The Challenges of Implementing Screening Programs Across Cancer Types

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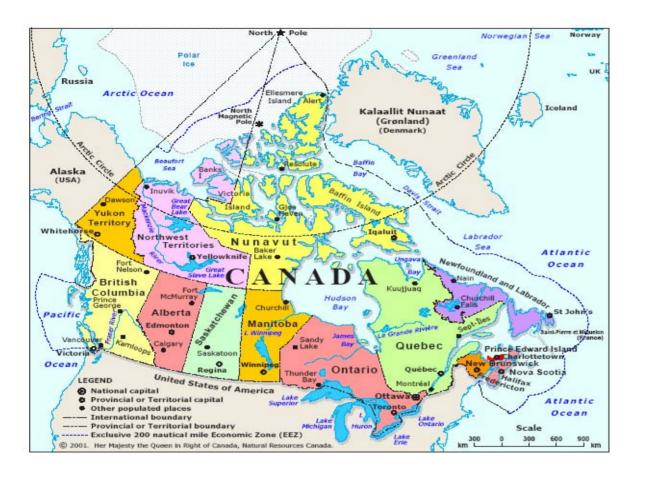


Objectives of Presentation

From the Canadian perspective:

- What is the current situation with regard to implementation of screening programs across cancer types (breast, cervix, colorectal) and why is this an issue, now?
- What are the factors that support the implementation of programs across cancer types?
- What are the barriers to implementation of programs across cancer types?
- Where does that leave us??opportunities for action and "must do's" to ensure programmatic screening is supported





- •13 provinces and territories – each is responsible for the provision of health care services
- •Population Estimate January 2006: 32,422,919
- Largest population:Ontario (12,599,364)
- •Smallest population: Nunavut (30,245)
- •7/13 have cancer agencies/boards to plan and oversee cancer services

Canadian Cancer Statistics 2006

(Canadian Cancer Society, National Cancer Institute of Canada, Statistics Canada, Provincial/Territorial Cancer Registries, Public Health Agency of Canada)

Cancer Type	# Deaths	Mortality rate per 100,000	# New Cases	Incidence Rate per 100,000
Colorectal	4600 (M) 3900 (F)	27 (M) 17 (F)	10,800 (M) 9,100 (F)	62 (M) 41 (F)
Breast	5300 (F)	23 (F)	22,200 (F)	106 (F)
Cervix	390 (F)	2 (F)	1,350 (F)	8 (F)

Definition of Screening

"the presumptive identification of unrecognized disease or defect by the application of tests, examinations or other procedures which can be applied rapidly to sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment." (Commission on Chronic Illness, 1951)



Cancer Site	Effectiveness of Screening
Breast	25% reduction in mortality with regular screening in 50-69 year olds
Cervical	90% is <u>preventable</u> with regular Pap tests
Colorectal	16% reduction in mortality with regular screening with FOBT, 20% reduction in incidence with regular screening

What about screening programs for these 3 cancer types?

- Breast screening programs are the most established; most (12/13) Canadian provinces and territories have programs – with key organized program components; variation across programs
- Cervical screening programs are less completely developed; active efforts underway in most jurisdictions to implement components of programmatic screening (e.g. personalized invitations,);
- Colorectal screening programs none established when??

Any Integration across Cancer types happening?



Why is the implementation of screening programs across cancer types an issue today?

- Funding issues, streamlining of efforts, women's health focus, all lead to questions re: integrated cervical/breast screening programs.
 - Annual # of deaths: Breast cancer: 5300 vs. Cervical cancer: 390
- Recommendations for colorectal cancer screening programs -- can we reduce costs by combining screening infrastructures?
- Other areas of cancer control are integrated systemic therapy (chemotherapy programs); radiation; cancer prevention
- Other integration is planned in the health care system for chronic disease prevention - address common preventable risk factors.
- Greater interest in cancer screening today than 10 years ago, leading to more questions re: why programs are not available equally for all sites; also - why is an organized program needed?



What factors that support the implementation of programs across cancer types?

What factors that support the implementation of programs across cancer types?

 Principles of Screening/ elements of organized screening programs are common for all screening, regardless of site

Basic Principles of Screening

(Wilson and Jungner, 1968)

- 1. The condition being screened for should be an <u>important</u> health problem.
- 2. There should be an <u>accepted treatment</u> for patients with recognized disease.
- 3. <u>Facilities</u> for diagnosis and treatment should be available.
- 4. There should be a <u>suitable test</u> or examination, in terms of sensitivity and specificity.
- 5. The test should be <u>acceptable</u> to the population.



Principles of Screening (Cont'd)

- 6. The <u>natural history</u> of the condition, including development from latent to declared disease, should be adequately understood, including knowledge that there is a recognizable <u>latent or early symptomatic stage during which treatment is more successful</u>.
- 7. There should be an agreed upon policy concerning whom to treat as patients.
- 8. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be <u>economically balanced</u> in relation to possible expenditure on medical care as a whole.
- 9. Screening should be a <u>continuous process</u> and not a "one-time only" event.



Key Elements of an Organized Population Cancer Screening Program

Screening Working Group of the Canadian Strategy for Cancer Control

- High quality, supported by minimum standards, evidence-based guidelines and promotion of best practice.
- Continuous monitoring and evaluation. The program must have the capacity to change its programmatic elements based on the results of evaluation.
- The program must have the capacity to modify screening standards, guidelines and best practices based on new scientific evidence.
- Screening programs must adopt a culture of continually striving to increase the benefits and minimize the harms of screening.



Key Elements of an Organized Population Cancer Screening Program

- Screening must be comprehensive, including recruitment, recall, follow-up and timely assessment of people with positive tests.
- Screening must be supported by public education and education of health care providers.
- All eligible people should have reasonable access to screening, diagnostic assessment and treatment.
- Participation in a screening program should be on the basis of a realistic understanding of the harms and benefits of screening and the manner in which health information will be managed.



Key Elements of an Organized Population Cancer Screening Program

- The program must be supported by an effective and efficient computerized information system designed to accommodate the needs for confidentiality and information sharing.
- There must be adequate resources (financial, physical, human and informational) to support all aspects of screening.
- Screening programs must include a consumer perspective in all aspects of their planning and operations.

Effectiveness of Programmatic Screening

Nieminen, Kallio, Anttila and Hakama case-control study (Int. J. Cancer, 1999):

COMPARISON OF TYPE OF CERVICAL SCREENING		
Activity	Adjusted Odds Ratio (95% CI)*	
Organized Mass Screening	0.38 (0.26 – 0.56)	
Spontaneous Pap Smears	0.82 (0.53 – 1.26)	

Organized Breast Screening (World Health Organization, 2002)

The evidence from randomized trials inviting women aged 50-69 to screening with mammography show that mortality from breast cancer is reduced by 25%.

Estimates made in some European countries with organized breast screening programs suggest that 20% reduction in mortality can be expected in the long term, taking into account the time it takes to achieve full implementation of national programmes and see the impact of regular screening.

Organized screening programs are more effective in reducing the rate of death from breast cancer than sporadic screening of selected groups of women.



What factors that support the implementation of programs across cancer types?

 Common principles have lead to the development of common indicators of performance, which are well known to the screening experts, but less understood by others



Result of a Hypothetical Screening Test

		DISEASE PRESENT	
		Yes	No
RESULT OF	Positive	True Positive	False Positive
TEST	Negative	False Negative	True Negative

Sensitivity =	True Positives (TP)	X	100%
	True Positives (TP) + False Negatives (FN)		
Specificity =	True Negatives (TN)	X	100%
	True Negatives (TN) + False Positives (FP)		
Positive			
Predictive =	True Positives (TP)	X	100%
Value	True Positives (TP) + False Positives (FP)		
Negative	True Negatives (TN)	X	100%
Predictive =	True Negatives (TN) + False Negatives (FN)		
Value			



Program Success Indicators

- Coverage
- Rescreening
- Quality of screening test
- Follow-up of abnormal results
- Quality of screening diagnosis
- Impact on cancer occurrence

- % of target population screened
- % of individuals (with a negative screen) rescreened within a reasonable time period
- % of screening tests rated unsatisfactory
- % of individuals with positive result who have no follow-up
- time to complete follow-up after a positive screen
- false positive and false negative rates
- cancer detection rates
- incidence and mortality rates of cancer in Ontario

OBSP Performance Indicators, Annual Report 2004-2005

Outcome Indicator		Total OBSP Mammography	Canadian Standard
Participation Rate [†] (%)	All screens	26.8	≥ 70% of eligible population
Retention Rate [‡] (%)	All screens	81.4	≥ 75% rescreened within 30 months
Abnormal Call or Referral Rate (%)	Initial Rescreen	10.0 6.2	< 10 < 5
Invasive Cancer Detection Rate (per 1000)	Initial Rescreen	5.0 3.8	> 5 > 3
Diagnostic Interval§ (%)	Within 5 weeks without tissue biopsy Within 7 weeks with tissue biopsy	85.0 57.1	≥ 90% within 5 weeks without open biopsy ≥ 90% within 7 weeks with open biopsy
Positive Predictive Value (%)	Initial Rescreen	5.9 7.4	≥ 5 ≥ 6
Benign to Malignant Surgical Biopsy Ratio	All screens	0.5:1	≤ 2:1
Invasive Cancer Tumour Size <= 10 mm (%)	All screens	38.1	> 25
Positive Lymph Nodes (%)	All screens	22.3	< 30% node positive
Post-Screen Detected Invasive Cancer Rate (per 10,000 person years)*	Within 12 months	5.3	< 6

Notes:

[‡] Percentage of women who last attended the OBSP in 2000 or 2001 with a two year screening recommendation who were rescreened within 30 months (i.e., up to 6 months after the recommended interval) of their previous screen. Both modalities of referral were considered.



[†] Data for 2003 and 2004 screen years were used to calculate a biennal (2 year) participant rate. Both modalities of referral were considered.

What factors that support the implementation of programs across cancer types?

- There are common data elements that are needed for a comprehensive information system
 - Eligible population
 - Screening episode information
 - Follow-up assessment information
 - Outcome information

Why Do We Need Screening Information Systems and Registries?

PROGRAMATIC COMPONENTS	PERFORMANCE & PROGRAM MONITORING
Recruit eligible population never screened or under-screened	Review participation rates, access to follow up tests, outcomes
Recall individuals overdue for screening	Quality assurance
Follow-up to ensure that individuals receive diagnostic procedures according to guideline	Performance feedback to practitioners
	Public reporting provincially and nationally

What Data Do We Need?

	Cervical Screening	Breast Screening	Colorectal Screening
The Test and Results of the Test	Pap Test	Mammogram	Fecal Occult Blood Test (FOBT)
Diagnostic Investigations and Results (cancer or no cancer)	Colposcopy Repeat Pap Tests, HPV Tests Biopsies	Ultrasound Special Mammograms Needle Biopsy Open Biopsy	Colonoscopy Biopsies
Eligible Population Data	Ontario Women	Ontario Women	Ontario Population Men and Women



Challenges and Issues for All Screening Programs

- How can we reach those at risk and not being screened?
- How can we avoid over-screening those not at risk?
- How can we more accurately measure how we are doing in provinces and Canada?
 - consistency in data,
 - common approaches to classification of screening test results,
 - national definitions of indicators
- How will we evaluate the added value of new technologies in screening?

Does value =

- reduction in burden of cancer?
- better test qualities over previous tests e.g.. Sensitivity?
- improvement of efficiencies in our system by reduction of unnecessary screening and follow-up?
- Ensuring existing systems are continuously reviewed & upgraded to meet growing needs

What factors that support the implementation of programs across cancer types?

- Common target population: Healthy population
 - Commonalities of subpopulations also across some cancer types e.g., gender (cervix, breast, and colorectal in women; over 50 age group for initiating breast and colorectal)
- Common barriers to screening behavior exist for breast and cervical screening (and likely colorectal too) for
 - the target populations and
 - primary care physicians who do recommend screening for all cancer types

Why Ontario Women Aged 50-69 Have Not Had a Mammogram In the Past 2 Years (CCHS, 2003)

Didn't think necessary	34.1%
Have not gotten around to it	27.1%

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20.9%

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Doctor didn't think necessary



Why Ontario Women Have Not Had a Pap Test in the Past 3 years (CCHS, 2003)

Didn't think it was necessary	29.1%
Have not gotten around to it	23.3%
Doctor didn't think it was necessary	15.9%



Family Physicians' Perceived Barriers to Providing Recommended Screening to Women

(Hutchison et al, 1996)

- Patient is healthy and does not visit
- Patient refuses or is not interested
- No effective patient reminder systems
- Priority is given to presenting problems
- No system to remind physicians about preventive services
- Not enough time during patient visits to address
- Intervention not clearly effective
- Intervention causes patient discomfort or inconvenience



Family Health Teams Preventive Care Payment Incentives in Ontario Established for Breast, Cervical and Colorectal Screening

Mammogram: Service Enhancement Fee (annual)

% of Enrolled Patients (between 50-70)	Fee Payable
55%	\$220
60%	\$440
65%	\$770
70%	\$1,320
75%	\$2,200



Family Health Teams Preventive Care Payment Incentives

Cervical: Service Enhancement Fee (annual)

65%

60%

70%

75%

80%

Pap Smear

Fee Payable

\$ 220

\$ 440

\$ 770

\$1,320

\$2,200



Family Health Teams Preventive Care Payment Incentives

Colorectal: Service Enhancement Fee (annual)

15%

20%

40%

50%

FOBT

Fee Payable

\$ 220

\$ 440

\$1,100

\$2,200



What factors that support the implementation of programs across cancer types?

- Stakeholders in primary care, health promotion and health education address all types of cancer screening in their communities
 - A cancer screening message overall could have a more holistic approach to screening, rather than separating each body parts
- What about new screening tests for cancer that apply to more than one cancer type?



January 17, 2006 New York Times

(Reference: McCulloch, Integrative Cancer Therapies, 2006)



- "In the small world of people who train dogs to sniff cancer, a little-known Northern California clinic has made a big claim: that it has trained five dogs three labradors and two Portuguese water dogs to detect **lung cancer** in the breath of cancer sufferers with 99 percent accuracy".
- (For **breast cancer**, with a smaller number of samples, the dogs were right about 88 percent of the time with almost no false positives, which compares favorably to mammograms)
- Dr. Berry, too, was interested but suspicious. "If true, it's huge," he said. "Which is one reason to be skeptical."



What are the factors that support the implementation of programs across cancer types?

- Consolidation of the key messages across cancer types would be helpful:
 - what types of cancer screening are supported by scientific evidence and what types of screening are not (and therefore, are not part of the cancer screening program), to reinforce the message that effective screening reduces the risk of death from certain cancer types.
 - pro's and con's of screening based on the science behind screening to support informed decision-making for all types of cancer screening



What is the Best Evidence of Effectiveness of a Screening Test?

 Therapeutic benefit that has been demonstrated by experimental evidence from randomized trials.

Is Early Detection Always Better?

- Lead time bias (in survival time)
 - lead time is the interval between the time of detection by screening and the time at which the disease would have been diagnosed in the absence of screening
 - because of the lead time, all individuals with disease identified as a result of screening will have a longer survival time than those diagnosed in the normal way
- Length time bias:
 - Less rapidly progressing cancers will not progress to symptomatic stages quickly and be more likely to be found by screening vs.. more aggressive cancers. Thus better outcomes seen in screen-detected vs. non-screen detected tumors
- Selection bias
- Overdiagnosis bias



Other Potential Negative Effects of Screening

- False positive test results (needless anxiety and follow-up investigations in asymptomatic, healthy individuals)
- False negative test results (patient has the disease, but this is not detected by the screening test; false sense of security)
- Complications from the testing (e.g., perforation of the colon from colonoscopy follow-up for FOBT positives)
- Labeling (the damage done when we tell someone who feels well that they are sick)

- Different Body Sites with differing
 - cancers that can occur
 - emotions and stigma attached to them

Screening promotion and recruitment approaches need to be tailored appropriately

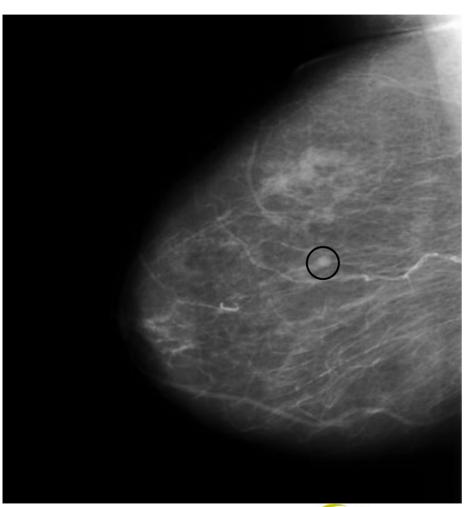
- Different screening tests carried out in different ways (target age groups, intervals)
- Different "testers" (family doctor- Pap, radiologist- mammogram, patient home test- FOBT) processed and reported on by different health care providers.
- Different specialists doing follow-up investigations, each group with their own community of practitioners: radiologists, gastroenterologists, gynecologists



- While basic screening performance indicators may be similar, cancer type specific indicators and benchmarks must be developed and analyzed by those who are expert in quality issues specific to the cancer type
- Therefore, a challenge to integrate breast, cervical and colorectal programs into one "cancer screening program" - - each cancer type will still need to have expert program committees to deal with quality issues specific to the cancer site



Mammogram Accreditation by the Canadian Association of Radiologists (CAR-MAP)



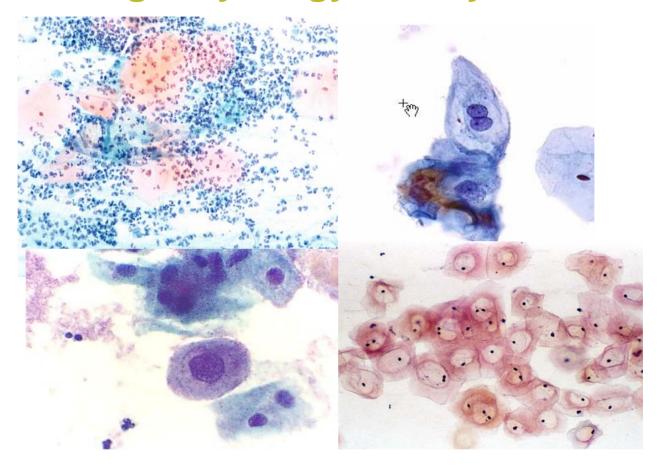
CAR-MAP sets standards for:

- equipment
- image quality
- radiology staff skills and qualifications

Colonoscopy Standards

- Expert Panel in Ontario, involving gastroenterologists
- What settings can colonoscopy be performed in?
 - Resources needed for best outcomes:
 - Infection control
 - Patient monitoring during and after procedure
 - Resuscitation capacity
 - Equipment standards
 - Evaluation and audit programs

Gynecologic Cytology Quality Assurance



Cytology lab standards, training and qualifications, rescreening, proficiency testing



- Separate funding envelopes exist for the different cancer screening programs and initiatives and these have been established at different times, based on program proposals developed for one cancer type.
 - Getting new programs for the healthy population through policy and funding decisions is a challenge

Cost issues –

- for new colorectal screening programs and for
- "retrofitting" existing programs into a new integrated model, including common IT population-based system.



Where does that leave us??opportunities for action:

- Health promotion and education initiatives, providing consistent, consolidated materials for public health nurses and primary care physicians, nurse practitioners – including pro's and con's of screening, to support informed participation.
- Performance reporting on cancer screening for breast, cervical and colorectal cancer sites should develop a common set of indicators, building on the extensive work in breast screening evaluation indicators
- With the capability of new information technology, evolution towards comprehensive information systems. As the rest of the health care system has become very interested in performance reporting, including wait times, and recognized the need for more population oriented data, there are opportunities to tie screening information system improvements into the bigger system initiatives
- Utilize the opportunities that present with the interest shown in colorectal screening to foster an integrated cancer screening strategy, and strengthen the existing programs.



"must do's" to ensure programmatic screening is supported

- Find more effective ways to make the case to funders
 (government) for organized screening programs for breast,
 colorectal and cervical screening in terms of economic benefit.
 This requires a shift from "health benefits" (e.g.. # of deaths
 prevented) to "# of dollars saved" in the system (timing and cost effectiveness, costs averted)
- Tie programmatic screening initiatives into the "bigger picture" health care initiatives in your jurisdictions
 - Primary Care Reform
 - Wait Times Benchmarks
- Education campaign to ensure that there is a good understanding of the difference between opportunistic/adhoc screening and organized programmatic screening; and principles of screening.



Key Components of Organized Screening Programs

Population-Based recruitment of eligible population e.g Letter of invitation	Population Information Systems target population screening data follow-up data results of screening & follow- up cancer and non-cancer outcomes	Evidence-based screening guidelines that are routinely reviewed & updated as new evidence emerges and implemented	Quality assurance programs in screening "right test given to right persons at the right timing"	Monitoring and evaluation of the impact of screening • accessibility /coverage • diagnostic test • utilization • yield, • positive predictive values • timelines of screening pathways • screening	Health promotion initiatives & evidence-based health education materials to support primary care and public health
				outcomes	

Models That May be Considered

Opportunistic Screening (current situation)	Focus on Development of Health Promotion & Educational Material Only	Focus On Primary Care Reforms Only (Family Health Networks)	Guideline Development & Dissemination With Measurement of Practice Patterns and guideline adherence	Fully Organized Program
			agnerence	

Dealing With New, Promising Screening Technology

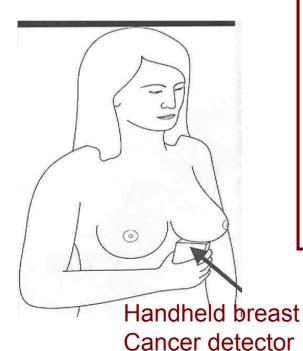
 Screening is a thriving industry - with many new technologies in production, some site-specific, some non-specific

Hand Held Optical Scanner for Early Detection of Breast Cancer

•a "first-line", affordable and easy to use mass screening

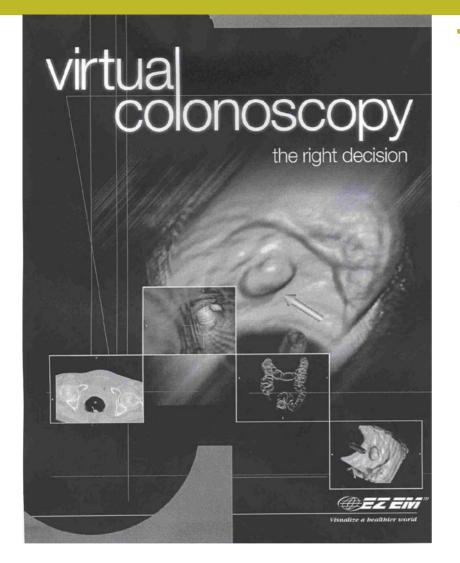
•available to the general population over the counter without a

prescription.



NIRScanner™ as a Personal Health Care Device

- •self-examination tool to complement periodic breast palpation.
- The NIRScan provides real-time, direct numerical and audible read out of the subsurface cancer location. The data is recorded in a computer or PDA for subsequent reading by the mammographer
- Based on pre-clinical tests (100 subjects to date)
 using laboratory prototypes, NIRScan provides 92%
 expectancy of correct diagnosis. This ROC (a
 measure of cancer discriminating capacity) is comparable
 to MRI and PET, hence better than X-Ray mammography.



The right time.... the right procedure.

While colorectal cancer is a highly treatable and preventable disease, patient resistance to the traditional diagnostic techniques means that only a small portion of those who should be tested actually are.

The time to begin colorectal cancer screening of the general population aged 50 and over – with an examination that studies the entire bowel – is now.

With tens of millions of prospective patients, colorectal cancer screening represents a significant opportunity for the right diagnostic technology.

Human Papilloma Virus Test: Magazine Advertisement





Conclusion

- There are definitely opportunities for integration
- Some of the programmatic barriers to integration need careful thought to determine which elements can be combined and when there must be unique cancer site specific elements.
- Integration can streamline cancer screening and strengthen cancer screening programs.
- Providing a sound basis for a "cancer screening program" can help us all tackle the evaluation of new technologies and provide key screening messages (regardless of cancer site) with a consistent approach
- Building a stronger foundation for justifying programmatic screening is needed – vs.. encouraging adhoc process improvements in the system.