JNCI J Natl Cancer Inst (2015) 107(6): djv120

doi:10.1093/jnci/djv120
First published online May 8, 2015
Commentary

COMMENTARY

Unifying Screening Processes Within the PROSPR Consortium: A Conceptual Model for Breast, Cervical, and Colorectal Cancer Screening

Elisabeth F. Beaber, Jane J. Kim, Marilyn M. Schapira, Anna N. A. Tosteson, Ann G. Zauber, Ann M. Geiger, Aruna Kamineni, Donald L. Weaver, Jasmin A. Tiro; on behalf of the Population-based Research Optimizing Screening through Personalized Regimens consortium

Affiliations of authors: Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA (EFB); Department of Health Policy and Management, Harvard T.H. Chan School of Public Health, Boston, MA (JJK); Division of General Internal Medicine, University of Pennsylvania, Philadelphia, PA (MMS); Department of Veterans Affairs Medical Center, Philadelphia, PA (MMS); Department of Medicine and The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth and Norris Cotton Cancer Center, Lebanon, NH (ANAT); Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY (AGZ); Division of Cancer Control and Population Sciences, National Cancer Institute, Rockville, MD (AMG); Group Health Research Institute, Seattle, WA (AK); Department of Pathology and University of Vermont Cancer Center, University of Vermont, Burlington, VT (DLW); Department of Clinical Sciences, University of Texas Southwestern Medical Center, Dallas, TX (JAT).

Correspondence to: Elisabeth F. Beaber, PhD, MPH, Fred Hutchinson Cancer Research Center, 1100 Fairview Ave N, M3-A306, PO Box 19024, Seattle, WA, 98109-1024 (e-mail: ebeaber@fredhutch.org).

Abstract

General frameworks of the cancer screening process are available, but none directly compare the process in detail across different organ sites. This limits the ability of medical and public health professionals to develop and evaluate coordinated screening programs that apply resources and population management strategies available for one cancer site to other sites. We present a trans-organ conceptual model that incorporates a single screening episode for breast, cervical, and colorectal cancers into a unified framework based on clinical guidelines and protocols; the model concepts could be expanded to other organ sites. The model covers four types of care in the screening process: risk assessment, detection, diagnosis, and treatment. Interfaces between different provider teams (eg, primary care and specialty care), including communication and transfer of responsibility, may occur when transitioning between types of care. Our model highlights across each organ site similarities and differences in steps, interfaces, and transitions in the screening process and documents the conclusion of a screening episode. This model was developed within the National Cancer Institute–funded consortium Population-based Research Optimizing Screening through Personalized Regimens (PROSPR). PROSPR aims to optimize the screening process for breast, cervical, and colorectal cancer and includes seven research centers and a statistical coordinating center. Given current health care reform initiatives in the United States, this conceptual model can facilitate the development of comprehensive quality metrics for cancer screening and promote trans-organ comparative cancer screening research. PROSPR findings will support the design of interventions that improve screening outcomes across multiple cancer sites.

It is well established that screening for breast, cervical, and colorectal cancers decreases disease-specific mortality (1–6), yet the cancer screening process in the United States remains fragmented, inefficient, and laden with failures (5,7–10). The Institute of Medicine identified six key areas for improving the US health care system: safety, effectiveness, timeliness, efficiency, equity, and patient-centeredness (11), and recently highlighted the importance of high-quality cancer care (12). However,

Received: November 10, 2014; **Revised:** February 18, 2015; **Accepted:** April 3, 2015

limited progress has been made to improve these areas within cancer screening (5,7–10). Overscreening (13), underscreening (14), and failure to follow-up abnormal screening results (15,16) remain considerable problems. While most prior research has focused on patients and providers, current evidence demonstrates the critical roles of facilities and health care organizations on successful completion of the screening process (17–21) and stresses the importance of evaluating multilevel factors in cancer screening research.

The National Cancer Institute (NCI) funded the Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium in 2011 in an effort to improve the delivery of the cancer screening process in the United States. PROSPR consists of seven research centers focusing on breast, cervical, and colorectal cancer screening and one statistical coordinating center. PROSPR research centers reflect a variety of health care settings across different geographic regions, including integrated health care delivery systems, mixed-model systems, primary care clinical networks, safety-net clinical provider networks, and providers and facilities captured by statewide registries. These diverse settings facilitate comparative effectiveness research across the consortium. The overarching goal of PROSPR is to conduct multisite, coordinated, transdisciplinary research to evaluate and improve cancer screening processes (22).

While there are several general and organ-specific conceptual models for cancer screening that provide a strong foundation for our work (16,20,23,24), none explicitly addresses similarities and differences in the screening process across organ sites. This may be because most cancer screening studies have examined a single organ site and often focused on one discrete step in the screening process (eg, receipt of a single screening test) (20). Additionally, US health care delivery is primarily organized to address cancer screening separately for each organ site, rather than leveraging resources across sites. A conceptual model that unifies multiple organ sites will facilitate the creation of standard meaningful quality metrics and terminology, which is an area in need of improvement (12). Moreover, a trans-organ conceptual model will facilitate identifying solutions to variances in screening processes that could substantially improve coordination and delivery of care.

In this commentary we: 1) describe a trans-organ conceptual model developed to unify the screening processes across breast, cervical, and colorectal cancers, 2) identify differences in transitions in the process across organ sites, 3) discuss applications of the conceptual model to health care delivery and key research areas, and 4) describe how our conceptual model relates to data needed for quality measures.

The PROSPR Trans-Organ Conceptual Model for Breast, Cervical, and Colorectal Cancer Screening

Overall Framework and Terminology

We built upon prior conceptual model work (16,20,23–26) to develop a trans-organ conceptual model applicable to breast, cervical, and colorectal cancer screening. We organized our model by the overarching goals of the cancer screening process: risk assessment, detection, diagnosis, and treatment (Figure 1). Types of care that are delivered to accomplish a specific goal, such as diagnosis, are represented as shaded black boxes in our model. Steps are the clinical events or actions arising within a type of care or transition and are depicted as boxes. Because of the numerous steps required during detection, we split detection into two phases: 1) receipt of the initial screening test and 2) completion of required follow-up tests after abnormal test results. Interfaces, represented by dashed boxes, are steps requiring transfer of information and/or responsibility across two different health provider teams, such as between primary care and radiology (27). Steps and interfaces that occur between risk assessment, detection, diagnosis, and treatment comprise transitions, which are necessary to move through the screening process (27). We used current breast, cervical, and colorectal cancer screening guidelines to define abnormal results that require additional steps to complete a screening episode (28–37).

A Single Screening Episode Across Organ Sites

Our conceptual model depicts a distinct screening episode for breast, cervical, and colorectal cancer among average-risk individuals (Figure 1). Our model shows factors acting at the provider, facility, health care system, and policy levels that impact the screening process and provides details at the individual level. For all organ sites, a screening episode can end because of normal screening results, resolution of abnormal screening results, or at the first course of cancer treatment. A patient and his/her provider may also choose to stop screening according to clinical guidelines because of poor health status, limited life expectancy, or for other reasons.

Across all three organ sites, the screening process begins with an evaluation of risk level that considers age and may include other cancer-specific factors such as family history. The screening process can be initiated in the following ways: a provider recommends a test, a patient requests it, or a health care system or provider sends an invitation. Providers often incorporate a patient's risk level, health status, and preferences when making a recommendation about screening modality (if there is more than one option) and screening interval (if the patient had a previous test). After initiation, the details of the screening processes diverge for breast, cervical, and colorectal cancer, but there are common pathways across the screening continuum.

For breast cancer, screening mammography results establish if the screening episode ends with a recommendation for future routine screening or if findings warrant additional immediate or short-term evaluation of any abnormalities—leading to a cancer diagnosis (ie, true positive diagnosis) or a determination that cancer is absent (ie, false-positive screening outcome). Emerging modalities available for breast cancer screening include digital tomosynthesis and alternative options for women with an elevated breast cancer risk (eg, ultrasound or magnetic resonance imaging). Follow-up testing consists of completing diagnostic mammography and/or other imaging. Those with abnormal results must undergo repeat diagnostic imaging, secondary alternative imaging, or advance to diagnostic evaluation where a biopsy is recommended. After assessing pathology findings from a biopsy, the provider may update the patient's risk profile and recommend returning to routine screening. Alternatively, pathology findings may indicate cancer and lead to a treatment referral. In that scenario, the episode ends at the first treatment course.

When the cervical cancer screening process is initiated, a provider chooses the method of screening (ie, Papanicolaou [Pap] testing alone or cotesting with Pap and human papillomavirus [HPV] test) based on the patient's age and health care system guidelines (29,36,37). Other factors such as patient preference, health insurance coverage, and resources of the patient and health care system may also impact screening method choice.

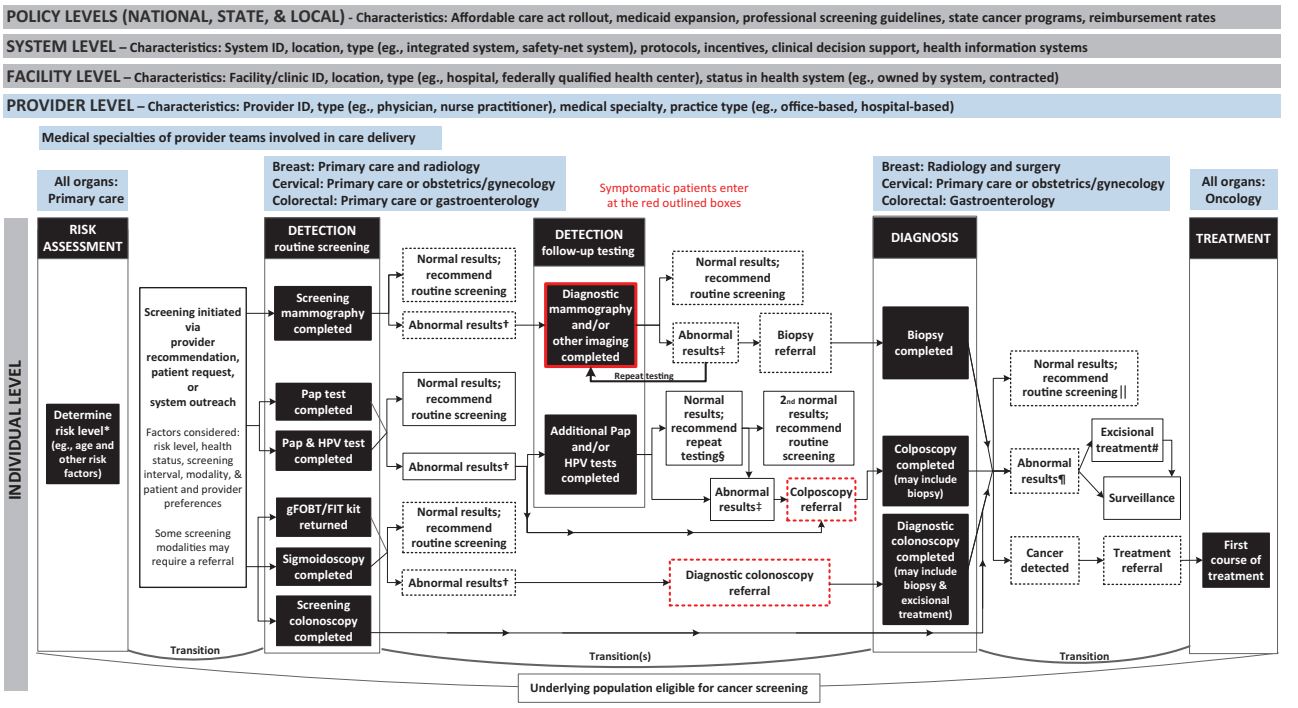

Figure 1. Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) trans-organ conceptual model for breast, cervical, and colorectal cancer screening.

■ = Type of care: care delivered to accomplish a specific goal, such as diagnosis.
□ = Step: medical actions or encounters within a type or transition in care.
⬚ = Interface: transfer of information and/or responsibility between two different health provider teams (e.g., primary care & specialist).
⌣ = Transition: steps and interfaces necessary to move from one type of care to another.

Abbreviations: ASC, atypical squamous cells; ASC-H, atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion; ASC-US, atypical squamous cells of undetermined significance; ASCCP, American Society for Colposcopy and Cervical Pathology; BI-RADS, Breast Imaging-Reporting and Data System; CIN, cervical intraepithelial neoplasia; FIT, fecal immunochemical test; gFOBT, guaiac-based fecal occult blood test; HPV, human papillomavirus; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; Pap, Papanicolaou; SIG, sigmoidoscopy.

* Risk level determined by age and other risk factors; if at elevated risk, then follow alternate guidelines (28,29,33–35,67,68).
† Breast: BI-RADS 0; BI-RADS 3, 4, & 5 are typically reported only after a diagnostic mammogram but in some cases are reported after a screening mammogram. BI-RADS 4 or 5 from a screening mammogram may lead directly to biopsy. Cervical: Go to additional testing (ASC-US or LSIL & HPV– or Pap– & HPV+) or to colposcopy (≥LSIL or ASC-US & HPV+, or HPV 16/18+). Some HSIL cases may go immediately to excisional treatment. Colorectal: gFOBT+, FIT+, or SIG+.
‡ Breast: Go to repeat testing (BI-RADS 3) or to biopsy (BI-RADS 4 or 5). Cervical: Go to colposcopy (≥ASC or HPV+, HPV+ after prior ASC-US, or HPV 16/18+). Management options vary for women ages 21-24 after ASC-US or LSIL and for pregnant women.
§ According to ASCCP guidelines, timing of repeat cotesting (e.g., 1 or 3 year interval) depends on age and results from Pap and HPV tests. Women with Pap– after prior ASC-US return to routine screening and do not undergo repeat testing.
‖ Breast: Update risk assessment. Cervical: Women with no lesion go to repeat cotesting according to ASCCP guidelines before returning to routine screening. Colorectal: Normal results include benign biopsies and rectosigmoid hyperplastic polyps <1 cm.
¶ Breast: Not applicable. Cervical: Women with CIN2+ go to excisional treatment. Women with CIN1 go to repeat cotesting according to ASCCP guidelines or to excisional treatment (if preceded by ASC-H or HSIL Pap). Management options vary for women ages 21-24 and for pregnant women. Colorectal: Timing of the surveillance regimen depends on number, size, and histology of polyps detected (e.g., tubular/villous adenoma, sessile serrated polyp, hyperplastic polyp ≥1 cm).
# Cervical: Excisional treatment may occur after receiving colposcopy results. Colorectal: Excisional removal of presumed precancerous lesions usually occurs at the time of the colonoscopy procedure.

Recent approval by the US Food and Drug Administration of an HPV DNA test for primary screening suggests that clinical guidelines may recommend HPV testing alone in the future (38); this issue is rapidly evolving. Similar to the breast cancer screening process, a normal initial screening test result completes a screening episode. Depending on the severity of the cytologic findings (and accompanying HPV test result in the case of cotesting), abnormal Pap and/or positive HPV test results can lead to either additional Pap and HPV tests or a colposcopic referral for diagnostic evaluation that may include a cervical biopsy (see current guidelines [28,29,35-37] and Figure 1 footnotes). If results from the additional Pap and/or HPV tests are normal/negative, another round of repeat testing with normal results is usually required before completing a screening episode and receiving a routine screening recommendation. Abnormal histology findings from a cervical biopsy can lead to either 1) surveillance, 2) excisional removal of presumed precancerous lesions followed by surveillance, or 3) a cancer diagnosis and referral for treatment. The choice between options 1 and 2 is conditional on the patient's age and histologic findings. Individuals with negative colposcopic results or normal biopsy results continue with shorter-interval repeat testing and return to routine screening if the repeat testing is normal/negative. The end of a cervical cancer screening episode can be challenging to determine because of the complex algorithms for management of abnormal/positive test results. Current guidelines require repeat testing over extended time periods (eg, 1–3 years) before returning to routine screening, which lengthens a screening episode (28,29,35–37).

Colorectal cancer screening guidelines currently recommend multiple modalities with differing screening intervals—guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) every year, flexible sigmoidoscopy every five years with gFOBT or FIT every three years, or colonoscopy every 10 years (31,33). Multitarget stool DNA tests were also recently approved, although the appropriate intervals for these tests have not been well defined (39). Once a gFOBT/FIT kit is returned or a sigmoidoscopy is completed, individuals with normal results complete a screening episode and receive a recommendation for routine screening. Time intervals for the next recommended routine screening test vary by modality because of differing abilities to detect precancerous or cancerous lesions (31,33). A distinctive feature of colorectal cancer screening is that the test used to follow-up all abnormal gFOBT, FIT, or sigmoidoscopy results is the same procedure used for pathologic diagnosis—diagnostic colonoscopy. Furthermore, when colonoscopy is performed as the primary routine screening test, individuals move from detection directly to receiving diagnostic results within the same procedure, thereby circumventing the transition from abnormal screening test to diagnostic testing required by other colorectal cancer screening modalities. Those with normal colonoscopy results end their screening episode and continue future routine screening (see Figure 1 footnotes). Presumed precancerous lesions identified through colonoscopy are generally removed via excisional treatment at the time of the colonoscopy. This is in contrast to cervical cancer screening, where excisional treatment may occur during a separate procedure, after receiving colposcopy-directed biopsy results. Pathologic findings determine whether colorectal cancer has been detected or if a surveillance regimen is recommended (34). Those with colorectal cancer detected receive a treatment referral and transition to their first treatment course.

Although the PROSPR trans-organ conceptual model depicts the screening process as a linear progression, screening in practice has additional complexities. For instance, after normal results, individuals return to routine screening and circle back to the beginning of the process (risk assessment). Risk assessment is often updated throughout the screening process and results from prior screening episodes may affect risk level and/or future screening intervals. Additionally, individuals with cancer signs or symptoms may bypass routine screening and enter the process at testing for detection and diagnosis (represented as red outlined boxes in Figure 1).

Transitions and Interfaces: Transfers and Health Provider Communication

Transitions occur between types of care and are necessary for moving through the screening process (27). Transitions require medical actions and transfers between patients and health providers. Our model shows four main transitions for breast and cervical cancer screening, but three transitions for colorectal cancer because the follow-up test is also the diagnostic procedure. Health provider teams and the design of the delivery system play an important role in moving patients through the screening process, and our model depicts the medical specialties involved in care delivery (represented as blue boxes in Figure 1). Initial risk assessment is generally completed by primary care providers for all three organ sites. Patients may be transferred to specialty teams at various points in the process depending on the organ site.

An interface is a transfer of information and/or responsibility between two different health provider teams (27). For breast and colorectal cancer, the first possible interface occurs during the detection process when patients may be transferred from primary care to a specialty team (radiology and gastroenterology, respectively). For cervical cancer an interface may not occur at all depending on the training or medical specialty of the provider team, or it may occur later at the time of diagnosis or excisional treatment. If cancer is diagnosed, responsibility transfers from specialty provider teams to oncology and surgical teams. Overall, our model illustrates that there are typically fewer steps and transitions in the colorectal cancer screening continuum, which in turn may result in fewer opportunities for breakdown in the screening process compared with breast and cervical cancer. However, the breast and colorectal screening processes may have the opportunity for a greater number of interfaces between different provider teams than for cervical cancer screening.

Comparing Screening Episodes Across Organ Sites: Summary and Potential Implications

One common concept across all three organ sites is the existence of two different pathways in the screening process—one for routine screening with normal results and a second for those with abnormal results. Individuals with abnormal results can eventually resolve and return to routine screening or advance to diagnosis and treatment. Our model also highlights variations in processes across organ sites that require comparative research of different providers, facilities, and health care systems to identify best practices (40,41). Determining the end of a screening episode is important for clinical practice and research. Clinicians and practices need to identify complete screening episodes and redirect patients, when appropriate, back to a routine screening pathway. Researchers must be able to identify screening underuse, overuse, and misuse. Our model depicts the repeated testing required in the cervical cancer process after an abnormal/positive result, thereby showing that the end of a screening episode may be more difficult to determine after an abnormal Pap and/or positive HPV test result compared with an abnormal breast or colorectal cancer test result.

Failures in the screening process occur for a variety of reasons at the levels of the patient, provider, facility, and health care system (7,9,15,16,42–48). Patients can face substantial challenges when navigating the screening process including interacting with new providers, engaging in complex shared decision-making, understanding the follow-up care required for abnormal results, and returning for follow-up appointments. These challenges can lead to nonadherence to follow-up testing. Some observational studies have documented breakdowns in the screening process at the provider level because of failures in information transmission, miscommunication, and ambiguous responsibility between different provider teams (42–48). While patient navigation interventions have shown some promise in improving communication between patients and providers, few provider-, facility-, or system-level interventions have focused on improving interfaces between primary and specialty care teams (49–51). The PROSPR consortium is gathering multilevel data to evaluate how factors at different levels may lead to screening process failures (Table 1). For example, the geographic location of specialty clinics could be associated with failing to follow up abnormal results for some patients because of long travel times to those clinics. At the facility level, the facility status in the health care system (owned vs contracted) and the breadth of services (screening and follow-up vs only screening) may create structural barriers that hamper care coordination and cause delays. At the provider level, team dysfunction such as poor communication and role delineation among physicians

Table 1. Data categories and common data elements

Data categories*	Example common data elements
Health care system–, facility-, and provider-level data	
System-level characteristics	System ID, state, county, zip code, type (eg, integrated health system, safety-net care system)
Facility-level characteristics	Facility/clinic ID, state, county, zip code, type (eg, hospital, Federally Qualified Health Center, ambulatory surgical center, office or clinic), status in health care system (eg, owned by system, contracted), screening services available (eg, screening only or screening and follow-up services for abnormalities detected), accreditation as a patient-centered medical home, aggregate proportions of cohort member characteristics† (eg, % nonwhite race, % with Medicaid coverage)
Provider-level characteristics	Provider ID, type (eg, physician, nurse practitioner), medical specialty, practice type (eg, office-based, hospital-based), provider team responsibilities and communication (eg, responsibilities for physicians vs nonphysician staff), aggregate proportions of cohort member characteristics† (eg, % nonwhite race, % with Medicaid coverage)
Individual-level data‡	
Cohort member characteristics§	Person ID, race, Hispanic ethnicity, height, weight (by year), insurance coverage (by year), number of primary care visits (by year), primary care provider ID (by year), Charlson comorbidity score (by year)
Risk assessment	Age (at cohort entry), number of sisters diagnosed with breast cancer, days since last Pap test
Event characteristics	Procedure date (actual date or time since a reference date), type (eg, sigmoidoscopy, colonoscopy), procedure indication, ordering provider ID, performing provider ID, results, recommendation
Screening episode characteristics	Initial screening and final outcome dates (actual dates or time since a reference date), final outcome, results communicated to patient date (actual date or time since a reference date), mode of communication
Cancer detected	ICD-O-3 diagnosis code, cancer diagnosis date (actual date or time since a reference date), tumor behavior, tumor size, tumor grade, AJCC stage grouping, estrogen receptor status, HER2/neu status
Cancer treatment	Cancer treatment initiation date (actual date or time since a reference date), type (eg, chemotherapy)

* Not all data categories are currently collected within the Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium. AJCC = American Joint Committee on Cancer; HER2 = human epidermal growth factor receptor 2.

† Aggregate proportions are not common data elements, but are recoded from cohort member characteristics.

‡ The individual-level data categories map to the following areas of the PROSPR trans-organ conceptual model (see Figure 1): 1) cohort member characteristics map to the underlying population eligible for cancer screening; 2) risk assessment maps to the goal of risk assessment; 3) event characteristics and screening episode characteristics map to the goals of detection, diagnosis, and treatment; 4) cancer detected maps to cancer detected; and 5) cancer treatment maps to the first course of treatment.

§ Cohort member refers to the individuals contributing data to the PROSPR central data repository. Some PROSPR research centers capture data from screened and nonscreened individuals, while others only collect data from individuals tested (eg, state-wide registries).

and nonphysician staff may adversely impact the delivery of strategies that facilitate the screening process (eg, patient reminders and performance feedback for providers). At the patient level, type of insurance coverage may limit the specialists available and affect timely delivery of care. Our conceptual model provides a framework for examining the effect of multilevel factors across organ sites. Comparisons of process failures and outcomes can inform patient-centered interventions that are relevant to all cancer screening tests.

Results reporting and federal notification requirements differ across organ sites and may also influence screening process completion. For example, the BI-RADS system provides structured reporting of imaging results for breast cancer screening (30) and the Bethesda system provides standard classification of Pap results for cervical cancer screening reporting (52), but colorectal cancer screening does not employ a universal standardized reporting approach. The Mammography Quality Standards Act regulates mammography quality of care (53). It legally requires facilities to provide a summary of the mammography report to patients in lay terms and a written report of the mammography examination to the patient's health care provider within 30 days of the mammogram. In contrast, there are no federal regulations mandating timely communication of cervical and colorectal cancer screening results to patients and providers. Differences in federally legislated standards may lead to fewer performance and communication failures in the screening process for breast cancer compared with cervical and colorectal cancer. Our conceptual model provides a framework for evaluating the impact of notification policies across organ sites.

Each organ site has particular vulnerabilities because of different characteristics of the screening process that may occur at varying steps in the process. Yet evidence quantifying these vulnerabilities is limited, especially after screening initiation. Recently, health services researchers have called for further evaluation of adherence to follow-up testing (16,23,54). The PROSPR consortium plans to conduct comparisons between health care systems, facilities, providers, and patient subpopulations to elucidate the impact of factors affecting adherence to follow-up testing, such as the role of primary care providers and patient health status.

Applications of the PROSPR Trans-Organ Conceptual Model

Our model can serve as a tool to help define and develop quality metrics for cancer screening in the United States, which are currently limited. A key goal of The Patient Protection and Affordable Care Act (ACA) of 2010 is to improve the quality of US health insurance and health care (55). The law includes provisions with incentives for quality care rather than quantity, such as rewarding Accountable Care Organizations that provide high-quality care and decrease health care system costs. However, the appropriate metrics for measuring quality care during the cancer screening process remain elusive. Specifically, our model will aid in determining the appropriate numerators and denominators across organ sites needed to calculate key screening process measures including the following: 1) the proportion of screened individuals with abnormal/positive results, 2) the proportion of individuals with abnormal/positive screening results receiving appropriate and timely follow-up testing, 3) the proportion of individuals with abnormal/positive screening results and follow-up testing receiving a diagnostic evaluation, and 4) the proportion of screened individuals diagnosed with cancer receiving a first treatment course. These process measures are seemingly straightforward, but our model depicts the unique considerations required for different organ sites. These process measures will build upon existing Healthcare Effectiveness Data and Information Set (HEDIS) performance measures because they will assess quality care across the entire screening process. Movement towards adjusting payment structures to reflect a continuum of quality care has already begun; currently, both public and private health insurers are considering bundled payments based on episodes of care, rather than individual services (56–58). Our model can aid in improving quality of care by defining episodes of cancer screening care that could be associated with bundled payments.

Additionally, our model can be applied to identify areas of the screening process prone to breakdown and amenable to intervention. Our model enables a more holistic approach to improving cancer screening, as it includes a unifying view across multiple organ sites and thereby considers differential impacts of health care system–level interventions on breast, cervical, and colorectal screening. This provides a patient-centered approach to quality metrics, rather than an approach within organ site silos. It also allows for expansion of the conceptual model framework to incorporate cancer screening for other organ sites, such as lung cancer. Researchers within the PROSPR consortium are using this model to guide trans-organ research projects aimed at improving screening processes (22). Ultimately, trans-organ studies can suggest common intervention targets and reorganization of clinical workflows within health care delivery systems and possibly lead to the development of a combined quality metric of screening across multiple organ sites.

While our model has many applications, there are also caveats to consider. Our model incorporates current screening guidelines, but it does not display all of the details because of the complexity of recommendations, particularly for cervical cancer screening. Although our model works well for studying the cancer screening process among average-risk individuals, it is not intended for evaluating high-risk groups following alternative screening guidelines, such as individuals with BRCA1 or BRCA2 mutations or familial adenomatous polyposis. Moreover, we depict usual care during the screening process using national screening guidelines, but processes vary in clinical practice. For instance, our model shows initial risk assessment occurring within primary care, but in some health care systems radiologists or gastroenterologists may assess risk level or risk level may never be evaluated. Test malfunctions, such as insufficient collapsing of the breast, failure to reach the cecum during a colonoscopy, or unsatisfactory samples are not shown in our model but may cause repetition of steps.

Common Data Element Development in the PROSPR Consortium

Assessing the quality of care across diverse health care settings requires the development of common data elements (CDEs). CDEs are standardized descriptors for the collection and/or sharing of data (59,60). CDEs improve data collection consistency within research consortia and facilitate comparative analyses of pooled data. Research consortia have documented strategies for CDE development, including soliciting input from experts across a range of disciplines, building upon CDEs and data standards from existing sources, piloting CDEs, and conducting annual CDE reevaluation and quality control (61–63).

In addition to these practices, the PROSPR consortium strives to use conceptual models to guide CDE development across the screening process (25,26). CDEs are nested within data categories, such as cohort member characteristics, risk assessment, and event characteristics, and are mapped to our trans-organ conceptual model (Table 1). This approach to data development is useful for: 1) ensuring that CDEs are scientifically grounded, 2) identifying areas in the screening process needing additional data collection, and 3) harmonizing CDEs across organ sites.

The PROSPR consortium focused initial data collection on detection and diagnosis. Currently, PROSPR is expanding data collection within some organ sites to include CDEs for risk assessment and treatment. This comprehensive data collection and harmonization effort will enable the calculation of process measures across the cancer screening continuum. These process measures may contribute to quality improvement in cancer screening within PROSPR research centers. They could also offer insights to other health care systems seeking to measure and improve the quality of care throughout the screening process. In the future, PROSPR plans to share data and collaborate with outside investigators in alignment with the Institute of Medicine's goal to improve the health care system within the area of cancer screening (11,12,64).

Conclusion

The United States is presently undergoing unprecedented transformation of health care delivery as a result of the ACA. Quality metrics for health care will be necessary as provisions of the law continue to take effect through 2020. The current lack of standardized metrics is a major obstacle to improving the quality of care (12). Frameworks such as the PROSPR trans-organ conceptual model for breast, cervical, and colorectal cancer screening can guide the development of these needed quality metrics. Moreover, trans-organ conceptual frameworks are important tools for designing comparative studies. Health services researchers in the cancer treatment area have demonstrated the utility of comparative studies in increasing our understanding of cancer outcomes and costs for newly diagnosed cancer patients (40,41). The cancer screening field needs similar comparative studies focused on delivery patterns of the cancer screening process. This research will enable identification of best practices to improve health outcomes and streamline delivery of the screening process across organ sites.

Our conceptual model recognizes the important contextual determinants acting at the levels of providers, facilities, health care systems/organizations, and including local, state, and national policies (20,21,23,65). It is critical to evaluate the impact of factors at different levels on delivery of the cancer screening process, as this knowledge can inform opportunities for interventions that improve screening process outcomes. Prior work suggests that both intra- and interorganizational changes can be key levers in improving the quality of care and cancer screening services (17,18,66), but the influences may vary by organ site and screening modality. Future research should build upon our trans-organ model by further incorporating the perspectives of providers and the complex activities occurring at the facility, health care system/organization, and policy levels. Comparative studies incorporating multilevel influences of the screening process will help to identify ways to modify clinical practice in the United States to promote appropriate screening and timely follow-up of all individuals.

Funding

This work was supported by the National Cancer Institute (NCI)–funded Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium (grant numbers U01CA163304 to MT, WB; U54CA163303 to DLW, BS; U54CA163307 to ANAT, TO, JH; U54CA163313 to KA, MS; U54CA163308 to CSS, EH; U54CA163308-04S1 to CSS, JAT; U54CA163261 to CR; U54CA163261-04S1 to JC, AK; U54CA163262 to AGZ, DC, CD, TL; U54CA163262-04S1 to DC, MS; and U54CA164336 to CW).

Notes

The contents of this manuscript are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Veterans Affairs or the United States Government. The authors have no conflicts of interest to declare.

The PROSPR consortium principal investigators and NCI representatives include Katrina Armstrong, Massachusetts General Hospital; Mitchell Schnall, University of Pennsylvania; Anna Tosteson, Geisel School of Medicine at Dartmouth; Tracy Onega, Geisel School of Medicine at Dartmouth; Jennifer Haas, Brigham and Women's Hospital; Brian Sprague, University of Vermont; Donald Weaver, University of Vermont; Carolyn Rutter, Group Health Research Institute; Aruna Kamineni, Group Health Research Institute; Jessica Chubak, Group Health Research Institute; Celette Sugg Skinner, University of Texas Southwestern; Ethan Halm, University of Texas Southwestern; Jasmin Tiro, University of Texas Southwestern; Douglas Corley, Kaiser Foundation Research Institute; Theodore Levin, Kaiser Foundation Research Institute; Michael Silverberg, Kaiser Foundation Research Institute; Chyke Doubeni, University of Pennsylvania; Ann Zauber, Memorial Sloan Kettering Cancer Center; Cosette Wheeler, University of New Mexico; Mark Thornquist, Fred Hutchinson Cancer Research Center; William Barlow, Cancer Research and Biostatistics; Ann Geiger, National Cancer Institute; Carrie Klabunde, National Cancer Institute; Paul Doria-Rose, National Cancer Institute; and Stephen Taplin, National Cancer Institute.

The authors thank Berta Geller, Tracy Onega, and Deanna Stelling for their helpful comments about data categories and mapping to the PROSPR trans-organ conceptual model.

References

1. Maciosek MV, Solberg LI, Coffield AB, Edwards NM, Goodman MJ. Colorectal cancer screening: Health impact and cost effectiveness. *Am J Prev Med*. 2006;31(1):80–89.
2. Nelson HD, Tyne K, Naik A, et al. Screening for breast cancer: An update for the US Preventive Services Task Force. *Ann Intern Med*. 2009;151(10):727–737.
3. Pignone M, Rich M, Teutsch SM, Berg AO, Lohr KN. Screening for colorectal cancer in adults at average risk: A summary of the evidence for the US Preventive Services Task Force. *Ann Intern Med*. 2002;137(2):132–141.
4. Vesco KK, Whitlock EP, Eder M, Burda BU, Senger CA, Lutz K. Risk factors and other epidemiologic considerations for cervical cancer screening: A narrative review for the US Preventive Services Task Force. *Ann Intern Med*. 2011;155(10):698–705.
5. Vesco KK, Whitlock EP, Eder M, et al. Screening for Cervical Cancer: A Systematic Evidence Review for the US Preventive Services Task Force. *Evidence Synthesis No. 86. AHRQ Publication No. 11-05156-EF-1*. Rockville, MD: Agency for Healthcare Research and Quality; 2011.
6. Whitlock EP, Lin JS, Liles E, Beil TL, Fu R. Screening for colorectal cancer: A targeted, updated systematic review for the US Preventive Services Task Force. *Ann Intern Med*. 2008;149(9):638–658.
7. Leyden WA, Manos MM, Geiger AM, et al. Cervical cancer in women with comprehensive health care access: Attributable factors in the screening process. *J Natl Cancer Inst*. 2005;97(9):675–683.
8. Nelson HD, Tyne K, Naik A, et al. Screening for Breast Cancer: Systematic Evidence Review Update for the US Preventive Services Task Force. *Evidence Synthesis No. 74. AHRQ Publication No. 10-05142-EF-1*. Rockville, MD: Agency for Healthcare Research and Quality; 2009.
9. Taplin SH, Ichikawa L, Yood MU, et al. Reason for late-stage breast cancer: Absence of screening or detection, or breakdown in follow-up? *J Natl Cancer Inst*. 2004;96(20):1518–1527.
10. Whitlock EP, Lin J, Liles E, et al. Screening for Colorectal Cancer: An Updated Systematic Review. *Evidence Synthesis No. 65 Part 1. AHRQ Publication No. 08-05-05124-EF-1*. Rockville, MD: Agency for Healthcare Research and Quality; 2008.
11. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C.: National Academy Press; 2001.
12. Institute of Medicine. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington D.C.: The National Academies Press; 2013.
13. Roland KB, Soman A, Benard VB, Saraiya M. Human papillomavirus and Papanicolaou tests screening interval recommendations in the United States. *Am J Obstet Gynecol*. 2011;205(5):447.e1–e8.
14. Smith RA, Manassaram-Baptiste D, Brooks D, et al. Cancer screening in the United States, 2014: A review of current American Cancer Society guidelines and current issues in cancer screening. *CA Cancer J Clin*. 2014;64(1):30–51.
15. Yabroff KR, Washington KS, Leader A, Neilson E, Mandelblatt J. Is the promise of cancer-screening programs being compromised? Quality of follow-up care after abnormal screening results. *Med Care Res Rev*. 2003;60(3):294–331.
16. Zapka J, Taplin SH, Price RA, Cranos C, Yabroff R. Factors in quality care--the case of follow-up to abnormal cancer screening tests--problems in the steps and interfaces of care. *J Natl Cancer Inst Monogr*. 2010;2010(40):58–71.
17. Anhang Price R, Zapka J, Edwards H, Taplin SH. Organizational factors and the cancer screening process. *J Natl Cancer Inst Monogr*. 2010;2010(40):38–57.
18. Arroyave AM, Penaranda EK, Lewis CL. Organizational change: A way to increase colon, breast and cervical cancer screening in primary care practices. *J Community Health*. 2011;36(2):281–288.
19. Lynch SM, Rebbeck TR. Bridging the gap between biologic, individual, and macroenvironmental factors in cancer: A multilevel approach. *Cancer Epidemiol Biomarkers Prev*. 2013;22(4):485–495.
20. Taplin SH, Anhang Price R, Edwards HM, et al. Introduction: Understanding and influencing multilevel factors across the cancer care continuum. *J Natl Cancer Inst Monogr*. 2012;2012(44):2–10.
21. Zapka J, Taplin SH, Ganz P, Grunfeld E, Sterba K. Multilevel factors affecting quality: Examples from the cancer care continuum. *J Natl Cancer Inst Monogr*. 2012;2012(44):11–19.
22. National Cancer Institute. Population-based Research Optimizing Screening through Personalized Regimens (PROSPR). http://healthcaredelivery.cancer.gov/prospr/. Accessed April 23, 2015.
23. Taplin SH, Yabroff KR, Zapka J. A multilevel research perspective on cancer care delivery: The example of follow-up to an abnormal mammogram. *Cancer Epidemiol Biomarkers Prev*. 2012;21(10):1709–1715.
24. Zapka JG, Taplin SH, Solberg LI, Manos MM. A framework for improving the quality of cancer care: The case of breast and cervical cancer screening. *Cancer Epidemiol Biomarkers Prev*. 2003;12(1):4–13.
25. Onega T, Beaber EF, Sprague BL, et al. Breast cancer screening in an era of personalized regimens: A conceptual model and National Cancer Institute initiative for risk-based and preference-based approaches at a population level. *Cancer*. 2014;120(19):2955–2964.
26. Tiro JA, Kamineni A, Levin TR, et al. The Colorectal Cancer Screening Process in Community Settings: A Conceptual Model for the Population-Based Research Optimizing Screening through Personalized Regimens Consortium. *Cancer Epidemiol Biomarkers Prev*. 2014;23(7):1147–1158.
27. Taplin SH, Rodgers AB. Toward improving the quality of cancer care: Addressing the interfaces of primary and oncology-related subspecialty care. *J Natl Cancer Inst Monogr*. 2010;2010(40):3–10.
28. American Society for Colposcopy and Cervical Pathology. Algorithms: Updated Consensus Guidelines for Managing Abnormal Cervical Cancer

Screening Tests and Cancer Precursors. http://www.asccp.org/Portals/9/docs/Algorithms%207.30.13.pdf. Accessed April 10, 2013.
29. Committee on Practice Bulletins—Gynecology. ACOG Practice Bulletin Number 131: Screening for cervical cancer. *Obstet Gynecol*. 2012;120(5):1222–1238.
30. D'Orsi CJ, Sickles EA, Mendelson EB, et al. American College of Radiology (ACR). *ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas*. Reston, VA: American College of Radiology; 2013.
31. US Preventive Services Task Force. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2008;149(9):627–637.
32. U. S. Preventive Services Task Force. Screening for breast cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2009;151(10):716–726.
33. Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: A joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *Gastroenterology*. 2008;134(5):1570–1595.
34. Lieberman DA, Rex DK, Winawer SJ, et al. Guidelines for colonoscopy surveillance after screening and polypectomy: A consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2012;143(3):844–857.
35. Massad LS, Einstein MH, Huh WK, et al. 2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. *Obstet Gynecol*. 2013;121(4):829–846.
36. Moyer VA. US Preventive Services Task Force. Screening for cervical cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2012;156(12):880–891.
37. Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *J Low Genit Tract Dis*. 2012;16(3):175–204.
38. US Food and Drug Administration. FDA approves first human papillomavirus test for primary cervical cancer screening. http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm394773.htm. Accessed April 24, 2014.
39. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med*. 2014;370(14):1287–1297.
40. Lipscomb J, Yabroff KR, Hornbrook MC, et al. Comparing cancer care, outcomes, and costs across health systems: Charting the course. *J Natl Cancer Inst Monogr*. 2013;2013(46):124–130.
41. Yabroff KR, Francisci S, Mariotto A, Mezzetti M, Gigli A, Lipscomb J. Advancing comparative studies of patterns of care and economic outcomes in cancer: Challenges and opportunities. *J Natl Cancer Inst Monogr*. 2013;2013(46):1–6.
42. Battaglia TA, Burhansstipanov L, Murrell SS, Dwyer AJ, Caron SE, The Prevention and Early Detection Workgroup from the National Patient Navigation Leadership Summit. Assessing the impact of patient navigation: Prevention and early detection metrics. *Cancer*. 2011;117(Suppl 15):3553–3564.
43. Battaglia TA, Santana MC, Bak S, et al. Predictors of timely follow-up after abnormal cancer screening among women seeking care at urban community health centers. *Cancer*. 2010;116(4):913–921.
44. Hysong SJ, Sawhney MK, Wilson L, et al. Provider management strategies of abnormal test result alerts: A cognitive task analysis. *J Am Med Inform Assoc*. 2010;17(1):71–77.
45. Katz ML, Young GS, Reiter PL, et al. Barriers reported among patients with breast and cervical abnormalities in the patient navigation research program: Impact on timely care. *Womens Health Issues*. 2014;24(1):e155-162.
46. Singh H, Petersen LA, Daci K, Collins C, Khan M, El-Serag HB. Reducing referral delays in colorectal cancer diagnosis: Is it about how you ask? *Qual Saf Health Care*. 2010;19(5):e27.
47. Singh H, Thomas EJ, Mani S, et al. Timely follow-up of abnormal diagnostic imaging test results in an outpatient setting: Are electronic medical records achieving their potential? *Arch Intern Med*. 2009;169(17):1578–1586.
48. Singh H, Wilson L, Petersen LA, et al. Improving follow-up of abnormal cancer screens using electronic health records: Trust but verify test result communication. *BMC Med Inform Decis Mak*. 2009;9:49.
49. Singh H, Kadiyala H, Bhagwath G, et al. Using a multifaceted approach to improve the follow-up of positive fecal occult blood test results. *Am J Gastroenterol*. 2009;104(4):942–952.
50. Taplin SH, Clauser S, Rodgers AB, Breslau E, Rayson D. Interfaces across the cancer continuum offer opportunities to improve the process of care. *J Natl Cancer Inst Monogr*. 2010;2010(40):104–110.
51. Yabroff KR, Zapka J, Klabunde CN, et al. Systems strategies to support cancer screening in US primary care practice. *Cancer Epidemiol Biomarkers Prev*. 2011;20(12):2471–2479.
52. Kurman RJ, Solomon D. *The Bethesda system for reporting cervical/vaginal cytologic diagnoses: Definitions, criteria, and explanatory notes for terminology and specimen adequacy*. New York, NY: Springer-Verlag; 1994.
53. One Hundred Second Congress of the United States. *Mammography Quality Standards Act*. United States; 1992.
54. Yabroff KR. Interventions to improve cancer screening: commentary from a health services research perspective. *Am J Prev Med*. 2008;35(suppl 1):S6-S9.
55. One Hundred Eleventh Congress of the United States. *The Patient Protection and Affordable Care Act*. United States; 2010.
56. Centers for Medicare & Medicaid Services. Bundled Payments for Care Improvement (BPCI) Initiative: General Information. http://innovation.cms.gov/initiatives/bundled-payments. Accessed February 12, 2015.
57. Bertko J, Effros R. Increase the Use of "Bundled" Payment Approaches. *Technical Reports, TR-562/20-HLTH*. RAND Corporation; 2010.
58. Hussey PS, Mulcahy AW, Schnyer C, Schneider EC. Bundled Payment: Effects on Health Care Spending and Quality. Closing the Quality Gap: Revisiting the State of the Science. Evidence Report/Technology Assessment No. 208. *(Prepared by the RAND Evidence-based Practice Center under Contract No. 290-2007-10062-I.) AHRQ Publication No. 12-E007-EF*. Rockville, MD: Agency for Healthcare Research and Quality; 2012.
59. National Cancer Institute. CTEP Common Data Elements. https://wiki.nci.nih.gov/display/caDSR/CTEP+Common+Data+Elements. Accessed May 2, 2013.
60. Nadkarni PM, Brandt CA. The Common Data Elements for cancer research: Remarks on functions and structure. *Methods Inf Med*. 2006;45(6):594–601.
61. Mohanty SK, Mistry AT, Amin W, et al. The development and deployment of Common Data Elements for tissue banks for translational research in cancer - An emerging standard based approach for the Mesothelioma Virtual Tissue Bank. *BMC Cancer*. 2008;8:91.
62. Patel AA, Kajdacsy-Balla A, Berman JJ, et al. The development of common data elements for a multi-institute prostate cancer tissue bank: The Cooperative Prostate Cancer Tissue Resource (CPCTR) experience. *BMC Cancer*. 2005;5:108.
63. Winget MD, Baron JA, Spitz MR, et al. Development of common data elements: The experience of and recommendations from the early detection research network. *Int J Med Inform*. 2003;70(1):41–48.
64. Institute of Medicine. *Fulfilling the Potential of Cancer Prevention and Early Detection*. Washington, D.C.: National Academy Press; 2003.
65. Clauser SB, Taplin SH, Foster MK, Fagan P, Kaluzny AD. Multilevel intervention research: Lessons learned and pathways forward. *J Natl Cancer Inst Monogr*. 2012;2012(44):127–133.
66. Landon BE, Wilson IB, Cleary PD. A conceptual model of the effects of health care organizations on the quality of medical care. *JAMA*. 1998;279(17):1377–1382.
67. Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: Recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *J Am Coll Radiol*. 2010;7(1):18–27.
68. Saslow D, Boetes C, Burke W, et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin*. 2007;57(2):75–89.