PCR222

The Value of 'No Cancer Signal Detected' Results from Multi-Cancer Early Detection Tests–Perspectives from the General Population

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INTRODUCTION

- Cancer is the second leading cause of death worldwide.[1] Early detection and intervention can significantly improve outcomes and reduce mortality.
- Multi-cancer early detection (MCED) tests, which detect a shared cancer signal (e.g., methylation pattern associated with cancer) in plasma cell-free DNA, are currently available or under development.[2]
- Beyond clinical and economic benefits, there are other potential benefits (e.g., emotional, social, cognitive, behavioral, and/or reduced uncertainty with additional information) that may add to the value of MCED tests.[3,4]
- Limited research is available on patients' perceived impact of a negative result (i.e., 'no cancer signal' detected) beyond clinical or economic aspects.

OBJECTIVE

- This study aimed to understand the perceptions of the United States (US) general population regarding the value of MCED screenings with negative results, based on performance characteristics of an actual MCED test.

KEY RESULTS

- Relief (84%) and reduced fear/concern/worry (84%) were the most commonly anticipated psychological/emotional benefits (**Figure 1**).

Figure 1. Perceived Emotional Impacts of Negative MCED Test Results[a]

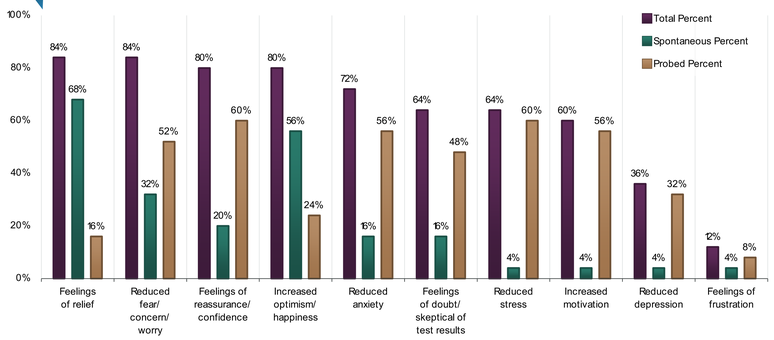
[a] Not mutually exclusive

Maybe reduce some worry, like…not even worry that I know is there, some back of your heart worry like oh it's good to know that I don't have cancer at this point in time…

It would give me a great amount of ease, probably not 100%, if it's something that's new. If it's something that's been around and they've done for a long time, but they're just combining it, I would probably have a little bit more ease. But I would still have my regular like, mammograms and unfortunately, colonoscopy.

..relief, happiness, less anxiety, all those type of things. I don't think I would have any other feelings about that.

-Participants' quotes

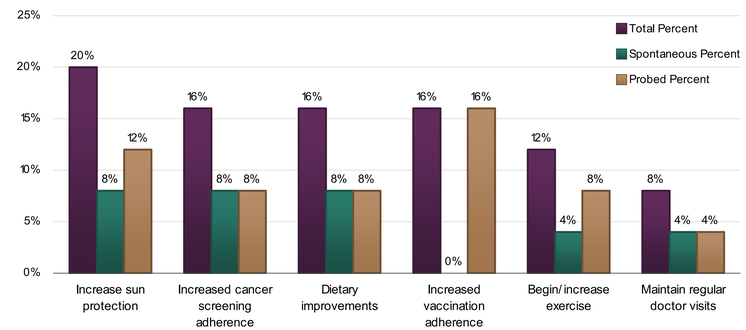


- Most participants felt that they would not decrease their preventive behaviors based on a negative MCED result and would either increase or maintain adherence to current preventive activities (60%) (**Figure 2**).
- Some participants reported that they would increase their adherence to sun-protective behaviors (20%), recommended cancer screenings (16%), and/or vaccinations (16%), as well as improvements to their diet (16%) (**Figure 2**).

Figure 2. Anticipated Impacts to Preventive Activities Based on Negative MCED Test Results[a]

I would take more precautions and I would get screened more. Yeah, that's what I would do. I would get screened more.

-Participant quote



[a] Not mutually exclusive

CONCLUSIONS

In addition to the clinical benefits, there are additional benefits of negative results from MCED tests, particularly in terms of emotional and psychological benefits to patients.

Additionally, patients might benefit from increased awareness from a result of no cancer signal detected from an MCED test that might lead to increased preventive health behaviors and even impact individuals' financial planning behaviors.

Comprehensive assessment of the value of MCED tests includes impact of both positive and negative test results.

LIMITATIONS

- This was a qualitative study conducted among a limited sample of participants, therefore findings may be not be generalizable to the general US population.
- This study followed an inductive concept elicitation approach. Future research should aim to explore the findings of this study deductively in a larger, more representative sample.

References

1. National Cancer Institute (NCI). What Is Cancer? https://www.cancer.gov/about-cancer/understanding/what-is-cancer. Updated October 11, 2021. Accessed July 14, 2022.
2. Stover DG, Parsons HA, Ha G, et al. Association of cell-free DNA tumor fraction and somatic copy number alterations with survival in metastatic triple-negative breast cancer. J Clin Oncol. 2018;36(6):543-553.
3. Coleman K, Wagner E, Schaefer J, Reid R, LeRoy L. Redefining Primary Care for the 21st Century. White Paper. (Prepared by Abt Associates, in partnership with the MacColl Center for Health Care Innovation and Bailit Health Purchasing, Cambridge, MA under Contract No.290-2010-00004-I/ 290-32009-T.) AHRQ Publication No. 16(17)-0022-EF. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); October 2016.
4. Wurcel V, Cicchetti A, Garrison L, et al. The value of diagnostic information in personalised healthcare: a comprehensive concept to facilitate bringing this technology into healthcare systems. Public Health Genomics. 2019;22(1-2):8-15.

METHODS

Participants

- Key Inclusion Criteria: Participants 40–80 years old; resident of the US; willing to provide informed consent; able to read and understand English; willing to be audio recorded; and willing and able to participate in a virtual interview.
- Key Exclusion Criteria: Participants receiving treatment for cancer at the time of screening; previously diagnosed with cancer; or demonstrating any cognitive impairment (as assessed by the screener and interviewer).

Study Design

- This was a cross-sectional study in which participants completed one-on-one web-assisted concept elicitation interviews that lasted approximately 60 minutes.
- During the interviews, participants reviewed written material describing a hypothetical MCED screening and were asked how they would feel about receiving negative MCED test results—including how they would be impacted by them—as well their perceptions about the value of negative results.
- Participants completed a brief web-based sociodemographic and clinical survey.
- Content analysis, an iterative coding approach based on organically emerging themes, was conducted based on transcripts using ATLAS.ti.

RESULTS

- Participants (N=25) were 64% female, 28% Black, with mean age of 50 years old (**Table 1**).

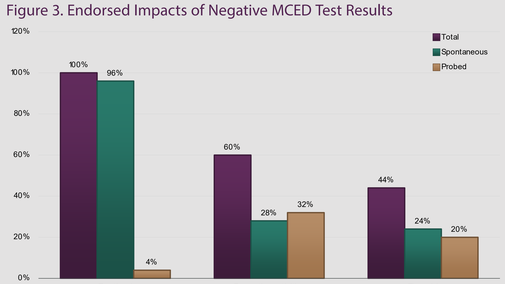
Table 1. Participant Characteristics

Characteristic	N=25
Age (years), Mean (SD) [Range]	49.4 (8.9) [40–72]
Sex at birth, n (%) (female)	16 (64%)
Hispanic or Latino ethnic background, n (%)	2 (8%)
Racial background[a], n (%)	
White	18 (72%)
Black or African American	7 (28%)
Highest education, n (%)	
High school	3 (12%)
Some college/university	6 (24%)
College/university (BA, BS)	10 (40%)
Masters	4 (16%)
Post-graduate degree (MD, PhD, PharmD)	2 (8%)
BMI[b], Mean (SD) [Range]	28.7 (6.8) [18.9–41.9]
Ever smoked, n (%) (Yes)	3 (12%)
Currently smoke, n (%) (Yes)	0 (0%)
Currently being evaluated or undergoing tests or procedures to confirm a cancer diagnosis, n (%) (Yes)	3 (12%)
Family history of cancer (parent, grandparent, spouse/partner, sibling, child), n (%)	19 (76%)

SD = standard deviation; BMI = body mass index
[a] Not mutually exclusive
[b] The standard calculation formula: [Weight in Kilograms / (Height in meters x Height in meters)] was used to calculate BMI. Three individuals were omitted from this calculation due to reporting a height and weight that yielded an infeasible BMI of <15 (n=2) or >70 (n=1).
[c] Per study targets, no more than five participants could be undergoing tests or procedures to confirm a cancer diagnosis at the time of enrolment.

- In general, all participants reported that an MCED test like the hypothetical one described to them in this study would be valuable (100%).
- All 25 participants perceived psychological/emotional benefits of a negative MCED test result (**Figure 3**).

Figure 3. Endorsed Impacts of Negative MCED Test Results



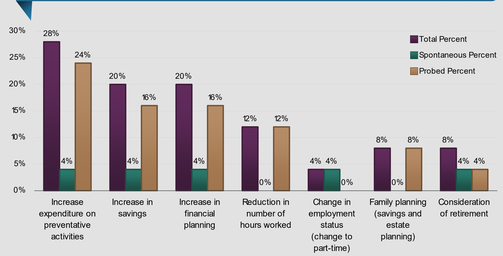
Note: Some endorsements of changes/impacts were reported spontaneously while others were probed by the interviewer. The percentages presented here are based on the total number of participants endorsing at least one impact within each theme spontaneous or probed.

- Some participants indicated that negative MCED test results would make them reconsider their financial planning (44%) (**Figure 3**), indicating that they would increase expenditures on preventive activities (28%), savings (20%), and financial planning activities in general (20%) (**Figure 4**).

Figure 4. Anticipated Financial Impacts of Negative MCED Test Results[a]

I think I probably would feel a little bit more conscientious of what I spent. I think I would put more money in my savings. I think I probably would maybe eat better because I'm going to live longer and I don't want to be unhealthy.

-Participant quote



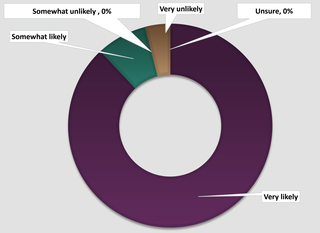
[a] Not mutually exclusive

- When asked about their willingness to take this test if offered by their doctor, the vast majority reported being very likely to take it (**Figure 5**)

Figure 5. Willingness to Take Hypothetical MCED Screening if Offered by Physician

I feel like early detection is key again. I can't stress that enough and if my doctor was to recommend that I take it, it probably would be for a specific reason. Yeah, I just feel like I would… would I want to know? I'd be scared but yeah, I think I would want to know. I would want to know early so maybe it could be cured or maybe I could get better help with early detection. Especially if it runs in my family again.

-Participant quote



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