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Oral Presentation Abstracts

Cervical Cancer Screening International Interest Group

The screen-and-treat strategy as an alternative screening for cervical cancer in remote regions of Colombia

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Background: The screen-and-treat strategy for cervical cancer control was recommended by the WHO in 2013. In 2011, Colombia approved the inclusion of this strategy within the Social Security Health Plan (POS) as a strategy for cervical cancer screening for women ages 30-50 years. **Methods:** The Colombian National Cancer Institute and the Ministry of Health implemented the screen-and-treat Strategy in remote Colombian areas which were selected for their high cervical cancer mortality rates, limited access to health services and poor adherence to cytology screening programs. Training and quality control systems were implemented. The evaluation of these systems was performed using the following criteria: screening coverage, percentage of positive tests, percentage of women fulfilling cryotherapy criteria, percentage of women receiving cryotherapy, percentage of women referred to gynecology, percentage of women who received the biopsy report and percentage of women with abnormal results receiving treatment. **Results:** 150 health professionals were trained in the screen-and-treat strategy; most of them nurses and gynecologists. During the three years in which this strategy was applied, 9,000 women have been screened; 11.4 percent were positive, of whom 76.3 percent received cryotherapy and 23.2 percent were referred to a gynecologist. The strategy was most effective in rural and remote areas, not in the urban areas. Women show great adhesion to the strategy and promoted it, in particular indigenous women, a group which normally is resistant against these types of interventions. Evaluation of the program showed that only 50 percent of positive women who had been referred, actually visited the gynecologist: among these, only 35 percent received the result of the biopsy. **Conclusions:** The screen-and-treat strategy for cervical cancer control was not optimally implemented at the regional level by local Health Authorities and Health Maintenance organizations (HMO). Probably, health professionals are so used to using Pap´s smear, they feel a certain resistance to changing their practices. Although the strategy was most effective in rural areas, these areas have far from optimal access for treatment of cancer. Based on this experience the Ministry of Health decided to include this strategy in Colombia´s 2012-2021 Cancer Control Plan; of which one of the aims is to implement the strategy in 100 percent of the municipalities of the selected departments by the year 2021.

Cervix cancer screening: HPV DNA testing versus visual methods in limited resource setting

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Introduction: Cancer burden in India is an emerging health problem in India with a changing cancer pattern, the remarkable one being the decline in cervical cancer incidence, 30 in 1980 vs 19 in 2010 per 100000 women in Chennai region. (MMTR 2010). This has happened, without any organized screening program ever being in place. Still, 36,000 new cases are predicted to occur over next five years in Tamil Nadu State. **Background:** Since there was no documented data on prevalence of HPV in the community, we conducted a cross-sectional study to ascertain the prevalence of HPV infection in Tambaram and Chengelpet Taluks of Kanchipuram District, Tamilnadu, between 19.02.2009 and 31.12.2009. 1523 cervical samples were collected and the overall prevalence rate of HR-HPV is found to be 12.7 percent, the most common type being HPV 16(27 percent). A follow up study to find the persistence of virus at one year interval is 29 percent and this is first such data in Indian population. An inbuilt study with HPV DNA test as primary screening test is compared to the Visual tests (VIA/VILI), the standard low resource technique. **Method:** Among the 1523 samples, the analysis was restricted to the women of age 25-54 years, total tests being 1312. VIA/VILI done on all women and all cases VIA/VILI negative confirmed with Colposcopy at primary screening and considered disease negative. Either or both positives were called again for cytology and Colposcopy guided biopsy. **Results:** 176 women tested positive for HR -HPV by HC-2 tests and 236 women tested positive for VIA/VILI. 48 women were positive for both. 219 women were evaluated and 7 cases of high grade dysplasias (CIN III -03, CIN II-04) detected among both positives, 7 cases (CIN III -01, CIN II-06) among HPV positive and VIA/VILI negative women and 3 cases of CIN II among VIA/VILI positive and HPV negative women. The sensitivity and specificity of HPV DNA testing are 82.5 percent and 87.76 percent and that of VIA/VILI are 58.8 percent and 82.55 percent respectively. **Conclusion:** The compliance for follow up evaluation being a limitation though, to accurately establish the efficacy of these primary screening methods, this pilot study provided a great learning experience to roll out a larger study using HPV DNA testing in a limited resource setting.

Small scale screening: working beside communities to create a sustainable solution to cervical cancer screening in the Peruvian Amazon

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Background: *DB Peru* has worked closely with Amazonian communities in the Napo River for 12 years. Health issues include remoteness, lack of resources, and poor health literacy. Cervical cancer is a common and stigmatized disease. However, provision of traditional pap-smear programmes is burdensome and inefficient: pap-smear results were frequently lost or delayed, and 83 percent of women we surveyed did not seek pap-smears due to distance, lack of transport, high transport costs, and environmental barriers. It is because of these issues that community members asked *DB Peru* to work with them to provide a sustainable, local cervical cancer prevention and education programme. There is a necessity for an innovative new approach that meets the community's needs. Our team sought more effective methods of cervical cancer prevention in low-resource and remote settings while exploring sustainable, long-term solutions in conjunction with local healthcare systems. **Methods:** We employed a community-based participatory model, using health and human rights philosophy to guide

us. Our initial needs assessment was performed in 2013. Ongoing community consultation was held in 2014. We plan to implement a 'screen-and-treat' program from April 2015, including baseline data collection, community education and collaboration, cervical screening and evaluation. **Results:** Based on our needs assessment and review of current literature and international guidelines, we propose a single visit 'screen-and-treat' program incorporating education, HPV DNA testing, visual inspection of the cervix with acetic acid (VIA) as a triage tool, followed by cryotherapy where necessary. HPV vaccination will occur in parallel to this. We will actively involve local health services and community health-workers during the program, with a vision to transitioning to locally-run services within ten years. Initial responses from the community have been positive with over 80 percent of community members supporting the benefits of sexual health education. Over 94 percent of women would participate in the 'screen-and-treat' program if offered. However, 63 percent of women interviewed still felt embarrassed, anxious or scared about having cervical screening, indicating that more needs to be in community education to improve the acceptability of cervical screening in this area. **Conclusion:** The community-based screen and treat model promises a sustainable long-term solution to cervical cancer screening in remote Peru.

Colorectal Cancer Screening International Interest Group

Colorectal cancer screening for safety net practices: strategies and opportunities to STOP colon cancer in priority populations

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Colorectal cancer is a leading cause of cancer death in the United States, and Latinos have particularly low rates of screening. *Strategies and Opportunities to STOP Colon Cancer in Priority Populations* (STOP CRC) is a partnership among two research institutions and a national network of 350 safety net clinics to promote colorectal cancer screening among populations served by these clinics. Nationally, Latinos represent 34 percent of the 20 million patients served annually by safety net clinics. The study will assess effectiveness of a systems-based colorectal cancer screening intervention in safety net clinics in Oregon and Northern California. The study has two phases: Phase 1 is a pilot phase in which we developed and tested our electronic health record (EHR) tools, and Phase 2 is a larger two-arm cluster-randomized comparative-effectiveness study involving 26 clinics (estimated population ages 50-74 = 30,000). Clinics in the intervention arm (1) will use an automated, data-driven, electronic health record-embedded program to identify patients due for colorectal screening and mail FIT kits (with pictographic instructions) to them; (2) will conduct an improvement process (e.g. Plan-Do-Study-Act) to enhance the adoption, reach, and effectiveness of the program. Clinics in the control arm will provide opportunistic colorectal-cancer screening to patients at clinic visits. The primary outcomes are: proportion of age- and screening-eligible patients completing a FIT within 12 months; and cost, cost-effectiveness, and return on investment of the intervention. Phase 1 findings showed an overall 38 percentage point increase in colorectal cancer screening in intervention, compared to Usual Care, clinics (39 percent vs. 1 percent), during the 6-month evaluation period. If successful, the Phase 2 program will prompt 12,000 patients to undergo FIT testing, and will detect about 40 new cancers. This large-scale pragmatic study will assess effectiveness of a scalable colorectal cancer screening program that will enroll a broad range of patients, including Latinos. Our EHR tools will realize a sustained impact on how screening is delivered in safety net clinics. Further research is needed to understand how to appropriately stratify patient populations to improve the efficiency of our direct-mail program.

Comparing measures to prevent imminent waiting lists for colonoscopy in fecal immunochemical test-based screening programs

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Background: In January 2014 the Dutch national colorectal cancer (CRC) screening program started (i.e. biennial FIT screening between ages 55 and 75 with a cut-off for referral to colonoscopy of 88 ng Hb/mL). According to the phased introduction scheme, individuals ages 63, 65, 67, and 75 were invited for screening. However, as a result of catch-up screening in 76-year-olds and higher attendance and referral rates than expected, the projected colonoscopy demand for 2014 substantially exceeded the colonoscopy capacity available. Hence, waiting lists were imminent. The aim of our analysis was to

determine which measure was best suited to reduce the colonoscopy demand for 2014: postpone screening in a particular age group or temporarily elevate the cut-off for referral in all age groups. **Methods:** We used the micro-simulation model MISCAN-Colon to simulate the Dutch screening program from 2014 up to 2026 given the observed attendance rate in 2014 and FIT test characteristics that were calibrated to the observed referral and detection rates (the 'no measures' scenario). Subsequently, we simulated 5 scenarios in which screening was postponed in one of the age groups (63, 65, 67, 75, or 76) and 3 scenarios in which the cut-off for referral in 2014 was elevated in all age-groups (150, 200, and 275 ng Hb/mL). For each scenario we determined the life-time increase in CRC deaths compared with the 'no measures' scenario as well as the reduction in colonoscopies required in 2014. The best measure to reduce the colonoscopy capacity required was defined as the measure that resulted in the largest reduction in colonoscopies per additional CRC death. **Results:** Postponing screening in 75- and 76-year-old individuals, which effectively means not screening them at all, reduced the number of colonoscopies required by 21 and 22 per additional CRC death, respectively. Postponing screening in 63-, 65-, and 67-year-old individuals, was somewhat more efficient, reducing the number of colonoscopies required by 54, 60, and 53 per additional CRC death, respectively. However, temporarily elevating the cut-off for referral in all age groups to 150, 200, and 275 ng Hb/mL reduced the number of colonoscopies required by 80, 75, and 68 per additional CRC death, respectively, and was most efficient. **Conclusion:** The best measure to prevent imminent waiting lists for colonoscopy in a FIT screening program is to (temporarily) elevate the cut-off for referral to colonoscopy in all age groups. If postponing screening in an age group is inevitable, a young age group should be chosen.

The New Hampshire Colonoscopy Registry: a comprehensive evidence base supporting individualized colorectal cancer screening

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Background: Since its origin in 2004, the New Hampshire Colonoscopy Registry (NHCR) has prospectively collected data on patients (demographics and risk factors), endoscopists, procedures (including quality variables and findings), and pathology from colonoscopies throughout New Hampshire. With nearly 10 years of follow-up data on early enrollees, the NHCR contains a uniquely valuable repository of long-term outcome data, to which new data are constantly added. By December 2013 the NHCR had collected data from over 80,000 baseline colonoscopies conducted by over 100 endoscopists, including more than 6,000 patients with both baseline and follow-up exams, and 9,000 patients with serrated polyps at baseline colonoscopy. **Methods:** Over 30 diverse academic and community endoscopy practices participate in the NHCR, introducing patients to the project and obtaining informed consent, collecting patient information and completing the NHCR Procedure Form. Pathology reports, requested from pathology laboratories for all exams with findings, are abstracted by trained NHCR staff, who record location, size, and histology linked to individual polyps identified on Procedure Forms. **Results:** Consent rates are uniformly high (over 80 percent), using an informed consent that grants permission for future contact. With data on over 80,000 exams, the overall Adenoma Detection Rate (2009-12) is 21 percent, the colonoscopy completion rate is 97.7 percent, and the rate of immediate complications is 0.25 percent. To date, colorectal cancer (CRC) has been detected in 329 patients (0.5 percent). NHCR molecular analyses have demonstrated that DNA methylation is important in the pathogenesis of both serrated polyps and conventional adenomas, and have also found distinct methylation signatures in left colon adenomas of smokers vs non-smokers, suggesting a possible link between smoking and DNA

methylation-driven adenomas. **Conclusion:** Comprehensive population-based data are essential to guide individualized screening programs. NHCR data, used in the collaborative investigation of research questions from gastroenterology, molecular biology, and pathology, can effectively stratify patients based on their risk of future CRC and high-risk polyps. Evidence-based clarification of patient risk will provide essential data for appropriate screening intervals, informing national and international guidelines for CRC screening and surveillance and helping to guide colonoscopy quality improvement efforts. The recently issued surveillance guidelines from the U.S. Multi-Society Task Force on CRC highlight several unresolved issues for effective screening that the data of the NHCR is uniquely suited to investigate, including assessing risk for advanced outcomes based on the type, size, location, and number of adenomas and serrated polyps found at baseline colonoscopy.

Impact of colonoscopy quality on the effectiveness and costs of colorectal cancer screening: A modeling study

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Background: Colonoscopy exam quality, as measured by the proportion of a physician's screening colonoscopy exams in which cancer or one or more adenomas is found (or adenoma detection rate), varies widely and is inversely related to patients' subsequent risk of colorectal cancer (CRC) diagnosis and mortality. The impact of colonoscopy exam quality on the lifetime effectiveness, complications, and costs of screening colonoscopy are unknown. **Methods:** We incorporated data from Kaiser Permanente Northern California on physician adenoma detection rates and interval CRC risks into the Microsimulation Screening Analysis (MISCAN) model, to analyze a simulated cohort of 10 million patients at average risk for CRC. We estimated the lifetime effects and costs of a colonoscopy screening and surveillance program according to adenoma detection rate quintiles (mean detection rate for each quintile ranged from 15.3 to 38.7 percent). The outcomes were lifetime CRC mortality risk, life-years lost due to CRC, number of colonoscopies, adverse events, and net screening costs. **Results:** The lifetime CRC mortality risk was 2.7 percent among unscreened patients. Among screened patients, the lifetime mortality risk decreased 62 percent between the lowest and highest adenoma detection rate quintiles (from 1.1 percent to 0.4 percent), and the life-years lost due to CRC decreased 58 percent (from 135.2 to 57.1 per 1,000 patients). Patients of physicians with the highest detection rates required more colonoscopies for post-adenoma surveillance and fewer subsequent screening exams, resulting in a net 15 percent increase in colonoscopies and a 0.9 percent to 1.4 percent increase in adverse events related to polypectomy. However, despite the increase in colonoscopy exams and adverse events, the higher-quality exams decreased net CRC screening costs by up to 84 percent due to averted cancer treatment costs. **Conclusion:** Based on MISCAN modeling, improving colonoscopy exam quality through higher adenoma detection may substantially reduce both the lifetime risk of death from CRC and the net cost of CRC screening and treatment.

International Interest Group on the Interface Between Primary Care and Cancer Screening

The role of primary care in cancer screening: international comparison study by Ca-PRI and the International Cancer Screening Network

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Background: Screening is a key feature of cancer control programmes worldwide. To date the roles for primary care in screening have not been described and compared in a systematic way. An international comparison may help optimise primary care's role in cancer screening. **Research Questions:** How does the role of primary care in cancer screening vary in a number of selected countries around the world? How does the local health service environment (structure, finance, constraints etc.) shape the role of primary care? **Methods:** Key informant interviews in 12 countries; Australia, Chile, Costa Rica, Netherlands, United States, Japan, Thailand, UK, Denmark, Israel, India and China complemented by a systematic literature review. **Results:** A number of key functions for primary care and cancer screening have been identified: *1) Pre-screening risk assessment:* the process by which invitation to screening is 'tailored' based on individual risk *2) Communication and information provision: 3) Promotion of uptake:* multiple factors determine uptake in cancer screening programmes, but engagement of primary care is typically associated with higher uptake. *4) Responsibility for screening coverage at practice or regional level: t*here is widespread variation in responsibility taken for coverage. *5) Actual provision of screening services:* There is a very broad range of providers of screening services, provision may be shared between PCPs and other agencies. *6) Coordination of follow-up after screening:* there is significant variation in the role of PCPs. **Discussion/Conclusion:** The organisation of both primary care and screening services vary considerably in the regions we have examined. The relative importance of the key functions for primary care depends on a range of factors including workforce capacity, availability of funding for cancer screening, and the place that primary care occupies within the health system of the country concerned. These differences and comparisons will be discussed in the presentation along with conclusions and recommendations about enhancing the role of primary care in a range of healthcare contexts.

Workshop on Overdiagnosis in Cancer Screening

Overdiagnosis due to mammography screening: estimates from South Australia

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Mammography screening is effective in reducing breast cancer (BC) mortality; however, there are widespread concerns that it may also lead to overdiagnosis, i.e., the detection of BC that would not have emerged clinically in a woman's lifetime had she not participated in screening. The extent of overdiagnosis due to mammography is contested, with published estimates varying from 0 percent to 54 percent. The principal aim of this research was to quantify the level of overdiagnosis of breast cancer due to population-based mammography screening in South Australia (SA). Two different methods were used to quantify overdiagnosis. Method 1 used a case-control design to compare screening histories for women with and without BC. Odds ratios (OR) were determined across different time intervals after screening to allow for lead-time effects. Cumulative incidence (CI) was calculated by applying these odds ratios to background reference rates, derived from projection of prescreening incidence trends. Overdiagnosis estimates were obtained by comparing CI with and without screening. Method 2 used a lead-time modelling approach in which estimates of lead-time duration and screening sensitivity and screening participation data were used to adjust the background incidence rates (without screening). This was achieved by iteratively adding the number of cancers expected to be brought forward by screening each year, then subtracting this number from the pool of cancers in future years. Overdiagnosis was calculated by comparing the lead-time adjusted CI with the observed CI. Both methods yielded similar estimates. Estimates from the case-control approach were 8 percent for invasive BC and 14 percent for all BC. Estimates were lower when adjustment was made for confounding due to higher background risk among screening participants. Estimates based on the lead time modelling approach were 8 percent and 12 percent for invasive BC and all BC respectively. These results are comparable with findings from long-term follow-up of screening trials and with several recent cohort studies of European screening programs, but are lower than many other estimates.

Reducing overdiagnosis by polygenic risk-stratified screening: findings from the Finnish arm of the European randomised study of screening for prostate cancer (ERSPC)

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Background: Overdiagnosis in prostate cancer and subsequent overtreatment impede the introduction of population-based screening. This study aims to estimate the mean sojourn time (MST) and sensitivity

and then use these estimates to derive the probability of overdiagnosis by polygenic risk group. **Methods:** We calculated the polygenic risk score based on 66 known prostate cancer susceptibility variants on 4,967 men from the Finnish arm of the European randomised study of screening for prostate cancer (ERSPC). We stratified the 80,179 Finnish trial participants into two risk groups below and above 50th percentile of polygenic risk. Using the maximum likelihood method based on interval cancers, we estimated the MST and episode sensitivity. We calculated the expected number of non-overdiagnosed screen-detected cancers over three rounds of screening. We estimated the proportion of screen-detected cancers that are likely to be overdiagnosed from the difference between the observed and expected number of screen-detected cancers. We derived overall and separate estimates of overdiagnosis by polygenic risk group. **Result:** Men in the higher risk group accounted for 73 percent of the cancers. The episode sensitivity was estimated as 0.55 (95 percent CI 0.45 to 0.65) and MST 6.3 (95 percent CI 4.2 to 8.3) years. The overall overdiagnosis was 42 percent (95 percent CI 37 to 52), and 58 percent (95 percent CI 54 to 65) in the lower risk group and 37 percent (95 percent CI 31 to 47) in the higher risk group. Compared to a population-based screening, targeting screening to men in the higher polygenic risk group was estimated to result in: 50 percent less screening episodes while detecting 80 percent of the non-overdiagnosed cancers and preventing 38 percent of the overdiagnosed cancers at a cost of missing 20 percent of the non-overdiagnosed cancers. **Conclusion:** Polygenic risk-stratified screening for prostate cancer is a promising approach to decrease overdiagnosis. Targeting screening to men at higher polygenic risk could improve the benefit to harm balance of screening.

Minimizing the harm of mammographic overdiagnosis

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Background: Mammographic screening is associated with diagnosis of ductal carcinoma in situ (DCIS), a precursor of invasive cancer, and also an example of harmful overdiagnosis, because of burdens of diagnosis-associated stress, mastectomy, or adjuvant breast radiotherapy (RT), among women who would not recur after breast conserving surgery (BCS). **Methods:** This work aimed to stratify risk among unifocal DCIS, resected with clear margins by BCS, by validating the DCIS Score, a 12 gene panel derived from the Oncotype DX Recurrence Score (Genomic Health, Incorporated), and tested in an ECOG prospective cohort. Original tissue blocks and slides were obtained for expert pathology review and for RNA extraction, facilitating the determination of the DCIS Score, among 457 Ontario women with unifocal DCIS, resected with clear margins by BCS between 1994 and 2003, who did not receive RT. This cohort has been followed up to 2010 for ipsilateral invasive and noninvasive recurrence using cancer registrations, pathology reports and hospital records. Time-to-event methods were used to examine the association between change in DCIS Score and (1) any ipsilateral recurrence, (2) ipsilateral invasive recurrence and (3) ipsilateral DCIS recurrence. **Results:** DCIS Scores were low risk for 298/457 women (65.2%), intermediate risk for 72/457 (15.8%) and high risk for 87/457 (19.0%). The 10 year risks of any local recurrence by DCIS score group stratified by risk group were: low risk = 9.7 percent; intermediate

risk = 27.1 percent; high risk = 27.0 percent (log rank p < 0.001). The 10 year risks of invasive occurrence were: low risk = 5.6 percent; intermediate risk = 16.7 percent; high risk = 16.3 percent, (log rank p = 0.017). The 10 year risks of DCIS recurrence were: low risk = 4.3 percent, intermediate risk = 11.4 percent; high risk = 12.1 percent, (log-rank p = 0.017). The HR for any local recurrence for a 50 unit increase in the DCIS score is 2.25 (95% CI 1.30, 3.89), for invasive recurrence is 2.15 (95% CI 1.05, 4.38), and for DCIS recurrence is 2.32 (95% CI 0.97, 5.52), adjusted for age, DCIS diameter, and morphologic subtype. Neither grade nor necrosis had any effect on the models. **Conclusions:** Risk of recurrence over 10 years among women with unifocal DCIS, completely resected with negative margins following BCS, can be stratified by the DCIS score, identifying a large number of these women (65.2%) who do well without any further treatment, and others (34.8%), whose risk of invasive recurrence within 10 years is much higher.

Session 1: Individualized Screening

A framework for developing risk-based screening guidelines: "Equal management of equal risks"

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To develop more "individualized" cancer screening regimens, attention has turned towards "risk-based screening", where a person's risk of disease is used to determine the course of action. We present, and critically examine, an intellectual framework for risk-based screening that we used to help inform the development of risk-based cancer screening guidelines. The key condition underlying our framework is that people with equal risk of disease also have equal benefit (and equal harm) from the intervention. Although this condition need not hold in general, it is a common unspoken assumption. Without evidence to the contrary, guidelines should enforce "equal management of people at equal risk of disease." Enforcement of "Equal management of equal risks" leads to simplified and consistent management of people with different risk factors or test results leading to the same disease risk, people who might also have a similar benefit/harm profile. First, we present our reanalysis of data from the National Lung Screening Trial, in which 3 annual rounds of CT screening reduced lung cancer mortality by 20 percent among heavy smokers. We developed a risk model for lung cancer mortality using information on demographics and smoking history, and divided participants into quintiles (Q1–Q5) of 5-year lung cancer death risk. Our key finding is that the number of lung cancer deaths per 10,000 person-years that were prevented by CT screening increased by risk quintile (0.2 in Q1, 3.5 in Q2, 5.1 in Q3, 11.0 in Q4, and 12.0 in Q5; p=0.01 for trend; Kovalchik et al., *N Engl J Med*, 2013). Although this finding suggests that CT lung screening guidelines could be based on risk, it inherently presumes "equal management of equal risks": that all people at same risk indeed experience the same benefit from CT lung screening. We present data critically examining whether "equal management of equal risks" holds for CT lung screening. We also present data that we delivered to a committee charged with developing cervical cancer screening guidelines for concurrent Pap and human papillomavirus (HPV) "co-testing." For example, women testing HPV-negative and Atypical Squamous Cells of Undetermined Significance (ASC-US) have cancer risk akin to that of women testing Pap-negative, for whom guidelines recommend a 3-year return. Thus, by "Equal management of equal risks", women testing HPV-negative and ASC-US might also return in 3 years (Katki et al., *J Low Genit Tract Dis*, 2013). We end by comparing our framework to other frameworks for "individualized" medicine.

The Nordic Information for Action eScience Center: advancing individualized screening in the Nordic countries

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Background: Cervical screening using cytological smears was introduced in the Nordic countries beginning already in the 1960s and has remained in principle mostly the same since. Despite the knowledge that human papillomavirus (HPV) is the causative factor in cervical carcinogenesis, the same

cytological screening recommendation currently typically is still used. Thus, all women are screened similarly, although it is well known that HPV16/18-positivity, for example, renders women to be at a relative risk of more than 10-20 compared to HPV-negative women. Yet, HPV-negative women are still recommended to participate equally often despite having a negligible risk for cervical cancer in the 10-year perspective. Despite all evidence to the contrary, universal screening guidelines thus persist, not the least due to a lack of IT systems capable of handling the organization and management of differentiating screening intervals according to individual, rather than age-based, risk. **Methods:** In order to address this lack of individualized screening and IT development, the Nordic Information for Action eScience Center (NIASC; www.nordicehealth.se), has been set up to advance the Nordic development of open source software designed for screening offices to be able to set up individualized, risk-adapted programs. The NIASC consortium contains, among others, representatives from the screening organizations in Sweden, Norway, Finland and Iceland, and specializes on large-scale collaborative projects in biobank and register linkage projects. Specific projects on cervical cancer includes machine learning methods for cervical cancer risk stratification based on women's entire past screening history; text mining of patient records for detection of early symptoms and side effects in screening; and methods for achieving improved screening engagement in high-risk individuals. **Results:** By the year 2018, NIASC aims to have introduced individualized, risk-adapted screening intervals in at least one screening program in at least one Nordic country. Expected deliverables include, among others, open source, free-of-charge risk-stratification software to be used by screening program offices, and improved evidence on methods for reaching high-risk individuals in the population. **Conclusion:** By addressing and advancing the development of adapted screening intensity to baseline risk, we anticipate better resource use in, and improved evidence-base for, cervical screening. Lessons learned can be transferred to other screening-preventable cancer forms.

Role of adherence in optimizing mammography screening

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Background: Although mammography is the most commonly used test for breast cancer screening and diagnosis, it has several potential harms such as false positives and unnecessary biopsies. The efficacy of mammography in cancer detection and mortality reduction is contingent upon personal risk factors and patient behavior (i.e., adherence to screening recommendations). In contrast to prior research and existing population-based screening guidelines/recommendations that consider only age, we propose a personalized mammography screening tool that accounts for both personal risk factors and different adherence behaviors of women. **Methods:** We developed an advanced decision-analytical model, a finite-horizon partially observable Markov decision process (POMDP) that uses tailored estimates of cancer risk based on risk factors and tailored estimates of adherence to optimize breast cancer screening. We use a validated micro-simulation model that was developed as part of US NCI's Cancer Intervention and Surveillance Modeling Network (CISNET) program to estimate input parameters and solve this POMDP model optimally for individual patients. **Results:** We find that our proposed personalized screening schedules outperform the existing guidelines with respect to the total expected quality-adjusted life years, while significantly decreasing the number of mammograms and false positives. We further find that women with low adherence should be recommended more frequent screening whereas low-risk women with high adherence rates should be recommended less frequent screening than most of the existing guidelines suggest. This finding has the following policy implications.

1) An aggressive screening policy such as annual screening may be promoted to the general population, 2) screening strategies should be adjusted in clinical practice based on women's adherence and screening intervals can be extended to two years for women with a history of high adherence 3) if US screening patterns change in the long run and women adopt biennial screening, then improving overall mammography adherence in the society becomes more critical. **Conclusion:** A personalized optimal mammography screening schedule strategy based on the probability of cancer at a given age while accounting for the non-adherence of a woman to the screening recommendations outperforms existing age-based screening recommendations. Our proposed statistics, probabilities of cancer and adherence, can be used to simplify the implementation of risk-based screening practices.

Exploration of the benefit of risk-stratified colorectal cancer screening based on common genetic variants: current status and future potential

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Objective: Common genetic variants contribute to colorectal cancer (CRC) risk and can be used to stratify the population into CRC risk categories. However, the discriminatory performance of such risk-stratification algorithms is currently limited. In this study, we investigate the current and potential future benefits of using risk-stratified colonoscopy screening, based on common genetic variants, versus uniform colonoscopy screening at ages 50, 60 and 70. **Methods:** We used the MISCAN-Colon microsimulation model to determine cost-effective colonoscopy screening strategies for people with a relative risk (RR) for CRC of 0.1, 0.2… 9.8, 9.9 and 10. The costs and effects of risk-stratified screening in the population were determined based on the current discriminatory performance of common genetic variants (area under the ROC curve (AUC) of approximately 0.6) compared to uniform screening at ages 50, 60 and 70 for all. Because it is expected that the discriminatory performance of risk-stratification based on common genetic variants will increase in the future, we also estimated costs and effects for risk-stratified screening based on hypothetical common genetic variants with higher levels of discriminatory performance (AUC of 0.65, 0.70, …, 0.90). **Results:** With current discriminatory performance, the optimal colonoscopy screening strategy ranged from no screening for people with a RR of 0.1 to screening every 3 years from age 40 until age 85 for people with a RR of 5.4 - 10. Screening at ages 50, 60 and 70 was optimal for people with a RR between 0.9 and 1.3. This stratification resulted in 1 percent more life years gained than uniform screening (less than 1 life year per 1,000 individuals) for the same overall costs. With increased discriminatory performance, the gain in life years increased from almost 4 percent for an AUC level of 0.65 to more than 18 percent for an AUC level of 0.90. **Conclusions:** Given the very modest discriminatory performance of common genetic variants in risk-stratification for CRC, the current benefits of risk-stratified CRC screening based on these variants are limited. New

variant discoveries are needed to yield a substantial improvement in discriminatory performance, and are necessary for risk-stratified screening to become clinically significant.

Do men and women need to be screened differently with the fecal immunochemical test? A cost-effectiveness analysis

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Introduction: Several studies have shown that positivity and detection rates of (advanced) colorectal neoplasia with fecal immunochemical test for hemoglobin (FIT) differ between men and women. Studies systematically evaluating the effect of these differences on FIT screening strategies are lacking. **Methods:** We estimated gender-specific FIT sensitivity and specificity based on first round positivity and detection rates in men and women observed in a FIT screening pilot (CORERO-1). Subsequently, we used the MISCAN-Colon model to estimate the harms, benefits and costs of 480 different gender-specific FIT screening strategies. We determined whether screening stratified by gender was more cost-effective than offering men and women the same screening strategy. **Results:** FIT sensitivity for non-advanced adenomas (0.8 percent versus 10.1 percent per lesion) and advanced adenomas (26.5 percent versus 46.7 percent per lesion) was significantly lower in women than in men. Consequently, annual FIT screening from age 50-80 was less effective in participating women (65 percent mortality reduction) compared to participating men (71 percent). FIT screening resulted in fewer QALYs gained (91 vs 116) and higher costs (€152,175 vs €40,899) in women compared to men. However, the *incremental* costs and benefits of this strategy compared to less intensive screening strategies were very similar (approximately €6,000 per QALY). Consequently, screening strategies stratified by gender resulted in similar costs and QALYs gained as uniform screening. **Conclusion:** FIT is less sensitive in women, especially for adenomas, and therefore screening with FIT is also less effective in women. However, FIT screening remains highly cost-effective in women. Despite the differences in sensitivity and effectiveness of FIT, FIT screening stratified by gender does not have benefits in terms of cost-effectiveness over uniform FIT screening.

Session 2: Implementation and Lessons Learned From Organized Programs

Comparison of cancer screening participation in the UK and the USA

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Background: The ways in which cancer screening is offered and delivered in the USA and UK are very different, due to differing health care policies and organisation. In the UK screening programmes for breast, cervical and colorectal cancer are provided through the National Health Service: patients in the eligible age-range are routinely invited for screening. In the USA, cancer screening is generally provided through a patient's family physician, and paid for through the patient's health insurance coverage, or Medicaid or Medicare. However, it is unclear to what extent screening coverage differs between the UK and USA. The purpose of this study is to compare coverage rates for breast, cervical, and colorectal screening between the two countries, and examine variation in coverage by sociodemographic factors. **Methods:** Data were compared for the year 2010 where available. Data for the USA were obtained from the U.S. National Health Interview Survey, a household in-person interview that includes questions on breast, cervical, and colorectal cancer screening utilization. In England, data on coverage for breast and cervical cancer screening were obtained from routinely available statistics, and for uptake of bowel screening from the NHS Cancer Screening Programmes. Data by Primary Care Organisation were linked to rural/urban classification and deprivation score. In Scotland, data were obtained from the SD/ISD Cancer Screening Division for breast, cervical, and colorectal screening. Coverage was defined as attending a mammography, cervical cytology, or colonoscopy or flexible sigmoidoscopy appointment or returning a completed FOBt kit within appropriate time periods and for target age ranges consistent with national screening guidelines. Comparative statistics on coverage rates, or uptake where coverage data were not available, were produced by age group (and gender for bowel screening) and for various sociodemographic factors, including deprivation and urban/rural classification. **Results:** Overall coverage was slightly higher in the USA than in England and Scotland for bowel screening (67%, 57%, 55%) and cervical screening (83%, 70%, 74%), but slightly higher in Scotland for breast screening (74.5% vs. 72% US, 68% England). Within countries, expected trends of decreasing coverage with increasing deprivation and lower educational attainment were observed, although differences by deprivation level were greater in the U.S. Comparisons of coverage in rural and urban populations suggested differing effects between countries. **Conclusions:** While coverage rates for breast, cervical, and colorectal cancer screening are generally higher in the USA compared with the UK, disparities for deprived groups appear to be greater in the USA.

Biting the bullet: from biennial Pap tests to 5 yearly primary HPV screening – renewal of Australia's national cervical screening program

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Background*:* Australia recommends 2-yearly cytological screening in women 18-69 years, and since 1991 the incidence and mortality of cervical cancer has halved. HPV vaccination was implemented in 2007 with subsequent reported falls of CIN2/3 in young women. A major review of the National Cervical Screening Program (NCSP) began in late 2011, which considered test, interval, age range and clinical pathway options for both HPV vaccinated and unvaccinated women against current practice. Pending policy approvals, Australia will implement a renewed program in 2016. **Methods*:*** A comprehensive dynamic model of HPV and cervical screening was used to evaluate the pathway options. The safety, effectiveness and cost-effectiveness of the options were independently assessed to make policy and funding recommendations for consideration by Governments. The Implementation Plan was and continues to be informed via stakeholder consultation, expert working groups, and the local Compass trial. **Results:** In April 2014, it was recommended that 5-yearly HPV screening with partial HPV genotyping in HPV vaccinated and unvaccinated women, 25-69 years of age, with exit testing to 74 years of age, should replace current practice. This strategy could result in decreases of up to 17-22 percent (unvaccinated) and 13-19 percent (vaccinated) in cancer incidence and mortality; decreases of 45-51 percent in the lifetime average number of screening/follow-up tests; and decreases of up to 10-17 percent (unvaccinated) and 21-29 percent (vaccinated) in treatments for CIN2/3. For partial genotyping, colposcopies would increase by 12-25 percent in unvaccinated women (driven by referrals in women 25-34 years) but decrease by 11-13 percent in vaccinated cohorts. Treatments would be more targeted, with a greater proportion in CIN3 versus CIN2. The Compass trial has demonstrated that screen-positive rates for HPV16/18 in women ages 25-33 years are low (0.9 percent (CI:0.3-1.9) for HPV16/18 and 13.6 percent (CI:11.1-16.3) percent for other oncogenic HPV) and comparable to those of older women. The Implementation Plan addresses subsidised health items, registers, workforce and practice change; quality and safety; and communication and information, involving both private and public healthcare providers. **Conclusions*:*** Holistic change requires an evidence based approach, consultation, collaboration and planning. Synergistic opportunities can be maximised and a tight timeframe garners momentum for action. Australia's renewed NCSP will be safe, at least 15 percent more effective and cost-effective. A large increase in colposcopies is not predicted due to the number of women HPV vaccinated in Australia.

Cervical cancer screening in Europe: quality assurance and organization of programs

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Background: Cervical screening programs have reduced cervical cancer incidence and mortality but the level of success is highly variable between countries. Organization of programs is essential for equity and cost-effectiveness. However, there are differences in effectiveness also among organized programs. In order to identify the key organizational components that determine effectiveness, we performed a

Europe-wide survey on the current status of organization and organized quality assurance (QA) measures in cervical cancer prevention programs as well as associated costs. **Methods:** A comprehensive questionnaire was developed through systematic literature review and reference to existing screening guidelines. The survey was piloted in a sub-set of countries and then sent to program organizers, Ministries of Health, and key experts in 34 EU and EFTA countries. Detailed aspects of program organization, quality assurance, monitoring, evaluation, and corresponding line-item costs were recorded. Documentation of program guidelines, protocols, and publications were requested. **Results:** Twenty-nine of 34 countries responded. The results showed that organized efforts for QA, monitoring and evaluation were carried out to a differing extent and were not standardized, making it difficult to compare the cost-effectiveness of organization and QA strategies. Most countries found it hard to estimate the costs associated with launching and operating the organized program. **Conclusions:** To our knowledge, this is the first questionnaire to request detailed information on the actual organization and QA of programs. The results of this survey can be used as a basis for further development of standardized guidelines on organization and QA of cervical cancer screening programs in Europe.

International comparison of recommendations and requirements for mammography screening program readers to start and continue reading screening mammograms

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Purpose: To describe and compare the recommendations and requirements to start and continue reading screening mammograms. **Method:** Seventeen mammography screening programs representing 13 countries responded to an ICSN web-based survey about audit feedback. As part of the survey we asked questions about the recommendations and requirements that the programs use for their mammogram readers to start and continue reading mammograms. We also collected data on the actions taken if readers or facilities did not meet their targeted guidelines. Descriptive data were analyzed using Stata and visual display* was created in Excel. **Results:** In general, the recommendations were more frequent that the requirements. Eight programs had both an academic and a review of a mentor requirement, 7 required a training program and 4 programs required that they shadow a reader to start reading mammograms. The UK required 6 different items before a reader could start to read while the USA only had one requirement. Seven of the 14 programs had more than one requirement. Recommendations and requirements changed for a reader to continue to read mammograms. Nine programs recommended that the reader achieve standards of reading according to guidelines or benchmarks but only 6 programs required this. The most common requirement (11 programs) was to read a specific number of mammograms. The UK had 7 different requirements to continue reading including the only country to require a quality plan if guidelines were not achieved. Four countries required that the reader participate actively in formal audit of reading performance. Only three countries required that the reader take part in screening and diagnostic mammography. Four programs required more than one remedial action for readers and six programs had at least one action for facilities to be taken if targeted guidelines are not achieved. **Conclusions:** Mammography screening programs have different recommendations and requirements to start and to continue reading mammograms. Some countries have very few requirements while others require many tasks from the

reader, particularly to continue reading mammograms. Quality improvement appears to be the basis for these recommendations and requirements.

*Figures will be included.

Does community-based integrated cancer screening lead to mortality reduction?

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Background: Community-based Integrated Screening (CIS) combining five major neoplastic (cervical cancer, breast cancer, colorectal cancer (CRC), oral cancer, and liver cancer) and chronic diseases (hypertension, diabetes, and hyperlipidaemia) has been implemented over the past decade in Taiwan. As the CIS mode covers a multitude of disease-specific interventions rather than a single one. It would be expected to see the reduction in all-cause and disease-specific mortality. The interest is also centred on how prevention of chronic disease makes additional combination to reduction in certain cancer-specific death (such as colorectal cancer). We therefore aim to evaluate the effectiveness of CIS in reducing all-cause death and disease-specific death and also assess the additional benefit of life-style modification related to metabolic syndrome through reduction in colorectal cancer mortality. **Methods:** We used the Keelung CIS (called KCIS) to demonstrate the benefit of CIS screening. Screening and population registry data for age over 30 was collected from Health Bureau of Keelung City from 1999 to 2009. The study design follows the principle of before-and-after quasi-experiment design by comparing the mortality before and after CIS with identical 10 year epoch. The projected CRC mortality reductions based on the disease natural history have been estimated using Markov Chain Monte Carlo simulation. **Results:** Total of 124, 345 eligible residents participated in the CIS program. The overall coverage rate was 56 percent. The relative rate (RR) for post-screening versus pre-screening was 0.80 (95 percent CI: 0.78-0.82) for ages 30-79. The most benefit of reduction mortality was a result of chronic diseases including cardiovascular disease, cerebrovascular disease, and diabetes mellitus and so on. The programme conferred the mortality reduction on cervical cancer for ages 30-69 (RR in female: 0.54; 95 percent CI: 0.43-0.67) and liver cancer for ages 30-69 (RR in male: 0.82; 95 percent CI: 0.75-0.90, RR in female: 0.72; 95 percent CI: 0.62-0.85). Around 23 percent reduction of mortality from breast cancer for women ages 40-49 years, the age range of peak incidence of breast cancer in Taiwan. Screening with FIT nested within this CIS programme demonstrated mortality reduction from CRC was 12 percent (95 percent CI: 0 percent-25 percent) given 70-82 percent attendance rate and 68-75 percent referral rate of undergoing colonoscopy. To add life style modification to the FIT screening let to 33 percent (14 percent Con-48 percent), 26 percent (6 percent-42 percent), and 23 percent (2 percent-39 percent) mortality reduction for annual, biennial, and triennial screening program, respectively. **Conclusion:** CIS has served over 120,000 Keelung people and saved numerous lives over the past decade. The 20 percent significant mortality reduction after 10 years of follow-up in the CIS programme has been demonstrated. Additional mortality reduction resulting from life style modification through CIS platform was noted. This suggests a multiple screening programme considering multiple disease prevention is effective in prolonging the life.

Session 3: Optimizing Benefits and Minimizing Harms

Mammography screening performance in the Dutch breast cancer screening programme: interval cancers 2004 to 2009

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Background: As of 2004, interval cancers occurring in the Dutch nation-wide breast cancer screening programme (BCSP) were identified by computerised linking of national screening data to the national cancer registry database. This results in full covering of all women screened so that they can be followed during their post-screening period being at risk for getting an interval breast cancer. Digitization of the BCSP started in 2008; in 2008 were 10 percent and in 2009 42 percent of all screening examinations digital. **Methods*:*** Records of 5.4 million women ages 50-75 years and screened during 2004-2009 were linked to the national cancer registry database. Unsure positive matches of identities were manually checked and all breast cancers classified as screendetected or interval cancer according to NETB guidelines. Age-adjusted recall (RR), detection (DR) and interval cancer rates (ICR), programme sensitivity and specificity with 95 percent confidence intervals (C.I.) were calculated by calendar year and age for all, initial and regular subsequent screening examinations. **Results:** Totally 11.885 interval cancers were identified within 24 months after screening, resulting in a crude ICR of 2.19 per 1000 women screened, and 2.08 per 1000 for invasive cancers only. The overall RR was 16.7 and the DR 5.46 per 1000 (4.54 per 1000 for invasive cancers only), the programme sensitivity 71.4 percent and the specificity 98.9 percent. The age-adjusted overall DR increased from 5.11 (95 percent C.I. 4.96; 5.26) per 1000 in 2004 to 5.85 (95 percent C.I. 5.70; 6.01) per 1000 in 2009, the ICR from 2.25 (95 percent C.I. 2.18; 2.33) to 2.35 (95 percent C.I. 2.27; 2.42) per 1000, and the programme sensitivity from 70.2 percent (95 percent C.I. 69.1; 71.3) to 72.2 percent (95 percent C.I. 71.2; 73.2). The DR of invasive cancers significantly increased, whereas ICR and the sensitivity showed a non-significant trend. In initial screens (12 percent of all screens), a slight but significant increase in sensitivity in 2009 could be observed. There was not statistically significant change in subsequent screen results (84 percent of all screens). **Conclusions:** The BCSP shows a stable and satisfying screening performance. Despite the significant 14 percent increase of the detection rate during the study period and the slightly increasing programme sensitivity, the interval cancer rate did not decrease. This is probably due to an increase of the underlying breast cancer incidence. The slight increase in sensitivity could be related to the transition towards digital screening in the recent years, but interval cancer results 2010 are needed to confirm it.

Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone within the PROSPR consortium

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Background: Digital breast tomosynthesis (DBT) in combination with digital mammography is increasingly used for breast cancer screening in the United States (US). Recent studies suggest that DBT reduces recalls and improves cancer detection compared to conventional digital mammographic (DM) screening. However, prior studies are limited by either small sample sizes at single institutions or lack of individual-level data. The National Cancer Institute-funded Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium offers a unique opportunity to assess screening across diverse health care settings in the US. **Methods:** The three PROSPR breast cancer screening research centers (University of Pennsylvania (Penn), University of Vermont (VT), and Geisel School of Medicine at Dartmouth in conjunction with Brigham and Women's Hospital (D-BWH)) include an integrated health care delivery system, statewide breast cancer surveillance system, and primary care clinical network. These three research centers combined data to evaluate screening DBT compared to screening DM in clinical practice. Logistic regression was used to estimate odds ratios (ORs) for screening recall and 95 percent confidence intervals (CI). **Results:** There were 17,511 bilateral screening DBT exams and 77,467 bilateral screening DM exams during the years 2011-2013 among women 40-74 years of age. Among DBT exams, 8.7 percent were positive (BI-RADS 0, 3, 4, or 5) compared to 9.9 percent positive among DM exams. DBT was associated with a lower risk of recall relative to DM (OR=0.87, 95 percent CI=0.82-0.92). The reduced risk of recall associated with DBT compared to DM appeared to be more pronounced among first screening exams (OR=0.73, 95 percent CI=0.64-0.83). There was a 19 percent reduced risk of recall associated with DBT compared to DM after adjusting for the radiologist interpreting the exam using conditional logistic regression (OR=0.81, 95 percent CI=0.75-0.88; number of radiologists=25). **Conclusion:** Our findings provide further support of a lower risk of recall associated with screening DBT relative to screening DM in clinical practice in the US. Supplementary analyses assessing patient age and breast density are underway. Additional performance metrics, including the positive predictive value for recall and the cancer detection rate, will be compared in future analyses.

Quantifying benefits and harms in cervical cancer screening: a decision-analytic approach

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Purpose: New triage strategies for women with abnormal findings may improve the effectiveness of the current Norwegian cervical cancer screening program. However, decision-makers are faced with a trade-

off between benefits (maximizing the detection of high-grade precancerous lesions (*i.e.*, CIN2+)) and harms (increasing the number of diagnostic tests (especially colposcopies)). To inform both decision-makers and screen-eligible women regarding the trade-offs between the benefits and harms, our objective was to enumerate the number of detected CIN2+ and colposcopies required by a set of candidate screening strategies. **Methods:** Using epidemiologic data from the Cancer Registry of Norway, we developed an age-stratified (25-33 and 34-69) probabilistic decision tree model following a cohort of women attending primary screening through one screening round (*i.e.,* 3 years), allowing for loss-to-follow-up and spontaneous regression of CIN2+. We compared the current triage guidelines involving co-testing (HPV and cytology) with nine alternative strategies involving reflex HPV-testing for women with low-grade or inadequate primary cytology results. Model outcomes included the number of CIN2+ detected and the number of colposcopies/biopsies associated with each strategy. As a performance indicator, we calculated the incremental harm-benefit ratios (IHBR) for each strategy compared with the next most harmful strategy, defined as the additional colposcopies required per additional CIN2+ detected. **Results:** For a cohort of 100,000 women we projected that the current guidelines would detect 1,325 and 473 CIN2+, and require 3,572 and 1,373 colposcopies, for ages 25-33 and 34-69, respectively. For the alternative strategies, these outcomes ranged from 1,366-1,725 CIN2+ and 3,022-5,560 colposcopies for ages 25-33, and 462-525 CIN2+ and 1,366-2,299 colposcopies for ages 34-69. For both age groups, the current guidelines represented one of the least efficient strategies *(i.e.*, strongly dominated) with respect to the IHBR, while the candidate strategies yielded IHBRs that ranged from 0.67 to 28.93 colposcopies per additional CIN2+ detected, depending on age. **Conclusions:** By adding reflex HPV-testing to primary screening there is a potential to improve both effectiveness and efficiency of the current screening program. Increased effectiveness, however, involves a trade-off between benefits and harms. The optimal strategy therefore depends on society's willingness to pay for additional precursors detected, as well as women's willingness to accept additional colposcopies.

The impact of overdiagnosis on the selection of efficient lung cancer screening strategies using low-dose computed tomography

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Background: The U.S. Preventive Services Task Force (USPSTF) recently updated national lung screening guidelines that recommend using low-dose computed tomography (LDCT) for screening for lung cancer till age 80. However, concerns are being raised on the risk of overdiagnosis among the older screened population. **Objective:** We estimate overdiagnosis of lung cancer under various CT screening strategies and evaluate efficient lung screening strategies that maximize the number of prevented LC deaths due to screening (D) per overdiagnosed cases (O) (D/O ratio). **Design:** Using four comparative models from Cancer Intervention and Surveillance Modeling Network (CISNET), 576 hypothetical scenarios are evaluated. Included is a direct comparison between the USPSTF scenario, which recommends 80 as a stopping age and the National Lung Screening Trial (NLST)-like, which stops at age 75. **Results:** Higher overdiagnosis rate is observed for the USPSTF scenario versus the NLST-like scenario (model range (MR): 5.5 percent-23.2 percent vs 4.4 percent-17.6 percent) due to extended stopping age. The NLST-like scenario has higher D/O value than the USPSTF scenario (MR: 2.1-5.6 versus 1.5-4.5); the difference of which is translated into 645 LC prevented deaths per 1000 overdiagnosed cases (MR: 380-1095 per

1000). All of the top efficient screening strategies selected to maximize D/O screen through age 75 and include the NLST-like strategy as one of efficient strategies. These results differ from the efficient strategies selected when maximizing D, all of which stop screening at age 80, which include the USPSTF recommendation. **Limitations:** Scenarios assumed 100 percent screening compliance. **Conclusions:** Overdiagnosis risk can affect the selection of efficient screening strategies. Strategies that stop screening at age 75 versus 80 produce greater efficiency in reducing LC deaths per overdiagnosed case, and merit closer review when balancing screening benefits and harms.

The (cost-)effectiveness of lung cancer screening in Ontario, Canada

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Background: The results of the National Lung Screening Trial (NLST) and the recommendations of the United States Preventive Services Task Force (USPSTF) have led other nations to consider implementing lung cancer screening policies. In this investigation, the benefits, harms and cost-effectiveness of implementing lung cancer screening policies in Ontario, Canada are assessed. **Methods:** The MISCAN-Lung microsimulation model was used to simulate different cohorts of men and women, using Ontario specific information on population characteristics such as smoking behavior. Screening policies utilizing the eligibility criteria of the NLST, the Dutch-Belgian lung cancer screening trial (NELSON) and the recommendations of the USPSTF were used as base policies. Variations of the base policies with regards to age and smoking related eligibility criteria and intervals between screenings were considered. The benefits (such as the reduction in lung cancer mortality and the number of life-years saved), harms (such as the amount of overdiagnosis and number of false-positive results), total costs (in 2013 Canadian dollars) and cost-effectiveness of each policy were investigated. **Results:** The base policies lead to reductions in lung cancer mortality between 8-11percent and have favorable cost-effectiveness ratios between $31,920-$35,917 per life-year gained. Biennial screening leads to marginal improvements in cost-effectiveness ($31,427-$34,387 per life-year gained) compared to annual screening, but major reductions in program effectiveness (reductions in lung cancer mortality between 5-7%). Starting at age 60 compared to age 55 leads to marginal improvements in cost-effectiveness ($31,635-$35,474 per life-year gained), but minor reductions in program effectiveness (reductions in lung cancer mortality of 7-10%). Stricter smoking eligibility criteria (e.g., higher cumulative smoking exposure) substantially improve the cost-effectiveness of lung cancer screening ($29,326-$34,705), with minimal reductions in program effectiveness (reductions in lung cancer mortality of 7-11%). **Conclusion:** Lung cancer screening policies based on the designs of the NLST, NELSON or the USPSTF recommendations can reduce lung cancer mortality in a cost-effective manner. However, utilizing more restrictive age and/or smoking related eligibility criteria compared to these designs may substantially improve the cost-effectiveness of

lung cancer screening with only minor differences in program effectiveness, due to the focus on screening persons at higher risk for lung cancer.

Effectiveness of quantitative fecal immunochemical testing in reducing colorectal cancer mortality from the One Million Taiwanese Screening Program

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Background: The effectiveness of the quantitative fecal immunochemical test (FIT) at reducing colorectal cancer (CRC) mortality has not yet been fully assessed in a large population-based service screening program, especially using different brands with same cut-off concentration. The study aim is to evaluate the overall effectiveness of colorectal cancer screening and compare each effectiveness of two brands FIT in Taiwanese population-based screening program. **Methods:** A prospective cohort study on the follow-up of approximately five million Taiwanese during the period of 2004 to 2009 was conducted to compare CRC mortality between the exposed (screened) group and the unexposed (unscreened) group in a population-based CRC service screening targeting whole residents ages 50 to 69 years in Taiwan. Given clinical capacity, this nationwide screening program has been rolled out since 2004. The total of 1,160,895 eligible subjects, covering 21.4 percent of 5,417,699 subjects of the underlying population, participated in a biennial nationwide screening program until 2009. Among the available FIT concentration, the 78 percent were tested using the OC-Sensor (Eiken Chemical Co, Japan) and 22 percent were tested using the HM-Jack (Kyowa Medex Co Ltd, Japan). Both cut-off concentrations for a positive finding was 20μg hemoglobin/g feces, based on a standardized reporting unit system. **Results:** The actual effectiveness of reducing CRC mortality attributed to the FIT screening was 62 percent [relative rate (RR) for the screened group compared to the non-screened group =0.38, 95 percent CI: 0.35-0.42)] with a maximum follow-up of 6 years. The program brought about a 10 percent [RR= 0.90 (95 percent CI: 0.84-0.95)] significant reduction in CRC mortality after adjusting for self-selection bias. The rate of interval cancer rate was 30.7 and 40.6 per 100, 000 person-year for those receiving the OC-Sensor HM-Jack test. Significant difference in test sensitivity (80 percent vs 68 percent, P=.005) was noted. After adjusting for differences in city/county, age, sex, ambient temperature, and colonoscopy quality, significant differences were observed between the tests in the positive predictive value for cancer detection (aRR= 1.29; 95 percent CI: 1.14-1.46) and the rates of interval cancer (0.75; 95 percent CI: 0.62-0.92). Each test was estimated to reduce CRC mortality by approximately 10 percent. There was lacking of significant difference in mortality reduction for the two brands. **Conclusion:** Nationwide CRC screening program can lead to a significant 10 percent CRC mortality reduction. Further reduction in colorectal cancer mortality would be expected if the population covered with fecal immunochemical test is to be expanded in ongoing program. Different brands of quantitative FITs, even with the same cut-off hemoglobin concentration, perform differently in mass screening. No significant difference in mortality was observed when the two groups were compared.

PSA testing for prostate cancer: would organised screening be cost-effective compared to current practice? Evidence from Ireland

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Background: In Ireland, as in many developed countries, prostate cancer incidence has been rising steadily for 20 years. In 2008, Ireland had the highest incidence rate in Europe. In addition, prostate specific antigen (PSA) testing is widespread in primary care. We undertook a cost-effectiveness analysis (CEA) of PSA testing in Ireland. **Methods:** Non-cost parameters were synthesised, using a Bayesian Multi-Parameter Evidence Synthesis framework, informed by incidence and clinical data from the National Cancer Registry Ireland for prostate cancers diagnosed 2009. The CEA used a semi- Markov model following a cohort of 100,000 men from age 30 to death to compare organised PSA testing versus no organised PSA testing (i.e. current practice). Men were assumed to be tested once-off at age 50, 55, 60 or 65; or, starting at age 50, every 5 years or every 10 years until age 70. In the base-case, the PSA cut-off for referral for prostate biopsy was 3ng/ml. A payer's perspective was adopted. Unit costs were estimated from a study survey, Irish reference costs, and the literature. Screening effectiveness and uptake parameters were derived from trials; data from the ERSPC was used in the base-case. Utility data was collected from 2,500 prostate cancer survivors in Ireland. Costs and benefits were discounted at 5 percent per annum as recommended for Ireland. **Results:** In the base-case a once-off PSA test at 50 years compared to current practice resulted in an incremental cost-effectiveness ratio (ICER) of €27,888 per life year gained (LYG) and €25,093 per quality-adjusted life year (QALY) gained. Once-off PSA testing at 55, 60 or 65 years resulted in ICERs of €32,503 per LYG and €41,919 per QALY gained; €45,797 per LYG and €39,506 per QALY gained; and €82,413 per LYG and €65,762 per QALY gained, respectively. PSA testing every 10 years starting at age 50 to age 70 resulted in an ICER of €59,166 per LYG and €49,765 per QALY gained and testing every 5 years to age 70, €139,750 per LYG and €105,584 per QALY gained. Estimates were sensitive to assumptions about screening effectiveness (as effectiveness decreased, ICERs increased) and utility weights. **Conclusion:** Depending on the cost-effectiveness threshold and the budgetary impact, once-off PSA testing at 50 or 55 years could be deemed cost-effective compared to current practice. However, the results were sensitivity to values of key parameters. This CEA contributes to the ongoing international debate regarding PSA testing and can provide much needed support to inform decision making in the healthcare system.

Likely effect of adding flexible sigmoidoscopy to the English NHS bowel cancer screening programme: Impact on colorectal cancer cases and deaths

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Background: From 2013, once-only flexible sigmoidoscopy (FS) at age 55 is being phased into the England NHS bowel cancer screening programme (NHSBCSP), augmenting biennial guaiac faecal occult blood testing (gFOBT) at ages 60-74. Here, we project the impact of this change on colorectal cancer (CRC) cases and deaths prevented in England by mid-2030. **Methods:** We simulated the life-course of English residents reaching age 55 from 2013 onwards. Model inputs included population numbers, invitation rates and CRC incidence and mortality rates. The impact of gFOBT and FS alone on CRC

incidence and mortality were derived from published trials. For FS plus gFOBT, we assumed the gFOBT effect to be 65 percent of the current gFOBT impact if FS uptake is 71 percent, and 75 percent if FS uptake is 50 percent. **Results:** By mid-2030, 8.5 million individuals would have been invited for once-only FS screening. If FS uptake is 71 percent, adding FS to gFOBT screening is estimated to prevent an extra 13,689 cases and 3,154 deaths by mid-2030. If FS uptake rate was 50 percent, an extra 9,627 cases and 2,207 deaths would be prevented. Sensitivity analyses revealed that uncertainty about CRC incidence and mortality rates and FS invitation rates impact these modelled predictions by up to 52 percent. **Conclusion:** Adding once-only FS at age 55 to the NHSBCSP will prevent approximately 10,000 CRC cases and 2,000 CRC deaths by mid-2030 if FS uptake is 50 percent. The actual reductions will depend on the FS invitation schedule and uptake rates.

Panel Discussion of Breast Cancer Screening in Light of New Evidence

IARC Handbook of Cancer Prevention Vol. 15: Breast Cancer Screening

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The first step in cancer prevention is to identify the causes of human cancer followed by an evaluation of the effectiveness of prevention strategies. In 1995, the *IARC Handbooks of Cancer Prevention* were launched to complement the *IARC Monographs* by providing evaluations of approaches to cancer prevention. Since the inception of the series, evaluations have included: chemo-preventive agents (NSAIDs, carotenoids, vitamin A, retinoids), preventive actions (use of sunscreens; weight control and physical activity; fruits and vegetables; cruciferous vegetables, isothiocyanates and indoles), effectiveness of screening (for cancers of the breast, and cervix) and effectiveness of tobacco control (reversal of risk after quitting smoking; smoke-free policies; tax and price policies). Breast cancer is the leading cancer in women worldwide both in the developed and developing world and the potential role of primary prevention is limited because most risk factors for breast cancer are directly linked with endogenous hormone levels and choices of child bearing. Therefore, secondary prevention encompassing all forms of screening for breast cancer is a priority. In 2002, IARC evaluated the efficacy and effectiveness of breast cancer screening. Numerous developed countries worldwide have since introduced breast cancer screening as an organized screening program to reduce mortality from breast cancer. Results from these population-based screening programs need to be evaluated in the context of improved survival from clinically diagnosed cancers. Further, significantly more data are now available on other screening modalities, such as self-breast examination, clinical breast examination, magnetic resonance imaging, and ultrasonography. Finally, tailoring of screening programs to country-specific resources needs to be considered. Therefore, an up-to-date, objective and independent evaluation of the benefits and harms of mammography screening in different age groups is urgently needed. Also, the effectiveness of mammographic screening for high-risk women needs a thorough evaluation, particularly in context with better data now being available on alternative screening methods. IARC will soon reevaluate the efficacy and effectiveness of breast cancer screening by conventional mammography, as well as by other modalities such as those issued from new technologies, and clinical breast examination and self-breast examination. The meeting will take place November 11-18, 2014. The outcome of the meeting will be presented at the conference.

The effect of population-based mammography screening in Dutch municipalities on breast cancer mortality: long-term follow up

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Background: In 2003, the effect of the mammography screening programme in The Netherlands on breast cancer mortality in women was assessed by analysing breast cancer mortality rates from 1980 to 1999, adjusting for the gradual implementation of the screening programme (i.e., between 1990 and 1997). Ten additional years of breast cancer mortality data are used to update this analysis. In addition,

the effect of screening women aged 70-74 on breast cancer mortality rates can now be assessed, because long-term data, since the extension of the upper age limit of the screening programme from age 69 to 74 in 1998, are now available. **Methods:** We collected data of 70,876 breast cancer deaths that occurred between 1980 and 2010. Time trends in breast cancer mortality were analysed, taking the calendar year in which screening was implemented in a particular municipality as year 0, thereby adjusting for differences in the calendar year of introduction of screening between municipalities. A non-linear Poisson regression model was used to estimate the time point (number of years after introduction of screening), at which a possible trend change in breast cancer mortality occurred. To assess a possible effect of screening women in the age groups 50-69 and 70-74 on breast cancer mortality rates, we estimated the trend change in the age groups 55-74 and 75-79, to account for a delay in the effect of screening. **Results:** The trend change in breast cancer mortality rates for women aged 55-74 most likely occurred in year 2 (after introduction of screening). Before this trend change, breast cancer mortality rates slightly increased by 0.05 percent (95 percent CI: -0.23–0.32) annually and afterwards breast cancer mortality rates decreased annually by 1.8 percent (95 percent CI: 1.6 – 2.0). For women aged 75-79, the trend change most likely fell in year 6 (thus, 6 years after the introduction of screening, which coincides approximately with the year the screening programme was extended to include the age group 70-74 years). Before year 6 breast cancer mortality rates increased annually by 0.5 percent (95 percent CI: 0.1–0.9), hereafter an annual decrease of 1.6 percent (95 percent CI: 1.3 – 1.9) was noticeable. **Conclusion:** The implementation of routine mammography screening in The Netherlands is related to a change in breast cancer mortality from a slightly increase towards a relatively stronger decrease among women aged 55-79. Our data support that mammography screening until age 74 contributes to a reduction in breast cancer mortality.

Session 4: Screening in Low-Resource Countries and Populations

Clinical trial to implementation: cost and benefits of scaling up cervical cancer screening in India

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There is a growing need to create the evidence-base for implementing and translating findings from clinical trials to make them operational and scalable. Several large and small clinical studies on cervical cancer screening have been conducted in many low- and middle-income countries (LMICs) and lessons learned from these studies can be extrapolated to assess the cost and benefits of scaling up screening programs. Adequate resources need to be allocated along the continuum of cancer care to ensure that screening programs are effective and result in the anticipated benefits.

We developed a detailed framework to translate the benefits, harms, and costs from clinical trials to the real world setting by identifying components that will be impacted during scale up. Key constructs of the framework are adherence to screening and follow-up, access to care, and quality of care. The critical pathways leading from randomized research studies to large scale screening programs are based on the review of the literature on screening implementation and expert interviews. Barriers and facilitators at the patient, provider, and health system level are incorporated in the framework.

We used data from two large scale screening trials in India from the Dindigul and Osmanabad districts to draw inferences on the benefits and cost of implementing large scale screening programs based on the translational pathways identified in the framework. The Dindigul district screening program was a cluster-randomized trial comparing visual inspection with acetic acid (VIA) with a no-screen control group (usual care) while the Osmanabad study compared VIA, conventional cytology, HPV DNA testing and a control group. Compliance with screening and follow-up recommendations anticipated to occur in the real world setting were used to assess potential benefits from the screening approaches (range estimates were used to reflect uncertainties in the estimates). Detailed activity-based cost data that were categorized into fixed and variable components were used to determine the estimated costs related to scaling up screening. This evaluation study is currently ongoing and the results will be available in early 2015 to provide the economics evidence-base to foster cost-effective scale-up of cervical cancer screening in India and other LMICs. We will also discuss additional research required to advance implementation science related to the economics of cervical cancer screening.

HPV DNA test as primary screening technology for cervical cancer screening in rural China: a real-world feasibility study

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Background: The national cervical cancer screening program for rural women has been expanded to 10 million women every year since 2012 in China, which was based on VIA/VILI and Pap smears. In low resource settings, the efficiency of VIA/VILI and Pap smears in the real world were unsatisfactory and it is difficult to set up effective screening systems. HPV test is now recommended as the primary screening. A low cost, rapid and simple test came into market recently (careHPV™ test; QIAGEN, Gaithersburg Inc.) Success of setting up a high-quality screening system by HPV test requires good performance when operated by personnel with limited laboratory experience. The main purpose of this study was to evaluate the feasibility of implementing the rapid HPV test as primary screening tool for cervical cancer screening by local health workers in rural China. **Methods:** Women participated voluntarily and were randomized into 3 arms and screened by careHPV test, Pap smears or VIA/VILI separately. Any positive and 10 percent negative women were referred to colposcopy. Directed biopsy and/or ECC were performed if necessary. A laboratory-inexperienced local worker was trained by a technician from NCC/CHCAMS. All the screening procedures were performed by local health workers. The final diagnoses were based on a histopathology expert from NCC/CHCAMS. Some of the screened women and rural health workers were invited to finish a questionnaire. **Results:** 900 women had careHPV test, 560 underwent VIA/VILI, and 579 had Pap smears. The overall detection rate for CIN2+ was 0.64 percent. The positive rates for HPV test, VIA/VILI, and Pap smears were 10.6 percent, 17.9 percent, and 5.7 percent respectively (p<0.001). The detection rates for CIN2+ showed no statistically difference (p=0.937). The false negative for CIN1 was 50 percent in Pap smears group. The compliance of careHPV group was significantly higher (p<0.001). 266 women and 25 health workers finished the questionnaire. 9.1 percent women with VIA/VILI complained about the pain (careHPV 4.5 percent, Pap smears 2.3 percent). The vast majority women (97 percent) and all the health workers preferred HPV test irrespective of the cost. **Conclusion:** After a simple training, experience-limited personnel could operate the careHPV test appropriately. The referral rate of HPV test is proper for population screening in the real world. Our study proved HPV test is possible to implement in rural areas technically and is acceptable to the women and rural health workers. It also implied that free and good quality screening methods may improve the coverage of cervical cancer screening for government initiated programs.

Use of cold coagulation as an alternative treatment modality in a "see and treat" programme of cervical screening in rural Malawi

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Background: Cervical cancer is the most common female cancer in Malawi, with incidence projected to increase in coming decades. Although government policy supports screening using visual inspection with acetic acid (VIA), in reality screening provision is limited due to lack of infrastructure and trained personnel, and the cost and availability of gas for cryotherapy. Recently, cold coagulation has been acknowledged as a safe and acceptable procedure suitable for low-resource settings. **Aim:** To introduce cold coagulation as an alternative to cryotherapy within a pathway of care (screening with VIA, treatment with cold coagulation, enhanced surgical skills for Wertheim hysterectomy, specific follow-up and palliative care clinics) at Nkhoma Hospital in central Malawi. **Methods:** Detailed planning was undertaken for VIA clinics, approvals obtained from the Ministry of Health, and Regional and Village Chiefs. Awareness sessions were held in hospital, health centre, and village settings. Two cold coagulators were introduced into the clinic setting and both theoretical and practical training were provided in safe use and maintenance of equipment. Daily screening clinics are held in Nkhoma hospital, with weekly clinics being introduced to associated health centres. **Results:** Over 3,500 women were screened with VIA in the first 9 months. VIA positivity is less than 10 percent. 80 percent of VIA-positive women received treatment using cold coagulation, over 75 percent on the same day. Treated women return for 3-month and 1-year follow-up visits. **Conclusions:** Introduction of cold coagulation has proved to be acceptable to both providers and patients in this setting. Provider support includes initial familiarisation and training, plus ongoing competency assessment. This treatment modality is one component of a pathway of care designed to reduce the incidence of and mortality from cervical cancer in this low-resource setting.

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Tailoring South Korea's breast cancer screening strategy to its incidence peak found in women aged 40-50

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Background and objective: South Korea is known as one of the four "Asian Tigers" that experienced rapid economic growth during the '80s and '90s of the twentieth century. This led to an increase in life expectancy, yet South Korea's public health faces increased cancer incidence and mortality. Breast cancer is currently the most common cancer in South Korean women. Although incidence and mortality are still relatively low compared to many European countries, South Korea introduced its National Cancer Screening Program (NCSP) in 1999. It recommends and offers biennial mammography screening for women over 40 years of age. In contrast to many European countries that observe a peak in incidence in women aged 50-60, South Korea's highest incidence levels are observed in women aged 40-50. Adherence to the breast cancer screening program doubled from 14 percent in 2002 to 30 percent in 2007. This rate is still relatively low compared to adherence rates observed in western countries such as the United Kingdom, United States, and The Netherlands. The purpose of this study is twofold: to quantify the effects of increased adherence under different screening scenarios on breast cancer incidence and mortality and to evaluate what screening strategy is optimal for women aged 40 years and older. **Methods:** We estimated the effects of several screening strategies with different adherence rates by using a well-established micro simulation model (MISCAN-Fadia). We calibrated the model to South Korean population data, incidence levels, and stage distributions in order to simulate millions of South Korean life histories. We quantified reductions in breast cancer mortality and gains in life-years for several screening strategies, varying by screening frequency, starting age, and screening uptake. **Results:** South Korea's current screening program with actual participation rates shows a 9.2 percent breast cancer mortality reduction compared to a no screening strategy. Preliminary results show that maximum screening uptake in ages 40-74 in a biennial scenario leads to a 21.9 percent mortality reduction. For the same ages, annual screening results in a 28.6 percent mortality reduction. Overall, we found that increased uptake of screening is more decisive than starting age and screening frequency in determining the optimal screening strategy. **Conclusions:** Screening biennially in ages 40-74 maintains 76.6 percent mortality reduction of annual screening. Screening annually in ages 40-50 and biennially in ages 50-74 maintains 86 percent. To further improve early detection of breast cancer South Korea should focus its effort on reaching more women making informed decisions about attending the screening program.

Assessment of colorectal cancer screening knowledge, attitudes, and practices among Brazilian health care providers

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Background: Colorectal cancer (CRC) is the fourth most common cause of cancer-related deaths among men, and third among women in Brazil. Brazil National Cancer Institute (INCA) recommends annual fecal occult blood tests (FOBT) for people over 50 years of age, and colonoscopy for any positive results. Since there is no national program for CRC screening, most screening occurs opportunistically. Our study aims to examine CRC screening-related knowledge, attitudes, and practices among physicians and nurses working in the Brazilian network of primary care units. **Methods:** In 2011, 1,600 health care units were randomly selected from all 26 states and the Federal District. One coordinator and one health care provider were selected from each unit for the interview. Response rates were 34 percent for physicians, and 65 percent for nurses. Descriptive analyses summarized sample provider characteristics, and CRC screening knowledge, attitudes, and practices among providers. Logistic regression was used to identify factors associated with not performing screening among physicians. **Results:** Physicians were mostly older, male, and had graduated 6 or more years ago. Nurses were mainly female, younger and graduated in the past 5 years. Only 33 percent of nurses reported being familiar or very familiar with FOBT compared to 77 percent of physicians. Sigmoidoscopy and colonoscopy were more often perceived as very effective exams for reducing CRC mortality. Forty percent of physicians and 37 percent of nurses perceived INCA recommendations for CRC screening as very influential. Among physicians, 47 percent did not perform CRC screening in asymptomatic patients. After adjusting for gender, years since graduation, patients seen per week, region, perception of influence of INCA recommendations, and of FOBT effectiveness, the odds of not performing CRC screening were higher among female physicians compared to male (OR 2.18, 95 percent 1.07-4.42), and physicians working in the north compared to the south of Brazil (OR 5.99, 95 percent 1.10-32.67). For each 5-year increase in years since graduation, the odds of not screening increased by 1.37 (95 percent 1.17-1.60). **Conclusion:** The majority of healthcare providers are aware of the effectiveness of CRC screening in reducing mortality and of current methods of screening. However, almost half of physicians did not perform CRC screening, possibly reflective of the opportunistic screening recommendations and lack of a national program. Given the increasing burden of CRC, this baseline information might be useful for Brazil. **Disclaimer:** This abstract was supported by Cooperative Agreement number U36/CCU300430 from the Centers for Disease Control and Prevention (CDC) and the Association of Schools and Programs of Public Health (ASPPH). The findings and conclusions of this abstract do not necessarily represent the official position of CDC or ASPPH.

Session 5: Risk Assessment and Informed Decision Making

Personalized risk assessment for breast cancer, discussion of risk, and intention to use screening

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Background: While national guidelines for breast cancer screening in the United States endorse the premise that screening should be "personalized," based on a woman's risk of cancer, tools to guide these discussions and personalized decisions are lacking. Health information technology (HIT) may promote personalized assessment of risk and individualized screening plans. Our objective was to evaluate the impact of a personalized risk assessment module, integrated with clinical care, on discussion of breast cancer risk and intended use of screening. **Methods:** We are conducting a pragmatic, cluster randomized controlled trial (RCT). Eligible women are age 30-75 years, English or Spanish speaking, without a prior history of breast cancer, who have an upcoming visit for a physical exam with their primary care physician (PCP) in one of 11 practices. We queried the electronic health record for eligible patients, and recruited via email/web-survey or automated phone call. Women in intervention practices complete a risk assessment before their visit and receive a 1-page risk report; those in control practices complete this process after their visit. Both groups receive a post-visit survey asking about discussion of risk and plans for screening. **Results:** 2,349 women have completed pre- and post-visit surveys (1,175 intervention; 1,174 control). The median age of participants is 54 years, 5 percent are African American, 5 percent are Latina. 20 percent are above average risk for breast cancer, 40 percent average, and 40 percent below average. Compared to individuals in the control group, those in the intervention group were more likely to report discussing their risk with their PCP (50 percent vs. 42 percent, p-value<0.0001); this was particularly true for women above (56 percent vs. 46 percent, p-value=0.03) or below (49 percent vs. 36 percent, p-value <0.0001) average risk. Overall, women in the intervention group were less likely to report that they planned to receive a mammogram in the next 12 months (78 percent vs. 85 percent, p-value<0.0001). Among high-risk women, there were no significant differences between intervention and control groups in plans for mammography in the next 12 months. In contrast, women of average (79 percent vs. 85 percent, p-value=0.002) and below average risk (71 percent vs. 83 percent, p-value<0.0001) were less likely to plan mammography in the intervention group compared to the control group. **Conclusion:** Systems for breast cancer risk assessment can be integrated into primary care practice to improve discussion of risk and promote guideline concordant screening. Future work will examine actual utilization and generalizability to other health conditions.

Baseline fecal hemoglobin concentration as a risk factor of interval cancers after colonoscopy in a fecal immunochemical test-based population colorectal cancer screening program

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Background: The interval cancer after colonoscopy is the crucial indicator for quality of clinical referral system, which was affected by multiple factors. However, how to identify those factors using existing resources plays the essential role in the quality assurance of screening program. Therefore, our study aim is to determine whether fecal hemoglobin concentration (FHbC) was associated with subsequent risk of interval cancer after colonoscopy (colonoscopy IC). **Methods:** During the period from 2004 to 2009, 41,136 subjects received colonoscopy as a confirmatory exam after positive fecal immunochemical tests (FIT) in the Taiwanese Nationwide Colorectal Cancer Screening Program. The definition of colonoscopy IC was based on the taxonomy proposed by the World Endoscopy Organization (WEO) and traced till the end of 2012 by the linking of the entire screened cohort with the National Cancer Registry. The incidence of colonoscopy IC was calculated in association with patient characteristics, index colonoscopic findings, endoscopic settings, and FHbC. Poisson regression analysis was performed to assess the potential risk factors for colonoscopy IC. **Results:** A total of 254 ICs developed after the index colonoscopy. The estimated incidence of IC was 1.65 per 1,000 person-years for the whole cohort. Older age [≥60 *vs.* <50-59 years: adjusted relative risk (aRR) = 1.48, 95% CI = 1.12-1.95], local hospital or clinic setting (aRR =1.57, 95% CI =1.06-2.32), incomplete colonoscopy (aRR = 1.86 95% CI = 1.38-2.49), baseline findings with advanced adenoma (aRR = 2.05, 95% CI = 1.38-3.05), and higher FHbC (ngHb/g feces) [100-149: aRR = 1.90, 95% CI = 1.22-2.97, 150-199: aRR = 1.78, 95% CI = 1.01-3.12; ≥200: aRR = 2.10, 95% CI = 1.47-2.99] were associated with increased risk of subsequent development of colonoscopy ICs in the whole cohort. For those with normal index colonoscopy, older age (≥ 60 *vs.* < 50-59 years: aRR = 1.58, 95% CI = 1.07-2.33), incomplete colonoscopy (aRR = 1.57, 95% CI = 1.04-2.36) and higher FHbC (ngHb/g feces) [100-149: aRR = 1.86, 95% CI = 1.00-3.45, 150-199: aRR = 2.00, 95% CI = 0.96-4.16; ≥200: aRR = 1.86, 95% CI = 1.12-3.12] were associated with increased risk of subsequent development of colonoscopy ICs. **Conclusion:** Several patient or operator-related factors were identified as risk factors for colonoscopy IC in a FIT screening program. FHbC was associated with the increased risk of development of colonoscopy IC. Thus, case management and modification of screening logistics based on hemoglobin concentration may be helpful.

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