

Cancer Screening in Primary Care: What is the role of MCED Testing?

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Disclosures

- Christopher V. Chambers, MD
 - Thrive: Research support
 - Exact Sciences: Research support
- Ronald E. Myers, DSW, PhD, SBMF
 - Thrive: Research support
 - Exact Sciences: Research support

Cancer Screening Primary Care: 2022 and Beyond

- Breast: Mammography, other
 - Colorectal: Colonoscopy, FIT, other
 - Cervical: Pap smear, HPV testing
 - Lung: LDCT
 - ? Prostate
-
- The Future: ?MCED testing

Multi-Cancer Early Detection (MCED) in Cancer Screening

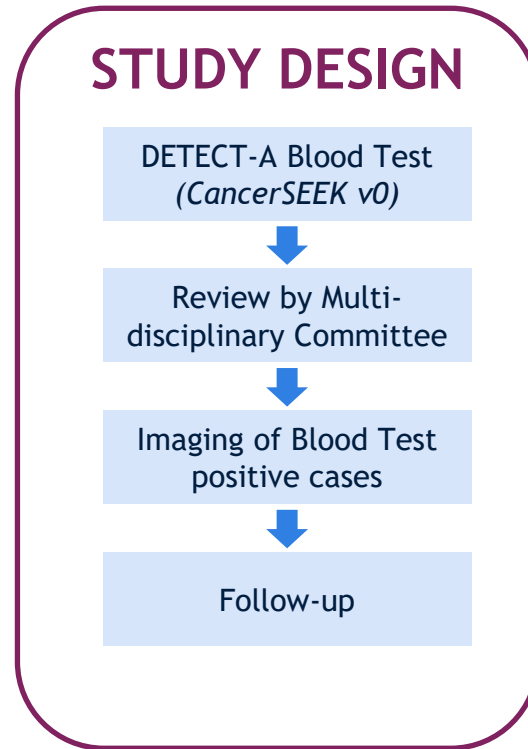
MCED: Pulls DNA from a blood sample looking for mutations in 16 genes known to drive the growth of various cancers and combines this information with established protein biomarkers and methylation signatures for some cancers.

DETECT-A Study: Thrive/Exact Sciences

STUDY GOALS

- Detect cancers not found by standard of care in the real world
- Pilot blood test and workflow in a large clinical population
- Manage patient care by delivering test results

STUDY DESIGN

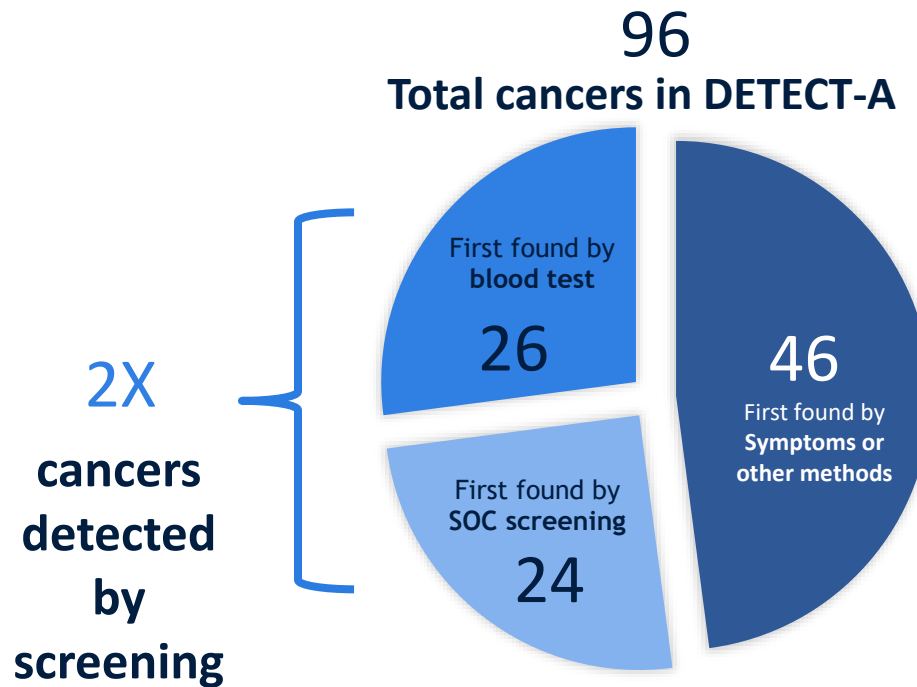


ENROLLMENT

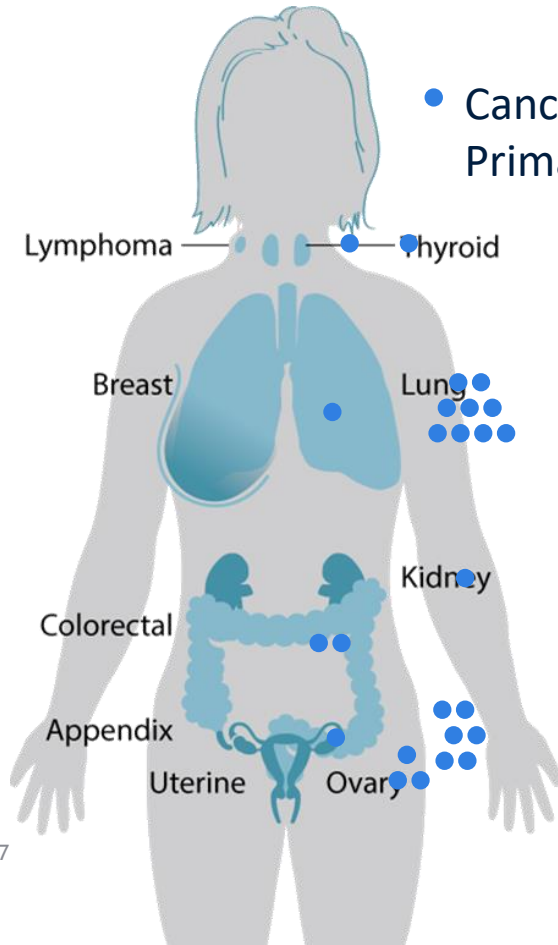
- 10,006 women enrolled (9,911 screened)
- Aged between 65-75
- September 2017 - May 2019
- Only exclusion criterion: No prior history of cancer



Blood test (CancerSEEK) Doubled Screen-detected Cancers Found Over an 18-month Observation Period



Cancer Detected in 10 Organs (No Standard of Care Screening Options in 7)



• Cancer of Unknown Primary (CUP)

10 ORGANS

7 ORGANS WITH NO SOC SCREENING

	CancerSeek Blood Test	SOC Screening
Ovary	✓	No screening tests available
Thyroid	✓	
Lymphoma	✓	
Uterine	✓	
Appendix	✓	
Kidney	✓	
CUP	✓	
Breast	✓	✓
Colorectal	✓	✓
Lung	✓	✓*

**LDCT only indicated for high risk populations*

Provider and Patient Views of MCED Testing: A Scoping Review

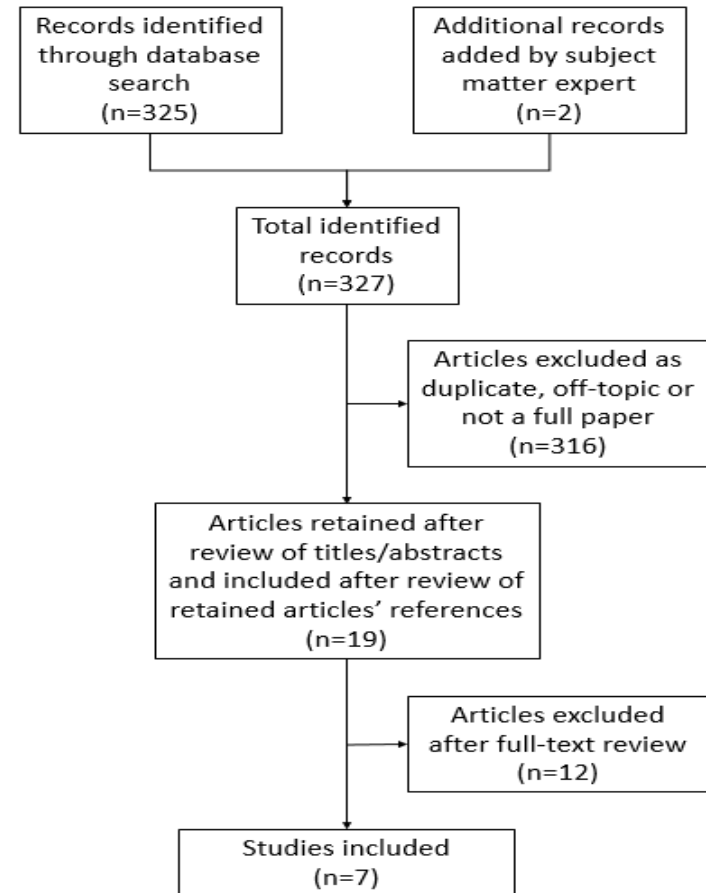
Perceptions of Multi-Cancer Early Detection in Primary Care: A Scoping Review

Davis K, Hallman MH, DiCarlo M, Wambua S, Jaffe R, Welsh A, Kerber C, Chambers CV, Myers RE

- Cancer is the second leading cause of death in the United States.
- New cancer screening modalities such as liquid biopsy and multi-cancer early detection (MCED) tests are being developed.
- These tools could be used to detect early-stage cancers for which there exist and do not exist recommended screening tests.
- We conducted a scoping review to learn what has been reported on factors likely to affect primary care provider and patient uptake of these tests.

Methods

- Scoping review guided by PRISMA-ScR
- Databases: PubMed, Scopus, Ovid
- January 2000-June 2021
- Search terms: multi-cancer screening, multi-cancer early detection, MCEd, multi-analyte testing, and liquid biopsy



Results

Authors (Year)	Study Design	Study Description
Abola et al., (2015)	Cross-sectional survey	Patients (n=423) underwent both colonoscopy and sDNA testing, then completed preference survey
Adler et al., (2014)	Observational study	Patients (n=172) who refused colonoscopy were offered either a FIT test or an Epi proColon blood test and completed a preference survey
Benning et al., (2014)	Discrete choice experiment	Participants (n=815) were presented with different CRC screening options and completed a preference survey
Berger et al., (2006)	Cross-sectional survey	Patients (n=1,211) completed a survey on their experience with sDNA testing for colorectal cancer
Schroy & Heeren (2005)	Prospective survey	Patients (n=4,042) completed a preference survey after completing sDNA testing, stool blood test cards, and colonoscopy
Schroy et al., (2007)	Cross-sectional survey	Patients (n=263) reviewed a colorectal cancer screening decision aid with a research assistant and completed a preference survey
Yang et al., (2014)	Cross-sectional survey	Patients (n=434) completed a preference survey on methods to screen for upper airway and digestive cancers

Results (continued)

- None of the identified articles focused on provider perceptions or preferences related to liquid biopsy or MCED in cancer screening.
- Six (6) of the articles on patient views focused on screening for a single cancer, while one (1) focused on multiple cancers.
 - Patients were receptive to liquid biopsy/MCED testing
 - Patients valued liquid biopsy/MCED test convenience, non-invasiveness, and effectiveness.
 - Patient views of liquid biopsy/MCED tests may be associated with sociodemographic background.

Conclusions

Further research is needed to:

- Assess provider and patient receptivity to the use of liquid biopsy/MCED testing as a method to screen for cancer.
 - Identify factors associated with provider and patient receptivity to liquid biopsy/MCED test use for cancer screening.
- Assess provider and patient uptake of liquid biopsy/MCED testing in cancer screening.
 - Identify factors associated with provider and patient uptake of liquid biopsy/MCED test use for cancer screening.
- Determine provider and patient response to implementation of liquid biopsy/MCED test use in cancer screening.

A Survey of Provider Knowledge and Perspectives Related to MCED Testing

Developing an MCED Testing Learning Community and Conducting a Pilot Study

- Engage a MCED learning community (N=95)
 - Coordinating Team, System Leadership Group, Steering Committee, Patient and Stakeholder Advisory Committee
- Conduct a Pilot Study
 - Recruit primary care practices (N=4), providers (N=36), and patients (N=500)
 - Train care coordinators to deliver a patient education and shared decision making program
 - Collect and analyze provider survey data on knowledge about and receptivity to MCED testing

Pilot Study Provider Survey

- Awareness of MCED testing
- Factors associated with provider receptivity to MCED test use
- Perceived competence in MCED test use
- Likelihood of ordering MCED testing in the future

Results

Provider Background Characteristics (N=27)

Variables	n (%)
Age (years)*	
<40	5 (19)
40-59	13 (50)
60+	8 (31)
Sex*	
Female	13 (50)
Male	13 (50)
Race/ Ethnicity*	
White	16 (62)
African American	1 (4)
Latino/ Hispanic	3 (12)
Asian	4 (15)
Other	2 (8)
Provider	
Physician	22 (81)
Nurse Practitioner	5 (19)

Results (continued)

Provider Awareness of MCED Test Development (n=27)

Variable	Strongly Disagree	Mildly Disagree	Uncertain	Mildly Agree	Strongly Agree
Aware that MCED tests are being developed for use in cancer screening	<u>n (%)</u> 0 (0)	<u>n (%)</u> 3 (11)	<u>n (%)</u> 3 (11)	<u>n (%)</u> 12 (44)	<u>n (%)</u> 9 (32)

Results (continued)

Perceived Competence in Managing MCED Test Use (n=27)

Variable	Strongly Disagree	Mildly Disagree	Uncertain	Mildly Agree	Strongly Agree
Mean=3.9, Range=2.5-5.0, Alpha=0.85					
Identifying patients who are eligible for MCED testing	0 (0)	1 (4)	7 (26)	13 (48)	6 (22)
Educating patients about MCED testing and follow-up*	0 (0)	2 (8)	9 (35)	7 (27)	8 (31)
Engaging patients in SDM about MCED testing and follow-up*	0 (0)	2 (8)	7 (27)	6 (23)	11 (42)
Guiding patients through MCED testing and follow-up	0 (0)	3 (11)	8 (30)	7 (26)	9 (33)

*Missing for one respondent

Results (continued)

Factors Limiting Provider Receptivity to MCED Test Use (n=27)

Variable	No Influence	A Little Influence	Some Influence	A Lot of Influence	Overwhelming Influence
Mean=3.4, Range=1.4-4.2, alpha=0.83					
Limited staff time to help patients decide about MCED testing	2 (7)	5 (19)	4 (15)	13 (48)	3 (11)
Concern about managing false positive and false negative results	1 (4)	1 (4)	9 (33)	11 (41)	5 (19)
No MCED testing insurance coverage	0 (0)	5 (19)	3 (11)	10 (37)	5 (19)
Uncertainty about explaining results	3 (11)	4 (15)	5 (19)	10 (37)	5 (19)
Lack of MCED test ordering guidance	0 (0)	5 (19)	3 (11)	10 (37)	9 (33)
Lack of FDA approval for MCED testing	3 (11)	3 (11)	7 (26)	7 (26)	7 (26)

Results (continued)

Factors Associated with Provider Receptivity to MCED Test Use (n=27)

Variable	No Influence	A Little Influence	Some Influence	A Lot of Influence	Overwhelming Influence
Mean=3.4, Range=1,4-4.2, Alpha=0.83					
Limited time to explain MCED test results to patients	2 (7)	4 (15)	10 (37)	9 (33)	2 (7)
Concern that patients will not continue with standard screening	2 (7)	7 (26)	7 (26)	9 (33)	2 (7)
Lack of sufficient data on test effectiveness	2 (7)	3 (11)	9 (33)	12 (44)	1 (4)
Lack of available MCED test blood	4 (15)	2 (8)	8 (31)	12 (46)	0 (0)

*Missing for one respondent

Results (continued)

Likelihood of Ordering MCED Testing in the Future (n=27)

Variable	Strongly Disagree	Mildly Disagree	Uncertain	Mildly Agree	Strongly Agree
Likely to order MCED testing for patients when it becomes available	0 (0)	0 (0)	5 (19)	5 (19)	17 (62)

Conclusions

- Most providers were aware that MCED tests are being developed for use in cancer screening
- Most providers were concerned about MCED test use due to limited data on test effectiveness, lack of test approval and guidelines, uncertainty about testing and follow-up, test impact on current screening procedures, time, and cost.
- Providers were receptive to MCED test use in the future, when such testing is approved for use.

Issues

Issues Related to Implementation

- Policy
 - Test capacity to identify early-stage cancers and location
 - Harms from over-diagnosis and incidental findings
 - Determination of interval for MCED testing in screening
 - Detection of cancers with no mortality benefit
 - Impact of MCED testing on cancer disparities

Issues Related to Implementation (continued)

- Providers and Patients
 - Provider use of MCED testing with/without standard screening
 - Provider management of MCED+ test results
 - Shared decision making about MCED testing
 - Patient response to MCED test results
 - Patient insurance coverage for MCED testing and follow-up