

*Colorectal Cancer Screening
and Access Roundtable*

*Colorectal Cancer Association
of Canada*

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March 28, 2007

Welcoming Cocktail Reception and Opening Remarks

Barry Stein, president of the Colorectal Cancer Association of Canada (CCAC), introduced Chairman of the Board Alain Gourd. Formerly the executive vice-president of Bell Globemedia, Alain Gourd has been a very encouraging influence not only on the CCAC's media campaign, but also in the organization's rapid development and impact across Canada, Stein said.

Gourd welcomed the conference participants on behalf of the board, noting that the conference was taking place in March, which is National Colorectal Cancer Awareness month.

The concern of the CCAC is the well being of patients. For cancer patients like himself, Gourd said, nothing about this mission is abstract. "Access to treatment is not a theoretical idea. It is a part of our daily lives." The challenge of securing treatment is a real human issue, Gourd said.

In 2005, the time and effort that went into addressing the federal government on the issues of screening and access was effectively doubled by the change in government. Working with two health ministers in one year led to the gratifying result of seeing the government approve new cancer medications. This success had personal significance for Gourd. "At the time, I didn't know that I myself would benefit from one of them, namely Avastin (bevacizumab). When I needed it, it was not available in Ottawa; I could only get it in Montreal."

Gourd has been able to commute to Montreal to receive his treatment. "I am lucky because I live only two hours from there, but what about the patients living in other provinces?"

Access to Avastin has spread through much of Canada. "But patients in New Brunswick, for example [where the drug is still not available], will call me.... What good answer can you give to them? We don't have any. We feel that this inequity to access between Canadians is unacceptable." Gourd said it was fitting that access to treatment is one of the themes of this conference.

Screening is another important issue. Many GPs are reluctant to recommend screening and in particular colonoscopies, but the quality of diagnostic information they offer is significant.

Noting that Ontario, Manitoba, and Alberta have committed to screening programs now, Gourd offered the hope that the conference could result in improved screening in other provinces. He thanked the Canadian Strategy for Cancer Control (now the Canadian Partnership Against Cancer), the Public Health Agency of Canada, Barry D. Stein and his team, and CCAC employees for their tireless work: "On behalf of every patient, many deeply felt thanks to all of you for taking time from your busy schedules to attend this important and timely conference."

Gourd said he sympathizes with those who work in the medical field and face the challenges and demands of a complex situation. As a cancer patient, “I am aware that there is no easy answer, but it is our job to push you!”

March 29, 2007

Day 1: Welcome

Understanding of the biology of colorectal cancer has come a long way, and it is now possible to foresee a significant increase in prevention, said Dr. Anthony Fields, Vice-President Medical Affairs of the Alberta Cancer Board and chair of the medical advisory board of the Colorectal Cancer Association of Canada. “We have the tools and the knowledge for effective population-based screening of this disease,” he said. Steady progress in the development of diagnostic tools as well as in treatment offers a richness of opportunity to combat the disease.

The objective of this roundtable was to focus on two facets of colorectal cancer control: screening and access to treatment. “It is heartening that at last we are beginning to apply the knowledge on the disease and its screening into systematic population-based provincial colorectal cancer screening programs,” he said.

Dr. Jean Maroun, a medical oncologist at the Ottawa Hospital Regional Cancer Centre and chair of the Gastrointestinal Cancer Practice Guidelines Committee of Ontario, noted the substantial progress made in treatment for colorectal cancer. However, significant challenges remain, related to high drug costs—an issue that will have to be addressed by Canadian physicians, patients, taxpayers, and society as a whole.

In bringing together key stakeholders, the Colorectal Cancer Association of Canada hoped to outline a strategy for colorectal cancer screening and access to care across Canada.

Opening Remarks

Barry Stein
President
Colorectal Cancer Association of Canada (CCAC)

Barry Stein welcomed participants, who came from diverse backgrounds but shared a common interest in colorectal cancer. He expressed his desire that the Colorectal Cancer Roundtable would become an annual event to encourage and facilitate colorectal cancer screening and access to treatment.

As a non-profit organization, the CCAC is dedicated to awareness and education about colorectal cancer; support for patients and their families; and the promotion of timely access to effective treatment and screening in each province.

Colorectal cancer care in Canada will improve with the federal government’s establishment of the Canadian Partnership against Cancer (CPAC), a body that will assist in the implementation of the Canadian Strategy for Cancer Control (CSCC) and serve as an information resource on prevention, diagnosis, and treatment of colorectal cancer.

At the provincial level, Ontario, Manitoba, and Alberta have now announced plans to implement colorectal cancer screening programs, while British Columbia has a program before its Ministry of Health. Nova Scotia announced in mid-March that it will provide \$300,000 toward planning a screening program, and Quebec is currently examining the feasibility of implementing population-based screening. “We believe we have played an important role in encouraging these programs to be implemented and we will continue to do so across Canada,” said Stein.

Stein indicated that with respect to access to treatment, the provincial governments have been challenged to address equalization and timely access to oncology medications. The creation of the Joint Oncology Drug Review (JODR) may result in timely access to diagnosis and treatment, though there are serious concerns that its primary focus will be on cost containment. Stein said he sincerely hoped that the JODR would provide better access to medications within treatment guidelines for patients across the country and that it would provide a fair and transparent process, accountable for its decisions.

To achieve the goals of finding new and creative ways to encourage and implement screening programs and achieve a better understanding of access to cancer medications, he encouraged the active participation and input of all representatives at the Roundtable and wished them all an excellent and productive conference.

Conference Overview

Facilitator Michel Trottier explained that the roundtable would comprise two streams: screening, and access to treatment. In each stream, participants would discuss different provincial approaches, challenges, and best practices, with a view toward developing a pan-Canadian strategy on colorectal cancer care.

Overview of Access to Treatment Stream

Dr. George Browman, chair of the Research Ethics Board of the B.C. Cancer Agency and chair of the CPAC Cancer Control Guidelines Action Group, pointed to the tension that currently surrounds access to cancer drugs in Canada—among patients and health care providers as well as among government policy-makers, who must find ways to meet public demand for treatment. This tension might be partially alleviated if there were better appreciation by the public and the media of the constraints under which resource allocation decisions are made, and the efforts made to achieve fair decisions.

Browman said participants would receive an overview of the scientific approach to policy decisions on the funding of new technologies; how provinces have coped with rising prices, limited budgets, and the limitations of the science; and different perspectives on access to treatment. Participants would also hear from health agencies, industry, patients, and health care advocates on access issues.

Participants would then form smaller groups to focus on key issues and recommendations, including how to better engage different stakeholders and achieve more fairness and transparency in public funding decisions.

Overview of Screening Stream

Use of screening programs and access to screening tools are shown to reduce mortality rates, said Dr. Heather Bryant, Vice-President and CIO of the Alberta Cancer Board, and chair of the cancer research advisory board of the Canadian Institutes of Health Research (CIHR).

Findings by the National Committee on Colorectal Cancer-screening, published in 2002, show that as many as 7700 colorectal cancer deaths in Canada could be prevented over 10 years. However, colorectal cancer is different from other cancers, and the committee noted that the colorectal cancer-screening cascade is accompanied by risk. Data based on past colonoscopy use show that 611 perforations and 75 deaths could potentially occur over 10 years.

The potential cost per year of life gained, about \$12,000, is quite acceptable and a good use of public resources, Bryant said. “Colorectal cancer screening should be made available to Canadians. In order to ensure quality screening that maximizes benefits and minimizes potential risks, ideally, screening should be within an organized and structured environment.”

Three provinces have announced plans to implement screening programs, and appear to be taking different approaches. Bryant noted, however, that these different approaches could represent a strength rather than a weakness, since the programs will work within the context of individual provinces. Provinces will also be able to learn from their counterparts about the benefits or downsides of different models.

A number of potential roadblocks exist, Bryant said, among them the misperception that guidelines alone will change practice and uptake. Despite guidelines such as those published by the Canadian Preventive Services Task Force in 2001, and the National Committee on Colorectal Cancer-screening population-based recommendations published in 2002, colorectal cancer screening rates range from 4% (female) in Newfoundland to 13–14% (male) in British Columbia, Saskatchewan, and Ontario, and 14% for average risk individuals in Alberta. By comparison, the 2006 US National Healthcare Quality Report states that the use of proven prevention strategies lags significantly behind other gains in health care, and that only about 52% of adults reported receiving recommended colorectal cancer screenings. “Things have to move ahead in Canada,” Bryant said.

A second roadblock is the perceived “ick” factor. Experience among front-line health care providers indicates a perception that patients will find the FOBT test unpleasant, and will therefore not comply. However, Bryant noted that two US surveys from 2000 show that 56% of primary care providers identified patient embarrassment or anxiety as a barrier to colorectal cancer screening—but fewer than 1% of adults identified this as their reason for not being current with screening.

In fact, testing by mail has yielded quite satisfactory participation rates: 42.5% in 20 months in Australia; 60% in two years in the UK, and 75% in Finland.

Bryant noted that similar misconceptions existed among physicians about patient boundaries regarding screening for cervical cancer when it was first introduced. “Cervical cancer screening has been available and efficacious since the 1950s. Practitioners espoused its use but believed it to be an embarrassing and frightening test for women.

However, a 1963 study reported that when approached in hospital by a married woman doctor about cervical cancer screening, there were only six refusals out of 1200 cases. In general practice, there was a 69% response rate in actively co-operative practices, and a 41% response, where “the doctors, while tolerating the practice, were less enthusiastic.”

A substantial decrease in cervical cancer incidence and mortality took place in Canada from 1950 to 1995; however, Bryant noted that these reductions took 40 years to achieve. Colorectal cancer screening must be implemented more rapidly, Bryant said.

A third roadblock is that several potential tests for colorectal cancer screening exist, with different intervals and different degrees of invasiveness. “Several of the tests could appear at different points on the screening and diagnostic pathway, which complicates population estimates of screening uptake,” Bryant said. This highlights the need for databases and programs to track what is going on with the population, she added. Several potential responses to multiple tests are available. A screening program could offer only FOBT, and those using other tests would be considered outside the program. This would mean losing the data on those with other patterns.

Another option is to develop algorithms to allow for other tests in particular conditions (for example, those at high risk). However, Bryant noted that consensus on guidelines is hard to reach. A third option is to develop a “quasi-consensus” model, with agreement on basic guidelines and a commitment to contribute to a program database to allow analysis of the impact of variations in testing.

A fourth roadblock pertains to the availability of resources for follow-up—critical to program development in Canada. Colonoscopy or diagnostic capacity may need to be enhanced.

Bryant noted other program challenges: some colorectal screening tests that do not have the same level of evidence as for other cancers; controversy about target groups and tests of choice; funding and cost effectiveness; harm potential; and the potential for false negative results.

Screening Stream Panel Presentations and Provincial Perspectives on Recently Announced Organized Screening Programs

Status of the National Screening Program in Australia

Dr. Mark Elwood
Senior Scientist, Cancer Control Strategy and Policy
British Columbia Cancer Agency

Dr. Mark Elwood described the national screening program in Australia, with which he has been involved for the last six years. He focused particularly on the relevance of specific issues to Canada.

Data from 2000 show similar incidence rates for colorectal cancer in Australia and Canada. Among Australian males and females diagnosed with cancer from 1992 to 1997, five-year relative survival rates were similar to the US survival rates as recorded in Surveillance Epidemiology and End Results (SEER) registries, with similar variations in survival rates according to the extent of disease (stage) at diagnosis.

In general, overall funding for health care is reasonably similar in Canada and Australia. However, Australia has a mixed private/public health care system. Meta-analysis of the randomized trials of CRC screening using fecal occult blood tests (FOBT) shows a 16% reduction in mortality in those offered screening and an estimated 25% reduction among those who accept the screening invitation. In addition, evidence from the Minnesota trial, which has longer follow-up, showed a 20% reduction in the incidence of colorectal cancer, due to detection and removal of pre-cancerous polyps. Thus, an annual or biennial screening program has been found to be effective for both detection of invasive cancer at an early stage and for detection of pre-cancerous lesions and prevention of incidence.

Dr Elwood noted that the main trials were published in 1996, so are now more than 10 years old. But response in terms of screening for colorectal cancer has been very slow, when compared, for example, to the current push towards the use of HPV vaccine based on recently released trials. Australia reacted quickly at first: a 1997 report by the Australian Health Technologies Assessment Committee recommended that population-based screening should be introduced. Pilot studies were proposed in 1998 and 1999. Cancer clinical guidelines in 1999 recommended a biennial fecal occult blood test (FOBT) for those 50 years and older. The Australian Cancer Strategies Group highlighted colorectal cancer screening as a priority and as economically feasible.

A key challenge was that while guidelines were established, there were few facilities (such as local hospitals) available to provide follow-up for large numbers of screen positive people. Unlike in Canada, cancer screening in Australia is a federal responsibility, and services are provided through federally funded state-level programs. This means that cancer screening competes with other federal government budget priorities. Colorectal cancer screening was included in the budget in 2000; however, the pilot programs did not start until more than two years later, from November 2002 until April 2003.

The Australian pilot programs were relatively small compared to those in the UK. Defined areas within the cities of Adelaide (South Australia) and Melbourne (Victoria), and the smaller centre of Mackay (Queensland) were chosen to represent, respectively, an area with special interest and expertise, a suburban area with a substantial immigrant population, and a semi-rural area with a substantial Aboriginal population. The program involved the first round of planned biennial screening of individuals aged 50–74. A key distinction of the Australian pilot programs is that they were based on immunochemical testing.

The pilot programs were initiated with considerable local interest and buy-in from voluntary groups. Publicity was focused locally to avoid the demand that would be generated from widespread publicity.

The pilots had several main features:

- A central, national, registry based within the Health Insurance Commission
- Invitations and self-testing kits sent to individuals by mail
- Instructions on self-completion and return by mail
- Two immunochemical tests (*Bayerdetect* and *Inform*), each requiring samples of fecal material from two separate bowel movements, which are put into a sealed container and returned by post
- FOBT results sent to participants, their general practitioner if identified by the participant, and the central register
- A telephone help line
- A pre-screening education program for health staff

Immunochemical tests are specific to human hemoglobin. Guaiac testing reacts negatively or positively to interference by dietary items including meat, vegetables, and vitamin C, whereas immunochemical testing does not. Thus, a significant practical difference is that immunochemical testing requires no dietary restriction or change, whereas guaiac testing within a population that eats a lot of red meat would produce many false positives.

Evidence shows that while immunochemical testing is more sensitive, the positivity rate seems to be higher. Immunochemical testing involves an automated, quantitative readout of test results. In principle, Canada could have one laboratory conducting immunochemical testing for the whole country.

Participation and dealing with the “ick” factor were two key considerations for the pilot programs. In early discussions, some believed that self-testing would not work and that the participation rate might not exceed 10%. Participation in the three pilot programs overall was 45%, with the highest participation in the smallest community—likely due to community and media interest. The participation rate was also higher among women than men, though not dramatically. Participation did not vary greatly by age or socioeconomic status, and there were small variations by language group.

The Australian pilot programs had a positivity rate of 9%, much higher than guaiac testing in the UK study, Dr Elwood said. In principle, the quantitative readout of immunochemical testing means that yield can be analyzed at different cut-offs towards

determining an ideal positivity rate. This has not yet been done in the Australian pilot studies but would be an important feature if Canada were to use immunochemical testing, Dr Elwood said.

A major shortcoming of the pilot programs was their failure to capture complete information about those with positive FOBT results, who then went on to have a colonoscopy. Follow-up requires getting feedback reports from all specialists doing colonoscopies following screening, and needs to be addressed in any Canadian program, Dr Elwood said.

The Australian pilot studies yielded several conclusions:

- Participation rates in the Australian pilot programs were adequate; national publicity would probably have resulted in higher participation.
- The positivity rate was high, but in principle could be modified.
- Referral for colonoscopy without positive FOBT was shown to be of little value. Empirical data shows a very low yield and indicates that without positive FOBT results, it would be better to avoid colonoscopy.
- Symptom history (for example, weight loss, bloating, change in bowel habit) is not predictive and should be omitted from the program. Family history is of only limited value.
- Data systems for the invitation and testing process were reasonable; however, registry set-up and operational costs need to be considered.
- Data follow-up systems were inadequate.
- Some problem areas were identified in the pilot programs:
- Focus groups, questionnaire responses, and informal feedback indicate that the information in the kits and consent process was too complicated.
- Data collection was incomplete and slow.

The clinical data system was inadequate and there was a failure to collect complete colonoscopy data, including identification of people who had positive FOBT results but did not go on to have a colonoscopy. This raises legal and clinical care issues.

- Communications between the register, participants, and clinicians were often poor, perhaps due to the registry being physically and culturally separate from the clinical community.
- Quality assurance in every aspect of colonoscopy and histopathology (for example, training, feedback and monitoring, and pathological reporting) is critical.
- Quality control for the activities of family doctors was particularly hard to achieve (for example, frequency of visits, and how patients were selected for screening).

A major consideration in setting up a national colorectal cancer-screening program is the appropriate level of surveillance of people found to have polyps.

In Australia, the 2005 budget included federal funding of \$43 million over four years to initiate the national colorectal cancer-screening program. The program involves free biennial immunochemical testing, with follow-up colonoscopy through arrangements with public hospitals or private clinics (with perhaps some patient payment).

Australia's national screening program is currently in phased implementation, with people aged 55 and those aged 65 invited to participate (representing 12% of the overall target group of people aged 55 to 74). Australian estimates have concluded that screening starting at age 55 is more cost effective than screening beginning at age 50—a cost-effectiveness argument, given that randomized trials show a benefit with screening from age 50.

Ultimately, Australia's objective is to produce a high-quality, cost-controlled, and centrally organized colorectal cancer-screening program, though this remains dependent on further budgetary allocations.

Australia's program has been successful to date for a number of reasons:

- Key support was received from leading gastroenterologists who have made a difference as FOBT champions, helping combat the notion that FOBT is ineffective and that colonoscopy should be used instead.
- The Cancer Councils (equivalent to Cancer Societies) have been important allies.
- The National Cancer Control Initiative has played an important role in the development and conduct of the pilot programs in Australia.

The decision to use immunochemical testing is a particularly interesting aspect of the program. The program uses central organization and limited involvement of general practitioners; patients need to see their general practitioner to arrange a colonoscopy only if they have positive FOBT results, although they may consult them at any point.

Dr Elwood noted some of the factors that have had neutral or negative influences on the Australian screening program:

- Limited support has been forthcoming from patient advocates; Australia has not had anything like the strong advocacy from the Colorectal Cancer Association of Canada.
- State health departments were largely neutral and regarded colorectal cancer screening as a low priority issue.
- The fact that colorectal cancer affects both men and women approximately equally was seen by some people as an advantage, but by others as a disadvantage, as many cancer control programs in Australia have benefited considerably by being identified as women's issues.
- Industry's push was limited since FOBTs have not been seen as very profitable.
- Getting support through the federal budget is a complicated process.

Progress in Australia has been slow: it has taken 10 years to get a program that is now inviting 12% of the target population for colorectal cancer screening, Dr. Elwood noted. Over this time, the costs of colonoscopies in general have increased considerably, without the assessment and monitoring required of the new screening program.

Overview of Ontario's Colorectal Cancer Screening

Dr. Verna Mai

Director, Screening Programs, Division of Preventive Oncology
Cancer Care Ontario

Context is important in understanding Ontario's movement and progress towards a programmatic approach to colorectal cancer screening, said Dr. Verna Mai, also Chair of the CPAC Screening Action Group. Mai presented an overview of colorectal cancer incidence in the province, as well as Ontario's planned development of a population-based colorectal cancer screening program. This program will be the first of its kind in Canada.

Ontario has one of highest rates of colorectal cancer in the world. Though it is preventable, colorectal cancer is associated with high mortality rates. In 2003, the provincial government presented a plan for better health care, with a platform that specifically cited colorectal cancer screening as a priority to be addressed. Since then, much work has been done by Cancer Care Ontario on documenting data and analyzing provincial statistics. Since 2001, the number of billings for FOBT has risen; however in 2005–2006, the screening rate was modest, at around 12% of the eligible population aged 50 to 74. Ontario must put increased effort into raising awareness and raising colorectal cancer screening rates to tackle the disease, Mai said.

Of Ontario's population of 12.5 million people, 3.5 million—over 25%—are in the colorectal cancer screening target age group of 50 to 74. The population is served by over 10,000 family practitioners, 6000 of whom work in various primary care group models, which have as one of their aims the enrolment of patients currently without a family doctor. Over 300,000 colonoscopies are performed in Ontario every year.

Ontario has been working towards a population-based colorectal cancer screening pilot program for a number of years. In June 2003, Cancer Care Ontario and the Ministry of Health and Long-Term Care initiated a pilot project to test different recruitment strategies for colorectal cancer screening using the FOBT in Ontario. This pilot project examined whether colorectal cancer screening can be increased with FOBT without radically shifting models. The pilot looked at best practices in the areas of reinforcing guidelines and improving screening rates, as well as an awareness and education arm for the public and physicians. In June 2005, Cancer Care Ontario submitted its final report and proposal for an FOBT-based colorectal cancer screening program to the health ministry.

Ontario continues to see low colorectal cancer screening rates, although rates are slowly growing. Following submission of a program proposal in 2005, discussions ensued with the ministry on the best model for a population-based colorectal cancer screening program in Ontario, Mai said.

The 2005 final report on the pilot project demonstrated the need to develop a cohesive approach to colorectal cancer screening. The participation rate for the pilot project on population-based screening was deemed a failure because recruitment rates did not go up in either of the arms.

Some lessons learned from the pilot project include:

- The whole population needs to be targeted in the program model.

- Supports must be in place to make it happen.
- Only two-thirds of those who had positive FOBT results received follow-up, highlighting the importance of linking screening to colonoscopy services.
- Awareness of FOBT for colorectal cancer screening is still low. Physicians surveyed said they were following guidelines and recommending FOBT; however, the majority of the population surveyed said they had never heard of FOBT.

In January 2007, the Ontario government announced the launch of a provincial population-based colorectal cancer screening program beginning in the spring. The target population is men and women aged 50 and older, and family physicians and primary care professionals will have central roles in program delivery. For the average risk population, the FOBT will be the primary screening tool. Colonoscopy will be the follow-up tool used for those who have a positive FOBT result or are at increased risk because of a family history of colorectal cancer with one or more first-degree relatives. The program will be rolled out over five years.

Year 1 (2007–2008) will focus on:

- Colonoscopy capacity and expanding capacity to accommodate those at increased risk and those who receive positive FOBT results
- The development of clinical standards for colonoscopies and for the provision of FOBT testing at the laboratory level
- Building awareness and support among key stakeholders at the provincial as well as regional levels
- Establishing a provincial network to help develop a regional implementation plan
- Creating and delivering health professional educational materials, supported by clinical guidelines; partnerships with the Ontario Medical Association, Ontario College of Family Physicians, Ontario Pharmacist Association, and the Canadian Cancer Society
- Using media relations to raise public awareness and understanding of colorectal cancer screening and Ontario's screening program

Once the groundwork is in place, Year 2 (2008–2009) will focus on:

- A large-scale public education and social marketing campaign on colorectal cancer screening
- Development of branded, traceable FOBT kits that would be widely distributed to the public, primarily through family physicians and pharmacists in provinces (pharmacies are being explored as a key distributor of kits as a way of addressing the family physician shortage in Ontario)
- Development of a new information management system (such as Telehealth) to invite, track and follow up with patients
- Financial incentives to family physicians and pharmacists to help implement the colorectal cancer screening program

Regarding colonoscopy funding and increasing capacity, Cancer Care Ontario is contracting with hospitals to deliver additional colonoscopies for patients at increased

risk—those with a family history or positive FOBT results. Based on an early 2007 survey of hospitals on capacity, Cancer Care Ontario has been modelling a program on uptake and impacts toward determining the extra capacity hospitals can provide. New funding to support the additional volumes will begin in April 2007.

Reporting requirements for the screening program will include volume and quality measures, wait times; and details such as rate of cecal intubation, whether there was adequate bowel preparation, and adverse events (such as bowel perforation). New colonoscopy standards will be introduced in alignment with the new colonoscopy services and funding.

The FOBT kits will be the primary screening tool for average risk patients. Kits will be widely available through family physicians, other primary care sites, and pharmacies, and through Telehealth Ontario beginning in 2008–2009. Patients will self-test and send their FOBT kit in a stamped, pre-addressed envelope for processing. The FOBT results will be sent to the family physician and the central information system at Cancer Care Ontario. Family physicians will follow up with patients with positive FOBT results to arrange a colonoscopy. Those with negative FOBT results will be captured in the system and sent a reminder about repeat screening in two years. Individuals who are at increased risk (with family history of a first-degree relative with colorectal cancer) will be referred through family doctors for colonoscopy screening; patients with positive results for cancer would then enter the treatment system, while those with positive results for polyps would require regular colonoscopy surveillance.

The development and implementation of a population-based colorectal cancer screening program in Ontario has been a partnership between Cancer Care Ontario and the provincial Ministry of Health and Long-Term Care, Mai said. Such collaboration is essential in bringing together different expertise and aligning messages and strategies towards achieving the best outcomes.

Overview of Manitoba's Colorectal Cancer Screening Program

Marion Harrison
Director, Screening Programs
CancerCare Manitoba

Marion Harrison described Manitoba's provincial colorectal cancer screening program.

The Manitoba Cancer Care Screening Advisory Committee was established in 2003 to consider the National Committee recommendations on colorectal cancer screening and their implications for Manitoba. The advisory committee reviewed the current screening activity in the province based on medical claims data. The committee also surveyed gastroenterologists and surgeons about colonoscopy capacity in the province, and estimated costs related to different delivery models for colorectal screening.

Data shows that colonoscopy and FOBT rates in Manitoba increased over the last 20 years. Still, fewer than 15% of those in the target age group (50–74) are tested, Harrison said.

The committee also surveyed colonoscopists and endoscopists in the province who are doing more than 50 scopes yearly; more than half of those surveyed responded (35 out of

69 surveys were returned). The volumes reported by the colonoscopists and endoscopists represented about 75% of the provincial total, according to the claims data. Primary reasons for the colonoscopy/endoscopy services were diagnostic/therapeutic indications (54%); surveillance/follow-up (24%); and screening (21%). About 85% of survey respondents said they would commit more time to performing colonoscopies, but were limited by factors including space, equipment, and support staff. Most colonoscopies are done in hospital, so the global hospital budget is a limiting factor. Another issue raised in introducing a population-based colorectal cancer screening program is whether adequate capacity exists in the health care system for the follow-up required.

In July 2006 the Manitoba Cancer Care Screening Advisory Committee recommended the introduction of population-based screening for colorectal cancer, beginning with a pilot program to address operational issues. The committee recommended using the FOBT and targeting the average risk population.

In the fall of 2006, the committee submitted a Phase 1 Plan to the Manitoba Ministry of Health for a pilot colorectal cancer screening project. The program was announced by the Minister of Health in January 2007 and will receive funding as of April 1, 2007. The pilot is seen as the first phase of a province-wide, population-based colorectal cancer screening program.

Key objectives in the initial phase include:

- Evaluating uptake and acceptability of screening based on different recruitment methods among urban and rural residents; about 10% of the eligible population will be targeted through FOBT kits by mail and in-person recruitment
- Assessing access and compliance with follow-up colonoscopy for those individuals with positive FOBT results
- Developing a screening registry system, including identification of the specifications and costs of a province-wide database system
- Evaluating the impact of screening on primary care and specialist consultation, referral patterns, waiting times, colonoscopy services, and workforce issues to determine requirements for a province-wide program
- Establishing and implementing quality indicators and processes throughout the screening pathway and setting up systems that could be extended to a provincial screening program
- Developing, providing, and evaluating colorectal cancer screening information resources and educational support for health care providers and the target population
- Assessing privacy issues and ensuring compliance with the Personal Health Information Act

A key component of the Manitoba colorectal cancer screening program is a strong partnership with the Manitoba Department of Health, which provides names and addresses from the Manitoba Health Information Registry, allowing recruitment on an individual basis. The relationship is essentially one in which CancerCare Manitoba is seen to be delivering the colorectal cancer screening program on behalf of Manitoba Health. The population data gathered from the colorectal cancer screening program will be linked to the Cancer Registry.

The plan in Manitoba is to mail invitations and FOBT kits to 20,000 individuals between the ages of 50 and 74, in rural and urban areas. Participants will mail their completed tests to a central lab designated for diagnostic services related to colorectal cancer screening. Result letters will be mailed to participants and a designated primary care provider. Anyone with a positive result will be required to follow up with a colonoscopy; program staff will facilitate referrals to designated sites for colonoscopy.

Consideration is also being given to distributing FOBT kits directly through breast cancer screening programs to capture women in the target age group and increase uptake. The information system for the colorectal cancer screening program will be modeled on the province's breast cancer screening program. The platform will be enhanced to include modules for letter management, data entry of test results, and follow-up. Surveys and focus groups of both participants and non-participants will be conducted to determine why people choose to have colorectal cancer screening.

The program is expected to take four to six months to set up. Implementation, including mailings and data collection, will span 18 months and be followed by a six-month post-implementation and program evaluation period. Following evaluation and assessment of the pilot, a plan will be developed for province-wide implementation. Implementation will rely on expertise and working groups in several areas, including lab services, education, colonoscopy, information systems, and evaluation.

Status of Colorectal Cancer Screening Programs in Other Provinces

Heather Bryant remarked on the different approaches taken by different provinces. Participants from a number of other provinces described the progress being made in population-based colorectal cancer screening in their regions.

Nova Scotia

The government of Nova Scotia has announced \$300,000 in funding to Cancer Care Nova Scotia to help lay the foundation for a provincial population-based colorectal cancer screening program. While no commitment has yet been made to fund a screening program, this initial funding is expected to lead to a greater funding commitment in the province. In the next year, Cancer Care Nova Scotia will survey and assess capacity and capacity needs in the province, and develop a model for population-based screening. A program is expected in about a year.

Alberta

The Alberta Ministry of Health announced plans in mid-March to formally establish a colorectal cancer screening program in the province, based on recommendations made by expert groups in Alberta. The target population will be those at average risk, between age 50 and 74. FOBT will be recommended as the primary screening test, but patients will have the choice of other screening tests. The planned entry point for those in the target age group and population will be the family physician. A Web-based approach is being explored for the segment of the population—as much as 20%—that does not have a family physician. Alberta's screening program will be implemented over five years to allow time to build the province's capacity to meet increased demand for services. The objective is to reach two-thirds of the target population for regular screening.

The province has established an advisory committee with wide representation from professional groups and government organizations to help plan the implementation process. The Alberta Cancer Board plays a coordinating role, while the regional health authorities will provide the screening and follow-up services.

Work has also begun on developing a colorectal cancer screening information system. A draft list of indicators and data points has been identified and a vendor is in place to design software that would combine the information systems for the province's two existing cancer screening programs with the new program for colorectal cancer. An internal implementation team has also been formed to tackle programming on a detailed level.

Work remains to be done on education and awareness, and standards and guidelines. The pilot program will help identify the best approach for province-wide implementation.

In Calgary, the focus has been on building capacity and providing endoscopic services. Screening cannot be undertaken without consideration of the potential impact on other aspects of care. Calgary has faced growing demand for colorectal cancer screening over the past seven years, due to growing public awareness and demand for screening, as well as increased referrals. The growing number of outpatient procedures has put an increasing burden on endoscopic services, acute care, and management of symptomatic patients. Calgary is building a community-based endoscopy centre that will provide gastroenterological care, as well as polyps screening, FOBT, and primary screening for colonoscopy. The objective of this centre is to use the endoscopists' time in the most efficient way, by having other health care providers take on responsibilities such as assessment, pre-procedure counselling, and post-procedure follow-up. This setting will help build capacity through training additional people.

Saskatchewan

The province has established an internal committee to examine the development of a colorectal cancer screening program in Saskatchewan. The province will likely adopt an approach similar to Manitoba's program, given the demographic similarities. The committee has collected billing data to look at colonoscopies and capacity in the province and has received strong support to move ahead.

Announcements about screening programs in other provinces have sparked a media frenzy in Saskatchewan cancer screening. Capacity in the province to accommodate additional colonoscopies is being examined, and a pilot program is being planned in a region with both urban and rural components.

British Columbia

Screening for colorectal cancer in B.C. is currently covered by a protocol jointly issued by the British Columbia Medical Association and the Ministry of Health. The health care system provides sigmoidoscopy, colonoscopy, and FOBT, depending on the category that patients fall into.

The province is looking into implementing this protocol in a population-based colorectal screening program. A three-phase plan has been developed, with the initial phase focusing on infrastructure and implementation in a single geographical area, which will be rolled out in areas with a health authority and followed by provincial implementation.

The initial phases are expected to take 18 months each; a full provincial program will be feasible in three years.

The province has analyzed billing data, surveyed gastroenterologists, and assessed facilities in B.C., along with the proportion of time and effort spent on screening and colonoscopy. The province is also studying ways to improve participation and cost-reduction outcomes (cheaper cost-per-service than traditional delivery), including evaluating the effectiveness of different procedures (for example, FOBT through the general practitioner vs. FOBT through a direct mail system) within public and health care professional spheres.

Funding was approved in 2006 for the phased approach to program implementation. Evaluation and assessment continues pending a funding commitment from the Ministry of Health.

Quebec

The province's work on colorectal cancer screening continues to progress, with the National Public Health Institute of Quebec currently under mandate from the Ministry of Health to examine the feasibility of a provincial population-based screening program. The province recognizes the scientific evidence of the benefits and gains of colorectal cancer screening; however, reservations exist about whether a 33% mortality reduction can be achieved. Currently, FOBT is not being used.

Through analysis of randomized studies, the Institute has identified three primary challenges to be addressed: participation rate, colonoscopy capacity, and colonoscopy complication rate. A key concern is that a colorectal cancer screening program needs to be considered from an integrated health care perspective and should be achieved without being detrimental to other patients. Another outstanding issue is how to address screening for a higher-risk asymptomatic population.

The institute is currently examining colonoscopy complication rates, actual colonoscopy capacity of hospitals in Quebec, and the potential to increase capacity within the current set-up. A pilot project on increasing colonoscopy capacity will be launched in Montreal. Quality assessment and wait time assessment will be built into the pilot.

A survey of the population on their attitudes and knowledge regarding colorectal cancer was performed and results are now being analyzed.

Discussion

One of the critical factors for success is how to engage government not just on screening guidelines, but also in supporting a screening program and committing to a provincial population-based colorectal cancer screening program.

It is crucial to engage ministry officials early, establish good relationships, and ensure that all parties start discussing possible solutions with the same basic knowledge about what is effective elsewhere, Mai said. The pilot project approach taken by some provinces helps get a program started while demonstrating its feasibility. The pilot project in Ontario helped answer many logistical questions and highlighted a multitude of issues.

Basic education is essential, Bryant agreed. Governments operate under different pressures than those in health care, but ultimately want to do what is best for the population. Focus on the objectives and benefits of colorectal cancer screening is important. A compelling approach is to underline that provincial population-based colorectal cancer screening is recommended; effort must be put into reaching the target population. The alternative is inefficient, chaotic, and expensive.

Regarding colonoscopy training and capacity, one participant said that a study on access by the Canadian Association of Gastroenterologists showed poor timeliness for FOBT evaluation results. Hospital endoscopy units are brimming at capacity. What is being done on a provincial basis to provide more infrastructure, and to encourage more training of people in these programs?

Marion Harrison said the Manitoba pilot project is looking at capacity to ensure that the system does not get overwhelmed initially. Endoscopists have confirmed their capacity to take on additional numbers, but say they are restrained by the availability of facilities. The pilot project will inform the province on the need for more support and resources to accommodate additional colonoscopies.

Facilities were also identified as a problem in Ontario, with the understanding that increased funding for infrastructure support could lead to a greater volume of colonoscopies, Mai said. Capacity must be enhanced and issues such as wait time and wait time guarantees need to be explored.

CancerCare Manitoba has found that by acting as a “patient navigator” and facilitating follow-up and referrals (rather than referring patients back to their primary care provider), the organization has been able to dramatically decrease wait time. In the role of patient navigator, CancerCare Manitoba is also better able to identify roadblocks and provide input into addressing problems.

The expansion of colonoscopy services and decisions to make colonoscopy the primary screening modality in Alberta is a massive undertaking, a participant said. What evidence is there about the effectiveness of colonoscopy for screening? Another participant said indirect evidence shows that colonoscopy does reduce cancers, but not at level of ICT. Practitioners drive this course on the ground with public support, and the province is fortunate to have the resources to fund program expansion, the participant said.

Components of an Organized Screening Program

Dr. Heather Bryant

Vice-President and CIO, and Director of Population Health and Information
Alberta Cancer Board

Different paradigms and program elements must be considered for colorectal cancer screening, said Dr. Heather Bryant. The National Committee on Colorectal Cancer Screening advocates making screening widely available to Canadians.

To ensure quality screening that maximizes benefits and minimizes potential risks, screening should ideally take place within an organized and structured environment, with the following elements in place:

- Clear, concise, and understandable information for patients and physicians on the

- risks and benefits of screening and on the administration of the test
- Informed consent following personal consultation with a family practitioner or equivalent
 - Standardized protocols and procedures with a single entry test and options for follow-up
 - Systematic tracking and evaluation of all screening invitations, testing frequency, results, follow-up, and outcomes

Bryant said the National Committee understands that resources for screening must be built up; however, given the disparity in human and financial resources, provinces may choose to phase in organized screening as resources permit.

The committee recommends that screening be offered to adults aged 50 to 74, using FOBT as the entry test. Annual screening is expected to result in greater mortality reduction, but requires increased resources. Screening should be followed by colonoscopy, with options of flex sigmoidoscopy or barium enema where this is not possible. Public awareness must also be improved; information for primary prevention and clear guidelines on symptoms should be part of the screening program. Quality assurance is critical, with monitoring and standards needed to minimize risk.

Following a general education and public awareness campaign and the evaluation of initial screening, active recruitment should begin—for example, through invitations and FOBT kits sent by mail. Including information with the kits on issues such as complication risks is important.

Screening Stream Breakout Sessions

Facilitator Caroline Kealey outlined the themes to be explored in the breakout session:

- Public education, promotion, and prevention
- Integrating screening and diagnosis, and coordinating follow-up
- Quality assurance, monitoring, and evaluation

Participants were asked to identify implementation challenges, possible solutions, and lessons learned, including best practices and existing models of success.

Public Education, Promotion, and Prevention

Conveying to the public the importance of colorectal cancer screening is the first step in colorectal cancer prevention and mortality reduction. Participants discussed the importance of developing a national message that transcends regional program differences. Many felt that a national approach is needed for colorectal cancer education, so that information is consistent no matter where one lives in Canada. However, while participants said the message should come from the national level, they also noted the challenge of getting different stakeholders to work together.

Much of the legwork in population-based colorectal cancer screening has already been done, as evidenced by success stories in Finland and the US. One participant noted the

striking difference between the US and Canada—the US colorectal cancer screening rate is over 50%.

Participants also discussed the difficulty of tackling the subject of colorectal cancer in public education—more so than breast or lung cancer. They cited, however, the Underwear Affair at the Segal Cancer Centre at the Jewish General Hospital, and the Booty Bash for cancers below the belt, held in Toronto—and identified both as fun and successful campaigns.

Celebrities can have a great impact in public awareness campaigns, participants said; they suggested finding a Canadian celebrity affected by colorectal cancer who could put a face to the disease.

Reaching the segment of the target population that does not have a family doctor is a key challenge. One possible solution is outreach through the pharmaceutical system: information on colorectal screening could be provided on prescription printouts to clients in the target age group. Pharmacies could also distribute test kits that would include information on colorectal cancer screening. Public education beforehand is essential, however.

Participants pointed to success models such as the public awareness campaign by the Canadian Breast Foundation, which included a road trip and powerful media campaign. The campaign's success was reflected in increased mammography participation rates. The campaign on cholesterol awareness, encouraging everyone to “know their number,” was also effective.

Participants identified key challenges and objectives for public education:

- Develop clear, consistent messages that are not confusing to the public.
- Create a catchy slogan for the colorectal cancer campaign.
- Overcome the stigma or perceived “ick” factor.
- Engage patient champions to get an emotional response from Canadians.
- Organize a Weekend to End Colorectal Cancer.
- Engage health professionals, educators, pharmacists, doctors, nurses, and advocacy organizations to help spread the message.

The public education challenge is threefold, a participant said: to convince Canadians that colorectal cancer is an issue; to convince them that something can be done about it; and to convince them that screening is not as bad as it seems.

Integrating Screening and Diagnosis, and Coordinating Follow-up

Funding is a major challenge for the implementation of colorectal cancer screening and the coordination of follow-up services, participants said. Finding funding to support follow-up services that will have to be delivered alongside a screening program is critical. One participant challenged the notion of a lack of funding to support screening, and called for increased transparency and accountability, as well as innovative ways of finding funds for colorectal cancer screening within existing budgets.

Another challenge is implementing population-based colorectal cancer screening without putting too much additional burden on health care professionals. Patients should be compelled to take an active role.

A participant noted that FOBT screening programs could present potential logistic and legal challenges. For example, mail-in samples contain DNA, and a protocol may be needed for their collection and disposal. Another participant said industry is exploring molecular diagnostics, with one test having been shown to reduce mortality.

Remaining knowledgeable and up to date on new products and developments is critical. Participants recommended developing a formal body to look at new technology and research related to colorectal cancer screening. Training more people in all disciplines—including internists, general practitioners, surgeons, and gastroenterologists—to accommodate the growing demand for screening, diagnostic, and follow-up services is also critical.

Gathering statistics and accessing information for analysis also presents a significant challenge. Better linkage among health care databases is necessary, but considerable bureaucratic barriers exist. Each province has its own terms of access for health care data, so developing a national database on colorectal cancer may be difficult. One solution might be to piggyback onto the breast screening information system by adding a field for tracking colorectal cancer.

Capacity also presents a challenge, and issues and solutions will vary from province to province. In some cases, increased capacity can be achieved by using endoscopic services at private centres. One participant recounted an innovative approach to cervical cancer screening in Mexico, where family practitioners in rural regions are performing culposcopies with a video link to an urban hospital centre, where a gynecologist observes.

Provinces will have to determine where to invest resources for the greatest impact. For example, building endoscopic capacity needs to be balanced with more selective colonoscopy, based on risks and costs. Each province must determine the most feasible and practical way to introduce a population-based colorectal cancer screening program.

Participants identified some key challenges and objectives:

- Identify barriers to colorectal cancer screening.
- Coordinate between screening, diagnosis, and follow-up.
- Coordinate information and links between the databases of different groups.
- Share best-practice methodologies such as standards by Canada Health Infoway and Canadian Institute for Health Information (CIHI).
- Model the colorectal screening system on the breast cancer screening system.
- Develop capacity to provide follow-up services.
- Coordinate patient follow-up and referrals to decrease wait time and increase quality control.

Quality Assurance, Monitoring, and Evaluation

Quality assurance, monitoring, and evaluation aim to ensure that program objectives are met. Participants noted that one of the challenges of population-based colorectal cancer screening is that the target group is that the average risk population—men and women age 50 to 74—not the highest risk group. Establishing a population registry on the national level would provide data useful for cross-program analysis and the development of standards and benchmarks, and possibly new targets.

Evaluation and quality assurance are important at each step along the screening pathway, participants said. Program variations across provinces make evaluation of colorectal cancer screening in Canada difficult. For example, some provincial screening programs do not include follow-up for positive results. One participant suggested taking advantage of the heterogeneity in approaches, if commonalities are also built in from the start.

Participants discussed quality assurance through professional accreditation. Accreditation would apply to both colonoscopy centres that are part of the colorectal cancer screening program, as well as to health care professionals. Colonoscopy centres and professionals must demonstrate their ability to practice to standards, a participant said.

Infection control standards and quality assurance around infection of equipment are critical. However, standards are not widely accepted by all providers. Standards, monitoring, and evaluation are also important in rural health regions, which often fail to evaluate and measure activities. Quality assurance surrounding patient care is also important; for example, excluding patients who are at risk from colonoscopy, or ensuring that patients receive follow-up within a reasonable timeframe.

Standards are needed as well for tracing and feedback, participants said. One participant suggested that ranking hospitals in terms of endoscopic treatment and outcomes would drive them to evaluate and improve their services. Participants also discussed the value of designated screening and colonoscopy centres, which would centralize activities and allow for better monitoring and quality control. A central reporting system would facilitate data collection and measurement, particularly when multiple professions are engaged in colorectal cancer screening. However, incentives may be necessary to encourage physicians to participate and fill out the forms.

Participants identified a number of quality assurance indicators for a colorectal cancer screening program: participation, compliance, detection rates, interval rates, complications, follow-up for positive results, and wait time.

They also identified the following key challenges and objectives related to quality assurance, monitoring, and evaluation:

- Use a central registry for monitoring, evaluation, and quality assurance.
- Identify the target population, which can change as new standards and benchmarks emerge.
- Develop programs jointly across provinces, and compare best practices.
- Invite gastroenterologists into the fold for screening and quality assurance.
- Provide incentives for engaging in data collection.
- Anticipate progress and innovations in the field, such as new and better screening

tests.

- Obtain national guidelines and consensus on quality assurance.
- Determine the mortality rate to which professionals will hold each other accountable.
- Ensure transparency and accountability at all levels.
- Examine the potential of alternative health care providers to perform endoscopies.

Screening Stream Wrap-Up

Public Education, Promotion, and Prevention

One of the challenges of educating the public on colorectal cancer screening is to develop clear, consistent messages, using partnerships with key stakeholders. For example, the B.C./Yukon breast cancer screening program involved many partners who helped raise awareness and disseminate information on the benefits of screening. The cholesterol awareness campaign in the US was branded with the catchphrase, “Know Your Number.”

Raising awareness of colorectal cancer in Canada will require overcoming the stigma surrounding bowel health and disease and making colorectal cancer part of the everyday vocabulary. Patient champions are needed to achieve this objective; testimonials by familiar faces are an effective way to get an emotional rise out of Canadians. An educational campaign can be applied to a Weekend to End Colorectal Cancer.

Engaging health care professionals in promoting colorectal cancer screening will require connecting with health care educators, medical professionals, pharmacists, patient associations like the Colorectal Cancer Association of Canada, and community organizations.

Integrating Screening and Diagnosis, and Coordinating Follow-up

Integrating colorectal cancer screening, diagnosis, and follow-up across Canada will require bringing together information from all players and linking their databases. The study of existing methodologies for data linkage would be useful in this regard. Best practices include the electronic medical records system in Edmonton, which has the capacity to link across databases. Canada Health Infoway and CIHI would be good vehicles to put the development of a national approach to colorectal cancer screening on the national agenda.

Another concern is determining whether screening programs should administer FOBT or provide the public with choice towards encouraging the highest participation rate.

Screening and follow-up capacity must also be addressed. There is a lack of skilled human resources in Canada and an acute need to train more health care professionals—and increase the number of health care professionals at all levels. Selective use of colonoscopy would make the system more efficient and avoid duplication. For greater efficiency, tracking, and quality assurance, follow-up is better done through screening programs than through family physicians.

Quality Assurance, Monitoring, and Evaluation

Quality assurance, monitoring, and evaluation of colorectal cancer screening programs are best done through a central registry. Program issues that need to be resolved early on include determining the best test (FOBT vs. colonoscopy) and defining the target population. A central registry and program are essential for analyzing screening and follow-up processes, as is having quality assurance at colonoscopy clinics, for both procedures and medical staff such as endoscopists.

Another major challenge is the overall lack of standards for quality, monitoring, and evaluation of colorectal cancer screening. Quality assurance is essential throughout the screening cascade, from delivery of the tests to the target population, through test completion, laboratory aspects, and colonoscopy. The time is right to develop screening standards jointly across provinces and their programs; the work done around breast cancer screening will provide a good model.

Variations in programs across provinces may present challenges, but they also represent an opportunity for monitoring, evaluation, and program comparison, to determine best practices.

Another challenge is the need to engage gastroenterologists in screening quality assurance. It may be necessary to find incentives and mechanisms, such as pay-for-performance, to get them to meet screening standards.

Finally, it is important to stay current on innovations in screening products.

Discussion

Barry Stein suggested that the components of an organized screening program could be brought before the provinces to help develop a national consensus on aspects such as programming, standards, quality assurance, and key messages. The Canadian Association of Gastroenterology is leading an effort toward nationalized quality assurance for endoscopy, another participant said.

Being prepared for new research and innovations is important, as is building into the system a mechanism for evaluating emerging technologies such as genetic tests, imaging tests, and protein tests, a participant said.

Quality assurance also applies to recruitment rates, percentage of individuals who return for follow-up, and false positives or negatives, a participant said. It is important to look at quality assurance globally. As standards are developed, the screening community will need to identify the percentage of mortality to which they will hold themselves accountable and build it into the system.

A family physician and health care researcher said he was offended by the suggestion that family physicians misperceive patients' responses and the "ick" factor. He acknowledged, however, that different approaches are being taken—some programs involve family physicians in the primary screening process, while others do not. This is an important issue that will have to be resolved, he said, adding that he is coming to believe that the best approach would be population-based screening not involving family physicians. More discussion is needed within the community, however.

A medical oncologist said he has never seen a health budget, hospital budget, or funding agency in which all funds are used with maximum efficiency. He questioned the notion that there are no funds to start a screening program. “I believe the funds are there and we should be able to access them. We’ve been led to believe that there is no money, but there is no transparent evidence to support that,” he said.

Another participant concurred, saying that budget transparency is a problem. The variety of options and services available in different provinces (e.g., imaging services, referral clinics, and private surgery centres) is also a major issue.

Scarce human resources and capacity for follow-up raise the need to examine alternatives such as having health care providers either offer endoscopy services or share the work processes. Pan-Canadian guidelines on indications and intervals for colorectal cancer screening would also be useful.

Access Stream Panel Presentations: Achieving Equitable Access to Successful Outcomes in Colorectal Cancer

The Use of Economic Evaluation Methods to Inform “Fair” Decisions

Dr. Stuart Peacock
Senior Scientist, Centre for Health Economics in Cancer
B.C. Cancer Agency

Dr. Stuart Peacock’s role was to help describe the traditional approach of health economics and how it is used as a decision tool. He defined economics as a tool for distributing scarce resources and making choices. Economic evaluation assists decision-makers with those choices, with the aim of maximizing the well being of the community. It identifies costs and aims to identify fair choices by comparing the costs and benefits of health programs. The prerequisites for economic evaluation are related to a program’s efficacy and effectiveness. Weighing those factors, the question becomes, “Should a program be provided, given other demands on the health care budget?”

Economic evaluation seeks to provide an alternative based on a program’s impact on the community’s overall health status and health care costs. Peacock noted the increasing call to capture quality of life and survival outcomes.

He reviewed the different types of economic evaluations, noting that cost-minimization analyses, where only the “cost side” is evaluated assuming equal effectiveness, are rare. Cost-effectiveness analyses are problematic since benefits are not explicitly valued. The logic of economic evaluation requires a comparison between at least two interventions where cost (expressed in dollars) per unit of benefit (e.g., expressed as life years gained—LYG) is compared between two interventions (e.g., drugs). He reminded the group that health economics is “...is not about cutting costs but about maximizing resources.”

Cost-utility analyses adjust LYG for their quality to yield a measure known as Quality Adjusted Life Years (QALYs). This comes from an economic desire to compare across a

broad range of programs, and look specifically at survival and quality of life. Cost-benefit analyses are not common. They measure both costs and benefits in dollar terms only.

Peacock illustrated the use of QALYs with a graph of quality of life vs. life years for end stage renal failure. Dialysis extends the lives of patients by 14 years and improves their quality of life. Transplants, however, are even better in terms of improving survival and quality of life. QALYs gained with transplants would therefore be higher.

Peacock reviewed the basic steps in economic evaluation. First, the study question and the perspective from which it is being asked (e.g., from a budgetary, personal or societal perspective) must be defined. Next, the costs and benefits are identified, measured, and valued. Those costs and benefits are then analyzed, focusing on what are called incremental, or marginal costs incurred to achieve an incremental benefit. Finally, incremental cost effectiveness ratios (ICERs) are determined to help inform decisions of relative value. He added that ICERs are often used by policy makers to define funding thresholds, but these thresholds are set arbitrarily.

Peacock explained the different recommendations for the adoption of new technologies by using a quadrant graph (2 X 2 table) of costs on one dimension (higher vs. lower) and benefits on the other (higher vs. lower). For instance, if a new technology costs more and produces less benefit than the alternative, or costs less and produces more benefit than the alternative, then these are clear losers and winners respectively, making the decisions easy. The problem lies in the quadrants where more benefit is associated with higher costs, or where there is less benefit to an intervention but with favourable costs. Almost all resource allocation problems lie in these quadrants.

That is the theory; what is the practice? Many jurisdictions now require an economic evaluation for reimbursement decisions, primarily for drugs. Whether pricing is linked to reimbursement varies with jurisdictions.

Giving the example of the Australian Pharmaceutical Benefits Advisory Committee (PBAC) and the National Institute for Health and Clinical Excellence (NICE) in England and Wales, Peacock noted that the reports on this type of evaluation have been broadly positive. Economic evaluations are also on the increase in Europe, where more and more countries require some form of economic data for decision-making, analyses, and validation.

Decision-makers use a range of thresholds. The PBAC, for example, uses an incremental cost per additional life year gained of \$40,000 (remember that this is an arbitrary threshold). Drugs below that threshold are recommended for adoption. Peacock noted that in Australia, price is related to reimbursement decisions. Above this threshold is a “variable region” where drugs could be recommended at the manufacturer’s suggested price, recommended at a lower price, or rejected.

Peacock noted that although economic data are important, clinical benefits are still paramount. On the other hand, with a large budget impact, economic analyses play a more important role. He pointed to the difficulty of applying the results of an economic evaluation from one jurisdiction to another.

Total refusal of a drug or program on the basis of economic evaluations is rare. A recommendation tends either to lead to restrictions in use or recommendations about

price. Of the first 100 technologies evaluated by the PBAC, the first 23 were cancer drugs that were not restricted in any way.

Peacock summarized by noting the increase in litigation by pharmaceutical companies when they are asked to lower the price of a drug. He also reminded participants that economic evaluation and data are just two pieces of the puzzle; other criteria, such as the seriousness of a condition, as well as “the political dimension in these decisions,” also play a role.

Do Current Economic Evaluation Models Inform Fair Decisions?

Dr. Amiram Gafni Professor

Centre for Health Economics and Policy Analysis (CHEPA)

McMaster University Faculty of Health Services

“The question is whether the flaws—and which ones—in the economic methods themselves, or the oversimplification of those methods, are responsible for the perceived or real lack of usefulness of this body of knowledge,” said Dr. Amiram Gafni. When economics is chosen as the mode of thinking for decisions about resource allocation to and within health care, the principles of the discipline must be followed, he said.

Gafni discussed the concept of efficiency, which stems from the reality of scarcity (i.e., whatever resources are available, they are insufficient to support all possible activities). Health care systems that aim to maximize the health of the population from available resources must make choices (i.e., what to do and what not to do). By choosing to use resources in one way, we forgo the opportunity to use them in a different way—this represents opportunity costs. Resources are used efficiently if and only if the **value** of what is gained in using the resources in the chosen way is greater than the **value** of what is foregone by not using them in another way. This is the notion of economic efficiency.

“I highlight the word ‘value’ rather than what we produce,” noted Gafni, indicating that fairness is integral to economic evaluation. Also, judging the success of economic evaluation “depends on where you want to go; if you don’t know, it doesn’t matter.” However, the goals of cost-effectiveness analyses (CEA) are known—they help decision-makers in a way that maximizes the community’s health from available resources. Thus, “we can judge if we have arrived.”

Gafni described the analytical tool of CEA, noting that it uses the incremental cost-effectiveness ratio (ICER), which is calculated by dividing the differences in costs between two programs by the difference in outcomes.

ICER is just a number, Gafni said. To know if a new intervention with a given ICER is worth supporting, decision rules are needed. The “league table approach” organizes programs and relative ICER values in descending order, while the “threshold approach” focuses on an absolute value of the ICER as the threshold. If there is a threshold like \$45,000 per QALY, the adoption of programs or drugs will depend on where their ICER falls with respect to that threshold.

Are the current decision rules working? Gafni offered the example of the choice between four new drugs. If the cut-off is at an ICER of equal or less than \$45,000, then only the drug that falls at or below that threshold would be selected. But “what you really need to

know is the total health gains and the cost,” Gafni said. In fact, the cost effectiveness ratio is not very helpful in determining the best allocation of resources because, for example, it does not tell whether the new program, which has an ICER lower than the threshold, requires additional resources that exceed a given budget. It also does not tell where the additional money will come from, and thus what are the opportunity costs of diverting resources to the new program.

The decision rules are helpful under certain conditions, but these conditions do not describe the reality that decision-makers face. It is interesting to note that those who want to use the model, in spite of this unrealistic assumption, do so in a way that is inconsistent with the model. The model tells us that the threshold ICER is equal to the ICER of the last program funded and is a function of the size budget (i.e., the larger the budget the larger is the threshold ICER). The latter implies that ICERs will differ by province, as provinces have different budgets.

Despite the fact that information is lacking, that a comprehensive league table cannot be produced, and that the value of the threshold ICER cannot be determined from the information available to the decision-maker, many have used the “arbitrary threshold” approach.

Calling the lack of justification for various threshold ICERs proposed, “the silence of the lambda,” Gafni noted that these thresholds have ranged from CAN \$20,000 to US \$265,000. In 1992, for example, Laupacis *et al.* suggested an ICER of \$20,000. The authors’ reference was a 1972 paper from California. Yet in a recent interview the lead author acknowledged that the number was made up.

Gafni said matters of efficiency could not be separated from matters of affordability: separating “value for money” from “affordability” cannot be done. Value for money is determined in relation to what that money can purchase; therefore, whether a program represents value for money is determined by the opportunity costs.

In the pursuit of efficiency, Gafni proposed that integer programming (IP) offers an approach for decision-makers, without the need to subscribe to unrealistic assumptions. He cited several papers that support mathematical programming techniques for maximizing health outputs. However, he cautioned that IP requires a lot of information and can become very complex.

Acknowledging the lack of data, Gafni proposed “a second best solution,” whereby the objective is modified from optimization to unambiguous improvement. To accomplish this, a proper, unambiguous measure of outcome is used. Then a program (or programs) that can be cancelled must be found to make resources available to operate the new program. Candidate programs for cancellation are those where the benefits forgone are less than the benefits gained from implementing the new program.

Gafni also talked about the relationship between efficiency and equity (i.e., fairness). He said that equity is an important consideration in health care decisions, although it is often left implicit. Every decision that talks about efficiency also involves equity and fairness, because efficiency involves the maximization of an objective that, by default, already incorporates equity considerations, subject to a constraint.

For example, the policy objective underlying the QALY literature is the maximization of the community's health. "A QALY is a QALY regardless of who gains it and who loses it." Gafni said this "seems like a great statement, but at a closer look, it means that young people have more QALYs than older people and that rich people live longer and healthier life than poor people." This implies that treatments aimed at younger people or richer individuals should be favoured, "if we do not care where we get our QALYs."

The proper process is as follows: Once the equity statements are chosen, they can be incorporated into the underlying model of constrained maximization, as an additional constraint on the system or into the objective function. Gafni suggested that this approach brings transparency to the system and gives explicit and systematic consideration of the opportunity costs of pursuing the chosen equity considerations.

"We have to lay [equity statements] on the table," said Gafni, noting that they have to be applied in a consistent matter that holds decision-makers accountable.

Using the drug Riluzole as an example of equity in action, he noted that NICE appraised the drug at between £34,000 and £43,000/QALY. Even though the NICE threshold (£30,000/QALYs) was exceeded, the recommendation was made to introduce Riluzole. NICE referred to severity of the condition and short life span as important factors. These special considerations are, however, already incorporated into QALYs.

Gafni's conclusion is that the economics discipline provides useful tools that are consistent with the goal of maximization of the community's health from available resources able to take into account the chosen equity criteria.

To answer his question of whether the flaws in the economic methods themselves or the oversimplification of these methods are responsible for the perceived (or real) lack of usefulness of this body of knowledge, he quoted A. Maynard: "Health economists, while seeking to colonize the clinical mind, may have lost their disciplinary head."

Drug Approval and Reimbursement Mechanisms in Ontario

Dr. Bill Evans

President, Juravinski Cancer Centre, Ontario

Regional Vice-President, Cancer Care Ontario

"The problem we are facing is only getting worse," said Dr. Bill Evans, who noted that cancer is increasing steadily, at 3% annually. The population is both aging and increasing; moreover, a large number of aging baby boomers will get cancer. These demographics and the cost of drugs will have a significant impact on the health care system.

Evans commented on the steady increase in treating individual cancer cases, indicating that when costs in Ontario's New Drug Funding Program (NDFP) are aggregated, there is a double-digit rise. In reality, however, the absolute increase equates to a small amount of money, most of which goes to intravenous cancer drugs. It is the rate of rise that has caught government's attention.

The drug approval process is complex. It begins with Health Canada, which evaluates a drug's safety, quality and efficiency after the manufacturer has made a New Drug

Submission. Drug manufacturers hope to get an unconditional Notice of Compliance (NOC), but even if they do, provinces may not allow reimbursement, noted Evans.

A conditional NOC means that a drug can be sold, but more information (for example, another trial to define efficacy) is required before the product can be fully marketed. A Notice of Deficiency prohibits companies from marketing entirely. A cancer drug almost always gets a priority drug review since either no similar drug is on the market or the new drug shows a significant increase in efficacy or decrease in risk. However, while the target for priority reviews is 180 calendar days, “this is not realistic.”

Outlining the essential elements of a Health Canada drug review, which includes various quality, non-clinical, and clinical aspects, Evans noted that the list of review criteria is long, though it is the same one used by the US Department of Agriculture and the European Drug Agency. The same drugs have generally passed through reviews in the US and in Europe long before the drug reaches Canada, because those countries represent a much larger market for manufacturers. One could ask why Canada is repeating the same reviews, Evans said.

Oral and intravenous drugs are reviewed separately in Canada. Once an oral drug has received an NOC, it goes through the Common Drug Review (CDR) where a multidisciplinary committee reviews it. The Canadian Drug Advisory Committee (CDAC) includes internists, pharmacists, one medical oncologist, health economists, and pharmacologists who consider a drug’s clinical efficacy and its cost effectiveness. It reviews evidence in various forms from industry, and internal reviews from the Canadian Agency on Drugs and Technologies for Health (CADTH); it has sometimes looked to the Cancer Care Ontario (CCO) guidelines.

The strength of the CDR is that it is evidence-based, uses internal and external reviews of clinical and pharmaco-economic evidence, does not rely solely on industry submissions, and is transparent in its decision-making process. Decisions and the reasons behind them are posted on the CDR website.

CDR decisions, however, are not binding on the provinces, which make their own recommendations about whether oral and IV drugs should be placed on the provincial formulary. Therefore, while a CDAC “no” means no, a “yes” means maybe.

Evans explained Ontario’s former approval mechanism for oral drugs. First, submissions illustrating drug efficacy and cost effectiveness were made by industry, and were reviewed by a committee. The committee, composed of medical experts, clinical pharmacologists, and health economists, considered factors such as clinical benefits, availability of alternative therapies, and cost-effectiveness.

A drug was funded not because government wanted it but because the expert evaluation was positive. The committee wrestled with the challenge of judging the clinical and pharmaco-economic information in light of existing evidence to arrive at a fair and reasonable decision.

The approval process for intravenous (IV) anti-cancer drugs differed in that cost effectiveness was not considered and the CCO made recommendations on the basis of clinical evidence provided by the province’s clinical practice guidelines. The economics of the drug “were figured out later.”

Evans described the practice guideline development cycle, noting that numerous internal and external reviews occur once the CCO PEB (Program in Evidence-based Care) decides to do a review. The guidelines can then inform policy and practice. CCO's website, www.cancercare.on.ca, provides practice guidelines for using or not using a particular drug. The process is transparent.

These two approval processes existed prior to 2004, but as Evans noted, it was not logical to have two separate streams, one considering cost effectiveness and the other not. As a result, a joint review mechanism—the aligned CCO-Ontario Drug Benefit Program (ODB) drug approval process—was devised to review both oral and IV anti-cancer drugs that have an NOC.

In this new process, the manufacturer still makes a submission with a cost-effectiveness analysis. Decision-makers look at this and at practice guidelines. Clinical benefit is the dominant determinant even if the cost of the drug is high. Evans noted that Ontario's Ministry of Health and Long-term Care have eventually approved every drug that was recommended.

The advantage of Ontario's NDFP is that it ensures all Ontario cancer patients have equitable access to new and expensive IV cancer drugs, he said. New, reviewed cancer drugs, in contrast to others, are placed on the Ontario formulary and are reimbursed if compliant with evidence-based guidelines. This link is unique to the NDFP.

With the *Transparency Act*, or Bill 102, the CEO of the ODB can approve decisions from the Committee to Evaluate Drugs (CED) in a more timely fashion. The process will be transparent, with patient representatives, Web postings of decisions and their rationale, and the formation of a Citizen's Council.

Other activities to improve the drug approval process include an effort to standardize pharmaco-economic evaluations for anti-cancer drugs between the National Cancer Institute of Canada (NCIC) and CADTH, and clinical trials for prospective collection of resource use data by the NCIC Working Group in Economic Analysis.

The Payer's Dilemma: Provincial Response to Rising Costs in British Columbia

Dr. Susan O'Reilly
Vice-President, Cancer Care
British Columbia Cancer Agency

Unlike Ontario, British Columbia funds comprehensive drug cancer treatment for both oral and IV and other injectables in a single drug system, Dr. Susan O'Reilly explained. PharmaCare, the provincial medical plan, has nothing to do with cancer drugs.

The British Columbia Cancer Agency (B.C.CA) provides treatment in four full-service cancer service centres and 60 other regional centres. The B.C.CA also covers take-home cancer drugs. Hospitals are then reimbursed for the drugs, noted O'Reilly, adding that the B.C.CA "gets excellent prices."

The B.C.CA has access to a great deal of information that helps with priority-setting, since all cancer patients are registered. Every time a patient is treated, that information goes into a comprehensive oncology drug database.

British Columbia's oncology drug budget has grown by about 20% per year—an increase that is causing alarm. Normally, the annual rate of increase is 2%. O'Reilly questioned if the equitable distribution of resources is reasonable, in light of this.

In 2004–2005, the number of patients receiving cancer drug treatment was 26,000; it has risen to 30,000, an annual increase of 6%. This is more than double the incidence rate; O'Reilly attributed it to the fact that people are staying on drugs longer than in the past.

O'Reilly described the iterative cycle involved in drug budget management. As with Cancer Care Ontario, guidelines and clinical information drive the process. The whole process “is kicked off by a guideline change,” she said, noting that various groups continuously review world literature. Whenever a significant change from well-conducted clinical trials appears, they come forward with proposals for funding and implementation. The proposal could be for a new drug or the expansion of an existing one.

Once the tumour group reaches a consensus, a proposal can go forward. The group completes a template only once a year, providing only one occasion for a breakthrough drug. Once the proposal is submitted, careful consideration of the pharmaco-economic impact takes place.

This has been the process for the past 10 years, noted O'Reilly, but there is no ready access to cost data—that information is difficult to get from government ministries. The process also involves an arm's length review by the Priorities and Evaluation Committee, which includes health economists and physicians of various backgrounds. That committee does a formal evaluation similar to the new interprovincial review process, and looks at current policies, the evidence, risks and harms, and resource impact, among other factors. The panel provides a ranking of proposals that enables the B.C.CA to recommend or reject.

“We can't master how to compare curative and non-curative (palliative) drugs,” said O'Reilly, adding that those drugs are currently reported separately. The report drives the decision-making process.

To do their job well, the PEC works by a set of guiding principles. For example, the scientific review has to be evidence-based, deliberate about fairness, timely, and clearly defined. It must also include a pharmaco-economic/cost-benefit evaluation. Once a decision about a drug is made, the B.C.CA immediately launches an education program aimed at physicians and patients. The latest information is also posted on the B.C.CA website.

The principles also outline universal access for eligible patients, compliance for the appropriate prescription of a drug, and the monitoring of drug use. According to O'Reilly, the best part of this provincial process is the periodic evaluation and the population-based outcome.

The B.C.CA's data sources include its own oncology drug databank, the provincial tumour registry, treatment data from the B.C.CA provincial tumour groups, and results from worldwide peer reviewed clinical trials. The B.C.CA also partners with pharmaceutical companies for additional data on the duration of treatment cycles.

In terms of the agency's pharmaco-economic process, the agency first tries to "get the best prices." That process is quite simple, O'Reilly said, and uses patient estimates, estimates of prevalence and compliance, number of cycles/course estimates, and the cost of drugs. "We don't have sophisticated data such as QALYs." She illustrated the pharmaco-economic approach using B.C.CA's adjuvant programs as an example.

The total cost of a drug such as Trastuzumab is very much determined by the number of eligible patients. The ICER per patient is \$4,000 per 1% increase in disease-free survival, but \$400,000 for each additional patient disease-free survival at two years. O'Reilly noted that this cost declines with time as more patients go into remission. This reflects the true costs of avoiding relapses and saving lives over time, provided treatment benefits are sustained.

O'Reilly illustrated the validation of provincial outcomes (that is, value for money) with Rituximab. The drug saved money overall and improved survival rates. Elsewhere, treatment of gastrointestinal stromal tumours with Gleevec is very effective, with 80% of patients alive five years after initial treatment. In another example, O'Reilly said that in 1995–1996, only 48% of metastatic colorectal cancer patients received Irinotecan and Oxaliplatin, while by 2003–2004, 60% received those drugs, which afforded them significantly higher survival rates.

In comparison to the health economics approach, pharmaco-economics is straightforward and easy; however, it overlooks the impact on the rest of the health care system. Health economics, on the other hand, requires a broader range of expertise, includes adjustments for patients' quality of life, uses various assumptions, and may be limited by the maturity of the data. The implementation of optimal health economic models is a key driver, said O'Reilly; "Every decision has to be made within an ethical framework."

O'Reilly presented an overview of the Joint Oncology Drug Review (JODR), explaining that it is a collaborative effort of all provinces except Quebec. It is a single, evidence-based review of clinical and pharmaco-economic data that arrives at one funding recommendation for all IV and oral oncology drugs. The process is based on the Ontario Committee to Evaluate Drugs/Cancer Care Ontario review process. The process is driven by evidence brought forward by tumour groups, and the total budget drives priority setting. The JODR will also consider new chemical entities.

O'Reilly reminded participants that if a drug is aimed at a large group of patients, the budget impact is much greater (for example, breast cancer drugs).

What should the essential components of a successful approval process be? O'Reilly suggested that it should be ethical; be evidence-based; have a clinically favourable balance of benefits versus toxicity; develop consensus with respect to cost-effectiveness and research on health economic projections; and include the development of resources for health economics.

Whatever comes out of such a process must be affordable, accessible (by expert tumour site groups or industry), timely, transparent, and multidisciplinary, and have stakeholder involvement. An interprovincial process must support guideline development by experts and the development of health economics models, O'Reilly said. It should also provide

consistency and should relate to the Canadian Partnership Against Cancer and the Guideline Development Group.

Patient Access to Effective Treatment: The Industry Perspective

Russell Williams

President

Rx&D, Canada's Research-based Pharmaceutical Companies

"I am not sure I can give an industry perspective without giving a patient perspective," said Russell Williams, who preferred to restate the question, "Should limits be set on what the public purse can afford?" as "Should we set limits and can we afford to?"

Williams said he has become concerned with the increasing number of issues around cost containment. When he learned about QALYs, he found as many biases in decisions based on them as in other economic approaches; "numbers seemed to trump people." He had hoped for the reverse, he said. While he agreed that health care dollars need to be spent responsibly, he said the cancer budget remains relatively small, at less than \$3 per patient (1998 figures).

Rx&D represents about 50 companies with about 20,000 employees focused on discoveries and patients. With proper use of new medicines, there have been significant declines in hospitalization rates, he noted. While the costs of drugs are thought to be 40–50% of the health care budget, innovative medicine only accounts for 8%.

Williams described a Columbia University study that showed a \$7 savings in health care costs for every dollar invested in innovative cancer drugs. That is true "if you look in silos," and becomes even more evident if one goes beyond health care.

Of every 10,000 molecules, only one makes it out as new medicine, said Williams, adding, "Luckily there are 650 in the pipeline." The number of new medicines available now is far greater than in 1997 and could be more so in the next 10 years. "But if we don't invest, we won't see this result."

He noted that the pharmaceutical industry invests \$1 billion annually in research; "We are one of the biggest research components in Canada." Currently, industry is below 10% reinvestment, but Williams affirmed that industry still wants to invest more in new discoveries.

The life cycle of a new medicine is long and complex, Williams said. The patient, however, cares only about when a new medicine becomes accessible. This is key: "We have to look at it more from their perspective." How can medicines reach patients as quickly as possible to save and improve lives?

Canada's highly regulatory environment employs many safety checks on both the government and industry side. Williams noted that while the JODR looked promising and transparent at first, it has fallen short of expectations. There is duplication of the CDR, adding another six to seven months to a patient's waiting time. He hoped that the JODR would learn from its mistakes and build partnerships. Why are timelines so important? Williams pointed out that an estimated 150,000 new cases of cancer are diagnosed every year and 70,000 deaths take place—and patients are asking why someone else has access to a life saving drug and they don't.

To illustrate how drug approval in Canada compares to other countries, Williams noted that while Canada approved 26 out of 50 drugs, Switzerland approved 40, and “this doesn’t even consider the provincial formulary decisions.”

The public and the patient need to have greater confidence in the system. As it stands, confusion appears to reign: “No means no; yes means maybe.” As a beginning solution, everyone must be at the table and they should all understand the process, Williams suggested. The establishment of clear goals, elimination of the silo approach, and a reduction in reviews would also help.

Williams asked whether a wait time strategy could be built in for pharmaceutical companies from a hospital perspective. He reiterated the need to focus on the patient and encouraged government to involve industry as a partner rather than supplier. This is easier said than done, but it could include the optimal use of programs to manage patients and progressive licensing. Decision-making could be streamlined and made more transparent, with proper recourse available.

Canada’s drug prices are 8% below the international median; “those are exciting figures for Canadians.” Williams also noted that industry is trying to reduce prices that are increasing in some areas of health care. Williams was in favour of a catastrophic drug program and emphasized the need to protect decisions between patients and their health care providers.

“If part of the outcome is that we find the right mechanism, then a partnership between industry, health, and maybe even finance could be fruitful,” suggested Williams, adding that the patient must also be involved. “I feel confident that, within our health system and innovative health care research system, we can grapple with these issues.”

The Patient Perspective

Jim Connors, Q.C.
Vice-President, Regulatory Affairs
Emera Inc.

Jim Connors, a lawyer by profession and an executive with Emera Inc., was diagnosed with advanced colon cancer in May 2006. Connors has become an advocate for early detection and greater access to treatment within Nova Scotia. As a patient, he has become frustrated as he has become increasingly aware of the gross inequities in access to cancer treatment across Canada.

Canadians live and die simply because of where they reside, he said.

He questioned the lack of screening programs and the fact that cancers are advancing past the curable stage while people endure delays getting tested, obtaining referrals and starting treatment.

In contrast, Connors asked why 99.5% of the cancer patients in the United Kingdom see the appropriate specialist within two weeks of GP referral and begin their treatment within 30 days of their diagnosis—yet this is not possible in Canada. Initiatives like the Canadian Partnership Against Cancer and the interprovincial interim Joint Oncology Drug Review are welcome news, but Canadians are dying needlessly, he said.

Last year, B.C. acted decisively and approved funding for rituximab (Rituxan) for the treatment of lymphoma in young patients. The result was a 50% reduction in the lymphoma death rates in that province. But because funding decisions were deferred in the rest of Canada, children continued to die unnecessarily.

Of 24 major cancer drugs that “make the difference between life and death for selected patients” British Columbia funds 20 while Nova Scotia funds only four and the rest of the country is “all over the map,” Connors said. He queried why some provinces have funded Herceptin and not Avastin. Herceptin is intended for metastatic breast cancer while Avastin is intended for metastatic colorectal cancer. The average cost of Herceptin is \$45,000–\$50,000 while Avastin costs \$35,000. The patient benefits of both drugs are very similar. But some provinces fund one drug and not the other.

He said an oncology professional had pointed out to him that patients express a lack of confidence in decisions that achieve such confusing and inconsistent results. If those on the front line of the medical profession are perplexed by these decisions then something is radically wrong.

He spoke of a 43-year-old nurse and mother in his home province who has colorectal cancer and was told she had perhaps had a year to live. Her oncologist wants to prescribe Avastin but that drug is not funded in Nova Scotia. And so this mother simply cannot afford it and goes without.

Connors indicated that he takes Avastin because he has the means to pay for it out of his own pocket. He called this “the worst of two-tier health care. It is wrong to allow a system that sets one standard for the wealthy and a second and lower standard for everyone else. Those who have the financial means to obtain these drugs will live longer while those who don’t will die sooner. It’s as immoral as that.”

Though speaking from the patient perspective Connors noted that decision-makers need to be aware that the patient’s friends and community as well as the general public are increasingly interested in access to treatment decisions. Fundamentally, patients want, and are entitled, to receive the drugs they need to sustain or save their lives.

This means patients expect:

- Drug approval and funding processes in which they can have confidence
- Politicians to stop saying we can’t afford drugs that nonetheless are highly effective
- Government to allocate scarce resources rationally
- Drug companies to behave “reasonably”
- A search for alternatives to ensure no one goes without treatment for financial reasons

Patients are very encouraged to see multi-disciplinary groups such as this working together to achieve solutions.

Connors identified several requirements for drug approval and funding processes in which patients and the public could have confidence:

- The process must be understandable.

- The process cannot be subject to arbitrary interference. Connors cited a situation in which a senior bureaucrat in Nova Scotia had interfered in the process, undercutting its effectiveness.
- The decision-making process must be open. In Nova Scotia, although the decision-making Committee was touted as “transparent,” an Access to Information Application had to be brought to get the actual decision. This concern is not confined to Nova Scotia: earlier this year, a study noted that a disturbing trend in access to cancer drugs across Canada is a “continued lack of...transparency of decision-makers”.
- The process must be fair and consistent. Decisions that do not reduce disparities between groups of patients in and between provinces are not fair.
- The process must be speedy. The inter-provincial Joint Oncology Drug Review intends to have an average time of 141 days from receipt of submission to final decision. Connors pointed out that in the same 141 days, on average, 27,196 Canadians would die of cancer. Patients, their families, friends and communities will say that 141 days is not fast enough.
- The process must be inclusive. Connors said every cancer group he is aware of recommends “involvement of patients in decision making.”
- The process must be accountable. Decision-makers are legally and politically accountable to the public. Connors cautioned against “giving lip service to the importance of accountability.” If a decision-making process is not understandable, free from arbitrary interference, open and inclusive, it will not meet the test of accountability.

Connors said drug companies “do yeoman service” through their work to improve chemotherapies and develop targeted therapies. They are entitled to a reasonable return on their investment. But they need to be much more open with their information about their drugs and “cost-effectiveness,” he said.

He also spoke of how packaging affects price. Sometimes expensive drugs come in limited sizes, which can encourage waste and drive prices higher than necessary. Connors gave the example of a drug that comes in only 400 and 100 mg sizes, but is prescribed based on the patient’s weight. Assuming the average patient requires 360 mg, this packaging means 400 mg must be purchased—although 40 mg will be discarded. Not only is this wasteful, but it results in higher company revenues—10% higher, in this case—than if more consumer-responsive packaging were adopted. There is no reason why approval cannot be obtained to provide drugs in smaller volumes, Connors said. “Sizes can drive higher prices. And it is higher prices that deter government funding.”

The World Health Organization says an aggressive prevention program could reduce the overall cancer burden up to 50%. Encouraging prevention through funding and attention will result in fewer cancer deaths, and save money that could fund treatments for those who do get sick.

Community-based screening programs such as for colorectal cancer not only save lives; they save money. Quantification is needed to determine how many millions of dollars the health care system would save through reduced hospital stays, lower demand for

chemotherapy, radiation, palliative care, other medications, etc., as the number and severity of cancer cases decreases.

- Existing waste and inefficiencies across the health care system must be confronted.
- Where possible, indirect costs of treatments must be reduced. Connors questioned whether the most economically efficient delivery system is always a big city hospital.
- Insurance companies should market more policies offering more Canadians back-up catastrophic drug cost protection through personal and group health plans.

But Connors said it is important not to forget the many Canadians who do not and will not have access to such plans. He cautioned against adopting “so-called “options” like “self-pay,” which would leave many Canadians with no access, resulting in a premature or unnecessary death.

Connors cited the case of Bob Loepky, a patient with colorectal cancer, who died Feb 14, 2006 in Saskatchewan; he spent the last years of his life fighting unsuccessfully to have his province’s government pay for Avastin. He once said, “It’s hard enough fighting the disease, let alone fighting the government.” Connors said it is in everyone’s interest—government, medical professionals, drug companies, insurers, health academics, patients and their families—to “pull together.” “It is too late for Bob Loepky,” he said. “But it is not too late for thousands of others.”

Connors thanked Roundtable participants for their leadership in this effort. He said he was encouraged by the breadth of the experience in the room, and was convinced that solutions could be found. Still, he said, everyone should be “very uncomfortable with the inequities that exist today in access to treatment.” It will not be until enough people are uncomfortable that governments will collectively do the right thing—and make the right choices between life and death.

Access Stream Breakout Sessions

Setting Limits on the Provision of Health Services

In the first breakout session, participants were asked to address the following questions or use them as a guide to frame their discussions:

- Should limits be set on what the public purse can afford?
- How should limits be set?
- How do we cope with setting limits, and what alternative mechanisms are there to improve public funding for drugs?

Should limits be set?

While most participants agreed that given the constraints on financial resources, limits should be set, they did not want arbitrary limits. Some felt strongly that the current limits are not acceptable since they were based on economics and not “big [societal] ideas”; others favoured loose and “moveable” limits that follow guidelines and are flexible according to the needs of the public.

A few participants said that, with respect to cancer drugs, there should be very few, if any, limits. “We haven’t met our targets yet and these drugs are but a small part of the overall drug budget.” They said that there is currently too much scrutiny on cancer drugs.

A participant noted the ongoing perception that chemotherapy is very expensive, when it really is not, compared to the overall cost of systemic therapy. Often, cancer drugs are only a quarter of the cost of cardiac drugs.

Discussing limits to cancer funding is easy, said one physician, but it becomes much more difficult to explain those limits “when in front of a patient.” Another participant said he would not even consider setting limits at this point because the data required for fair and consistent limits was lacking.

Setting limits: How?

Participants’ opinions differed on how limits for cancer drug funding should be set, but they offered many ideas. For most, though, it is essential that patients be informed about how limits are set, given that decision-making bodies also have a responsibility to the public.

Other participants said that limits must be set in a fair, transparent, and rational manner, not by political decisions or lobby groups. Fairness should be determined by disease severity and indication. The review process needs to be simplified, noted several participants; currently it is too bureaucratic. One participant referred to “death by process.” Some were also concerned that provinces may or may not follow CDR recommendations.

One group agreed that limits to funding for the entire health care service system, including cancer drugs, should be evidence-based and benchmarked to other jurisdictions. The current budgetary process could also be improved through public engagement. Economists cannot make recommendations about cancer drugs in the absence of broader values.

Some participants said that public funding policy—and therefore, limit setting—should be submitted to a dynamic and flexible review of limits in view of standard of care. This could be done through the establishment of a multidisciplinary committee that involved the general public, government, healthcare professionals, and patients.

Several discussion groups suggested looking at the global health care budget for efficiency improvements and to “get beyond the silo mentality to funding.” Cost savings from prevention programs could make money available for cancer treatment, for example. A “cancer control continuum,” rather than silos dealing with different cancer drugs, was suggested.

According to some participants, Ontario should not be used as a funding model, since it does not gather data appropriately and the gathered data differs from one region to another. Participants favoured a model based on the British Columbia process, which gathers sufficient comparable data that is instrumental in making funding decisions.

The lack of agreement on drug spending thresholds poses a problem. Each province could have different thresholds depending on drug affordability, although different thresholds do not necessarily mean different funding decisions.

Participants had additional comments about how to set limits.

- Drug funding should consider that value for money varies based on life expectancy.
- Provinces should be funded per capita.
- Actual funding is based on what was spent in the previous year, when it should take into account actual need.
- Setting limits based on clinical data that is funded by the pharmaceutical industry may be questionable since the trial outcomes may not be neutral.

Alternative mechanisms for improvement

Given the time needed to evaluate a new drug, one participant said risks should be shared between the pharmaceutical industry and the medical body. For example, the industry could pay for the first two treatment cycles and if the benefits were conclusive, the hospital would pay for the rest.

Private insurance for cancer drug coverage could be encouraged if the portion paid by the patient is subsidized by the government or possibly by industry. While private insurance can facilitate drug access, coverage can vary dramatically among companies.

Some participants favoured the British NICE model, which is a stop-and-start policy that “leaves no one behind.” That policy is more about setting some parameters but not necessarily about capping treatment, and is not restricted to curative situations. Other participants pointed to Sweden’s system, which has the world’s best drug access.

One participant talked about the limits of outpatient medication, especially in colorectal cancer cases. “For some medications, I need to admit the patient, which is more expensive than treating him as an outpatient,” he said. Another participant added that the US favours alternatives that avoid expensive admission.

A participant suggested that when a jurisdiction does not provide screening or preventive care, it has an obligation to provide treatment to an affected patient. Jurisdictions that “let down taxpayers” in this way have an ethical and moral responsibility to pay for treatment, the participant said.

Another participant said that the current debate points to the need to look at new models for health care funding, but he doubted political support for such a change. He added that, while the future holds the promise of improved therapies, much depends on reinvestment in research and “less waste in the system.”

Participants had other ideas for alternative mechanisms, including:

- Catastrophic drug coverage as a way to fund cancer drugs
- The benchmarking of generic products, given that Canada has relatively high prices compared to other countries
- A tax break on treatments the government does not pay for
- Delisting lifestyle medications such as Lipitor, which could have a strong budget impact
- Finding a way to take stable patients off treatment

Equal treatment

Participants in all groups wanted to see equity in drug funding and access to drugs. Why should a patient with a particular disease receive treatment while another patient with a different disease not? Equal access to treatment should be available, regardless of illness and the “visibility” of the disease.

Access to treatment should not be a matter of patients’ financial resources, nor should private, for-profit organizations be able to offer access to treatment and specialists. In discussing how to set limits, one participant said that equity and efficiency should not be separated. “With one, you get the other, and without equity, you can’t be efficient.”

Not all participants believed that the drug-pricing process was fatally flawed. Some noted that the process is better today than in past and that often, pricing is negotiated in the marketplace. In terms of decisions to list drugs, a few participants said that making different decisions for different drugs was natural. They said the equity versus equality issue came out of the Canadian sense of entitlement—“we pay taxes, therefore...”—and suggested that greater public and patient representation throughout the process would enhance understanding of the issue.

Timeliness of the review process

In general, most participants wanted a faster review process since the current wait time means lives are being lost to treatable colorectal cancer. Many said the British system was a goal to aim for, where diagnosed patients wait only two weeks to see a specialist and only 30 days for the beginning of their treatment. Canada should aim to have the fastest review process among the G8 countries—not the slowest.

Many participants questioned the need to review drugs that have already been reviewed elsewhere in the world. The European Union and the US generally review drugs long before they reach the Canadian market—could there not be a fast track mechanism for internationally reviewed drugs, or some sort of partnership with other countries to expedite the process? Some participants, however, cautioned against harmonizing drug review processes with other countries, citing thalidomide as an example of what could go wrong.

Other issues

One participant was concerned that Ontario is trying to bring down Canada’s standards regarding cancer management. Another participant disagreed, noting that Ontario has a larger power of negotiation within Canada compared to other provinces, and uses it well.

Some participants discussed patients’ lifestyle habits and how they should affect access. Some disagreement was voiced on whether poorer patients have equal access to healthy lifestyles. Some participants said that the poor have limited or no access, while others pointed to programs designed to help them.

What happens when a drug is ineffective? Should taxpayers still pay for it? Although targeting patients who respond to a given drug would be ideal, there is no way of predicting who will respond.

General comments

- Some participants were unclear about the value of cost-benefit evaluations, suggesting that this type of economic analysis was not appropriate for cancer drugs.
- Economic evaluations are different in each jurisdiction and should be standardized.
- The buying power of provinces should be equalized through proportionate federal transfer payments.
- Better public education on health care will empower patients.

**Plenary Wrap-up and Presentation:
Screening Stream**

Public Education and Promotion

Dr. Heather Bryant remarked on the screening of the SCRUBS video clip, saying it was appropriate in light of the afternoon discussion on raising awareness and removing the stigma of colorectal cancer. Just as cancer in general has lost its stigma over the last 40 years, and breast cancer in the last 20 years, so too will colorectal cancer, she said.

Participants discussed patient champions and the need to raise awareness with the help of well-known Canadians who could put a face to the disease. Participants also identified the need for clear, consistent, and concise communication. “We need an easy catchphrase that is humorous and easy to relate to,” Bryant said. Health professionals, educators, pharmacists, doctors, nurses, and advocacy groups should all help spread “a core message.”

In discussing outreach to communities, Bryant said barriers to screening, such as cultural and linguistic differences, must be removed. “Not all communities are comfortable discussing the bowel process,” she said. Privacy issues must also be addressed to ensure follow-up on those with positive stool tests, said Bryant.

Integration of Screening, Diagnosis, and Follow-up

Verna Mai said the key challenge highlighted by this session is the need for information and database linkages. Because many databases reside with different sectors, the priority must be to create a national database to better track a patient’s history and standardize methodologies, she said. CIHI and the Canadian Infoway were cited as models.

Participants identified the need to develop capacity for follow-up. Mai said that streamlining workflows for colonoscopies would ensure efficient use of human resources. Participants also discussed guidelines for the use of colonoscopy and the need to remain abreast of new screening techniques around the world. Mai said, “We don’t want to still be doing fecal occult blood testing years and years from now.”

Quality Assurance, Monitoring, and Evaluation

During this session, a population registry was seen as the underpinning of an organized screening program. Some discussion took place about whether screening produces enough information to perform a complete analysis. Participants agreed the need exists to

develop colorectal cancer screening targets and indicators on participation, recall, detection, complication, positive predictive values (PPV), and sensitivity rates.

Participants also discussed the different types of tests, lack of consensus on standards for tests, and wait times between screening and diagnosis. “Right now in Canada,” said a participant, “there are a number of colorectal cancer screening pilot projects being planned, but they are all very different. We need an opportunity to evaluate the differences between them.” The creation of a national dataset to collect the information would ensure an exploratory analysis to set rates and targets for a better programmatic screening.

Plenary Wrap-up and Presentation: Access Stream

Should Limits be Set on What the Public Purse Can Afford?

Lynne Penton of the Canadian Association of Nurses in Oncology said the discussion had been controversial and contradictory, with little consensus. Participants emphasized the need for a global perspective rather than silos. Cancer drugs should not be limited, said Penton. Patients who have no access to screening programs should have access to care.

How Should Limits on Public Funding for Health Services be Set?

Participants said limits on public funding should be evidence-based. The process was described as bureaucratic, inefficient, and in need of simplification. Penton said the public and patients should be properly represented and engaged in the decision-making process.

The group focused on cancer control and access in general. “We don’t want to focus all of our limited resources on treatment itself,” said Penton. Participants discussed the PharmaCare effect and the need to look through a wider cancer-controlled lens—one that incorporates feelings. They said limits should be set with transparency and under rational, rather than political, decision-making. “We are far more focused on ensuring a robust picture in the clinical realm than on public engagement in decision-making,” said Penton.

What Alternative Mechanisms Should be Considered?

The most important issue addressed in this session was the deficit of public opinion, said Pat Kelly of the Campaign to Control Cancer. Alternative mechanisms and the Joint Oncology Drug Review (JODR) were also discussed. The Ontario Ministry of Health was said to be very restrictive, and the suggestion was made to create more partnerships between industry and government, given that the review system sets market value. Kelly said, “We need a national standardized cancer surveillance system.” Another suggestion was to consider making medical costs a taxable claim.

Before turning to the closing presentation, the facilitator asked for quick comments or questions.

One participant said, “We need to get the terminology straight” regarding a national drug plan. The government is talking about a formula-based insurance plan for drugs routinely covered by most provinces. She referred to Avastin, a crucial drug in the fight against colorectal cancer, which is not on the drug plan.

Another participant challenged the routine claim of inadequate funds and called for increased budget transparency and accountability, as well as innovative ways of finding money within existing budgets. He said, “Just to say there are no funds, without explanation, is not productive.”

Wrap-Up

Dr. Brent Schacter

CEO

Canadian Association of Provincial Cancer Agencies (CAPCA)

To sum up the spirit of the day, Schacter paraphrased a quote by American humorist H.L. Mencken: “To every complex question, there is a simple answer...and it is wrong.” The subjects that people have tackled at this conference are difficult, he said, but the ideas surfacing are hopeful for development of better approaches to colorectal cancer care and screening.

Schacter said breast cancer mortality rates in Canada are decreasing at the rate of 2.7% annually. He attributed this phenomenon in large part to the advent of organized mammography screening. “We are on the cusp of similar advances in decreasing mortality and reducing the incidence of colorectal cancer through population-based screening.” He also said there was room for improvement, and that the onus is on learning from the collective experience and moving best practices forward.

Since the prime minister announced \$260 million in funding over the next five years, the Canadian Partnership Against Cancer will advance the control of colorectal cancer through several initiatives. These include the Cancer Control Guidelines, to help develop evidence-based recommendations on colorectal cancer systemic therapy, and the Screening Action Group to enhance population-based colorectal screening programs across Canada. The Canadian Association of Provincial Cancer Agencies is also a leader in encouraging consensus building and the adoption of innovative approaches to colorectal cancer control.

Schacter said he was encouraged by the possibilities for improvement across Canada. “Much excellent work has been done. We need to continue to draw the threads together.” He thanked the facilitators, speakers, and organizers for a job well done on the first day of the conference.

March 30, 2007

Day 2: Keynote Presentations

Facilitator Caroline Kealey introduced Steven Lewis, a health policy and research consultant based in Saskatoon who is currently Visiting Scholar at Simon Fraser University in Vancouver. Lewis was invited to speak on the theme of “public engagement,” a term he said he favours over “public consultation.”

Fair Resource Allocation Decisions and the Emerging Role of the Public

Steven Lewis
President
Access Consulting, Saskatoon

Public engagement (PE) is a consensus-finding exercise, the purpose of which is to bring citizens closer to the deliberations and to prevent decision-makers from becoming too remote from their constituents. To be successful, PE needs to improve decisions as well as increase public understanding of certain issues. When the public participates in decision-making, they start to share the decision maker’s dilemma: “Maybe when the respect quotient increases, more and better people will run for office.”

However, a process becomes manipulative when the information available is presented so as to achieve a predictable outcome, or when the wrong questions are asked; it is insincere when the people consulted are screened to exclude certain groups. It is also at risk of failing when there is an imbalance between people close to an issue (patients or patients’ families) and people more distant from the issue (taxpayers, for example). Problems can also occur when covert representatives of interest groups “hijack” a consultation. All that being said, it is impossible to engineer the perfectly balanced group.

Too many or too few options will make participants feel either lost or constrained. The larger and more diverse the consultation, the more difficulty in finding common ground, and only a small minority may be pleased by the outcome. It is also problematic when people invited to participate assume that they will get to decide the outcome. In these circumstances, “if you don’t do what they say, they are not happy,” said Lewis.

But the timing is perfect for public engagement, and since PE has become a growing trend, many models and approaches have yielded excellent results: the Romanow Commission, the HIV/AIDS consultation, and the B.C. Citizens Forum on Electoral Reform all show that it is possible to engage the public in a consultation process.

“If there is genuine uncertainty, this is where PE earns its stripes.” It is an instrument of teaching that can generate creative insights and options, but respect for one another and openness to other views is crucial. “Without that, you get a lot of noise but not a lot of decisions.”

Lewis suggested the need for a new drug policy framework. The traditional approach to pricing is to accept “whatever the industries charge.” He suggested many alternatives, including pricing in proportion to the proven therapeutic value. He also said that the

Common Drug Review process is “a step towards transparent and value-oriented decision-making.”

Reducing the Impact of Colorectal Cancer: Opportunities and Challenges

Dr. Bernard Levin
Vice-President for Cancer Prevention and Population Sciences
UTMD Anderson Cancer Center, Houston, Texas

Dr. Bernard Levin said Canadians could be proud because Canada spends less on health care but has a higher life expectancy than the US.

Just last year colorectal cancer took the lives of half a million people worldwide. Japan has the highest incidence of colorectal cancer in the world, followed closely by New Zealand and Australia, and North America. In Canada alone, 20,000 people will develop colorectal cancer and 8,000 will die from it this year. Colorectal cancer neoplasia can be prevented with screening, chemoprevention, and good lifestyle habits.

The two objectives of screening are to prevent cancers by detection and resection of adenomatous polyps, and to detect surgically curable colorectal cancers (stages 1 and 2). Screening methods include fecal immunochemical tests, molecular markers, flexible sigmoidoscopy, colonoscopy, double contrast barium enema and CT/MRI colonography.

In the case of fecal immunochemical testing, some advantages exist: a user-friendly brush technique, an automated reading, higher sensitivity than guaiac FOBT, and an adjustable positivity cut-off rate. However, more data should be collected on adenoma detection. With gene-based testing, the main advantage is no bowel preparation.

A 2006 study suggests that virtual colonoscopy shows a sensitivity rate higher than 85% for polyps larger than 9 mm; the rate decreases as the polyp size range decreases. Medical consensus is that polyps larger than 1 cm are clinically significant, but smaller polyps can also be dysplastic or even malignant. This type of screening has been known to detect extra-colonic abnormalities such as ovarian cancer, renal cell cancer, and lung tumours, but due to its lack of contrast, it cannot successfully diagnose cystic lesions. Later this year, ACRIN II, a US-based study, will include 2,500 patients from 15 sites.

At present, the threshold polyp size for referral for optical colonoscopy is not defined. Other questions exist relating to cost-effectiveness, radiation exposure, and the interpretation and management of extra colonic findings.

Novel endoscopic advances include a pneumatic, self-propelling, self-navigating omni-directional scope (Aer-O-Scope), the Navigator™ Endoscopy System, and capsule colonoscopy. But with all the screening methods available—and not counting those to come—screening is still underused.

Levin concluded by mentioning the European Code against Cancer, which states that men and women over the age of 50 are entitled to quality screening. In order to reduce the mortality rate, he encouraged everyone dedicated to colorectal cancer. “It takes a village to eliminate colorectal cancer,” he said.

Screening Stream Breakout Sessions

Communications and Networking across Canada

Facilitator Caroline Kealey said that developing a pan-Canadian colorectal cancer screening program would require collaboration across professional, provincial, patient, and advocacy groups. She explained that the objective of the breakout session was to identify current communications and networking activities and key players, as well as ways to ensure efficient and effective knowledge transfer.

Chair Heather Bryant encouraged participants to think broadly about ways to move colorectal cancer screening forward in Canada. The task is to identify essential steps towards a comprehensive and successful national program, such as public awareness, professional awareness, recruitment, laboratory aspects, diagnosis, follow-up and treatment, quality assurance, and information and database links. Participants were also asked to identify which group or association should be responsible for specific elements of a colorectal cancer network.

Participants identified several stakeholders that should be involved in a pan-Canadian colorectal cancer screening network:

- Federal government (Health Canada, Public Health Agency of Canada)
- National and provincial professional groups (physicians, pharmacists, nurses, health educators, gastroenterologists, pathologists, radiologists)
- Provincial ministries, programs
- Provincial epidemiological, health assessment, and guideline groups
- Canadian Partnership Against Cancer (CPAC)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Canadian Cancer Research Alliance
- Cancer agencies
- Clinicians, and cancer and health care services researchers
- Industry
- International bodies
- Model Based on Breast and Cervical Cancer Structures

Learning from other cancer sites would be useful, participants said, rather than reinventing existing systems. Existing resources should be leveraged. The breast cancer screening initiative in Canada has experienced great success; that initiative could serve as a model for a colorectal cancer screening initiative. It would be worthwhile to see if any studies have explored the fit of colorectal cancer with the breast cancer screening model.

A major difference between breast cancer and colorectal cancer screening is that a mammogram is relatively cheap, involves one test, and is accepted and considered accurate, a participant said. Colorectal cancer screening, on the other hand, is insensitive, involves multiple tests, and requires costly infrastructure and resources.

Canada-Wide Information System

A pan-Canadian information system that links data from provinces and territories will allow cross-program analyses and will help show the way towards a national approach, participants said. The system needs to capture screening, results, and pathology. Databases would ideally have common standardized reporting, data definitions, and critical comparable elements to be compatible with the overall Canadian network.

At the same time, participants noted, some political realities pose challenges to a pan-Canadian system. Not all provinces have colorectal cancer screening groups, which makes it harder to get a program established at the national level.

A diversity of players is present at the provincial level, including provincial governments, health departments, and public health and cancer agencies. The mandate and autonomy of these bodies can vary across regions, but bringing the different players involved in program delivery together is important, so that they can learn about initiatives and approaches in other provinces. This information sharing from different regions will define an infrastructure for a pan-Canadian system. Non-governmental organizations (NGOs) such as the Canadian Cancer Society, the Canadian Breast Foundation, and the Colorectal Cancer Association of Canada, should be involved too.

A participant expressed concern that if too many players are involved, the process will get unwieldy, making progress difficult. Another participant suggested that this problem could be avoided by establishing a core group of representatives from health ministries and NGOs, which would then carry out focus groups with patients and physicians.

Clinical Guidelines on Colorectal Cancer Screening

Professional and clinical guidelines on aspects of colorectal cancer screening such as FOBT sensitivity and specificity changes would be useful to practitioners. Physicians, specialists, pharmacists, nurses, health educators, and pathologists all have a contribution to make to the development guidelines. Provincial guidelines review groups should also be engaged.

Quality Assurance and Core Quality Indicators

Indicators and quality determinants are needed for performance monitoring and evaluation of new technologies. Professional awareness of quality determinants and indicators and the importance of reporting data should be increased. Indicators should be agreed upon at the national level, with the flexibility to customize at the provincial level. Health services researchers, clinicians, and provincial epidemiological and health services organizations should be engaged. Each province's performance in colorectal cancer screening should be measured to determine whether they are meeting standards and to identify areas in which they are falling behind.

Participants said a group should be established that would attempt to identify a core set of indicators for colorectal cancer screening. Surveillance of risk factors along with screening activities is also needed.

Mechanism for New Technology Review

Standards, indicators, and quality assurance are key elements of evaluating whether new technologies achieve targets. A mechanism is needed for reviewing the efficacy of new

technologies, adapting programming, and introducing new tools, participants said. A technology review board could involve the Canadian Agency for Drugs and Technologies in Health, Canadian Partnership Against Cancer, Canadian Cancer Research Alliance, provincial health technology assessment groups and evidence-based organizations, and patient advocacy groups.

Communications and Patient Engagement

Changing perceptions and increasing public awareness about colorectal cancer screening is critical, as is identifying the target audience and effective colorectal cancer advocates. Patient advocacy groups, health professional groups, cancer agencies, government, industry, and international organizations all have a role to play in collaboratively developing a common message, tactics, roles, and responsibilities.

CCAC can move public education forward. A participant said that patient organizations tend to lead national organizing, with the help of physicians; patient organizations are created around the disease and around effective advocates.

The breast cancer pink ribbon campaign has been very successful in raising awareness among the public, as well as in garnering corporate support. A blue ribbon campaign could be similarly effective for colorectal cancer.

Focusing on bodies that represent the target age group, such as the Canadian Association for Retired Persons, would be an effective way to reach segmented parts of the population based on, for example, age and gender.

Structured Financial Support to Maintain the Network

All the resources required for colorectal cancer screening must be addressed, participants said. A pan-Canadian system must get the patient who tests positive for colorectal cancer to the next step. The view at the provincial level is that the only way to achieve provincial buy-in and realize colorectal cancer screening across Canada is for the federal government to provide funding for it.

Networking with Various Groups

Planning a cross-Canada program needs to engage the professionals involved in cancer screening, participants said. Some professionals will need to be convinced of the importance of reporting, and some will expect a fee for service. It is important to identify all the professional organizations involved in screening (for example, nurses play a big role), and communicate the message of a pan-Canadian approach to colorectal cancer.

Input on a framework for patient education and advocacy is necessary from all stakeholders—provinces, NGOs, health and cancer agencies, professional organizations (including the Canadian College of Physicians, and the Canadian Association of Gastroenterology), and the general public. Reaching Canadians who do not have their own general practitioner is also important.

List of Players

A view of the spectrum of stakeholders in colorectal cancer screening and treatment in Canada—a list of who's who and who's doing what—would facilitate the development of networks and collaboration.

Colorectal Cancer Screening Kits

Decisions must be made about which colorectal cancer screening kit to use and whether different tests will be piloted in different regions or programs. In a pan-Canadian approach, bulk purchases of kits across the country could save money. On the other hand, if different tests are used, the provinces that are first to use a specific test could share their experiences with other provinces.

CPAC as Overarching Group

Participants felt that the CPAC Screening Action Group would be an appropriate overarching group under which colorectal cancer screening could be addressed, given that it has representation from across the country as well as committees on cervical and breast cancer screening. This collaboration would encourage cross-fertilization, a participant said, adding that the CPAC Screening Action Group has found that issues common to cervical and breast cancer have elevated analysis and information for screening. Another participant said that creating a new network would not be efficient, whereas piggybacking any new cancer program onto the existing model will provide economies of communication and cost. The Colorectal Cancer Association of Canada will play a key role in communicating the importance of a pan-Canadian strategy for colorectal cancer screening.

Access Stream Breakout Sessions

The breakout groups were asked to address the following questions as a way to focus their discussions:

- What would be the key features of a transparent process for priority setting in colorectal cancer treatment? What criteria could be used to measure this transparency?
- Can the public's views and values be realistically represented in a process of fair decision-making to set priorities for new cancer drug funding? If so, how?
- Can advocacy groups accept the need for priority setting? What role can they play in promoting alternative mechanisms for funding? What role can and should industry play in ensuring equitable access?
- What is transparency?

Participants emphasized that a definition of transparency is critical since government, patients, and the general public interpret the term differently. For a number of participants, disclosure alone is not an adequate definition of transparency; disclosure "after the fact" is certainly not acceptable. While many participants agreed, "It's transparency if everybody was involved from the beginning," some indicated that this kind of participation is not always possible.

Transparency: Where?

Generally, all participants wanted to see greater transparency in the drug-pricing process and in the drug-listing decision-making process. Transparency in the process would change the public's perception of drug plan coverage and would put into context other

costs in the health care system. Transparency must apply to all parts of the cancer treatment and health care system; “[we] should all drink from the transparency pool.”

Others added that industry needs to better explain to the public and government how they set their prices. “Patients can’t escape the reality that sometimes pricing falls on their shoulders.” At the same time, the patient has “zero power to negotiate prices,” added a participant. A member of the industry agreed, “We’ve done a very poor job of informing the public of how we come up with these prices.” Whether or not patients should actually be involved in drug pricing was a point of disagreement. Many said that patients already have a lot on their minds and participation in that process would be a burden.

While participants recognized the need for industry to keep proprietary information and contract information confidential, some called for greater transparency from companies who supply information and set the price for drugs. One participant suggested that all socioeconomic information and research results should be disclosed unless there is a strong reason not to do so.

Some participants indicated that a degree of confidentiality should exist, however. They referred not only to proprietary information from industry but also to protection in terms of stakeholder input so that they are not reluctant to participate in consultations. One participant said that industry does inform the public to some extent through its own stakeholder groups.

A few participants also suggested that transparency is necessary between governments and review bodies; these groups should have access to each other’s information to avoid a triplicate process.

Public and patient input

Prior to the discussions, several participants made the distinction between the public and the patient, and agreed with Steven Lewis’s comment that once the public gets educated, they are not the public any longer.

The majority of participants called for greater public and patient input into decision-making processes around cancer drug access and pricing. “Why are we so reticent and sloppy about engaging the public? If we invested as much in the public process as in the clinical research that goes into the JODR, we would have more confidence.” After all the “public knows what they want,” said one participant.

Public involvement in a transparent process should aim to enhance understanding. Currently, some patients are confused about what the thresholds are for listing drugs; this implies a need for more publicly available socioeconomic information. As one patient explained, “I want to know upfront what the rules, criteria, values, and elements are in the decision-making process.”

A suggestion was made that drug review committees need good representation from multiple disciplines, including ethics, which could consider public/patient views. Some people were worried about the “Pharmacare effect,” which resulted in too narrow a perspective when reviewing drugs.

Stakeholders need to understand the values (and weights) given to different criteria used in decision-making. To this end, background for the issue must also be provided.

Transparency in a decision-making process would also mean an early entry point for all impacted stakeholders who would have their roles defined. A clear approach, guiding principles, and a vision are needed.

Inclusive public consultations are a necessary part of any transparent process, and patients should be represented at all stages where they will feel an impact. When the public and patient are represented in the decision-making process, they should be knowledgeable about the issues, said one participant, so that “it is not a go-fish scenario.” One participant reminded the group that the public and patients have a powerful voice to influence politicians. Some suggested the formation of a citizens’ council.

Full access to information

Another group wanted full access to methodology and deliberations in how a decision is reached, since the methods of evaluation are currently biased. Some suggested the latter statement could be a skeleton definition of transparency. Other participants added that accessibility to the decision-making process is key; therefore, the information must be disseminated much more broadly than simply a posting on a website.

The decision to list or not list a drug should be made publicly available, as should the reason. Transparent processes are understandable, fully explainable, easily accessible to all, and open to scrutiny. Clear terms of reference must exist for decision-makers so everyone understands what the decision was and why it was made.

Other features

For some discussion groups, transparency also implied accountability and involved setting expectations, particularly with respect to what information will be available when. Furthermore, a truly transparent process must also have a recourse/appeal mechanism available. Transparency also entails clarifying and determining the relevant issues and questions.

The need exists to establish a clear socioeconomic model that can be consistently applied. Other participants noted that there is a problem with the governance model of the priority setting process. For example, CADTH is a not-for-profit organization and is not, therefore, subject to the Access for Information Act.

How to ensure transparency? One group of participants suggested a website or toll-free number that tracks the decision-making process step by step and is updated regularly. Any tracking website should be two-way so that “people can look in and provide input on decision-making.”

Measuring transparency

Some participants suggested that simple measures—the number of participants at consultations or on committees, the number of timelines met, the number of submissions received, or the publication of summary reports—could be used to determine the degree of transparency achieved. Direct feedback from patients could also help in this regard.

Representing public views in priority-setting

With respect to representing the public’s views in fair decisions on priorities of new cancer drugs, most participants indicated that this could be achieved, although there were

some questions about who exactly the public was—patients, loved ones, or anyone on the street?

Asked exactly how the public's views could be represented, one participant suggested that a process of deliberative polling could be employed whereby a broad range of stakeholders inform randomly selected members of the public, who are subsequently consulted on an issue.

The public's views could also be solicited through an electronic forum that seeks to engage the public. Such a website would have to be widely advertised to ensure good feedback. Linked to this forum could be an advisory committee of patient and public representatives that provides direct input into the process.

Advocacy groups

Advocacy groups must recognize the importance of priority setting, according to some participants; if they do not, they will fail. Most participants agreed that advocacy groups could accept priority setting and participate in it when the limits for those priorities are clear, reasonable, consistent, and fair. If “we want to become part of the political agenda, we need to work within it to further our own agenda,” said one group in discussing advocacy.

What can advocacy groups bring to the decision-making process? A lot, indicated participants, who pointed to the example of successful public advocacy in tobacco control. “Advocacy groups can bring knowledge, different perspectives, and new options to the table.”

They can also ensure accountability and speak to process issues that are not evident to those intimately involved in the process or those who have the silo mentality. Advocacy groups could also highlight process efficiencies and perhaps offer solutions (for example, fast tracking drug approvals). Advocates can also play an important role in educating the public.

One participant suggested that perhaps advocacy groups could learn from industry, which does not plan for the past but forecasts for the future.

One participant noted that the approximately 200 groups in Canada that have “‘cancer’ in their name” should be brought together. Competition is not the best interest of the patient. In order for advocacy groups to be relevant, they have to consult their constituents and engage them in discussion.

Part of the problem, according to one participant, is that currently, advocacy groups feel that they are not heard. That is why there are so many groups—they feel disenfranchised, excluded, abandoned, and alone.

What is the role of industry in priority setting? Some participants indicated that industry should be left to “do what it does best”—that being research and production. A few participants saw a role for industry in informing the public with respect to the process of introducing new drugs. Others said that, in general, the industry voice needs to be more present within the community.

Other comments

Many participants said that the cancer drug funding process must have federal input and should not be left to the provinces. Provincial decisions are not just about the relative wealth of provinces. For example, Newfoundland pays for Evastin while Ontario does not, which indicates that decisions to list and fund drugs are more about value systems and the court of public opinion.

Two points of view emerged from one of the discussion groups regarding cancer drug funding. Some of the participants said cancer is a unique disease and should have distinct funding. Others, however, said that all dollars should be open to all takers to be divided equitably.

One participant suggested that “Astroturf” organizations [lobby groups] exist that simply act as a front to get a certain drug listed. Another participant reminded participants that there are good stories too—many good partnerships exist between the pharmaceutical industry and Canada’s health care system.

Another participant suggested that clinical trials conducted by industry should include patients that are third, fourth, and fifth in line, since they do not have access to trial results.

One group discussed external influences on Canada’s drug prices. Some in the group said Canada’s prices are set by the US and other larger markets, leaving “us no room to negotiate.” Others said that Canada could negotiate since the whole drug pricing structure needs to and will change over the next decade.

A number of participants said that cancer drug funding has to be a national responsibility; it cannot be left to the provinces. Despite its efforts, the JODR will have the same result—provincial differences in drug funding and, therefore, inequities in drug access. Arbitrary influence in priority setting is not uncommon, but it is unacceptable.

Concern was raised that government reacts too often to events that affect drug funding, but it should put more emphasis on being proactive.

One participant suggested that the provincial ministries of health should get out of health care management altogether and only set the standards.

Summary Wrap-up and Next Steps

Dr. Heather Bryant
Vice-President and CIO, and Director of Population Health and Information
Alberta Cancer Board
Member, Screening Action Group
Canadian Partnership Against Cancer (CPAC)

Bryant thanked conference organizers, facilitators, and participants and re-emphasized the two different fronts upon which progress needs to be made: Screening and Access. “We have the evidence that we can make a difference,” she said, as the screening programs have already been “birthed.” She pointed to the many pilot programs currently underway in the provinces and said that many more were moving towards

implementation. However, the reality is that only about 14% of the targeted population are getting screened in Canada. The situation in Australia is similar, she said, as described yesterday by Dr. Mark Elwood.

The conference presentations also revealed the many screening models that exist throughout the various provinces in Canada. “The stakes are high,” she noted. “We are very careful; we are busy researching and asking questions without trying anything.” Bryant encouraged everyone to start taking risks to find the answers. “We need to get moving; we need to set up a network and learn from each other.” This conference has provided a foundation from which to move forward, she said.

Bryant referred to the importance of humour in enabling people to become comfortable with colorectal screening. Screening programs need to “pull the colorectum out of the cubicles,” Bryant said. Breast cancer awareness has risen and people are comfortable speaking about it. “We need to laugh about the colorectum,” she said.

Bryant said that the Australians and the British refer to the colorectum as the bowel, and she explained the significance of the word. The word “bowel” had a lot of dignity in the past, she explained, and was originally seen as the seat of all deep emotions. “We still have remnants in the English language” of the bowel’s significance in phrases such as “I feel it in my gut” or “gut feelings.” But the bowel had other functions, Bryant explained, and so the believed seat of sentimental feelings shifted to the heart.

Bryant emphasized the importance of continued discussion, reminding participants of the “many folks we have lost” and the many others who are still suffering. “This is the number two cancer killer out there and we can make a difference,” she said, adding that she was pleased to see the inauguration of the conference. She thanked everyone for participating.

Dr. George Browman
B.C. Cancer Agency
Chair, Cancer Control Guidelines Action Group
CPAC

Dr. George Browman thanked organizers for allowing him to design the Access Stream. The issue of access is on everybody’s mind, he said, and the way to make a difference is to inform the public and stakeholders of the need for transparency.

Public involvement can only improve the decision-making process, Browman said, adding, “There is more to this process than science.” He called on participants to “role model the process” they want with regards to drug access. Informing people and then engaging them in some way in the process of decision-making is essential, he said.

If people are properly informed and properly engaged, then they understand better and accept the circumstances under which decision-makers are functioning, Browman said. He explained that both societal and individual perspectives needed to be taken into account. “We can’t accept all outcomes,” he said, “but we can accept the process.” Browman noted that this was the main message of the Access Stream.

Another important message, said Browman, is that “transparency begins at the beginning, with the framing of the issue.”

“Why are cancer drugs undergoing more scrutiny than [drugs for] other diseases? Why is there such a budget around cancer drugs but not other drugs?” These are questions that decision-makers need to answer, he said. “If the problem is framed in this context, there will be more trust in terms of decisions that need to be made.”

Browman said the Access Stream discussions were very useful and that Steven Lewis “put his finger on it” when he spoke about legitimacy. Decision-makers are making decisions because of the public and must ensure that these decisions are seen as legitimate. Legitimacy cannot be achieved without transparency, Browman said. In most countries, drug assessment focuses on scientific legitimacy, but “this is not sufficient for overall legitimacy—we also need social legitimacy.”

Browman talked about the methods of government lobbyists in acquiring preferential treatment for a particular disease, calling these methods a “legitimate process in a democratic society.” However, he asked advocacy groups and physicians, “Do we want to let the decision be made through the competition of special interest groups? Yes, it’s an acceptable way, but we want something transparent” that balances the larger societal perspective with the scientific spectrum. He called on participants to bring this complementary model forward and to be effective in their advocacy at a time when “Canada is very much in listening mode around drug funding.”

Barry D. Stein
President
Colorectal Cancer Association of Canada
Member
Screening Action Group, CPAC

“It’s not difficult to put together a conference,” said Barry Stein. “What is difficult is to find a group of extremely passionate and knowledgeable people who together over a two-day period are able to sustain the original enthusiasm they had at the beginning of the conference.” He credited the success of the conference to everyone in the room “working hard together to find solutions and address common issues concerning colorectal cancer.”

He thanked the participants for their compassion, and for their commitment to both the Access and Screening Streams—the two major platforms of CCAC. The two platforms are intertwined, he noted. “If you can have effective population-based screening, then ultimately you will have fewer people to treat and more favourable outcomes for those already touched by the disease. Government must offer effective treatments within the treatment guidelines in a timely manner to obtain these favourable outcomes.”

Stein discussed the production of the final conference report, as well as the creation of a section on the CCAC website, www.colorectal-cancer.ca, devoted to screening and access to treatment. He invited all participants to forward information to the CCAC to post and link to the section; doing so will provide an invaluable tool for continued discussion. He encouraged the participants to use the website to “keep the issues alive and to see what’s going on across the country.” He said CCAC will provide for another roundtable conference in the coming year.

Stein noted that apart from excellent ideas and collaboration that are essential to ensuring an effective conference, “It is very exciting to us as organizers” to see such a diverse and

dynamic representation from ministries of health and public health agencies, pharmaceutical companies, patients, patient advocates, cancer agencies, cancer boards, medical associations, cancer agencies and cancer centres, advisory boards and health economists, to mention a few groups that were represented at the conference from across the country. Stein noted the importance of sharing information whenever and wherever possible. “Sharing of information is an essential part of the follow-up so that we can effect change. We hope this conference has provided a forum for future sharing of information to the benefit of all.” He thanked everyone for making the conference “a fantastic success.”