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THE IMPACT OF INSIGHT:



Patient Preferences in
Novel Screening
Technologies for Cancer

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INTRODUCTION

Patient preferences and insights are increasingly considered throughout the medical product life cycle in addition to clinical outcomes.¹ We know that incorporating patient preferences in the product life cycle can create meaningful results and improve potential adherence for patients using or relying on medical products.²

The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research first released guidance on including patient preference information in the development of medical products in 2015.³ Given that this is a relatively new approach, patient preferences were not broadly considered in developing many of the predominant cancer screening modalities we rely on today for population-level cancer control, such as mammograms, colonoscopies, and Pap smears.⁴ The lack of patient considerations incorporated into the development of screenings may impact adherence to recommended current screening guidelines, negatively influencing patient outcomes and, ultimately, survival.⁵ The incorporation of patient preferences into the development and advancement of early intervention technologies and treatments is equally important. As screening technologies advance and detect cancer earlier, it is imperative that the development process for early intervention modalities includes patient insights.

The lack of patient considerations incorporated into the development of screenings may impact adherence to recommended current screening guidelines, negatively influencing patient outcomes and, ultimately, survival.

The Rising Tide Foundation for Clinical Cancer Research, a cancer research funding organization, approached FasterCures about researching the potential influence of patient preferences and insights on the future development of new cancer screening modalities and early interventions. Based on the success of this initial research, we expanded our work into this full report. Exploring patient preferences in cancer screening modalities and early interventions builds on FasterCures' work to embed the experiences and preferences of patients across the biomedical ecosystem to address patient needs and improve outcomes.

BACKGROUND

Cancer is a leading cause of death in the US, second only to heart disease.⁶ Approximately one in two men and one in three women will be diagnosed with cancer during their lifetimes.⁷ Screening tests aim to find cancer before a person has any symptoms or the cancer has had an opportunity to metastasize. Finding cancer early or before it has spread improves the likelihood of treatment success, long-term survival, and quality of life.⁸ When identified early, the five-year survival rate for some cancers is at least 90 percent.⁹

Cancer screenings have directly led to a reduction in mortality over time; however, adherence to the recommended routine screenings has historically been an issue.¹⁰ For example, despite breast cancer being the most common cancer affecting women, screening adherence is low—especially in racial, ethnic, and cultural minority populations, leading to later diagnoses, worse prognoses, and increased mortality due to many barriers to access.¹¹

According to the Prevent Cancer Foundation's annual Early Detection Survey conducted in January 2023, 65 percent of survey respondents are not up to date on at least one of their routine cancer screenings.¹² Forty percent of those who said they are not up to date on at least one of their cancer screenings in the same survey said they would be more likely



Sixty-five percent of Americans are not up to date on at least one of their routine cancer screenings.

to prioritize screenings if an at-home test was available. Similarly, 32 percent said if there were a less-invasive test or screening available, they would also be more likely to prioritize screening;¹³ of the routine cancer screenings available, half are considered invasive, which may deter people from scheduling a screening despite eligibility.

Currently, in the US, there are routine screenings for five cancers recommended by the United States Preventive Services Task Force (USPSTF): breast, cervical, colorectal, prostate, and lung. These screenings include mammography, Pap smear, colonoscopy, prostate-specific antigen (PSA) test (on an individual basis based on personal preference and risk), and low-dose computed tomography scans (LDCT).¹⁴ However, other cancers for which we do not have recommended routine screenings account for nearly 71 percent of cancer deaths.¹⁵ The detection of these other cancers depends on people presenting with symptoms and relies heavily on extensive imaging and invasive biopsies without designated screening tests.

Cancers for which we do not have recommended routine screenings account for nearly 71 percent of cancer deaths.

Given that the majority of cancer deaths are from cancers that currently have no form of early detection or recommended routine screening test, life science companies and device manufacturers are interested in developing innovative, novel approaches to cancer screening to identify cancers beyond the five modalities currently in use—including those that presently have no screening modality and those that are most lethal, like pancreatic cancer.

METHODS

We conducted an informal review of peer-reviewed and grey literature published between 2018 and 2022 on studies examining patient preferences in cancer screening completed across the United States and Europe and cancer types. Following the literature review, we conducted a landscape assessment of currently available and novel cancer screening modalities in the US and Europe.

To better understand patient preferences in cancer screening, early detection, and interventions, we engaged the following stakeholders:

7

Key opinion leader interviews

pressure-tested our preliminary findings and key questions in our interview guides for the roundtable and patient focus group to follow

8

Cancer-focused organizations

gleaned their perspectives on how they engage patients throughout their work and what patient perspectives they have captured related to early detection, screening, and early intervention

19

People with lived experience with cancer

shared their own perspectives, preferences, and challenges and opportunities across cancer screening and early detection modalities and early interventions

PATIENT PREFERENCES

Based on our extensive research and engagement with stakeholders, we have identified the following patient preferences in cancer screening, early detection, and interventions.

Patient Preferences in Cancer Screening and Early Detection

1

Accuracy

Accuracy is a critical factor in cancer screening and early detection preferences. Patients desire technologies that display high sensitivity and specificity to avoid receiving false positive results or that require a second opinion or additional follow-up tests.

2

Administered by Primary Care Physician

Patients prefer that their cancer screenings are recommended and administered by their primary care physicians rather than specialists or labs.

3

Cause Minimal Harm

When given a choice, patients prefer screening modalities that are minimally invasive and cause minimal harm.

4

Minimal Discomfort & Prep

Patients prefer screening modalities with minimal complications, discomfort or pain, side effects, and modest prep leading up to the screening.

5

Convenience

In addition to being administered by a primary care physician, patients prefer screening modalities performed conveniently close to home or in their physician's office rather than a hospital or specialty setting.

6

Open to New Technology

Patients are open to the use of emerging technologies, such as machine learning or artificial intelligence, that may improve the sensitivity of results or return results faster when used with current radiology or pathology methods.

Patient Preferences in Early Interventions

1. **Assessing Risk**

People want to know their risk for cancer. Genetic testing is recommended for those with well-documented familial history; however, increasing frequency and access to genetic testing may identify risk earlier in those with unknown history.

2. **More Personalized Care**

By leveraging biomarkers, patients want personalized care customized to their condition, preferences, and desired outcomes—including targeted therapies and immunotherapies.

3. **Better Treatments**

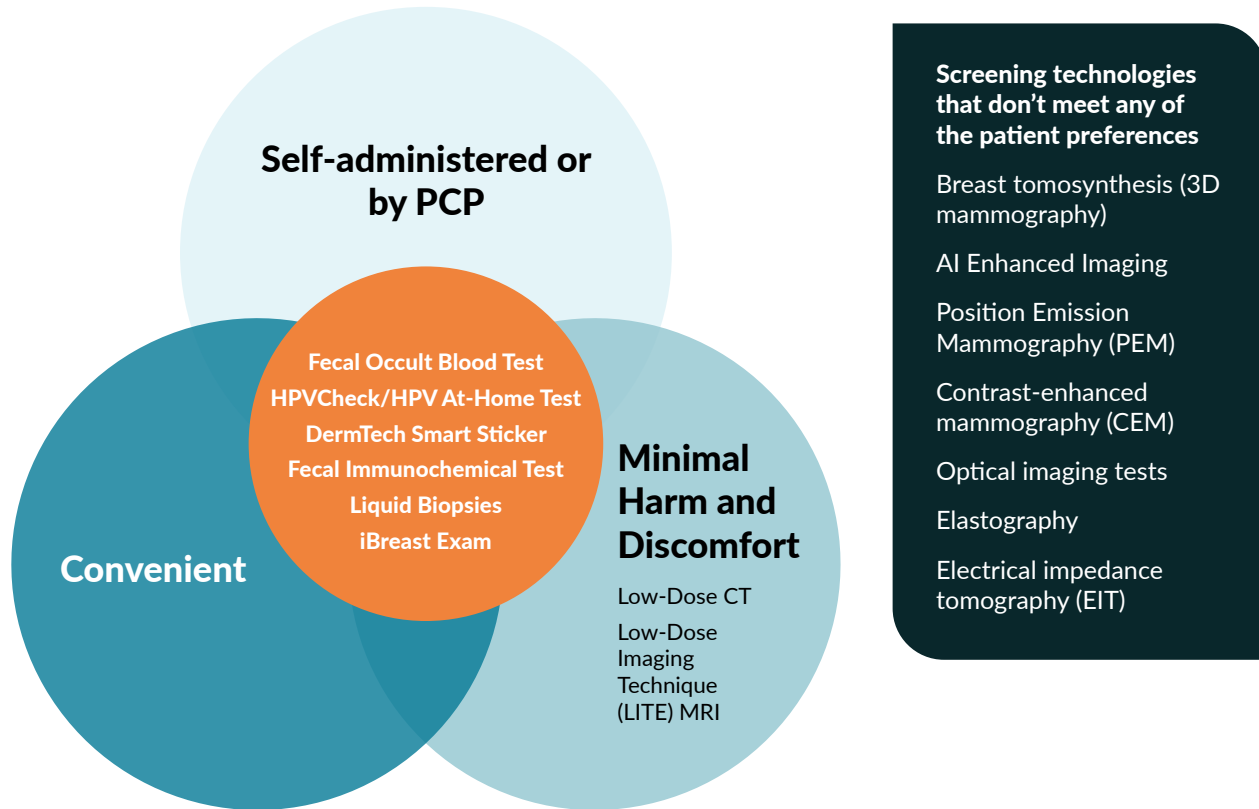
Patients value a better quality of life as much as, if not more than, an extension of life. As more people are diagnosed with earlier stages of the disease, they prefer newer approaches to treatment or anticancer therapies that are less toxic and debilitating, emphasize survival beyond five years, and minimize the use of life-altering surgeries.

RECOMMENDATIONS

Our conversations with patient advocates and people with lived experiences of cancer emphasize the potential impact that patient preferences have when considering developing new cancer screening and early intervention approaches. Developing future modalities according to the patients' preferences might resolve key challenges of cancer screening and early interventions.

We analyzed and compared 15 new cancer screening modalities according to the preferences that patients identified. Although the list of screening modalities in Figure 1 is not exhaustive, of the 15 screenings, we concluded that about half failed to meet three of the most commonly cited patient preferences we captured, including whether the test could be self-administered or by a primary care physician, was conveniently located (outside of a specialty facility or hospital), and if the test was minimally invasive, harmful (including radiation exposure), or caused potential discomfort. We see there is a great opportunity to better meet the needs of patients throughout the development process.

Figure 1: Many New Cancer Screening Technologies Do Not Meet Patient Preferences



Source: Milken Institute (2023)

The following recommendations aim to guide key stakeholders, from medical device manufacturers to research foundations, on ways in which patient insights can be actionably embedded throughout the development of new cancer screening and early intervention modalities.

KEY ISSUE: Unawareness of Individual Risk of Cancer and Recommended Screenings

Insights	<ul style="list-style-type: none">• Many people who present symptoms of cancer—even cancers for which there are recommended screenings—fall outside the recommended guidance due to their age or because they are unaware of their familial history of cancer.• Some cancers in the US are on the rise in younger people and minority communities, including colorectal cancer, leading to the amended recommended age of screening for colon cancer from 50 to 45.¹⁶• However, screening recommendations by the USPSTF take years to amend and are broadly applied based on age and gender.
Recommendations for Action	<ol style="list-style-type: none">1. Invest in a better biological understanding of cancer. Invest in research to advance our current understanding of the biology of cancer. Research should include discovering and innovating biomarkers and developing tests for particular biomarkers.2. Change the screening paradigm. Instead of recommended screenings based on age and gender at the population level, stratify the population based on genetic risk, lifestyle, and behavior. Increase the use of genetic testing to target those with familial history.3. Implement unique screening modalities based on stratified patient risk. Increase frequency and expand genetic testing recommendations to include those with an unknown familial history of cancer. Currently, genetic testing is limited to those with a well-documented familial history; however, increasing frequency and expanding recommendations might help to identify risks earlier.

KEY ISSUE: Lack of Diversity in Research

Insights	<ul style="list-style-type: none">• Diversity in clinical trials may increase the uptake of screenings and ensure that the screenings are tailored to specific subpopulations based on risk factors, later informing guideline development and treatment or intervention options.
Recommendations for Action	<ol style="list-style-type: none">1. Account for diversity in research and data. Ensure that clinical trials for novel technologies include adequate diversity to confirm that all patients, regardless of race, gender, or age, are using products tested on patients from their communities.2. Prioritize that data informing the development of artificial intelligence algorithms are representative of diverse populations.



KEY ISSUE: Access to Screening Tests

Insights	<ul style="list-style-type: none">• With the proliferation of at-home and self-administered COVID-19 tests and digital health tools, people are more accustomed to collecting health information or biometric data to share with their providers via telehealth or mail.• Traditional screening for HPV in women through Pap smear has reduced cervical cancer mortality by 50 percent over the past 50 years. However, one in four women do not receive regular HPV screenings, and half of those diagnosed with cervical cancer were not screened.¹⁷ Developers of at-home HPV tests for cervical cancer hope to alleviate this gap and increase adherence for screenings. In a recent study completed by a health system, mailing at-home HPV kits increased screening adherence by 50 percent.¹⁸• Recent innovative technology allows patients to collect skin cells of a suspicious spot on their skin via a smart sticker or bandage that is sent to a lab to be tested for genomic markers associated with melanoma and other DNA driver mutations.¹⁹ In the case of a positive test, patients are scheduled to follow up with a dermatologist to determine an appropriate diagnostic and treatment plan.
Recommendations for Action	<ol style="list-style-type: none">1. Invest in accessible screening technologies. Technologies such as liquid biopsies and compact or mobile imaging units have the potential to both meet multiple patient preferences and increase access.2. Invest in initial, self-administered screenings in the home. New technology allows some initial screenings to be self-administered by patients in their homes. The results of these tests can then determine whether follow-up or more rigorous testing is needed for a diagnosis with a clinician.

KEY ISSUE: Lack of Patient Engagement in the Development of Medical Products

Insights	<ul style="list-style-type: none">• Patient preferences and insights can be leveraged to develop new screening and early interventions for cancer that may increase adherence resulting in overall increased survival and quality of life.
Recommendations for Action	<ol style="list-style-type: none">1. Continue to engage patients in the development of novel screening modalities and early interventions for cancer treatment. Patient-driven research should be continuous across the research and development life cycle. Continuing to engage patients and caregivers in decision-making is paramount in ultimately meeting research goals on behalf of the patient.

KEY ISSUE: Limited Current Screening Tests

Insights	<ul style="list-style-type: none">• Although currently recommended cancer screenings are for commonly diagnosed cancers, they are not the most lethal cancers.• Much of the innovation occurring in the cancer screening landscape is to increase the overall accuracy of existing modalities that are already in use, not expanding the number of cancer types for which we can screen.
Recommendations for Action	<ol style="list-style-type: none">1. Prioritize the development of screening modalities for lethal cancers and cancers without current screenings.

ADDITIONAL INSIGHTS FROM PATIENTS

While engaging stakeholders across the cancer and patient engagement continuum, we identified two additional findings that were frequently cited as fundamental to the current cancer screening and early intervention landscape.

Patient and Provider Education

We acknowledge that cultural differences across regions may influence patient-provider dynamics and access to information.

Many eligible people do not know their specific recommended screening options and are not informed by their providers.

We recommend that patient and provider education initiatives be considered when investing and introducing novel screening or treatment approaches to ensure providers as well as patients are informed and empowered in their care.

Insurance Coverage

We acknowledge that insurance dynamics, reimbursement, and coverage vary dramatically by country or region.

Whether a particular screening modality or intervention is paid for by insurance often predetermines adherence.

We recommend that novel screening technologies and treatments meet multiple patient preferences and, to the greatest extent possible, consider likely insurance coverage and patient cost.

CHALLENGES AND BARRIERS ASSOCIATED WITH NEW TECHNOLOGIES

Despite the opportunities to consider patient preferences in developing new cancer screening tools to positively impact patient outcomes and survival, we identified challenges associated with new screening modalities and groundbreaking early interventions. The challenges include significant issues related to cost, access, and the risk of exacerbating existing or creating new inequities.

Cost-Associated Barriers to New Cancer Screening Modalities

Regardless of the opportunities and excitement surrounding the advancement of innovative screening modalities, there is real concern about cost-associated barriers and access. The cost of these tests without public and private insurer coverage will be a financial burden and prohibitive to patients unable to afford the full cost-share. For example, a common multicancer early detection (MCED) liquid biopsy test that might be recommended annually costs approximately \$950.²⁰

Since the passage of the Affordable Care Act, Medicare and private insurers have covered cancer screenings recommended by the USPSTF for eligible beneficiaries at 100 percent. However, coverage depends on FDA approval and an A-level recommendation by the USPSTF. Until newer cancer screening modalities are approved by the FDA and recommended by the USPSTF, Medicare will likely not cover the tests, leaving patients with the total cost burden. The process from FDA approval through USPSTF recommendation can take over 10 years. Some employers and insurance companies are beginning to provide access to their employees or beneficiaries at little-to-no cost as a temporary stopgap. Yet until coverage of new and innovative screenings is widespread, inequities will persist and likely be exacerbated based on the cost of the screening.

Screening Equipment-Related Barriers to Access

Although many forms of new cancer screening promise expanded access, such as portable imaging devices or liquid biopsies that a phlebotomist can administer at a pharmacy, novel imaging technologies frequently require specific, specialty equipment such as positron emission mammography scanners that might not be available in all community hospital or clinic settings.²¹ We heard concerns about developing technologies and devices that patients may only be able to access in National Cancer Institute-designated cancer centers or sizeable academic health systems versus community-based hospitals and clinics closer to people's homes. Innovative early-detection technologies are only helpful if people can access them.

It is important to acknowledge that racial inequities and geographic location will likely compound any screening and early detection challenges. Developing novel screening and early detection modalities could work in two ways: They could mitigate racial and geographic inequities by making screening and early detection more accessible and cost-effective or exacerbate existing health inequities. Developers need to be intentional about designing with equity in mind.

Integration-Related Challenges

With the recent proliferation of at-home or direct-to-consumer tests available in cancer screening, patients may receive cancer-risk or screening results independently of or before their clinician. Regardless of whether the test is initially prescribed by a physician, these at-home tests must thoughtfully integrate into a diagnostic and care pathway with a clinician for interpretation and early anticancer interventions.

CONCLUSION

Patients, caregivers, and key opinion leaders alike emphasize the potential impact that including patient preferences in the development of novel screening, early detection, and early intervention modalities may have on adherence and, subsequently, health outcomes.

Life science companies and device manufacturers must consider the role of patient preferences in developing future cancer screening tests to influence adherence positively, reduce late-stage cancer diagnoses, and ultimately save lives.

PATIENT PREFERENCES

in Cancer Screening & Early Detection

These findings are a culmination of a 2022 literature review, key opinion leader interviews, a patient organization roundtable, and a focus group of people with lived experience of cancer.



Accuracy

Patients overwhelmingly prefer screening modalities with high sensitivity and specificity and expressed concern over false positives.



Administered by PCP

Patients prefer that their cancer screenings be recommended and administered by their primary care physician (PCP).



Causes Minimal Harm

When given a choice, patients prefer less harmful and minimally invasive screening modalities over those that require invasive techniques.



Minimal Discomfort & Prep

Patients prefer screening modalities with minimal complications, discomfort or pain, and side effects as well as modest prep.



Convenience

Patients prefer screening modalities that are performed by their PCP in their office, rather than a hospital or specialty setting, and prefer to be screened close to home.



Open to New Technology

Patients are open to new forms of technology that may improve the sensitivity of results or return results faster.

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ABOUT THE AUTHORS

Hadly Clark is an associate director at FasterCures. She is an experienced health-care professional focused on the intersection of health and technology. Clark leads oncology-focused initiatives exploring innovative screening technologies and advancements in anti-cancer treatments. Prior to her tenure at the Milken Institute, she led quality improvement programs at the American Society of Clinical Oncology. Clark has 10+ years of experience as a dedicated patient advocate helping people navigate through the complex, often opaque US health system. She holds a Master of Science in health systems administration from Georgetown University's School of Health.

Katie O'Connor was a senior associate at FasterCures, providing research support on various workstreams, including health equity and oncology. Prior to the Milken Institute, O'Connor worked as a research associate at Truth Initiative, where she advanced health outcomes and health communication research in the context of tobacco and e-cigarette use. In addition to health equity and oncology, O'Connor's interests lie in maternal and child health, mental health, and substance use disorder research. O'Connor received her master's degree in public health with a concentration in global health epidemiology and disease control from the George Washington University and a BS in psychology and a minor in neuroscience from the University of Pittsburgh.



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