

THE BURDEN OF PROOF

AN ALBERTA MODEL FOR ASSESSING PUBLICLY FUNDED HEALTH SERVICES

Final Report of the

Expert Advisory Panel to Review Publicly Funded Health Services



March 2003

For additional copies of this document, or for further information, contact: Alberta Health and Wellness 10025 Jasper Avenue Edmonton, Alberta T5J 2N3

Telephone: (780) 427-7164 Fax: (780) 427-1171 Web site: <u>http://www.health.gov.ab.ca</u>

ISBN Number: 0-7785-2410-8 ISBN Number: 0-7785-2412-4 pdf

For Appendices 3 and 4, contact: Strategic Planning Division Telephone: (780) 427-2653

INTRODUCTION

The Expert Advisory Panel to Review Publicly Funded Health Services was established in May 2002 to review and make recommendations on public funding for the current basket of health services and to recommend an appraisal process for reviewing new and existing health services on an ongoing basis. The objective is to ensure that Alberta's publicly funded health services remain comprehensive and sustainable for the future, and provide the best value.

Since the Panel was established, its work has focused on:

- Reviewing models and approaches in place in other provinces and countries around the world
- Consulting with health stakeholders
- Developing principles and criteria to guide decisions on public funding for health services, treatments and technologies
- Developing a three screen review process including:
 - A technical screen assesses whether a service or treatment is safe, has demonstrated benefits, is effective in treating or preventing particular health problems, and is well-integrated with other health services
 - A social and economic screen assesses the impact of decisions to provide or not provide public funding for the service or treatment on individuals' access to the service, possible ethical issues affecting groups of individuals, the impact on the health system, the availability of other options, and consistency with health reform
 - A fiscal screen assesses the financial costs and implications of continuing to fund existing services or providing funding for new services or treatments on the sustainability of the health care system and deciding whether a service or treatment should be publicly funded in whole or in part
- Applying the three screen process to a review of four services (optometry, podiatry, chiropractic services, and community physical therapy) referred to the Panel by the Minister of Health and Wellness and providing recommendations to the Minister
- Applying the three screen process to broad categories of currently funded health services and providing recommendations to the Minister.

Further information on the Panel's principles and criteria and the recommendations on four referred services and broad categories of currently funded services are included in the Panel's earlier reports. The Panel's proposed principles and criteria are outlined in Appendix 1 and a chart outlining the Panel's three screen process is included in Appendix 2.

The final task of the Panel is to propose a unique Alberta process for reviewing and making decisions on public funding for health services and treatments. The process would apply to both currently funded services and to new services, treatments and technologies.

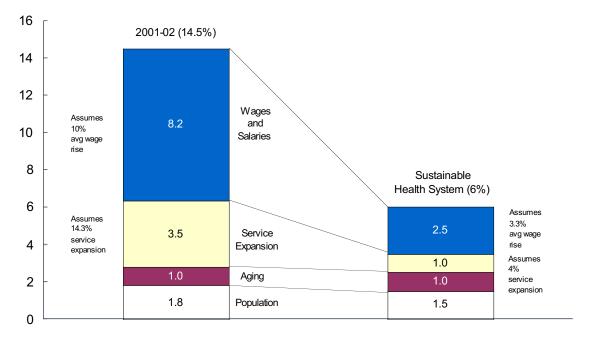
To complete this task, the Panel relied on the work of the Research Group to review existing models in place in other jurisdictions, identify best practices, propose a model for Alberta, and help build a sound business case. The Research Group's full report is available along with the Panel's report and recommendations and contains more detailed information, particularly about best practices in the United Kingdom, Australia and the Netherlands. The Panel also consulted with health stakeholders to seek their views and advice on the viability of the proposed new process for Alberta.

This report outlines the Panel's recommendations for a new appraisal process for health technologies and services in Alberta. The proposed process is comprehensive and rigorous and would make Alberta a leader in appraisal of health services, treatments, and technologies in Canada. It would streamline and replace some of the ad hoc committees and decision-making processes currently in place. The process would be open and transparent to all parties, including the public, so people would know the outcomes of appraisals and the reasons why certain services or treatments are recommended or not recommended for public funding. Perhaps most important, it would assure Albertans that the best decisions are made and provide the best value from the basket of health services funded in the province.

CONTRIBUTING TO SUSTAINABILITY

The Panel's work is a key part of the province's goal of achieving a sustainable health system for the future. The Panel shares concerns that costs in health care are growing substantially and the rate of growth from the past few years is not sustainable on an ongoing basis.

As noted in the following chart, there are a number of components that drive higher costs in health care including wages and salaries for health care providers, a growing and aging population, and expansions in health services. The Panel's work is focused primarily on ensuring that the best use is made of existing funding to support services that work, produce the best health outcomes, and improve the health of Albertans.



Components of Health Spending Growth

Source: Research Group, March 2003

At the outset, there was speculation that the Panel's work would result in "de-listing" services with a focus on saving money in the short term. In reality, the mandate of the Panel and its impact on sustainability is more long term. As outlined by the Minister of Health and Wellness:

"I agree with the Panel's observation that its most important contribution to sustainability lies in developing an open and rigorous approach for decisions about the public funding of new services ..."

The Panel's reports and recommendations do not provide a "quick fix" or substantial savings in the short term. They do, however, provide a sound direction for the future and will complement the work underway in Alberta through a variety of health reform initiatives. Currently, there are a number of ad hoc processes in place for making provincial decisions on which new services and treatments receive public funding. Regional health authorities face continuing challenges in trying to decide whether innovative new approaches and techniques should be adopted. As some have said, much of the innovation in the health system simply "shows up in the operating room" and only the larger health regions have the capability to assess the effectiveness, costs and benefits of these innovations. The proposed new appraisal process would address these concerns and provide a rigorous and credible process for evaluating services and treatments and making decisions in the future. It would provide an invaluable tool not only to the province but also to health authorities, health providers, industry, and the public.

The Panel believes that the proposed process will contribute directly to the future sustainability of Alberta's health system by ensuring that:

- Decisions about whether or not services or treatments are funded are based on the best available evidence
- A sound process is in place to assess the effectiveness, costs and benefits of innovative approaches and new services and treatments on an ongoing basis
- New services, treatments and technologies are added if they provide high quality services, result in positive health outcomes and are affordable and sustainable within the overall health budget
- There is a continuous review not only of new services and treatments but also of currently funded services to ensure that the most effective treatments and services are funded.

STARTING WITH CRITERIA

To guide the Panel's work in reviewing appraisal processes in other jurisdictions and developing a proposed process for Alberta, the Panel began by identifying the following four criteria:

- **Transparency** the process should be clearly defined and made available to stakeholders and the public
- Rigor appraisals should meet current best standards for evaluation of health technologies and include technical, social, ethical and economic, and fiscal assessments
- Openness the process for appraisal of new and existing health services should be open to all interested parties
- **Timeliness** the timelines for appraisals should be specified, take stakeholder timelines into consideration, and include a specified schedule for review and audit.

These four criteria are essential for establishing a credible process and building support from a variety of stakeholders, including health care providers, industry and the public.

REVIEWING BEST PRACTICES

On behalf of the Panel, the Research Group reviewed 35 processes currently in place in jurisdictions around the world. Based on the four criteria noted above, the Research Group identified best practices in three countries: United Kingdom, Australia, and the Netherlands.

The Research Group's report provides detailed information on the processes used in these three countries as well as the roles and responsibilities of the various bodies and organizations involved. The following are highlights of the three approaches:

United Kingdom – National Institute for Clinical Excellence (NICE)

NICE is considered the "gold standard" in appraisal processes. It is responsible for assessing the clinical and cost effectiveness of health care interventions (including pharmaceuticals) and for developing clinical practice guidelines. Its decisions on whether or not services and treatments will be publicly funded are final. The process is governed by a small Board made up of health policy experts, physicians, and public members. The Board reviews applications for appraisals (which can come from government, industry, professional and patient groups, or academic institutions), sets priorities, appoints an Appraisal Committee of experts to oversee the appraisals, receives recommendations from the Appraisal Committee, hears appeals, and makes decisions. The actual assessments are done by one of six academic health centres selected to conduct the assessment. Stakeholders are able to request appraisals, participate in the assessments, participate in consultations with the Appraisal Committee, and appeal recommendations to the NICE Board. A staff of about 40 employees manages the process for NICE and total costs are approximately \$36 million CDN.

Australia – Medical Services Advisory Board (MSAC)

The Australian process also is governed by a Board, however, in this case, the Board makes recommendations to the Minister who in turn is responsible for making decisions. The MSAC Board includes practicing and academic physicians, health policy experts and public representatives. It is responsible for receiving applications for appraisals (which come from government), determining whether services are eligible for an appraisal, setting priorities, referring appraisals to Supporting Committees, receiving their recommendations, and making recommendations to government. Supporting Committees are chaired by a member of the Board and are responsible for overseeing appraisals and making recommendations to the Board. Actual assessments are contracted from one of six independent agencies. Stakeholders can make applications for appraisals. The Board is not responsible for

developing clinical practice guidelines. If the appraisal involves a surgical procedure, a separate body is responsible for developing clinical practice guidelines. A small staff of about 12 employees manages the process at a cost of approximately \$5 million CDN.

The Netherlands

The Netherlands approach is more complex, reflecting their mix of private and public health care coverage and delivery. Government is responsible for hospital care services. It reviews requests for appraisals and sets priorities. Requests for appraisals of hospital-based services are directed to the Health Council, a body with 160 appointed members, to perform health technology assessments and provide recommendations to government. The Health Council reviews its appraisals on a four year cycle and also is responsible for preparing clinical practice guidelines. Requests for appraisals of non-hospital based services are received by the Health Insurance Council (representing employers, trade unions, insurers, physicians, consumer groups, and government) and the National Society of Private Healthcare Insurers (represents private insurers and is responsible for negotiating contracts with providers and establishing benefit packages for privately insured clients). Appraisals of non-hospital services are undertaken by TNO, a large, independent private consulting agency. The results of these appraisals are provided to government and private insurers for decisions.

Based on its review, the Research Group found that all three models have considerable strengths and several aspects that would fit well within the Alberta context. From the Panel's perspective, it is important to note that only the Netherlands undertakes appraisals that include all three screens contained in the Panel's three screen process. The primary focus of the Australian and NICE models is on the technical screen.

The following chart summarizes the Research Group's overall assessment of the three models based on the four criteria of transparency, rigor, openness and timeliness.

CRITERIA	UK	Australia	THE Netherlands
Transparency	 Excellent Process clear and detailed Explicit templates and requirements at every stage 	 Excellent Process clear and detailed Explicit templates and requirements at every stage 	Fair Process laid out but not easily accessed
Rigor	 Good Uses current best HTA methods No fiscal screen Corresponding CPGs prepared Explicit review cycle 	 Good Uses current best HTA methods No fiscal screen CPGs prepared by parallel surgical body No explicit review cycle 	 Excellent Uses current best HTA methods Uses fiscal screen Corresponding CPGs produced Considers ethical, social and legal issues Explicit review cycle
Openness	ExcellentAll interested parties consultedDecisions posted on website	 Good Applicant consulted Other interested parties may not be consulted Decisions posted on website 	 Fair No external application process Stakeholders consulted Limited information for public on website
Timeliness	 Excellent Explicit published timelines All reviews completed in about 12 months 	Unknown	 Good Market driven approach Corresponds to budget-setting process

A PROPOSED ALBERTA PROCESS

The proposed appraisal process for Alberta builds on many of the elements of the three best practice jurisdictions. With some adjustments and additions, the Expert Advisory Panel endorses the process developed by the Research Group. The following summarizes the objectives and the key components of the proposed process for Alberta.

Objectives

The proposed Alberta process is designed to meet the following objectives:

- It should lead to the optimal mix of publicly-funded health services
- It should contribute to the sustainability of Alberta's health system
- It should meet the four criteria of transparency, rigor, openness, and timeliness
- It should contribute to a larger body of knowledge on health assessments in Alberta, Canada and around the world.

Overview of the Proposed Process

The Expert Advisory Panel believes that its proposed process would meet the objectives and provide a credible and sound process for reviewing services and treatments and making decisions in Alberta. The process should be governed by an appointed Board supported by a small staff. The Panel believes that members of the Board should reflect the multidisciplinary nature of the health system and include expertise in health as well as representatives of the public. Members of the Board should not be appointed to represent particular sectors or stakeholders in the health system. The appraisal process would be managed through an Appraisal Committee and actual assessments would be done by assessors with academic and health technology assessment expertise. The assessment process should address the first and second screens proposed by the Panel in its earlier reports. The third screen, the fiscal screen, should be applied by the Appraisal Committee. An explicit review process should be built in so currently funded services and treatments are reviewed on a regularly scheduled basis. Audits of the implementation and impact of prior decisions to add new services or treatments or to continue funding for existing services and treatments should be the responsibility of government.

In terms of the scope of the appraisal process, the process should be limited to appraisals of current and new health services, treatments and technologies. The Expert Drug Committee, which currently reviews and approves pharmaceuticals, should continue to be responsible for decisions on whether or not new pharmaceuticals are approved for coverage in Alberta. However, if pharmaceuticals are being reviewed along with other treatments or as a substitution for other treatments, those reviews should be undertaken through the proposed new process. The Panel also understands the importance of developing clinical practice guidelines on the most appropriate use of new services, treatments and technologies. However, the Panel does not recommend that responsibility for clinical practice guidelines should be transferred to the proposed new appraisal process and Board. Explicit linkages should be established between the appraisal process and current bodies responsible for developing clinical practice guidelines in Alberta.

The appraisal process should also be clearly linked to ongoing work in regional health authorities to review the effectiveness and efficiency of various innovative approaches suggested by physicians and other providers in their regions. Regional health authorities would continue to review and assess innovative approaches before they are adopted in their region, particularly if they are intended to decrease costs. At the same time, more extensive and costly innovations or new services, treatments and technologies would be referred to the new appraisal process. This would provide a useful resource to regional health authorities and also ensure that province-wide implications are assessed.

The appraisal process should be open, providing ample opportunities for stakeholders to be involved throughout the process. The Panel feels that this type of open process with active participation of stakeholders is the best way of ensuring their support and the credibility of the process. Transparency is critical, and that means decisions at every step in the process must be explained and available to the public through a website and other communications vehicles.

In earlier reports, the Panel identified its concern with the lack of primary research available to provide the type of assessment information that is critical to decisions about whether or not to fund a service or treatment. The Panel feels that the proposed Board can play an important role in advising government and other research agencies on priorities for primary research on an ongoing basis. Staff of the Board can also play an important role in scanning trends and new developments in health care services and technologies and providing an "early warning" on the types of research that may be needed in the future.

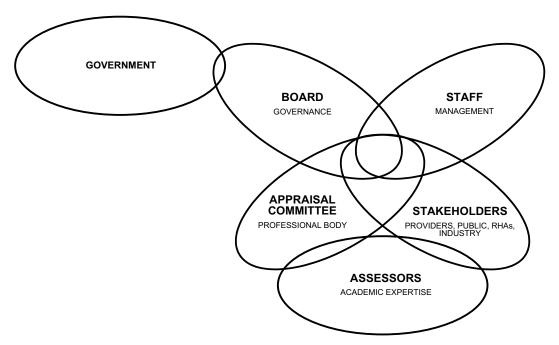
The Panel believes that the work of the proposed Board and appraisal process will be increasingly important in the future as the number and diversity of new health technologies, treatments and services continues to grow at a rapid pace. Given this dynamic growth in new technologies, all provinces and many countries around the world face increasing challenges in assessing and making the best decisions about whether or not to approve and fund new services, treatments and technologies. Clearly, this provides an opportunity for jurisdictions to share expertise and information about the outcomes of appraisals. While Alberta is not large enough to have the capability of national systems such as the UK or Australia, there is much to be gained from having an explicit process in place, developing expertise within the province, and establishing clear links to a growing network of health technology assessments done around the world. To the extent possible, the appraisals in Alberta should build on existing research and appraisals done in other parts of Canada and around the world. There also are opportunities to work with other provinces, particularly in western Canada, to share expertise and outcomes of the appraisals.

Roles and Responsibilities

The proposed Alberta appraisal process outlines important roles and responsibilities for:

- Government
- A governing Board
- Staff to manage the process
- An Appraisal Committee to oversee the appraisal process
- Assessors to undertake the technical and social and economic assessments
- Stakeholders and the public
- Regional health authorities.

Alberta Proposal



The following outlines the roles and responsibilities of the key components of the process.

Government

- Funds the Board
- Sets fiscal targets, outlining how much spending on health care is expected to increase over time as a result of factors such as labour costs, aging, and an increasing population, and indicating how much additional funding is available for expanding services or introducing new treatments and technologies within the health system
- Appoints Board members
- Initiates requests for appraisals of new and currently funded services and provides them to the Board
- Receives recommendations from the Board
- Makes decisions and develops implementation plans
- Identifies potential for interprovincial cooperation on implementation
- Conducts horizon scanning

Board

- Includes 5 9 eminent citizens appointed for a fixed term. Membership should reflect the diversity of the health system and include both health expertise and representatives of the public
- Accountable to the Minister and the public
- Governs the appraisal process
- Meets on a minimum of once a month
- Hires and supervises a CEO
- Receives requests for appraisals from government and stakeholders
- Sets criteria and establishes priorities for reviews
- Appoints Appraisal Committee
- Refers questions to the Appraisal Committee and receives their recommendations
- Hears appeals from stakeholders if required on two grounds:
 - Findings of the process are perverse
 - Process was not followed
- Makes recommendations to government
- Reports its recommendations to the health care community and the public
- Identifies areas where additional primary research is needed and conveys this information to government and other research agencies
- Identifies areas where clinical practice guidelines are needed

Staff

- Includes three senior executives along with the necessary technical and administrative support
- Provides administrative support to the Board, Appraisal Committee and stakeholders
- Manages the appraisal process
- Receives applications from stakeholders, conducts pre-appraisals of applications, and recommends priorities for appraisals
- Refers all applications to the Board for prioritization along with pre-appraisals and recommended priorities
- Coordinates communication and dissemination activities
- Liaises with Board, government, stakeholders, and public
- Liaises with health technology assessment (HTA) groups, Canadian Coordinating Agency for Health Technology Assessment (CCOHTA), and the International Network of Agencies for Health Technology Assessment (INAHTA)
- Liaises with government and Alberta Heritage Foundation for Medical Research (AHFMR) on needs for primary research
- Liaises with professional organizations responsible for developing clinical practice guidelines
- Liaises with regional health authorities

Appraisal Committee

- Includes 5 expert members appointed by the Board for a fixed term
- Brings in "experts for the day" people with specific expertise needed for the appraisal
- Meets bi-weekly and is not a full-time body
- Receives requests for appraisals from the Board
- Defines the scope of the question to be addressed in consultation with stakeholders and assessors
- Commissions assessments from independent assessors for the technical and the social and economic screens
- Reviews the outcomes of the technical and social and economic assessments
- Applies the fiscal screen
- Receives comments from stakeholders on the outcomes of the assessments
- Makes recommendations to the Board
- Recommends the schedule for review and audit
- Identifies potential areas for regional and/or interprovincial applications

Assessors

- Include independent academic/research centres with expertise in HTA, including the AHFMR
- Undertake the technical and social and economic assessments referred by Appraisal Committee
- Meet with Appraisal Committee and stakeholders as required
- Report to Appraisal Committee

Stakeholders

- Includes regional health authorities, the Cancer Board, clinicians, researchers, industry, patient groups, and public
- Submit applications for appraisals
- Participate in process to determine the scope of the question to be assessed
- Consult with Appraisal Committee and assessors during appraisal process
- Appeal recommendations to the Board
- Aid in dissemination process
- Facilitate development and dissemination of clinical practice guidelines with professional groups and the public

Appraisal Process

The following summarizes the proposed process that would be used. The process as outlined applies to new services, treatments and technologies. The process also should be used to review currently funded services on an ongoing basis. Priorities for reviewing currently funded services should be recommended by the government and stakeholders and set by the Board. An explicit schedule should be in place for evaluating and auditing implementation of new services on an ongoing basis. For currently funded services, staff and the Board would be responsible for identifying priorities for reviewing currently funded services in consultation with government and stakeholders.

The Panel recommends that an explicit audit schedule should be put in place to ensure that decisions on public funding for services and treatments be reviewed within two years of implementation. The audit would address whether or not the new services had been implemented as planned and whether or not the expected benefits have been achieved.

Request and prioritize

- Applications for appraisals are referred to the Board.
- Applications come from government (including committees within Alberta Health and Wellness) and stakeholders including regional health authorities, the Cancer Board, the Alberta Medical Association, Alberta Association of Registered Nurses, and researchers, patient and consumer groups. Applications could also come from the Alberta Medical Association and government in cases where they are unable to agree on whether to add new services to the Schedule of Medical Benefits.
- Applications include information about:
 - The condition the service, treatment or technology is intended to treat
 - Background information including a description of current therapies
 - Evidence, if available, that compares the effectiveness of the treatment, service or technology to existing therapies
 - Rationale for the timing of the request for appraisal
 - Resources needed to implement the intervention.
- A pre-appraisal is done by staff to clarify information requirements, availability of prior research and assessors with necessary expertise, potential cost of an appraisal, eligibility for review (i.e. within the scope of the Board's responsibilities).
- All requests for appraisals are referred to the Board.
- The Board assigns priorities based on explicit criteria.
- The Board also sets priorities for reviewing currently funded services, treatments and technologies.
- Decisions about whether or not to undertake an appraisal and the assigned priority are communicated to stakeholders and the public, including the rationale for decisions.
- The Board refers requests for appraisals to the Appraisal Committee.

Assessment and appraisal

- The Appraisal Committee determines the type of appraisal required. Appraisals could be:
 - \circ $\,$ Based on HTAs and research done in other jurisdictions $\,$
 - Submitted by the applicant as part of the application process and verified/reviewed by the Appraisal Committee and independent assessors
 - o Undertaken by independent assessors in Alberta
 - Undertaken cooperatively with assessors in other jurisdictions
 - Done by existing networks including regional health authorities, the Alberta Cancer Board, and the AHFMR.

- Reviews and audits of currently funded services address key questions such as whether or not the service, treatment or technology was implemented as recommended and whether the expected outcomes were achieved.
- The Appraisal Committee commissions assessments from independent assessors.
- The Appraisal Committee, assessors and stakeholders determine the scope of the specific question to be assessed.
- Stakeholders present evidence and input to assessors.
- Assessors complete their assessment, including the application of the technical and social and economic screens and recommendations regarding collection of data for subsequent audit, and provide their findings to the Appraisal Committee.
- Stakeholders receive the assessors' findings and provide comments to the Appraisal Committee.
- The Appraisal Committee reviews the findings on the technical and social and economic assessments and applies the fiscal screen.
- The Appraisal Committee makes recommendations to the Board. Recommendations could include approval of the service, treatment or technology, rejection, or approval on a limited or interim basis.
- The Appraisal Committee's recommendations include timing for review and audit of the decision following acceptance by government and implementation in the health system.

Recommendations

- The Board receives and reviews recommendations from the Appraisal Committee.
- The Board hears any appeals of the recommendations from the Appraisal Committee.
 Appeals may be lodged based on two grounds:
 - The recommendations were inconsistent with the research findings
 - The process was not followed.

The Board may also choose to refer the appeal to a third party to review and provide recommendations to the Board.

- Following any appeals, the Board provides its recommendations to government.
- The Board's recommendations are communicated to stakeholders and the public by posting on a website and other communications approaches.
- The Board identifies any areas where further research is needed and conveys this to government and other research agencies.
- The Board confirms the schedule for review and audit. As noted above, the Panel recommends that all decisions on public funding for new services and treatments should be audited within two years following implementation.

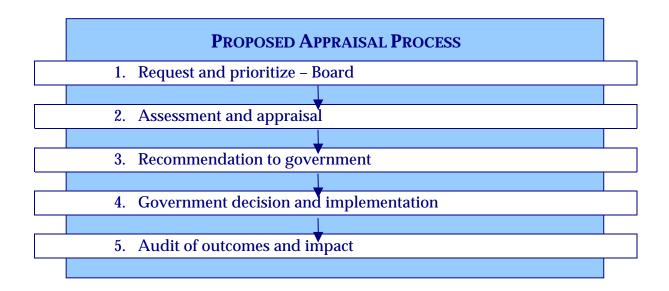
 The Board identifies whether clinical practice guidelines are needed and should be developed by professional bodies on a priority basis.

Decisions and implementation

- Government reviews recommendations from the Board and makes decisions. Stakeholders
 who are not satisfied with the outcomes of the appraisal process could take their case to the
 government before a final decision is made.
- If government approves the decisions, plans are made for implementation including:
 - Timelines for implementation
 - Responsibilities of regional health authorities and providers
 - Dissemination and development of clinical practice guidelines.
- Staff and stakeholders assist in dissemination and implementation.

Audit of outcomes and implementation

- Decisions to publicly fund new services or to make changes to existing services are reviewed within two years following implementation of the decision.
- Collection of the necessary data and information needed to undertake the audit begins as soon as the decision is implemented.



Priorities for Appraisals

Realistically, the appraisal process will not be able to accommodate all the various requests for appraisals in a given year. Priorities will need to be established by the Board. To establish priorities, two questions need to be addressed:

- What criteria should be used to select existing services for appraisal?
- What criteria should be used to rank requests for appraisal of new services?

The Panel believes that a flexible approach is necessary and that, once the process is in place, the Board should determine the most appropriate criteria to be used. At the same time, the Panel suggests that a number of "filters" should be considered.

Selecting existing services

As noted earlier, the Panel believes that public funding for existing services should be reviewed on an ongoing basis. As new technology and new treatments are developed and appraised, they could replace or modify currently funded services. New evidence may be developed that calls into question the effectiveness of existing services. New pharmaceutical treatments may replace existing surgeries or other treatments. And reviews of clusters of services or the treatment of certain diseases may identify gaps in services that need to be addressed.

Within that context, the Panel suggests that the following filters should be considered in setting priorities for reviews of existing services:

- What is the impact on sustainability of the health system?
 - Are the services high cost?
 - Is the utilization of the existing services growing at a rapid rate?
- What is the impact on patient care?
 - Is there new evidence that raises concerns about the outcomes?
 - Are there new services, treatments or technologies that may be more effective?
- Is the appraisal feasible?
 - Is there sufficient evidence available or is primary research needed?
 - Does the appraisal process have the capacity to undertake the appraisal and is it more important or more significant than other services?

New services, treatments and technologies

The key challenge for new services will be setting priorities among what will undoubtedly be a growing list of new services, treatments and technologies. To establish a ranking of new services for appraisal, the Panel suggests that the following filters should be considered:

- What is the impact on patient care?
 - Will the proposed new service, treatment or technology make a significant difference in the health of patients?
- What is the impact on sustainability of the health system?
 - What are the anticipated costs of the new service, treatment or technology?
 - What utilization is expected?
 - Would the new service, treatment or technology result in offsetting reductions in costs in terms of reducing hospital stays, replacing more expensive treatments, or preventing more serious health problems in the longer term?
- Is the appraisal feasible?
 - Is there sufficient evidence available or is primary research needed?
 - Does the appraisal process have the capacity to undertake the appraisal?
- Is the timing critical?
 - Is the new service, treatment or technology publicly funded in other provinces?
 - Is there a pressing reason to undertake the appraisal on an urgent basis?

BUSINESS CASE

There is little doubt that the proposed process would provide an open, transparent and rigorous process for making decisions on what services, treatments and technologies should be funded in Alberta. It would provide an opportunity to consolidate, streamline and rationalize existing processes and decisions that often are made on an ad hoc basis or through processes that are not well understood by stakeholders or the public.

The Board, and key aspects of the proposed process, would become a "node" connecting to the growing network of expertise in health technology assessments in Alberta, across Canada and around the world. As such, it would build on existing knowledge and expertise and provide an invaluable tool for regional health authorities, the Cancer Board, clinicians and other stakeholders to coordinate and expand Alberta's capability to access information and undertake appraisals.

At the same time, the process will add costs and must be justified in terms of the potential benefits it can provide. The Research Group assessed the potential costs and offsetting benefits/savings that could be achieved through the recommended appraisal process. Their estimates were based on 20 full appraisals and another 20 reviews or audits of currently funded services performed on an annual basis.

Based on the Research Group's work to date in reviewing currently funded services and their assessment of the costs and benefits of the proposed process, the Panel concurs with the Research Group's findings that the process would result in substantial quality improvements as well as cost savings.

For example, in the case of hemodialysis, previous work done by the Research Group indicated that total costs for hemodialysis grew at a rate of 20% per year for the period 1998-99 to 2000-01. Hemodialysis is required for patients with end-stage renal disease. The two most common causes of chronic renal failure are hypertension and diabetes. In many cases, both of these conditions are preventable and treatable. The Research Group recommended that prevention strategies should be expanded and treatments for hemodialysis should be evaluated. If we assume that these steps are taken and the result is to reduce the rate of growth in services from a medium term growth rate of 10% per year to 5% per year, the value of the potential savings is estimated at \$40 million over a five year period. These savings could be used to fund prevention initiatives and other health services, as well as more than offsetting the estimated costs of operating the health appraisal process on an annual basis.

Examples of similar work from other jurisdictions confirm that substantial savings are possible when services and treatments are appraised and the findings are used to guide practice in the health system. The National Institute for Clinical Excellence compared the costs and effectiveness of hemodialysis performed at home, in satellite clinics and in hospitals and found that:

- Clinical outcomes were more favourable for patients receiving home hemodialysis compared with hospital hemodialysis
- The annual costs of home hemodialysis were £19,300 per year compared to £21,000 for satellite hemodialysis and £22,000 for hospital dialysis
- While home hemodialysis had higher start-up costs for training and equipment, the increased costs were more than offset by savings in other areas including the costs of medical and nursing staff in hospitals and satellite units, fewer days in hospital, and lower costs associated with complications that arise during dialysis.
- There is a survival advantage for some patients on home hemodialysis. As a result, the lifetime costs of dialysis for patients receiving home hemodialysis were higher than for those receiving satellite hemodialysis.

Another example comes from what is known as the "Ottawa ankle rules." Many patients who have ankle and foot injuries undergo X-rays but fewer than 15% of them actually have a fracture. The Ottawa ankle rules provide a questionnaire for physicians to use in evaluating patients and avoiding unnecessary radiography. A 1995 study in Ontario indicated that using the Ottawa ankle rules saved \$730,145 per 100,000 patients that presented in an emergency with a sprained ankle. In the United States, studies suggest that the savings varied between US \$614,226 and US\$3,145,910 per 100,000 patients, depending on the cost of radiology.

Based on these examples, the Panel believes that a strong case can be made for implementing the proposed process.

CONCLUDING COMMENTS

Since the Expert Advisory Panel was established, its focus has been on deliberately and decisively approaching each of its tasks and providing the best advice to the Minister.

As requested, the Panel has:

- Proposed principles and criteria to guide decisions on public funding for health services, treatments, procedures and technology
- Reviewed and made recommendations on continued funding for four specific services as well as broad categories of currently funded services
- Proposed a comprehensive new process for reviewing new and currently funded services, treatments and technologies on an ongoing basis.

The Panel believes that the proposed process would provide substantial benefits to the province. Initial consultations with various health care stakeholders indicated strong support for the proposed process. Representatives of physicians, nurses, and health authorities saw the proposed process as an opportunity for Alberta and welcomed a process that would address the challenge of making increasingly complex decisions on which services and treatments should be publicly funded in the province.

As the growth of new treatments and technologies continues at a dramatic pace, an open and rigorous process is essential to ensure that the best decisions are made. The proposed process would contribute directly to the future sustainability of the health system by ensuring that only the most effective services, treatments and innovations receive public funding. It would benefit Albertans by ensuring they continue to get access to not only the latest, but also the best basket of health care services and treatments.

Looking forward, a number of issues should be addressed as part of the next steps in moving ahead with implementation:

- The relationship between the work of the proposed process and health technology
 assessments done in regional health authorities on operational issues needs to be clear so that
 duplication is avoided.
- The establishment of clinical practice guidelines by professional bodies will be essential to follow through and implement recommendations coming from the proposed new process. It

may be necessary to consider new ways to encourage the development and adoption of clinical practice guidelines.

.

- One of the greatest opportunities for savings may well lie in a review of currently funded and new prescription drugs. While the Expert Panel recommends that the proposed process not include drugs, there are considerable linkages between appraisals of new treatments and technologies, many of which often include new prescription drugs. Islet cell transplants for treating diabetes are a case in point. A decision to provide public funding for islet cell transplants must include coverage for the costs of the prescription drugs involved – the two decisions cannot be separated. Therefore, the Panel suggests that consideration be given to providing explicit linkages between the two processes and also exploring whether a similar process should be established for the review and approval of new prescription drugs.
- Making decisions about whether or not new services or treatments should be publicly funded or changes should be made in currently funded services is only the first step. Change in practice in the health system takes time and deliberate effort. Considerable emphasis should be placed on disseminating the outcomes of the appraisal process, implementing clinical care pathways, and working with regional health authorities and providers to ensure that the necessary changes are implemented.

The Panel strongly encourages government to proceed with implementation of the proposed new appraisal process. From our experience in reviewing currently funded services and looking at models in place in other countries, we firmly believe that a transparent, rigorous, open and timely process is essential. The decisions on which new services and treatments should qualify for public funding will only get more complex and more difficult with the pace of new developments in health care. Alberta needs a clear and credible process for making the best decisions, now and for years to come.

Appendix 1 Goals, principles and criteria

Overall Goals

Human Worth

All people are equal in worth and dignity and have a right to a healthy life.

Social solidarity

Albertans view medicare as a trust and believe those who are ill or injured must always be cared for, particularly those who are most vulnerable in our society.

Fairness and Equity

All Albertans will be assured of the universality and accessibility of appropriate health services regardless of their individual characteristics or circumstances.

Principles for Publicly Funding Health Care Services

- The Government of Alberta is committed to the principles of the Canada Health Act: comprehensiveness, universality, portability, public administration, accessibility.
- Publicly funded health care services must be sustainable now and in the future.
- The cost of treating illness and injury must not create undue financial hardship for individual Albertans.
- Saving lives and significantly improving quality of life are priorities within our health system.
- Alberta's health system supports innovative models of care.
- A sustainable health system requires a responsible user and a provider that supports responsible use.
- Services that promote wellness, protect health and prevent disease and injury are necessary to support a healthy population.

<u>Criteria for Reviewing and Recommending Public Funding for</u> <u>Health Care Services</u>

Safety

• Do the expected benefits outweigh the potential risks?

Demonstrated Benefits or Effectiveness

- What is the available evidence of benefit or effectiveness?
- What is the impact of benefit relative to cost?
- Can the equivalent service and benefit be delivered at lower cost through different delivery models?
- Does the service significantly improve quality of life?
- Does the health service support early detection/health promotion?
- Does the health service support independent living and/or optimal quality of life given an individual's circumstances, e.g., physical, psychological, social, spiritual?

Impact of Decisions on Individuals and the Health System

- What is the impact on the health system and other services?
- What is the impact on individuals who require the service?
- What other options are available for individuals to receive the service?
- Are co-payments or private insurance appropriate options?
- What are the implications relative to alignment with other provinces?

Consistency with Health Reforms

• Is the decision consistent with directions and priorities set for Alberta's health system?

Sustainability/Financial Implications

- Does the service represent an appropriate use of resources?
- What are the limits on available resources?

