Reducing Variation in the "Standard of Care" for Cancer Screening

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Reducing Variation in the "Standard of Care" for Cancer Screening: Recommendations From the PROSPR Consortium

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Standard of care for cancer screening: the term implies certainty and consensus. Physicians, patients, and organizations have created guidelines, policies and regulations regarding how, when, and for whom screening should be used or reimbursed; cumulatively, these actions become the standards of care. However, these standards vary markedly across organ type, often without rationale or evidence.

In principle, standards of care should originate from common systematic methods and goals and create consistent, evidence-based recommendations for screening methods, implementation and desired outcomes. However, current practices are guided by sometimes conflicting clinical studies, professional society opinions, independent panels, advocacy groups, legislative mandates and payer regulations.[1,2]

In this Viewpoint, we highlight three areas in which cancer screening standards differ markedly for breast, colorectal, and cervical cancer: funding, quality measures, and reporting. These variations were delineated through a cross-disciplinary collaboration among scientists, healthcare organizations, and society leaders within the National Cancer Institute's Population-Based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium.[3] PROSPR studies how breast, cervical and colorectal cancer screening is implemented in diverse, real-world settings in the United States. We illustrate the absence of a cohesive approach to cancer screening, suggest key questions to address, and outline a framework for creating true "standards of care" to provide more consistent, effective and patient-centered cancer screening.

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FUNDING OF CANCER SCREENING AND FOLLOW-UP

Federal/State Programs

Federal and state funding varies substantially by organ type (Table-online). Congressional legislation, through the Breast and Cervical Cancer Mortality Prevention Act of 1990, directed the Centers for Disease Control and Prevention (CDC) to create the National Breast and Cervical Cancer Early Detection Program. This program provides free breast and cervical cancer screening and diagnostic services to women ages 21-64 years at ≤250% of federal poverty levels. In 2000, Congress added the Breast and Cervical Cancer Prevention and Treatment Act to provide program members with detected cancers treatment through Medicaid coverage, an option ultimately implemented in all 50 states.[1]

For colorectal cancer, a leading cause of cancer deaths, the CDC's Colorectal Cancer Control Program is structured much differently.[2] First, this program was funded in 2009, almost 19 years after the breast cancer legislation and 13 years after the US Preventive Services Task Force (USPSTF) recommended colorectal cancer screening. Second, it predominantly provides education and outreach rather than screening services. Third, it does not provide treatment for detected cancers. Fourth, it currently covers only 25 states plus four tribal organizations.

Reflecting these differences, the National Breast and Cervical Cancer Early Detection Program supported 331,313 breast and 208,682 cervical cancer screening exams in 2013.[1] In comparison, the Colorectal Cancer Control Program directly supported only 13,425 colorectal cancer screening exams in 2014, even though colorectal cancer affects both men and women.[2]

Medicare

Among Medicare beneficiaries, cancer screening coverage varies by organ and test results. Medicare started coverage for mammography in 1991, for cervical cytology in 1990,[4] for fecal blood testing in 1998 and for colonoscopy in 2001. For screening procedures already approved by Medicare, the 2010 Affordable Care Act (ACA) requires coverage without patient cost-sharing (e.g., co-pays, deductible charges) of preventive services recommended by the USPSTF. However, unlike private insurance companies, the ACA allows Medicare discretion regarding whether to cover new preventive services, even if recommended by the USPSTF. This recently resulted in controversy regarding whether the USPSTF's new recommendation for lung cancer screening for some smokers, with computerized tomography, might not be covered by Medicare.

However, for all these cancers, coverage "loopholes" exist for diagnostic services. For example, if a screening colonoscopy removes a polyp, it is converted to a "diagnostic" exam, subject to cost-sharing.[5] Similar unexpected fees may occur for colonoscopies performed after positive fecal blood tests, and for evaluations performed after abnormal breast or cervical cancer screening tests, even if the follow-up exams are normal.[5]

Medicaid

Medicaid coverage includes cancer screening through the National Breast and Cervical Cancer Early Detection Program for eligible individuals. Medicaid also authorizes colorectal cancer screening; however, unlike Medicare, there is no uniform coverage for any cancer type. Medicaid reimbursement varies between states and even within states.

Similar to Medicare, Medicaid coverage differences also extend to the follow-up and treatment of positive screening tests across all three cancer types, though these vary by state. In California, for example, patients with breast or cervical cancer are eligible for no-cost treatment through Medicaid, if not eligible by federal requirements, even though coverage is not available for other life-threatening conditions, including colorectal cancer.

Private and self-insured plans

The ACA also requires private plans to cover recommended breast, cervical, and colorectal cancer screening tests without co-payments. However, controversy surrounding the 2009 USPSTF recommendations regarding starting biennial mammography at age 50 led to the ACA covering mammography at an earlier starting age and more frequently than USPSTF recommendations, whereas no such USPSTF recommendation exceptions exist for cervical or colorectal cancer screening. State laws regarding cancer screening also vary by cancer; for example, all states except Utah require private insurance coverage of screening mammograms though, similar to Medicare, for all organ types, plans may require cost-sharing of procedures classified as “diagnostic”.

QUALITY MEASURES FOR TEST PERFORMANCE AND FOLLOW-UP

Screening test quality and follow-up standards vary widely across organs. Many mammography standards are federally mandated. In 1992, the Mammography Quality Standards Act tasked the Food and Drug Administration (FDA) with developing regulations for mammography performance, facility inspections, and other factors. For breast and cervical cancer screening, the National Breast and Cervical Cancer Early Detection Program established benchmarks for timely care (e.g., diagnostic testing <60 days after abnormal screening and treatment <60 days after cancer diagnoses). For colorectal cancer screening, no uniform quality measures for performance or standards for timely follow-up exist and practices vary.[6] Thus, at one extreme, the mandated prompt follow-up of abnormal mammograms attains uniform methods and rapid test completion, but with modest evidence regarding patient outcomes from these resource-intensive efforts. At the other extreme, few quality standards exist for testing or follow-up of positive fecal or cervical tests, despite outcome data regarding possible harms from delayed follow-up.

REPORTING OF SCREENING TEST RESULTS

Reporting standards for screening test results also vary widely by organ. The Mammography Quality Standards Act requires facilities to notify patients and providers of normal results within 30 days. Some abnormal results require provider communications within 3 days and patient notification within 5 days. As of August 2015, 24 states require patient notification of high breast density, an independent breast cancer risk factor which limits

mammography's accuracy. Breast cancer screening also uses a standardized terminology, the Breast Imaging-Reporting and Data System, for findings and risk estimates. Although of unknown effect, no such laws or mandates exist for colorectal or cervical cancer screening, apart from minimum requirements for the National Breast and Cervical Cancer Early Detection Program. Some medical organizations recommend standardized formats, but their use and effectiveness are unknown.

CONCLUSION

Cancer screening tests are commonly performed procedures, yet standards for their funding, quality metrics and reporting vary widely across organ types, without clear rationale. Breast cancer screening has many standards; some exist for cervical cancer, and few for colorectal cancer. These differences in screening standards may result, in part, from a system in which scientists, clinicians, legislators, and advocates focus on specific cancers rather than on common issues. Legislative approaches may improve standardization, but can create uneven care across organ types; non-evidence-based mandates may also enhance costs and burdens without improving outcomes or decreasing harms from screening.

Greater integration is needed to decrease cross-organ differences in cancer screening funding, quality, and reporting. The potential for a more comprehensive approach is reflected in NCI's PROSPR initiative and with recent federal requirements for shared decision-making in lung cancer screening.[7] PROSPR scientists identified several important questions for greater standardization across cancers, including:

- how to achieve consistent financial coverage of screening, follow-up testing, and treatment
- whom to screen
- when to screen
- appropriate follow-up intervals for abnormal results
- which quality metrics enhance outcomes
- how to provide uniform, clear and actionable result reporting

Consistent answers to these questions require specific, integrated cross-organ strategies and data to inform legislative changes and recommendations. We propose using patient-centered approaches and absolute incidence estimates of benefit, mortality, and harms across cancers. Such common metrics and goals may better unify the interests of patient advocacy, medical specialty, and payer groups; optimize effective screening practices; and diminish standards that are ineffective or even harmful. Using cross-organ metrics is a new approach, different from current legislative, USPSTF or guideline methods, which largely employ focused, serial, single-test and/or single-organ evaluations. An integrated approach can leverage new "big data" sources and innovative measurement approaches, such as in PROSPR, to compare screening processes and outcomes across organ types, and to develop more personalized strategies consistent with precision medicine. The next few years will be critical, given the rapidly changing landscape for current and new screening tests (e.g. computerized tomography for lung cancer and stool DNA testing). Cross-cutting data and dialogue across

the traditional organ-specific silos of research, clinical care, and advocacy are needed to achieve coherent, evidence-based, personalized, and effective standards of care for cancer screening.

This commentary is from centers that are part of the National Cancer Institute (NCI)-funded consortium Population-Based Research Optimizing Screening through Personalized Regimens (PROSPR). The overall aim of PROSPR is to conduct multi-site, coordinated, transdisciplinary research to evaluate and improve cancer screening processes. The ten PROSPR Research Centers reflect the diversity of U.S. delivery system organizations. National Cancer Institute grants Kaiser Foundation Research Institute (U54CA163262, 3U54CA163262-04S1); Group Health Research Institute (U54CA163261, 3U54CA163261-04S1); Parkland UT Southwestern (U54CA163308, 3U54CA163308-04S1); University of Pennsylvania (U54CA163313); University of Vermont (U54CA163303); Geisel School of Medicine, Dartmouth and the Brigham and Women's Hospital, Harvard University (U54CA163307); University of New Mexico (U54CA164336); and the Fred Hutchinson Cancer Research Center (U01CA163304).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

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