All groups)
The average data for all participants in the Better Prescribing Project trial.

The number in the bar is the exact percentage that the bar represents.

What do the vertical lines represent?

The vertical lines in the 2nd and 3rd bars are standard deviations. This means that the middle 67% percent of participants are included within the extremes of those lines.

What do the numbers below the bar represent?

Below the bars are the number of hypertensive patients used to calculate the percentages and the average age of those patients. This may help you compare your data with other physicians. If you want to calculate an estimate of the total hypertensive patients, you can divide the number of patients by the percentage and multiply by 100.

What are potential limitations of the data?

The data includes antihypertensive drugs prescribed for conditions other than hypertension (eg. beta blockers for migraine prevention). PharmaNet data, like any large database, may have coding errors. We have made every effort to eliminate error and ensure that your personal data is as accurate as possible.

If you have concerns, questions or comments, please call Jeanne Legare at the Better Prescribing Project office (604-875-3609).

附錄八

Therapeutics Initiative Conflict of Interest Guidelines

THERAPEUTICS INITIATIVE
CONFLICT OF INTEREST GUIDELINES

All Therapeutics Initiative (TI) activities must be free from any potential for undue influence arising from the private interests of the individuals involved. The Committee will operate on the basis of "full disclosure" and the following conflict of interest procedures apply to all committee and working group members, expert reviewers and staff.

1. The TI must be meticulous in attempting to avoid any situation where their interests conflict, or appear to conflict, with their impartial functioning in the activities and decisions of the TI.

2. TI members and their immediate families shall have no direct or indirect financial interest in the company sponsoring an application or trial. Any known financial or other significant consideration received from the company must be declared in writing to the Chair. These include:
   a) If they, or their group, are receiving a grant from the manufacturer or its direct competitors.
   b) If they are receiving a salary from the manufacturer or its direct competitors.
   c) If they have an equity interest (other than mutual funds) in the manufacturers' company or its direct competitors.
   d) If they have an ongoing consultancy with the manufacturer.
   e) If they serve on a scientific advisory committee of such a company.
   f) If they receive payment for educational activities sponsored by the company or its direct competitors.

3. TI members should not realize any personal financial gain that has not been approved by the chair, as a direct or indirect result of any TI decision or TI sponsored project, including promotion of books, articles or publications. In all situations where any such apparent conflict exists the individual must inform the Chair of the Committee and abstain from any deliberations relating to the decision or project.

4. Confidentiality of materials or discussions: No member shall knowingly divulge any confidential information relating to specific drugs to any

person other than another member of the Therapeutics Initiative unless legally required to do so.
No member shall use the information obtained as a result of his or her appointment for personal benefit.

5. Patentees are advised not to make direct contact with members of the Therapeutics Initiative pertaining to T.I. matters. T.I. members contacted by a patentee respecting a drug product related to the T.I. must at first opportunity disclose the nature of the contact to the chair of the T.I.

6. In any situation where a real or an apparent conflict exists for a TI member, the following actions must be taken:
   a) The conflict will be recorded in writing in the appropriate minutes.
   b) The individual will absent himself/herself from the meeting during the deliberations on the project and will not be eligible to vote on the project decision.

CONFLICT OF INTEREST STATEMENT

Similar to disclosures required when submitting articles for publication, reviewers of assessments by the Drug Assessment Working Group of The Therapeutics Initiative need to disclose all circumstances which could possibly be perceived to be a conflict of interest. Please note that "yes" responses do not necessarily disqualify you as a reviewer.

Please indicate whether you have any of the following affiliations with companies who manufacture products mentioned in the assessment or with companies who manufacture competing products:

		No	Yes
1.	Ownership of **stock or stock options** or other financial instruments of this product's manufacturer or manufacturers of competitive products (does not include mutual fund ownership).	[ ]	[ ]
2.	Ongoing paid **consultancy** with manufacturer or a competitor (current or within the last 2 years).	[ ]	[ ]
3.	**Employment** with manufacturer or a competitor (current or within the last 2 years):	[ ]	[ ]
4.	Honorarium or other compensation from manufacturer or a competitor for **writing** a publication or for participating in the development of a publication	[ ]	[ ]
5.	Grant, honorarium or other compensation from manufacturer or a competitor, for conducting **research**.	[ ]	[ ]
6.	**Speaker fees and/or educational grants** from manufacturer or a competitor (current or with the last 2 years).	[ ]	[ ]
7.	**Travel assistance** from manufacturer or a competitor to attend meetings (current or within the last 2 years).	[ ]	[ ]
8.	Any **other** financial relationship with the manufacturer or a competitor which could possibly be perceived to be a conflict of interest. • if yes, please describe:	[ ]	[ ]

Date _____ Name (please print) _____ Signature _____

附錄九

英屬哥倫比亞省藥物經濟評估
--Pharmacoeconomic Initiative 所用的工具

Pharmacoeconomic Initiative (PI) of BC

The University of British Columbia, Vancouver B.C.

PI Drug Submission Form*

Version 2, March 2000

The completed form should be submitted to the BC Pharmacare Program as part of the new drug application dossier.

© Pharmacoeconomic Initiative (PI)
620-1081 Burrard St.
Vancouver, BC V6Z Y6
Tel: 604 – 806 - 8712
Fax: 604 - 806 - 8778
Email: pi@hivnet.ubc.ca

* This form was prepared after consulting various economic guidelines such as the "Guidelines for Economic Evaluation of Pharmaceuticals Canada" (CCOHTA 2nd Ed., 1997) and the "Ontario draft guidelines for economic analysis of pharmaceutical products" (Detsky, 1994; Ontario Ministry of Health, 1994).

Pharmacoeconomic Evaluation Summary
(Confidential when complete)

SECTION 1 : MANUFACTURER INFORMATION

- List name and address of manufacturer. Include name/address of contact individual.
- Note, it is not necessary to submit this form for "line extension" products

Manufacturer :	**Date of Submission** DD | MM | YY
Address:	
City: **Province:** **Postal Code:**	
Contact:	

SECTION 2: DRUG INFORMATION

- All fields must be completed.
- For current clinical practice, please cite any relevant published guidelines **(cross-reference with Section 8)**.

Brand Name : **Generic Name :**	
Formulation :	
Therapeutic classification :	
Alternate Drugs in this category :	
Indication(s) for reimbursement eligibility:	**Usual Dose Regimen/Duration per indication:**
Description of current clinical practice (Guidelines) relating to indication(s):	

SECTION 2 : (CONTINUED)

- All fields must be completed. *Please attach separate sheet* if necessary.
- All available pack sizes in Canada along with prices must be provided.
- For acute medications, include daily cost and cost per course of treatment (based on usual dose regimen/duration, as stated above).
- For chronic medications, include daily cost and cost for 30 days of treatment therapy.
- Costs must be based on manufacturer list price, excluding all dispensing fees.

DIN	Strength	Dosage Form	N.O.C Received
1)			Yes ☐ No ☐ Date:
2)			Yes ☐ No ☐ Date:
3)			Yes ☐ No ☐ Date:

Available Package Size	Price Per Package	Unit Price	Cost per patient for drug acquisition
1)			• Daily cost: • Cost per course of treatment:
2)			• Daily cost: • Cost per course of treatment:
3)			• Daily cost: • Cost per course of treatment:

SECTION 3: COMPARATOR DRUG/TREATMENT INFORMATION

- Please indicate all appropriate drug comparators and/or treatment comparators for this product. Include generic name/strength/dosage form, and therapeutic classification. *Please attach separate sheet* if necessary.
- Indicate selection criteria.
- Where the appropriate comparison is not a drug but another treatment, *please attach a separate sheet* outlining the treatment and indicating why it is the appropriate comparator.

Comparator Generic name/Strength/dosage)	Cost per patient for drug acquisition	Selection Criteria
1) Generic name: Form/Strength: Equivalent Dosage Regimen: Therapeutic Classification: Unit Price:	Daily cost: Cost per course of treatment:	Lowest cost alternative ☐ Common practice ☐ Same Indication ☐
2) Generic name: Form/Strength: Equivalent Dosage Regimen: Therapeutic Classification: Unit Price:	Daily cost: Cost per course of treatment:	Lowest cost alternative ☐ Common practice ☐ Same Indication ☐
3) Generic name: Form/Strength: Equivalent Dosage Regimen: Therapeutic Classification: Unit Price:	Daily cost: Cost per course of treatment:	Lowest cost alternative ☐ Common practice ☐ Same Indication ☐

SECTION 4: THERAPEUTIC / CLINICAL ASSESSMENT

- For each comparator listed in **Section 3**, list any or all-relevant clinical studies **comparing it to your product (cross-reference with Section 9)**. Indicate type of study. *Please attach a separate sheet if necessary*.
- Provide brief summary of clinical studies. *Please attach a separate sheet if necessary*.
- Where a meta-analysis has been conducted to establish clinical efficacy, *please attach a separate sheet* outlining the method and results.
- All unpublished/company-sponsored studies **must be listed and submitted for assessment.**

Comparator #	Clinical Study (Reference No.)	Study Abstract/Summary
1)		
2)		
3)		

SECTION 5: PHARMACOECONOMIC EVALUATION - SUMMARY

- Please provide all pertinent Pharmacoeconomic information. All relevant fields must be completed.

Study Title:			
Study Author(s) {See Section 8}:			
Target Audience:	☐ Provincial Formulary ☐ Patient Purchaser ☐ Prescriber ☐ Government Regulators ☐ Post-marketing surveillance ☐ Others (ie. hospitals, insurers) Specify:	**Study Perspective:**	☐ Societal ☐ Provincial ☐ In-Patient ☐ Out-Patient ☐ Other, Specify:
Type of Analysis	☐ Cost Comparison ☐ Cost-effectiveness ☐ Cost-Benefit ☐ Cost Consequence ☐ Cost-utility ☐ Provincial Budget-Impact ☐ Other, Specify		
Analytic Horizon:		**Discounting :**	
Outcome Measurement: (if relevant)	☐ **Clinical Outcome** of Primary ☐ Secondary ☐ Specify: ☐ Other (Specify):	☐ **Health-related quality of life instrument** (HRQoL) Specify:	☐ **Quality-adjusted Life Years (QALYs)**
Cost Measurements:	☐ **Direct Costs** Health Care Costs ☐ Specify: Non-Health Care ☐ Specify: Side Effects ☐ Specify:	☐ **Indirect Costs** Productivity Loss /Lost Time (Patient) ☐	
Is the evaluation an incremental analysis? :	Yes ☐ No ☐	**Incremental to what?**	

SECTION 6: PHARMACOECONOMIC EVALUATION - SUMMARY OF ANALYSIS & RESULTS

- The background, objective(s), hypothesis, and approach should be summarized.
- The study results should be summarized as outlined.
- Cross-reference all tables/charts/appendices from the study.

A:OBJECTIVE/HYPOTHESIS

B: METHODOLOGY USED
(Note, include all applicable data tables and data collection instruments)

C: RESULTS

D: BOTTOM- LINE

- Summarize sensitivity analysis
- Outline any and all study limitations
- Cross-reference all tables/charts/appendices from the study.

E:SENSITIVITY ANALYSIS

F: LIMITATIONS OF ANALYSIS

SECTION 7: Disclosure of Relationship

- Please list all study authors, including Institutions and Positions/Appointments held. *Please Attach separate sheet* if necessary.
- For each author, please disclose all funding and reporting relationships, including contractual arrangements, investigators' autonomy and publication rights.

Names / Institution/ Addresses /Telephone No.	Position/Appointment/ Area of Expertise	Statement of Relationship
1)		
2)		
3)		

SECTION 8: References (A+B)

- Indicate/List all pertinent references for each of the categories described in the guidelines. *Pleaseattach separate sheet* if necessary

A:CLINICAL TRIALS AND STUDIES:

B: PHARMACOECONOMICS STUDIES:

APPENDIX FIVE

FEEDBACK FORM

Pharmacoeconomic Initiative
Department of Health Care and Epidemiology,
Faculty of Medicine
University of British Columbia

PI Feedback Form

GENERIC (BRAND) NAME:

MANUFACTURER:

INDICATION:

REVIEW DATE:

CRITICAL ASSESSMENT:	Not Applicable	Yes Appropriate	No Inappropriate	Pharmacoeconomic Initiative Scientific Committee (PISC) Comments
Comparator				
Choice of drug /treatment comparators				
Selection criteria				
Dose equivalence clearly established				
Therapeutic equivalence and/or advantage established				
Resource Utilization				
Direct				
Indirect				
Cost Estimates				
Direct				
Indirect				
Economic Evaluation				
Target audience				
Study perspective				
Analytic horizon				
Discounting				
Outcome measurement				
Effectiveness analysis				
Incremental analysis				

Pharmacoeconomic Initiative
Department of Health Care and Epidemiology,
Faculty of Medicine
University of British Columbia

PI Feedback Form (continued)

Generic (Brand) name:

Manufacturer:

Indication:

Review Date:

Critical Assessment:	Not Applicable	Yes Appropriate	No Inappropriate	Pharmacoeconomic Initiative Scientific Committee (PISC) Comments
Transparency of Study				
Objective				
Hypothesis				
Methods				
Results				
Replicable				
Sensitivity analysis				
Sub-group analysis				
Limitations				
Cost Estimates				
Direct				
Indirect				
Economic Evaluation				
Target audience				
Study perspective				
Analytic horizon				
Discounting				
Outcome measurement				
Effectiveness analysis				
Incremental analysis				

Pharmacoeconomic Initiative
Department of Health Care and Epidemiology,
Faculty of Medicine
University of British Columbia

PI Feedback Form (continued)

Generic (Brand) name:

Manufacturer:

Indication:

Review Date:

Further Comments:

Confidential When Complete

附錄十

加拿大英屬哥倫比亞省(BC)
Medical Services Plan
訂定 Guidelines & protocols 的發展

GUIDELINES & PROTOCOLS
UPDATE
May 2001

Protocols, Guidelines and the Art of Medicine: Science, Experience and Common Sense

by Dr. Marshall Dahl, BCMA

There are a number of reasons to take an optimistic view of the future of our health care system. Despite concerns about the lack of uniform and timely patient access to high quality care and about the impending shortages in nursing and physician workforces, there are areas where improvements will continue to occur.

One such area is the "made in BC" approach to designing clinical protocols and guidelines to assist physicians in providing high quality, cost-effective care.

During medical training, we received a considerable amount of academic information that has accumulated from the western scientific method of hypothesis, experiment and conclusion. During the last ten years, this approach has been applied on an epidemiologic basis to populations and has resulted in the evidence-based medicine movement that has clarified many of our diagnostic and therapeutic decision processes. As scientific practitioners, we are comfortable with the restless and questing nature of self-examination of medical practice.

We also recognize that there is an Art of Medicine that complements the scientific approach in our interactions with the individuals who are our patients. This Art has ancient roots in the humanistic, Hippocratic tradition.

Art intersects with Science at the level of individual variations in personality and disease behaviour. This is a level of detail that cannot be captured by broad-based epidemiologic evidence. Our individual patients continue to present us with unique biologic experiments that lead to inspiration and medical advancements.

Finally, medicine is eminently practical. Doctors have a pragmatic approach to problem-solving and recognize that it is not always possible to achieve ideal goals in the real world.

British Columbia's Protocol and Guideline process represents a blend of these traditions. Evidence-based medical results are reviewed by practicing clinicians with the goal of producing practical advice for real-world situations.

The recent Second Master Agreement between Government, the BCMA, and the Medical Services Commission reaffirms the importance of these initiatives. The profession has signaled that we wish to continue to improve the quality and cost-effective nature of the practice of medicine in BC through coordinated action by doctors and the public service.

The Guidelines and Protocols Advisory Committee has been a welcome focus of meaningful co-operation between government and the medical profession since 1995. Most doctors have welcomed the balanced, education-oriented approach of the materials sent to the profession. Physicians have also been reassured by the knowledge that their individual judgment will still take precedence over general guidelines according to the merits of the clinical situation.

The credit for this successful, balanced, and quality-of-care oriented endeavor belongs to the profession, to the physician and government members who serve on GPAC and its committees and, in particular, to Co-Chair Dr. Arun Garg. We are all indebted to him for his clear vision, high ethical standards and dedication to ensuring that the Art and Science of Medicine continue to steer the development of Clinical Guidelines and Protocols in BC.

We look forward to continued leadership from Dr. Garg and the committees as they seek further innovations that will improve cost-effective patient care in the future.

Guidelines and Protocols Development Community

May 2001

Medical Services Commission

- Provides general direction
- Adopts guidelines

Guidelines & Protocols Advisory Committee (GPAC)

Co-chairs: Dr. Arun Garg, Cathy Stigant

- Selects guideline topic
- Determines scope of topics
- Approves subcommittees & working groups
- Approves draft guidelines for external review
- Approves final guidelines
- Develops implementation strategies
- Guides evaluation
- Participates in other activities designed to improve the effective utilization of medical services

BC Medical Association (BCMA)

- Administers funds
- Hosts meetings
- Co-chairs GPAC
- Suggests topics to GPAC
- Approves guidelines

Medical Services Plan

- Allocates funding to BCMA for GPAC
- Co-chairs GPAC
- Organizes meetings
- Supports subcommittees & working groups
- Provides background research & analysis
- Analyzes utilization data
- Administers external review
- Publish[illegible] & distributes Guidelines & Prd.

Subcommittees & Working Groups

71 physicians, 2 MSP staff, 3 health experts:

- Suggest topics to GPAC
- Review literature
- Consult experts
- Draft guidelines
- Revise guidelines following external review
- Raise implementation issues: fee items, coverage, requisition

External Reviewers

- Review draft guidelines for appropriateness, clarity and ease of use

50 – 200 respondents for each guideline including:

- Random selection of GPs
- High orderers
- Academic physicians
- Laboratory managers
- Public advocacy groups
- Professional organizations
- Medical Health Officers

Laboratory Nuclear Medicine
Chair: Dr. Max Zahir

Working Groups:
- Antinuclear Antibody
- Oral Anticoagulation
- Anticonvulsant Therapeutic Drug Monitoring
- Cardiovascular Risk Assessment
- Lipid Testing Review
- Hematology Profile
- Hemochromatosis
- Iron Deficiency
- Viral Hepatitis Testing
- Thyroid Testing Review
- Microalbumin
- Ova and Parasite Review

Clinical Medicine
Chair: Dr. Maureen Leis-Stephen

Working Groups:
- Asthma
- 24-Hour Ambulatory ECG Review

Gastrointestinal
Chair: Dr. J.R. Gray

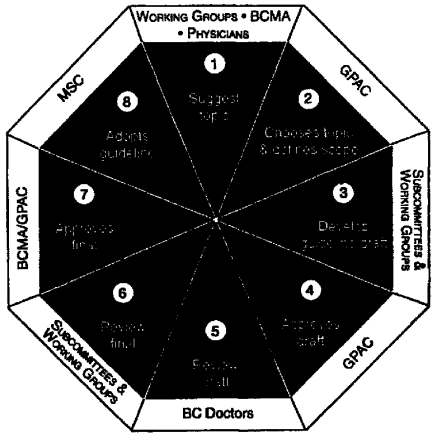
Working Groups:
- Gallstone Guideline

Diagnostic Imaging
Chair: Dr. Charles Coffey

Evaluation
Chair: Dr. Philip White

Working Groups:
- Clinical Management of Hepatitis
- Acute Chest Pain in the Ambulatory Setting

Guidelines and Protocols Development Process



Dr. Howard Platt
Ministry of Health

Guidelines and protocols strive to bring the elegant simplicity of a mathematical proof to the intensely human and complex world of medicine. All of medicine is constructed on the concept of similarity. What is learned from hard experience with one patient may help another. Knowledge derived from scientific study can be distilled for the benefit of future patients.

Earlier dreams that guidelines and protocols would reduce overall expenditures were soon dashed. While costs fell where care had been excessive, costs grew where care had been inadequate. The success of guidelines and protocols comes from improved appropriateness and quality of care. It would not have been so without the help of thousands of doctors in British Columbia who have contributed to their development and implementation. They have justifiable reason to be proud and celebrate.

The way ahead is to take what we have learned from guidelines and protocols for isolated situations, and construct similar guidance for the management over time of those with chronic disease. Evidence shows there is much to gain and that improved outcomes will more than justify the effort. But success will require a system that assists doctors in their work rather than impedes them, as is often the case at present.

In another context, doctors have shown what can be done by setting benchmarks for care and providing the tools to achieve them. The current remarkably low perinatal mortality was not achieved by accident but by hard work. Similar improvements in the outcomes for common chronic disorders should be possible. The promise is worth all the effort and cooperative goodwill that we can muster.

Next Steps for Guidelines and Protocols

This anniversary issue celebrates seven years since the BCMA and the Ministry of Health introduced a joint guideline and protocol initiative in BC. We look with pride at the 32 guidelines and protocols that speak to the success of their joint endeavours. Building on these achievements, GPAC will begin work with the BCMA/MSP Joint Utilization Committee (JUC) in the area of disease management. JUC provides direction on behalf of the Medical Services Commission in a number of utilization management areas, and has identified chronic illness as a key priority for action. The shared goal of GPAC and JUC is to improve quality of care for patients with long term debilitating illnesses focussing on improved outcomes and efficient use of resources.

Why Disease Management?

While guidelines and protocols have proven successful, they have limited application in occasional care provided for brief episodes of illness or injury. Although the majority of the population only require episodic care, a small proportion (about 10%) receives more than half of all physician services provided in a year. Evidence suggests that health outcomes for this group, the majority who suffer chronic disorders, could be improved through a greater focus on planned management of patients' diseases over time. For example, a case management program at St. Paul's Hospital in Vancouver showed improved patient care for chronic heavy users of its emergency department along with a reduction from an average of 26.5 to 6.5 visits per year (CMAJ 2000;162:1017-1020). On the other hand, the consequences of poorly managed care for patients with chronic illnesses can be fatal, as reported in another study undertaken by St Paul's Hospital. This study showed that persistent inappropriate use of asthma medications lead to higher risks for fatal or near-fatal asthma attacks and resulted in significantly more use of health care resources than patients with appropriate medication use (CMAJ 2001;164:625-631). Evidence such as the above provides compelling motivation to manage care better.

General Practitioner Offices:
The indexes inserted into your newsletter are intended to help you keep your copies of guidelines & protocols organized. Included are an alphabetical list and a list by date of publication or product number. You may wish to organize the guidelines and protocols by product number using the indexes for easy reference. We have supplied a spine label should you choose to file them in a binder.

E-mail your comments to:
guidelines.protocols@moh.hnet.bc.ca

Website:
www.hlth.gov.bc.ca/msp/protoguides

GUIDELINES & PROTOCOLS
ADVISORY COMMITTEE

Guidelines and Protocols Binder Index
By Topic

May 2000

TOPIC	NO.	GUIDELINE OR PROTOCOL
Anemia	10	Use of Serum Ferritin and Total Iron and Iron Binding Capacity
Ankle injury	28	X-ray for Acute Ankle Injury, Revised 2000
Bone density	23	Bone Density Measurement
Bone scans in prostate cancer	11	Investigation of Metastatic Bone Disease in Newly Diagnosed Prostate Cancer Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000
Bone scans in suspected osteomyelitis	8	Investigation of Suspected Osteomyelitis in Normal Bone Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000
Cataracts	5	Treatment of Cataract in Adults
Chest x-ray	4	Chest X-rays in Asymptomatic Adults
	6	Routine Pre-Operative Testing
Cholecystectomy	2	Treatment of Gallstones in Adults
Cholesterol	1	Cholesterol Testing: Adults Under 69 Years
Colonoscopy after colorectal cancer	20	Follow-up of Patients After Curative Resection of Colorectal Cancer
Coronary artery disease and cholesterol	1	Cholesterol Testing: Adults Under 69 Years
Cytogenetic testing, prenatal	31	Prenatal Cytogenetic Testing, Revised 2000
Diabetes, glucose and HbA_{1C}	22	Use of Glucose and HbA_{1C} Tests in Diagnosis and Monitoring of Diabetes Mellitus

Guidelines and Protocols Advisory Committee
1515 Blanshard Street 1-2
Victoria BC V8W 3C8
Telephone (250) 952-1347 Fax (250) 952-1417
Email guidelines.protocols@moh.hnet.bc.ca

TOPIC	NO.	GUIDELINE OR PROTOCOL
Dyspepsia	24	Clinical Approach to Adult Patients with Dyspepsia
	27	Detection and Treatment of Helicobacter pylori Infection in Adults
ECG	12	24-Hour Ambulatory ECG (Holter Monitor)
	30	Electrocardiograms, Revised 2000
	6	Routine Pre-Operative Testing
Endoscopy	24	Clinical Approach to Adult Patients with Dyspepsia
	21	Clinical Approach to Adult Patients with Gastroesophageal Reflux Disease
ESR	15	Erythrocyte Sedimentation Rate
Gallstones	2	Treatment of Gallstones in Adults
Gastroesophageal reflux disease	21	Clinical Approach to Adult Patients with Gastroesophageal Reflux Disease
Glucose measurement in diabetes	22	Use of Glucose and HbA_{1C} Tests in Diagnosis and Monitoring of Diabetes Mellitus
Helicobacter pylori	27	Detection and Treatment of Helicobacter pylori Infection in Adults
	24	Clinical Approach to Adult Patients with Dyspepsia
Hepatitis, viral testing	17	Viral Hepatitis Testing
Holter monitoring	12	24-Hour Ambulatory ECG (Holter Monitor)
House calls	18	House Calls, Reviewed and unchanged April 2000
Iron	10	Use of Serum Ferritin and Total Iron and Iron Binding Capacity
Lipid Testing	1	Cholesterol Testing: Adults Under 69 Years
Mammography	16	Use of Diagnostic Facilities for Mammography
Osteomyelitis and bone scans	8	Investigation of Suspected Osteomyelitis in Normal Bone Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000
Osteoporosis	23	Bone Density Measurement

TOPIC	NO.	GUIDELINE OR PROTOCOL
Ova and parasites in stool	9	Ova and Parasite Testing of Stool Samples
Prenatal testing	31	Prenatal Cytogenetic Testing, Revised 2000
	3	Prenatal Ultrasound
Pre-operative testing	30	Electrocardiograms, Revised 2000
	6	Routine Pre-Operative Testing
Prostate cancer and bone scans	11	Investigation of Metastatic Bone Disease in Newly Diagnosed Prostate Cancer Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000
Serum ferritin	10	Use of Serum Ferritin and Total Iron and Iron Binding Capacity
Sleep disorders	29	Assessment and Management of Obstructive Sleep Apnea in Adults, Revised 2000
	26	Primary Care Management of Sleep Complaints in Adults
Stool testing for ova and parasites	9	Ova and Parasite Testing of Stool Samples
Thyroid testing	14	Use of Thyroid Function Tests in the Diagnosis and Monitoring of Patients with Thyroid Disease
Ultrasound, prenatal	3	Prenatal Ultrasound
Urinalysis	19	Macroscopic and Microscopic Urinalysis and Investigation of Urinary Tract Infection
Urinary tract infection	19	Macroscopic and Microscopic Urinalysis and Investigation of Urinary Tract Infection
Viral hepatitis testing	17	Viral Hepatitis Testing
X-ray of ankle, following injury	28	X-ray for Acute Ankle Injury, Revised 1998

GUIDELINES & PROTOCOLS

ADVISORY COMMITTEE

Guidelines and Protocols Binder Index

By Date of Publication

May 2000

NO.	GUIDELINE OR PROTOCOL	
1	Cholesterol Testing: Adults Under 69 Years	June 1996
2	Treatment of Gallstones in Adults	July 1996
3	Prenatal Ultrasound	July 1996
4	Chest X-rays in Asymptomatic Adults	October 1996
5	Treatment of Cataract in Adults	October 1996
6	Routine Pre-Operative Testing	December 1996
7	~~Electrocardiograms~~, Superseded (see No. 30)	April 1997
8	Investigation of Suspected Osteomyelitis in Normal Bone Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000	April 1997
9	Ova and Parasite Testing of Stool Samples	June 1997
10	Use of Serum Ferritin and Total Iron and Iron Binding Capacity	June 1997
11	Investigation of Metastatic Bone Disease in Newly Diagnosed Prostate Cancer Using Nuclear Medicine Techniques, Reviewed and unchanged April 2000	July 1997
12	24-hour Ambulatory ECG (Holter Monitor)	August 1997
13	~~Prenatal Cytogenetic Testing~~, Superseded (see No. 31)	August 1997
14	Use of Thyroid Function Tests in the Diagnosis and Monitoring of Patients with Thyroid Disease	August 1997
15	Erythrocyte Sedimentation Rate	October 1997

Guidelines and Protocols Advisory Committee
1515 Blanshard Street 1-2
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Email guidelines.protocols@moh.hnet.bc.ca

NO.	GUIDELINE OR PROTOCOL	
16	Use of Diagnostic Facilities for Mammography	January 1998
17	Viral Hepatitis Testing	February 1998
18	House Calls, Reviewed and unchanged April 2000	March 1998
19	Macroscopic and Microscopic Urinalysis and Investigation of Urinary Tract Infection	March 1998
20	Follow-up of Patients After Curative Resection of Colorectal Cancer	December 1998
21	Clinical Approach to Adult Patients with Gastroesophageal Reflux Disease	March 1999
22	Use of Glucose and HbA_{1C} Tests in Diagnosis and Monitoring of Diabetes Mellitus	March 1999
23	Bone Density Measurement	May 1999
24	Clinical Approach to Adult Patients with Dyspepsia	July 1999
25	~~Assessment and Management of Obstructive Sleep Apnea in Adults~~, Superseded (see No. 29)	November 1999
26	Primary Care Management of Sleep Complaints in Adults	November 1999
27	Detection and Treatment of Helicobacter pylori Infection in Adults	January 2000
28	X-ray for Acute Ankle Injury, Revised 1998	January 2000
29	Assessment and Management of Obstructive Sleep Apnea in Adults, Revised 2000	March 2000
30	Electrocardiograms, Revised 2000	April 2000
31	Prenatal Cytogenetic Testing, Revised 2000	April 2000

附錄十一

加拿大英屬哥倫比亞省(BC)
Capital Health Region 科技評估的工具

INTRODUCTION

This workbook has been designed to provide staff in the Capital Health Region with an administrative framework for deciding whether or not to acquire new health care technology or assess technology currently in use.

The overall technology assessment process in the Capital Health Region is described on Page 1.

Checklists on pages X to XX

Non-Medical Assessment Checklist.....

Medical Assessment Checklist.....

Operational Assessment Checklist .....

Community Assessment Checklist.....

Vendor/Equipment Assessment Checklist.....

Financial Assessment Checklist.....

TAC Process .....

TAC Request.....

The Terms of Reference of the Technology Assessment Committee are included in the Appendix.

TECHNOLOGY ASSESSMENT COMMITTEE (TAC) PROCESS

I. **Sponsor completes Medical/non-Medical Technology Assessment checklist**

Submits it to TAC Chairman.
The Chairman of TAC may request the sponsor to summarize his/her submission in a presentation at a TAC meeting.
Proposal may be sent back to sponsor for clarification.

II. **Development by Technology Assessment Working Group.**

a) Selection of Project Leader: Project Leader will most often be the clinical sponsor of the technology with the support of a CQI Associate.

b) Selection of Project Team: Project Leader will select team members with help of TAC chair and CQI Associate.

c) Completion of Assessments (Project Team)
   i) Medical
   ii) Community
   iii) Operational
   iv) Vendor/Equipment
   v) Financial
   vi) Post Implementation Evaluation Framework

d) Project Leader presents completed proposal to TAC Chair for final review for completeness

III. **Final Presentation to TAC.**

Project leader/sponsor presents final proposal to TAC
(Members of project team may attend TAC.)

IV. **TAC approves the proposal (based on criteria) or recommends approval of proposal to SMG.**

V. **When required, Chairman of TAC presents proposal with summary of assessment and recommendations with appropriate criteria to the Strategic Management Group (SMG) for final approval.**

VI. **Technology Assessment Committee acquisition request forwarded to Manager, Capital and Business, as appropriate.**

VII. **Implementation of technology.**

VIII. **Follow-up evaluation of technology by Clinical/Hospital Department/Community.**

IX. **Presentation of follow-up evaluation of technology to TAC.**

X. **Presentation of evaluation of technology to SMG by TAC Chairman, as appropriate.**

NON-MEDICAL ASSESSMENT CHECKLIST
(TO BE COMPLETED BY SPONSOR OF THE TECHNOLOGY)

Traditionally, the first step is to search the scientific literature for studies which examine the technology in question. It is important to consider all possible alternatives, especially since future development may render the technology obsolete.

In addition to surveying the scientific literature, information may be obtained by soliciting reports from vendors or other user facilities.

#	ITEM	DATE COMPLETED
1	Do you have approval of your Functional Officer/Department Head?	
2	Describe the Technology - brief narrative, including function	
3	Is this technology being requested as a result of accreditation, C.S.A., or other regulatory change such as WCB?	
4	Are there other alternatives to this technology?	
5	(a) can this technology be accommodated in an alternative setting? i.e. common location, shared services (b) is this technology currently available elsewhere? (c) why would CHR bring this technology to Victoria? (d) describe the suitability of this technology to CHR.	
6	Under normal conditions: (a) describe the benefits of this technology (b) describe any risks associated with this technology Staff/Patient/Safety	
7	Within CHR, where will this technology be ideally located?	
8	Does this technology require specialized training? Operator/Service	
9	Is there potential to use this technology in other settings in the CHR?	
10	What is the potential impact of implementation of this technology on other programs/departments/services?	
11	Complete an appropriate literature search. * (See #6 page 3)	

* If you require assistance in performing a literature search or review, contact the Manager, Library Services or the Manager, Research and Accreditation.

MEDICAL ASSESSMENT CHECKLIST
(TO BE COMPLETED BY SPONSOR OF THE TECHNOLOGY)

Traditionally, the first step is to search the scientific literature for studies which examine the technology in question. In determining if the technology "makes sense" from medical and epidemiological points of view, comparative studies of alternatives for treating the same clinical condition will be particularly valuable. As mentioned earlier, it is important to consider all possible alternatives (both medical devices and procedures), especially since future medical developments may render a technology obsolete. If randomized clinical trials are available, please include them in the literature review.

In addition to surveying the scientific literature, facilities may obtain information by soliciting reports from vendors, or querying knowledgeable medical staff. Other sources of technical information are HANYS' Compendium of Clinical Protocols, Criteria and Efficacy Research.

#	ITEM	DATE COMPLETED
1	Do you have approval from your Section/Department?	
2	Describe the technology - brief narrative, including function	
3	Identify the procedure or treatment that will be replaced by the new technology OR if it is an entirely new procedure/treatment for CHR	
4	Are there other alternative approaches or procedures to this technology	
5	a) Can this technology be accommodated in an alternate setting e.g. community clinic or doctor's office. b) Is this technology currently available in another centre? c) Why would CHR bring this technology to Victoria? d) Describe the patient population suitable for this technology (include number, classification, inpatient vs. outpatient).	
6	Complete an appropriate literature search * • Brief history of technology • Is there evidence that technology has been proven in the clinical setting (no white rats!!) • Has a critical appraisal of the technology from the literature been done? • Clearly state objectives of introduction of technology	
7	Describe the benefits and risks of the technology.	
8	Within CHR where will this technology be ideally located? (eg. OR, Medical Imaging etc).	
9	Does this technology require specialized credentialling?	
10	What other Sections/Departments could utilize this technology?	
11	What is the potential impact on other areas? List all areas/services that may be impacted by the implementation of the technology.	
12	For diagnostic technology: Describe how this technology will improve reliability and accuracy of the diagnostic process (eg. faster, more reliable).	

* If you require assistance in performing a literature search or review, contact the Manager, Library Services or the Manager, Research and Accreditation.

OPERATIONAL ASSESSMENT CHECKLIST
(TO BE COMPLETED BY PROJECT TEAM)

The purpose of this Assessment is to examine internal operational factors related to the implementation of the new technology. This will help to determine the organization's requirements related to the new technology and should also clarify any limitations. The assessment is also designed to determine the potential impact of the technology on quality of care.

The initial Assessment of a new technology must include the following information. Subsequent assessments need only be updated.

#	ITEM	DATE COMPLETED
1	Explain how the technology is consistent with the CHR Strategic Plan (Mission, Philosophy, Role Statement, Goals & Objectives)?	
2	Explain how the technology is consistent with the Strategic Plans of the Programs/Departments directly involved in implementing the technology?	
3	Is the technology complimentary to other programs and servicesin the CHR? Please describe.	
4	How does the technology enhance the quality of care in the CHR?	
5	Do we have the diagnostic/screening tools to properly identify the patients that will benefit from the technology?	
6	Are hospital staff currently trained/certified to operate this technology? If not, what education/training is required?	
7	Describe the impact this technology will have on other programs, departments and/or services (eg. laboratory, OR, Booking, etc.). Obtain signatures of all Regional Director's of affected departments. (see sign-off sheet).	
8	Will the provision of this technology generate additional demands on existing technologies (eg. - pacemaker after ablation)? Specify the technologies affected and what the impact will be.	
9	Does implementation of this technology require additional space and/or renovation work? Please provide provisional plans/estimates, as required.	

Project Leader Signature _____

Date of completion _____

EXTERNAL FACTORS CHECKLIST
(TO BE COMPLETED BY PROJECT TEAM)

The purpose of this assessment is to determine the characteristics of the environment external to the CHR that affect the provision of quality health care as it relates to the new technology. The external environment is scanned for health care needs, resources, opportunities for the organization and possible obstacles to the implementation and operation of the new technology.

#	ITEM	DATE COMPLETED
1	Identify the potential patient catchment area.	
2	Develop a profile of the population that will benefit by the technology.	
3	Identify major governmental and regulatory issues which have implications for the organization.	
4	Identify and evaluate issues of competition and duplication of services.	
5	Are there resources available in the community to support the technology and is the community aware of the potential impact? (explain fully). Obtain signatures as required (see sign-off sheet)	

Project Leader Signature _____

Date of completion _____

FINANCIAL ASSESSMENT CHECKLIST
(TO BE COMPLETED BY PROJECT TEAM)

The initial acquisition cost of a new technology - ie. whether the equipment is expensive or inexpensive - may not be indicative of the potential ongoing operating costs. A technology may have a low initial acquisition cost, but its frequency of use could result in considerable operating costs. This situation often occurs in high use diagnostic technologies and in treatment technologies for chronic conditions. Certain diagnostic procedures, however, may be billable to MSP, and the resulting revenue may partially or completely offset the additional operating costs. In order to assess the financial feasibility of the new technology, a cost/benefit analysis, which includes a comparison of the operating costs of the new versus the current technology is required. It is important that this analysis reflects the cost for all departments impacted by the implementation of the new technology.

#	ITEM	DATE COMPLETED	SIGNATURE
1.	Cost Benefits Analysis: compare the new versus the current technology - Identify workload volumes - determine staffing levels (Regular + Relief) - Calculate staffing costs supply costs offsetting revenue		
2.	Summarize the incidental "costs/savings"		
3.	Identify Startup-operating costs (staffing and supplies,education)		
4.	Identify Capital Costs (equipment and construction/renovation)		

VENDOR/EQUIPMENT ASSESSMENT CHECKLIST
(TO BE COMPLETED BY PROJECT TEAM)

The purpose of the Vendor/Equipment Assessment is to examine and compare the advantages/benefits of each vendor and/or item under consideration. This assessment should determine the full operating requirements of the technology - the reliability and business strength of the vendor and the scope of possible contractual agreements with the vendor. The unit under consideration should be evaluated against comparable models available from other vendors, including the available options. Some of this assessment is not required until after the technology has been approved.

A special warning is in order for equipment that has recently been introduced. In many cases, no reliable information will be available, the price is likely to drop considerably the year following its introduction, and it may be rendered obsolete by a more refined version.

	DATE	SIGNATURE
Proposed Equipment: User Department: (1) Will this equipment/instrumentation replace existing equipment/technology:		
Equipment Description:		
Approximate Price:		
Options/Accessories: $		
Consumables (estimated annual cost)		
Manufacturer/Distributor:		
Additional Information: Approximate installation price $		
Estimated Construction/Renovation Costs: (including drawing, if appropriate)		

VENDOR/EQUIPMENT ASSESSMENT

PROPOSED EQUIPMENT ASSESSMENT

VENDOR INFORMATION	Vendor #1	Vendor #2	Vendor #3
Manufacturer (oem)			
Distributor			
Brand/Model			
Market release date (HAW/CSA/FDA Approval)			
Head Office			
Service Department			
Delivery			

Current Users comparison Info:

For completion after approval of technology in some cases.

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VENDOR/EQUIPMENT ASSESSMENT

PROPOSED EQUIPMENT ASSESSMENT

COST	Vendor #1	Vendor #2	Vendor #3
Base Price			
GST			
PST			
Freight			
Customs/Brokerage			
Installation: (By Vendor)			
Installation: By CHR * a) Utilities - Air - Plumbing - Electrical b) Construction - Weight/ Dimensions			
Consumables: (estimated annual cost)			

*to be completed by Plant Services

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VENDOR/EQUIPMENT ASSESSMENT

PROPOSED EQUIPMENT ASSESSMENT

SERVICES/WARRANTY	Vendor #1	Vendor #2	Vendor #3
Warranty Period			
Warranty Cost			
Service Contract			
Term:			
Type:			
Price:			
Inservice Education On site/Off site			
Duration			
Service Training			
Level			
Price			
On site/off site			
Manuals: Operation Service Schematics Troubleshooting			

TECHNOLOGY ASSESSMENT COMMITTEE (TAC) PROCESS
PROJECT WORKSHEET

I. INITIAL PRESENTATION TO TECHNOLOGY ASSESSMENT COMMITTEE

A) **Sponsor completes Medical/non Medical Technology Assessment checklist**

Date_____Sponsor's Signature_____

B) **Technology Assessment Committee approves proposal for further development by the Technology Assessment Working Group.**

Date_____TAC Chairman's Signature _____

C) **TAC does not approve proposal for further development:**

Date_____ Returned to Sponsor yes ☐
no ☐
Forwarded to SMG for consideration yes ☐
no ☐

TAC Chairman's Signature_____

II. PROPOSAL DEVELOPMENT BY WORKING GROUP

A) **Selection of Project Leader**

Date_____

B) **Selection of Project Team Members**

Date_____

Team Members (Select members from affected/related areas)	**Department**

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TECHNOLOGY ASSESSMENT COMMITTEE (TAC) PROCESS

C) Completion of Assessment

		DATE	SIGNATURE
i)	Medical		
ii)	Community		
iii)	Facility		
iv)	Financial		
v)	Vendor/Equipment		

D) Project Leader presents completed proposal to TAC Chair for final review .

Date_____ TAC Chair_____

III. PRESENTATION TO TAC

A) Project leader and sponsor present final proposal to TAC
(Members of project team may attend TAC.)

B) TAC Approves Proposal

Date_____ Signature of TAC Chairman_____

IV. PRESENTATION TO SMG (when required)

Date_____

Approved Yes ☐
No ☐

Technology Acquisition form sent to _____

Date_____

V. IMPLEMENTATION OF TECHNOLOGY

Date_____

VI. EVALUATION OF TECHNOLOGY REPORT

A) Presentation to TAC

Date_____

B) Presentation to SMG (when required)

Date_____

TECHNOLOGY ACQUISITION REQUEST
(TO BE COMPLETED BY CHAIRMAN OF TAC AND FORWARDED TO MANAGER, CAPITAL AND BUSINESS)

Department(s) _____
_____
_____

Prepared by: _____
Project Leader

Date_____

1. Equipment/service requested
Type:_____ Quantity_____
_____ Date of expected acquisition_____
_____

2. Priority
- ☐ Urgent (required immediately for patient/staff safety)
- ☐ Necessary (required for continued operation of the service/department)
- ☐ Desired (required to expand or improve services)

3.A Type of item
- ☐ New item service
- ☐ Replacement item/service
- ☐ Expansion item/service

3.B
- ☐ Budgeted
- ☐ Not Budgeted

4. Which departments/providers will use this equipment/service?
Name(s) of department service (providers) _____
_____
_____
_____
_____

5. Does this equipment/service duplicate existing technology?
- ☐ No
- ☐ Yes, describe

_____
_____
_____

6. Does this equipment/service replace existing technology?
- ☐ No
- ☐ Yes, describe

_____
_____
_____

Date of Approval at [redacted]_____

Chairman of TAC _____
Signature

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