

Providing Timely Information on New Screening Trial Results to Screening Planning and Policy Stakeholders

Co-Chairs:

Dr. Verna Mai (Canada) and Dr. Otis Brawley (United States)

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The Issue with New Publications from Major Trials

- Large randomized controlled trials evaluating potential screening tests:
 - are the best promise of definitive answers on screening efficacy - will screening reduce the risk of dying from cancer?
 - Mortality benefit results are obtained after years of follow-up in trials, thus - for years, not “top of mind” in planning
 - Once published, there can be much enthusiasm if benefit is shown; and much interest with negative results too!
 - Communications and media planning by journals has become an important part of journal publications - creating more media and public interest than ever.

How can we provide timely information on new screening trial results to screening planning and policy stakeholders?

The Challenge:

Often the progress of trials - are they reaching their endpoints and are they about to be published? - are not known (outside of the trial investigators)

But the results could provide very important information that changes our approach to screening tests and screening programs.

When can one expect trial results to be published?

- The long pathway to publication is somewhat unpredictable - peer review/ editor processes
- Getting the proposed publication date from journals and authors is a challenge.... Some mystique...
- “Advanced notice” helps - but this means only about 24-48 hours in advance under strict confidentiality
- A recent colleague’s perspective: Preservation of the “magic of the opening night on Broadway”

Major Trials Evaluating the Effectiveness of Screening for 4 Cancer Sites have published Mortality Outcomes over the past 3 years

- **PSA testing for prostate cancer** - March, 2009
 - publication of results of the ERSPC (European) and PLCO (U.S.) trials on PSA screening in the New England Journal of Medicine

Headlines in March, 2009

PSA Screening Cuts Deaths by 20%, Says World's Largest Prostate Cancer Study

Wed Mar 18, 2009 12:00pm EDT

STOCKHOLM, Sweden, March 18 /PRNewswire/ -- Screening for prostate cancer can reduce deaths by 20%, according to the results of the European Study of Screening for Prostate Cancer (ERSPC) published online March 18 in the New England Journal of Medicine (NEJM). The ERSPC is the world's largest prostate cancer screening study and provides robust, independently-verified evidence for the first time, of the effect of screening on prostate cancer deaths. The study commenced in the early 1990s involving eight countries: Belgium, Finland, France, Italy, Netherlands, Spain, Sweden, and the United Kingdom. The study included more than 180,000 men with an overall follow-up of up to 12 years. Participants

Studies show small benefit or none at all to prostate-cancer screening

U.S. and European studies tracked the health of over 250,000 men

Last Updated: Wednesday, March 18, 2009 | 4:42 PM ET Comments46Recommend32

CBC News



Higher than normal PSA levels could indicate prostate cancer. (CBC)

Two large international studies added fuel to the controversy Wednesday over whether prostate cancer screening saves lives of middle aged men.

The U.S. and European studies tracked the health of over 250,000 men. The U.S. study found no benefit from cancer screening, and the other study detected only a modest 20 per cent reduction in deaths.

The screening test in question is a blood test that measures levels of prostate-specific antigen, or PSA. When levels are high, a biopsy is needed to confirm a tumour, which could be so slow-growing that it doesn't pose a threat.

"Either that there was so little or no benefit that it clearly wasn't worth the risks. Or that the benefit was so large, that it was. What we're left with is something in between — that the benefit is fairly small ... and the risks are pretty big."

"My interpretation of the two studies together is that PSA screening likely does save some lives but does significant more harm."

— Dr. Otis Brawley

Major Trials Evaluating the Effectiveness of Screening for 4 Cancer Sites have published Mortality Outcomes over the past 3 years

- Flexible sigmoidoscopy (FS) for colorectal screening - 4 major trials internationally started in the 1990's

Trial	Start Year	Mortality Results Published
NORCCAP (Norway)	1999	2009
U.K. FS (U.K.)	1996	2010
SCORE (Italy)	1995	2011
PLCO (U.S.)	1993	2012

Good evidence that screening with flexible sigmoidoscopy can reduce mortality risk

- PLCO trial: 26% and 21% reduction in CRC mortality and 55-74.
- 3 of the trials show a statistically significant reduction in incidence of colorectal cancer and 2 of the trials found statistically significant reductions in colorectal cancer mortality.
- *How widely known or understood is this new status of flexible sigmoidoscopy as one of the options for screening? Is it known that colonoscopy does not have this much evidence backing its use?*

Major Trials Evaluating the Effectiveness of Screening for 4 Cancer Sites have published Mortality Outcomes over the past 3 years

- **Screening for Ovarian Cancer**

- publication of results from the Prostate, Lung, Colorectal and Ovarian (PLCO) trial on ovarian cancer outcomes in 2010

- **Lung Cancer Screening**

- results of National Lung Screening Trial (NLST) ***announced*** in November 2010 - “lung screening in High risk group effective”
- Publication of the NLST(U.S.) results Aug, 2011 (online June, 2011)
- Publication of PLCO (U.S.) results in October, 2011



This Session: What screening program planners and policy makers need

- This session will stimulate discussion on what type of “intermediate” information or briefing intervention is needed by screening policy and planning stakeholders and how that information need can be addressed by cancer organizations involved in knowledge transfer.
- Session presenters have been invited to speak on
 - What are the information needs of those stakeholder working on screening policy or in screening programs at or around the time of new publications on major screening trial results
 - What initiatives have been initiated in Canada and the U.S. to provide the right information at the right level of detail to address stakeholder needs.

Presenters and Chairs

- Dr. Tom Pickles (Canada) , B.C. Cancer Agency
 - Dr. Verna Mai (Canada) Canadian Partnership Against Cancer (CPAC)
 - Dr. Barnett Kramer (United States) National Institutes of Health
 - Dr. Otis Brawley (United States) American Cancer Society
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- B.Kramer and O.Brawley: National Cancer Institute's PDQ Screening and Prevention Editorial Board
 - T.Pickles: Chair of the PSA Testing Expert Panel, CPAC

- For Discussion
- What type of “quick response” information is needed in a timely manner, and what sort of format would be useful (between the actual scientific article itself and all of the background publications related to the RCT and the comprehensive literature review of the subject - which often takes a year or more to complete).
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- What approaches are being utilized in other countries?
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- Any Lessons learned?
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