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Cancer screening and early detection in the 21st century

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Abstract

Objective—To review the trends in and principles of cancer screening and early detection.

Data Sources—Journal articles, United States Preventive Services Task Force (U SPSTF) publications, professional organization position statements, evidence-based summaries

Conclusion—Cancer screening has contributed to decreasing the morbidity and mortality of cancer. Efforts to improve the selection of candidates for cancer screening, to understand the biological basis of carcinogenesis, and the development of new technologies for cancer screening will allow for improvements in the cancer screening over time.

Implications for Nursing Practice—Nurses are well-positioned to lead the implementation of cancer screening recommendations in the 21st Century through their practice, research, educational efforts and advocacy.

Keywords

cancer screening; sensitivity; specificity; screening recommendations; decision-making; early detection

The goal of cancer screening and early detection is to cure cancer by detecting the malignancy, or its precursor lesion, at an early stage prior to the onset of symptoms, when treatment of cancer is most effective. Indeed, overall cancer mortality has decreased by 25% from 1990 to 2015 for the United States U.S.), with even greater declines in the mortality rates for colorectal cancer (47% among men and 44% among women) and, breast cancer (39% among women). A portion of this decrease can be attributed to the introduction of high-quality cancer screening for colorectal and breast cancer.[1] The most successful cancer screening programs lead to the identification of precursor lesions (e.g., cervical intra-epithelial neoplasia (CIN) with cervical cancer screening and colonic polyps with colorectal

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cancer screening) where the treatment of the precursor lesion leads to a decrease in the incidence of invasive cancer over time. The guiding principles of screening for disease were proposed in 1968 by Wilson and Jungner[2] of the World Health Organization (Table 1). Not all cancer screening recommendations meet each of these guiding principles; historically there has been a balance between the identification of early or precursor lesions and the avoidance of overdiagnosis which may lead to overtreatment (Table 2).

Application of Cancer Screening Principles

U.S. population screening for cervical cancer serves as an exemplar of a successfully designed and implemented screening program that has been modified as the biological mechanism of the carcinogenesis of cervical cancer is more clearly elucidated and methods for primary prevention (i.e., HPV vaccination) are developed. Cervical cancer screening programs in particular adhere to several of Wilson and Junger's principles, most importantly, that the natural history of the disease be understood and that it be an important health problem. Chronic human papilloma virus (HPV) infection is the underlying etiologic agent of the carcinogenesis of cervical cancer. Chronic HPV leads to a precancerous lesion (i.e., cervical intra-epithelial neoplasia) which can be visualized, after the detection of a positive cytology (through Pap testing), with colposcopy. The removal of the precancerous lesion using colposcopy successfully led to an overall decrease in the incidence of cervical cancers, even though there was over treatment of some early lesions. Cervical cancer screening represents an example of the use of an accurate screening test (i.e., PAP, colposcopy and now HPV testing) with adequate sensitive, specificity and positive and negative predictive value (PPV and PNV) leading to the identification of a high risk population, a pre-cancer or a cancer (Tables 3 and 4). Population screening for colon cancer also conformed to many of Wilson and Jungner's principles and led to improvements in overall survival of individuals who adopted screening recommendations.[1] A key feature of both cervical and colon cancer screening is the ability to directly access the tissue of interest and apply an adequate screening test. Population screening for cervical cancer reduced the incidence and mortality rates from cervical cancer and led to enthusiasm that screening programs for other cancers, or pre-cancers, would be equally successful. However, screening, detection and removal of pre-cancer or early cancer in other cancer types has not always been as successful.

A major assumption about the natural history of carcinogenesis is based on the models of carcinogenesis of colorectal cancer proposed by Vogelstein et.al.[3] The model predicted a slow-growing, linear progression from a pre-cancer to a localized cancer that would occur at a rate of time that was amendable to cancer screening, similar to the pattern of carcinogenesis observed in cervical cancer. It also assumed that there was similarity within cancer types, such that all prostate or breast cancers behaved similarly. Based on that assumption, population-based screening programs for other solid tumors were developed including breast and prostate cancer screening. However, outcomes from multiple screening programs between 1980–2010 demonstrated that breast and prostate cancers are a heterogeneous group of diseases that do not necessarily conform to the pattern of carcinogenesis as initially proposed in the Vogelstein model.[4] After population screening was introduced for breast and prostate cancer and outcomes documented overtime, lessons learned (Table 5) included that

- Breast and prostate cancers were not uniform in their biology (they are heterogeneous)
- Not all early lesions (i.e., ductal carcinoma insitu or indolent prostate cancer) lead to invasive cancer
- Early detection does not always lead to improvements in overall survival, and
- There is risk to individuals when introducing screening interventions in otherwise healthy populations, including overdiagnosis and overtreatment (Table 2)

In addition, other cancer screening techniques rely on indirect methods to screen for cancer such as radiographic imaging (e.g., mammography) or measuring a biomarker associated with cancer (e.g., CA-125 or PSA), rather than direct visualization and access to the target organ as in colorectal and cervical cancer screening. These indirect methods of cancer screening led to compromised screening efficacy due a decrease in performance characteristics of the screening technique [(including false positives and false negatives (Table 6)] and an increase in overdiagnosis and overtreatment.[4] As more evidence of screening efficacy accumulates, changes in cancer screening recommendations and practice continue to occur. Prostate cancer screening guidelines changed to include shared decision-making as it became evident that the risk-to-benefit ratio of routine prostate cancer screening in men over the age of 50 was unfavorable; routine prostate cancer screening led to overdiagnosis of indolent cancer without a survival benefit while placing men at greater risk of injury related to the treatment of indolent prostate cancer.[5]

Improving the Precision of Candidates for Cancer Screening

Ideally, cancer screening is undertaken when the risk of cancer is high enough to justify the risk of overdiagnosis and overtreatment in an otherwise healthy population.[6] Cancer screening in healthy populations balances patient tolerance of risk, personal attitudes and the choice of a screening program most likely to have net benefit to the individual. In low-to-average risk populations, the recommended age to begin routine cancer screening is the age at which the risk of cancer begins to rise (e.g., 50 years for colorectal cancer screening) and when the tumor develops slowly. Slow tumor progression allows for the identification of a malignancy (or pre-malignancy) at an early stage which reduces the incidence of late stage cancer. For instance, the optimal screening interval for colorectal cancer screening with colonoscopy in the general population is 10 years, which allows for the removal of the pre-cancerous lesion, the adenomatous polyp, thereby reducing colon cancer. Cancer screening does not work as effectively for rapidly growing tumors or those that disseminate early, as they tend to occur between screening intervals and present with symptoms.

Integrating exposure history is commonly used to improve the identification of individuals at higher risk of cancer than the general population.[4] Targeting smokers with a 30 pack-year for low-dose chest tomography (CT) to screen for early lung cancer and identifying women with HPV infection to define a high risk population at risk of cervical cancer demonstrate efforts to use risk stratification in order to offer screening to individuals most likely to benefit and reduce screening in low risk individuals.

Risk-prediction models attempt to identify individuals at higher risk of cancer than the general population. The Breast Cancer Risk Assessment Tool[7] was one of the first tools aimed at identifying women who could benefit from breast cancer chemoprevention trials and accounts for clinical risk factors (i.e., family history, personal history, breast biopsy) as well as hormonal exposures (i.e., age of menarche). More recent risk-prediction models incorporate exposures (i.e., radiation exposure), breast density as well as biomarkers (i.e., single nucleotide polymorphisms) in an effort to improve risk-stratification.[8]

The contribution of genetics and genomics to risk-stratification has steadily progressed since the identification of the germline p53 mutation in Li Fraumeni Syndrome.[9,10] The ability to identify individuals who carry a germline mutation associated with a hereditary cancer syndrome greatly improves risk-stratification and helps identify those individuals who may benefit from more frequent cancer screening and other preventive procedures. For example, individuals at high risk of cancer due to inherited cancer susceptibility (such as carrier of a *BRCA1* or *BRCA2* mutation) undergo aggressive cancer screening for the tumors associated with the syndrome and may also consider prophylactic surgery to reduce their risk of cancer. Within a family with a known *BRCA1* mutation, those family members who did not inherit the mutation do not need to undergo intensive screening nor do they need to consider prophylactic surgery to prevent cancer. As the expense of genetic sequencing decrease, there is an increase in the use of genetic testing panels and other genomic technologies for risk stratification. However, important clinical challenges exist with these technologies regarding the classification of the identified genetic variants, reporting of the variants or unknown significance and how to handle incidental findings.[11] Multiple organizations have developed standards and guidelines for interpreting sequence variants and conclude that clinical genetic tests should be performed in Clinical Laboratory Improvement Amendments (CLIA)-approved labs and the results should be interpreted by a board certified clinical molecular geneticist, a molecular genetic pathologist or the equivalent.[12]

When it is not so Simple to Screen: ovarian cancer

Ovarian cancer is rare, with incidence of 11.9 per 100,000, and a 5-year survival rate of only 46%.[13] It is also the most lethal of all cancers of the female reproductive system.[14] Recent evidence suggests that high-grade serous ovarian cancer, the most common and dangerous type, actually arises from malignant cells in the fimbriated end of the fallopian tube.[15] Much of this lethality is due to the difficulty of diagnosis because ovarian cancer's vague symptoms include bloating, abdominal fullness and pain, and fatigue.[16] This leads to delayed detection, with 60% of cases diagnosed at a late stage with distant metastasis.[13] The median age at ovarian cancer diagnosis is 63, and is more common among women with a family history. Since 1975, 5-year survival has increased from 33.7% in 1975 to 46% in 2008.[13]

Given its lethality, it is essential to develop effective screening strategies for ovarian cancer in order to intervene earlier in the process of disease. The challenge of ovarian cancer screening lies with the site. Unlike the uterine cervix, whose cells can be sampled directly through cervical cytology or by testing for human papillomavirus,[17] the ovaries and fallopian tubes lie deep in the pelvis, making them inaccessible to routine evaluation. This is

especially problematic for asymptomatic women with germline mutations in *BRCA1 or BRCA2* that place them at much higher risk of ovarian cancer (lifetime risk of 10%–25% for *BRCA1* or *BRCA2* vs 1.7% for the general population), but it is also problematic for the general population.[16] Ovarian cancer risk in a high-risk population can be determined through taking a careful family history, and this is a reasonable and inexpensive "Precision Public Health" intervention.[18] Population-based genetic testing for hereditary breast and ovarian cancer, called for by Mary Claire King in an opinion piece published as she accepted the 2014 Lasker Award from the National Institutes of Health [19] may identify more women who can benefit from targeted ovarian cancer screening strategies, though there is no consensus for this recommendation to date.

For asymptomatic, low risk women, strategies for ovarian cancer screening have included direct examination through bimanual examination during pelvic examination, and visualization through transvaginal (TV) ultrasonography and Doppler studies.[20,21] Both approaches attempt to evaluate the ovaries for abnormal, possibly cancerous, masses. Despite its recommended use, bimanual examination suffers from low sensitivity for both adnexal masses in general [22] and for ovarian cancer specifically,[23] and is associated with harms from false positive results resulting in unnecessary surgical biopsies.[24] Currently some have begun to question the inclusion of the bimanual examination in primary care guidelines as a screening test for ovarian masses.[25] Similarly, a one-time transvaginal ultrasound of asymptomatic women did not result in reduction in ovarian cancer mortality in the United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKTOCS) and is not recommended as a stand-alone screening test for ovarian cancer.[26]

Serum biomarkers such as CA-125 and others have been tested for efficacy in screening for ovarian cancer. CA-125, also known as MUC16, is a large glycoprotein membrane marker from the MUC family found on ovarian cancer cells, but it is not specific to them.[27,28] Serum levels of CA-125 are elevated in ovarian cancer and many non-cancerous conditions such as ovarian cysts and liver cirrhosis, and also in non-ovarian malignancies.[29] CA-125 as a standalone screening test is relatively insensitive for ovarian cancer, finding only about 60% of women with ovarian cancer.[30] Other serum biomarkers such as human epididymis protein (HE4) and human chorionic gonadotropin (HCG) have been tested in combination with CA-125 to improve performance characteristics of serum biomarker screening for ovarian cancer as standalone serum screening tests,[29,31] though evidence suggests that CA-125 is the most robust biomarker of the group.[32]

The most promising approach for ovarian cancer screening is a strategy combining serum CA-125, with or without other biomarkers, and TV ultrasound. The UKTOCS in the UK[26] and the Prostate, Lung, Colorectal and Ovarian Cancer Screening (PLCO) trial in the US[33] tested similar strategies. Despite its promise, this co-testing strategy has not resulted in overall reduction in mortality due to ovarian cancer.[26,33] The UK trial tested a proprietary algorithm named ROCA® that adjusted the biomarker level cut-off for normal results based on women's clinical characteristics and the TV ultrasound result.[31] The promotion of ROCA® (Abcodia, Cambridgeshire, UK) serum testing with TV ultrasound ran afoul of the Food and Drug Administration (FDA) for the claim that the ROCA® test detects ovarian cancer early and reduced mortality. In late 2016 FDA issued a warning against using

commercial screening tests for ovarian cancer, saying that, especially for women at high risk for hereditary ovarian cancer, “women and their doctors may not take appropriate actions to reduce their future risk if they rely on a result that shows no cancer currently present.”[34] FDA further stipulated that they did not recommend the use of ovarian cancer screening tests in the general population.[34]

The history of ovarian cancer screening is a cautionary tale for nurses in considering the use of screening tests in low risk populations. It also highlights the importance of understanding the potential for harm with using what may prove, with more evidence, to be effective screening strategies that save lives.

Improving the Infrastructure for Cancer Screening

Continued progress to reduce death rates from cancer in the United States will only be achieved if there is broad commitment to understanding the determinants of cancer, including access to care, affordability, and social and environmental factors associated with cancer risk.[1] National cancer registries, linked to cancer screening programs, can support detailed cohort studies to improve outcomes research leading to quality improvements in cancer screening programs. Indeed, the Breast Cancer Screening Consortium[4] has linked data from regional mammography registries to increase the diversity of their sample populations and the American College of Radiology’s national lung cancer screening aims to develop outcomes-based research in support of quality improvements. Such efforts support evidence-based practices and will allow for continuous process improvement in outcomes of cancer screening and research methodologies.

The selection of ideal candidates to screen or not screen is an understudied area ripe for future research. As individuals age and acquire co-morbidities (competing risks), the balance between risk and benefit of screening may shift in favor of increased risk with limited- to no-benefit. One risk prediction model, e-Prognosis (http:eprognosis.ucsf.edu/) uses age and specific health measures to predict overall survival at different ages. Future research will address the utility of these tools across all cancer screening recommendations to identify those who will benefit most from screening and those most likely to be harmed.[35]

Implications for Nursing Practice

The translation of cancer screening research into effective public health policy requires nurses to be cognizant of the multiple levels of policy complexity.[36] As evidence of screening efficacy is demonstrated through research, healthcare legislation requires insurance coverage for screening recommendations developed by the United States Preventive Services Task Force (USPSTF). Changes in screening recommendations by the USPSTF can ignite professional, public and political controversy as evidenced by the debate surrounding the revised 2009 Task Force recommendation for breast cancer screening.[37] All healthcare providers should plan to effectively communicate the scientific underpinnings of new research and the potential for cultural, political and policy implications. A well-developed communication plan incorporates a review of the research, the basis of the recommendation and the implications of the research for all stakeholders (including the

public, politicians and policymakers). Nurses play an essential role in the dissemination of research and the evaluation and implementation of new cancer screening programs to the public and other stakeholders.

Cancer screening practice in the 21st century will integrate genomics, risk prediction, patient preferences and improvements in health care delivery systems into patient care services. Essential nursing functions will continue to be in high demand as the aging population of the United States increases and more individuals have access to care (Table 7). Nurses will lead the transformation of cancer care in all healthcare settings and work to ensure that all patients receive high quality cancer care.[38] Cancer screening recommendations have been shown to significantly decrease the mortality from certain cancers (i.e., cervical and colorectal), while more modestly decreasing mortality of others. At every point of care, and every level of practice, nurses will improve cancer screening through their interactions with patients and families to increase understanding of the rationale for and importance of adherence to cancer screening recommendations. As always, nurses will continue to follow the evidence for practice to maintain nursing practice at the state-of-the-art of cancer screening and advocate in support of public policies that expand access to care.

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Table 1

Wilson and Jungner Criteria for disease screening[2]

1	The condition of screening should be an important health problem
2	There should be treatment for patients diagnosed with the disease
3	Facilities to diagnose and treat the disease should be available
4	There should be a recognizable latent or early symptomatic stage
5	A suitable test or examination should be available
6	The test should be acceptable to the population
7	The natural history of the condition should be adequately understood
8	There should be agreement in the policy of whom to treat as patients
9	The cost of screening, diagnosis and treatment should be economically balanced within the total cost of health-care spending
10	Screening should be a continuing endeavor to allow for refinement in screening methods, outcomes and process improvement

Table 2

Potential negative outcomes of cancer screening.

Overdiagnosis: When tumors are detected that would never become symptomatic or lead to death
Overtreatment: When tumors are detected that would never become symptomatic or to death but are treated none-the-less

Table 3

Characteristics of an accurate screening test.

The screening test (e.g., mammogram, coloscopy):
Is reliable → delivers same result each time, each instrument, each rater
Has validity → delivers the correct result each time:
Sensitive = correctly classify cases (pre=cancer or cancer)
Sensitivity=Cases found/all cases
Specificity = correctly classify non-cases (things that are not cancer)
Specificity= Non-cases identified/all non-cases

Table 4

Performance characteristics of a screening test

Positive Predictive Value: The chance that a person with a positive test (e.g., an abnormal pap test) has cancer or pre-cancer
Negative Predictive Value: The chance that a person with a negative test (e.g., a normal pap test) does not have cancer or pre-cancer

Table 5

Lessons learned from population screening for breast, prostate and colon cancer

1	The success of cancer screening is more likely when the targeted cancer is slow growing and of uniform biology
2	Not all precancerous lesions lead to invasive cancers
3	Effective screening and removal of early stage cancer should cause a decrease in the incidence of late-stage cancers
4	Age matters: not all individuals will benefit equally from cancer screening

Table 6

Possible test outcomes of cancer screening

True Positive: Correctly indicates there is cancer *when cancer is present*
False Positive: Incorrectly indicates there is cancer *when no cancer is present*
True Negative: Correctly indicates that no cancer is present *when no cancer is present*
False Negative: Incorrectly indicates that *no cancer is present when cancer is present*

Table 7

Nursing actions in support of cancer screening

1	Identify patients at high risk of cancer as they assess family and personal health history
2	Support and encourage adherence to cancer screening practices
3	Consult with individuals and families about their preferences for care delivery
4	Advocate to decrease barriers to screening for all individuals
5	Advocate for legislative policies to support access to cancer screening and prevention services
6	Educate the public about the state of the art in cancer screening
7	Provide care throughout the cancer prevention and screening continuum
8	Perform research into improved methods and outcomes of cancer screening
9	Counsel patients and other healthcare providers about the benefits and risks associated with cancer screening
10	Adapt to rapid changes in health care delivery and health care technology
11	Maintain competence through professional continuing education activities
12	Support patient access to clinical trials