10608

Impact of Negative Cancer Screening Results on Patient-Reported Outcomes and Behavioral Intentions

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INTRODUCTION

- Half of US adults are "very" or "somewhat" worried about developing cancer[1]
- Multi-cancer early detection (MCED) tests have the potential to expand the number of cancers detected at earlier stages, which could lead to better clinical/disease outcomes
- However, the value of MCED tests may be affected by perceptions and behavioral intentions following receipt of test results
- Some potential impacts of a cancer screening test result have been identified in the literature:
  - Positive cancer screening results have been associated with temporary low to moderate levels of distress[2]
  - Negative cancer screening results have been associated with a positive impact on mental health[3]
  - Negative cancer screening results may also cause a false sense of reassurance, potentially leading to complacency and delays in future cancer screening[4]
- We sought to determine the likelihood of these patient-reported outcomes following receipt of an MCED test result

OBJECTIVE

- To evaluate the observed and hypothetical impacts of a "no cancer signal detected" (NCSD) MCED test result on patient-reported outcomes and cancer screening behaviors in two independent data sources
  - An online survey of the US general population who have not taken an MCED test
  - Patient-reported outcomes (PRO) collected in the PATHFINDER clinical study (NCT04241796)

KEY RESULTS: NCSD MCED TEST RESULT MAY PROVIDE ADDITIONAL VALUE TO ADULTS BEYOND ITS CLINICAL BENEFIT

- The general population group surveyed was smaller but more diverse than the group enrolled in the PATHFINDER study **(Table 1)**

Table 1. Demographics

	General Population Survey (N=1073)	PATHFINDER Study (N=6621)[5]
Age, mean years (SD)	58.2 (10.9)	63.4 (8.6)
Female sex at birth, n (%)	566 (52.8)	4204 (63.5)
Racial/Ethnic background, n (%)		
White, non-Hispanic	715 (66.6)	6071 (91.7)
Black, non-Hispanic	129 (12.0)	90 (1.4)
Hispanic	130 (12.1)	134 (2.0)
Other races[a]	99 (9.2)	195 (2.9)
Highest education level, n (%)		
High school[b] or less	145 (13.5)	560 (8.5)
Some college	310 (28.9)	1705 (25.8)
College graduate or higher	618 (57.6)	4276 (64.6)
Other/Missing	0 (0.0)	80 (1.2)
Smoking status, n (%)		
Current smoker	199 (18.5)	268 (4.0)
Previous smoker, but not currently	338 (31.5)	2229 (33.7)
Never smoker	536 (50.0)	4124 (62.3)
Prior cancer, n (%)	37 (3.5)	1622 (24.5)
Known genetic cancer predisposition, n (%)	88 (8.2)	425 (6.4)
Family history of cancer, n (%)	637 (59.4)	5666 (85.6)

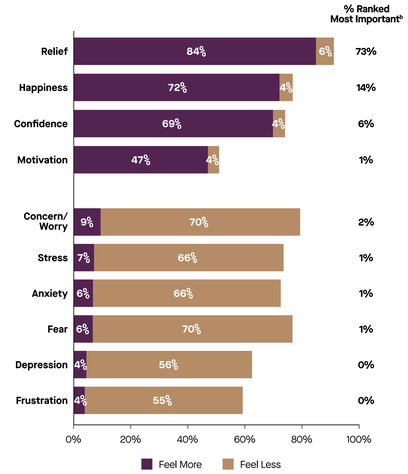
[a]For the survey, 'Other Races' includes participants who self-identified as Asian (n=61, 5.7%), Native Hawaiian/other Pacific Islander (n=2, 0.2%), American Indian/Alaska Native (n=10, 0.9%), multiple races (n=17, 1.6%), or preferring not to answer (n=20, 1.9%). For PATHFINDER, 'Other Races' includes participants who self-identified as Asian/Native Hawaiian/other Pacific Islander (n=129, 1.9%), American Indian/Alaska Native (n=10, 0.2%), other/unknown (n=56, 0.8%). [b]High school graduate/equivalent (eg, GED).

Survey Results

*A General Population Survey of 1037 Participants Demonstrated Increased **Relief, Happiness, and Confidence** after an NCSD MCED Test Result*

- Survey participants ranked relief as the most important emotional or psychological impact from an NCSD MCED test result
- After an NCSD result, the most common hypothetical impacts were:
  - Feeling more relief, happiness, confidence, and motivation **(Figure 1)**
  - Feeling less concern/worry, stress, anxiety, fear, depression, and frustration **(Figure 1)**

Figure 1. Hypothetical Emotional/Psychological Impacts After NCSD Result (n=807)[a]

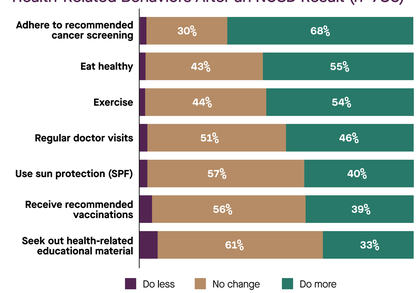


[a]The subset of 1073 participants who indicated that they would anticipate an emotional/psychological impact from receiving an NCSD result, ie, participants were asked about specific changes only if they anticipated an overall impact. [b]Rankings were asked only of participants who selected 2 or more emotional/psychological impacts.

Projected Impacts of NCSD MCED Test Result Include Positive Changes in Health-Related Behaviors

- The majority (73%) of survey participants reported that they would maintain or improve their health-related behaviors after an NCSD result
  - These health-related behaviors included adherence to recommended cancer screening (98%; 68% increase, 30% maintain current level) and regular doctor visits (97%; 46% increase, 51% maintain) **(Figure 2)**
- Of those who said they would engage in these activities more than they currently do, most were very-to-extremely certain of these increases

Figure 2. Hypothetical Changes in Attitudes Toward Health-Related Behaviors After an NCSD Result (n=783)[a]



[a]The subset of 1073 participants who indicated that they would make a change to their health-related behaviors due to receiving an NCSD result, ie, participants were asked about specific changes only if they anticipated an overall impact.

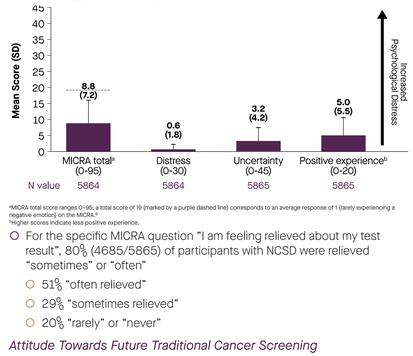
PATHFINDER Participant-Reported Outcomes

- PROMIS and SF-12v2 survey data were collected in the PATHFINDER study and showed small, temporary increases in general anxiety that returned to baseline by end of study (ie, 12 months post MCED test)
  - COVID-19 pandemic is a possible confounding factor for anxiety measures, as this trial enrolled between Dec 12, 2019, and Dec 4, 2020; for more information, please refer to additional publications[5]
- The results presented here focus on the perspectives/intentions of the PATHFINDER participants who received an NCSD test result

Adapted MICRA

- Adapted MICRA total mean score for participants with NCSD was below 19, indicating a very low level of distress[6] **(Figure 3)**
  - MICRA subscale scores were similarly low

Figure 3. Adapted MICRA Total and Subscale Scores After MCED Results Disclosed



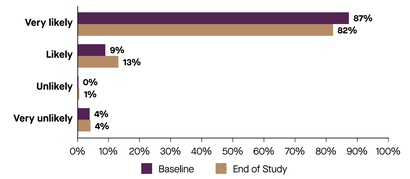
[a]MICRA total score ranges 0–95; a total score of 19 (marked by a purple dashed line) corresponds to an average response of 1 (rarely experiencing a negative emotion) on the MICRA.[6] [b]Higher scores indicate less positive experience.

- For the specific MICRA question "I am feeling relieved about my test result", 80% (4685/5865) of participants with NCSD were relieved "sometimes" or "often"
  - 51% "often relieved"
  - 29% "sometimes relieved"
  - 20% "rarely" or "never"

Attitude Towards Future Traditional Cancer Screening

- In the PATHFINDER study, participants with an NCSD MCED test result had a high likelihood of cancer screening adherence
- At end of study, 95.7% (5016/5242) of participants with NCSD who had both a baseline and end of study assessments indicated they were "likely" or "very likely" to adhere to cancer screening recommendations in the future **(Figure 4)**

Figure 4. How Likely Are You to Follow Your Healthcare Provider's Cancer Screening Recommendations? (n=5242 NCSD)

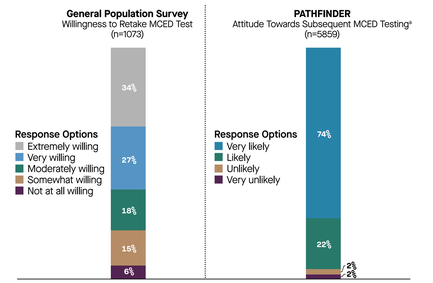


- Comparing participant responses at baseline to their responses at end of study, 3.6% (187/5242) of those with NCSD indicated at end of study that they were *less likely* to do recommended screening in the future
  - A similar number (3.2%; 166/5242) indicated they were *more likely* to undergo recommended screening

Satisfaction and Attitude Towards Future MCED Testing - Survey Results and PATHFINDER

- Of those in the PATHFINDER study with NCSD, 96.0% (5624/5859) indicated that they were "likely" or "very likely" to undergo subsequent MCED testing
  - This result was likely associated with participant-reported satisfaction with the MCED test
  - High overall satisfaction was reported by the 5861 responding PATHFINDER participants with NCSD (mean 83.4 [SD: 16.7])
  - When participants were asked "When taking all things into account, how satisfied or dissatisfied are you with the MCED test", a high proportion of participants with NCSD (97.2% [5698/5861]) were satisfied with the test
- A similar willingness to/likelihood of taking a future MCED test was reported by those taking the survey (hypothetical test) and PATHFINDER (Galleri) participants (**Figure 5**)

Figure 5. How willing/likely are you to have a subsequent MCED test?



[a]PATHFINDER participants were asked about their willingness to retake a hypothetical MCED test a year after receiving an NCSD result.

METHODS

General Population Survey

- A web-based, 30-minute survey of the US general population was used to ascertain attitudes toward a hypothetical MCED test
  - Eligible respondents were adults aged 40-80 years without a cancer diagnosis in the previous 5 years
  - The survey assessed the perceived value of negative results (ie, NCSD) and the projected impact on post-test behaviors
- For additional details, please refer to ISPOR 2024 poster:

PATHFINDER

- The prospective PATHFINDER study (NCT04241796) of adults aged ≥50 years who underwent MCED cancer screening included post-MCED test PRO assessments:[5]
  - PROMIS anxiety - General anxiety measure
  - SF-12v2 - Health status/quality of life
  - Adapted Multidimensional Impact of Cancer Risk Assessment (MICRA)
    - The MICRA is a previously validated instrument that assessed different levels of impact of genetic test result disclosure[6–8]
    - For PATHFINDER, the MICRA was adapted with permission to measure impacts of MCED result disclosure
    - The adapted MICRA had 21 items addressing three domains (distress, uncertainty, positive experience) and a total score
      - Score ranges are:
        - Total 0–95; a total score of 19 corresponds to an average response of 1 (rarely experiencing a negative emotion) on the MICRA[6]
        - Distress 0–30
        - Uncertainty 0–45
        - Positive experience 0–20
  - Satisfaction with MCED test
    - Overall satisfaction was assessed via a three-item questionnaire
      - Measured on a 0-100 scale, where higher scores represent greater satisfaction
    - The specific satisfaction question "Taking all things into account, how satisfied or dissatisfied are you with the MCED test?" was assessed on a 7-point Likert scale
      - Those who responded "extremely satisfied", "very satisfied", or "satisfied" were classified as "satisfied with the MCED test"
  - Attitude toward future testing, both MCED and traditional cancer screening
    - Intention to participate in future recommended cancer screening after results disclosure was assessed using two questions:
      - "How likely are you to follow your healthcare provider's cancer screening recommendations?"
      - "How likely are you to undergo a subsequent multi-cancer early detect test?"

CONCLUSIONS

- Results from a general population survey and a prospective clinical study indicated that an NCSD MCED test result may be associated with positive cancer screening intentions
- An NCSD result may also positively impact psychological health
- While these findings suggest that an NCSD does not result in harm by leading to complacency or reduced uptake with guideline-recommended screening, future research is needed to confirm and delineate the wider behavioral and social impact following MCED screening

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