

Employer-Based Implementation of Galleri® Multi-Cancer Early Detection Testing to Address Socioeconomic Disparities in Receipt of Screening

AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, September 29-October 2, 2023

William Cance, MD,¹ Wayne Lilyestrom, PhD,¹ Tim Johnson,¹ Robert Winn, MD,² Ahmedin Jemal, DVM, PhD³
¹GRAIL, LLC, Menlo Park, CA, ²Virginia Commonwealth University Massey Comprehensive Cancer Center, ³Surveillance & Health Equity Science Department of the American Cancer Society, Atlanta, GA

INTRODUCTION

- Social, environmental, and economic disparities contribute to disproportionate cancer burden in some groups¹⁻⁶
- Educational attainment can be used as a surrogate for socioeconomic status (SES), which is a major contributor to cancer health disparities^{1,7-9}
- Innovations in cancer screening may help reduce disparities and improve cancer outcomes¹⁰⁻¹²
- A multi-cancer early detection (MCED) test (Galleri®, GRAIL, LLC, Menlo Park, CA) is available as a complement to existing single-cancer screening tests and as a screening option for cancers that do not have USPSTF-recommended screening (Figure S1)^{13,14}
- This MCED test detects a shared cancer signal from abnormal methylation patterns of tumor cell-free DNA in blood using a targeted methylation assay and machine learning algorithm
- When a cancer signal is detected, a 'cancer signal detected' result (positive result) is reported with 1 or 2 predicted cancer signal origin(s) (CSO)
- The MCED test had consistently high specificity and similar sensitivity across racial and ethnic groups¹⁵
- Implementing an MCED test as an employee benefit offers an approach to detect cancers for which there is no screening method and a potential to address socioeconomic disparities in screening

OBJECTIVE

- To evaluate implementation of MCED testing as an employee benefit among individuals of low SES and identify potential barriers to adoption

KEY RESULTS: ON-SITE EMPLOYER-SPONSORED EVENTS WITH TRUSTED EMPLOYEE MESSENGERS FACILITATED UPTAKE OF AN MCED TEST IN POPULATIONS OF LOWER SOCIOECONOMIC STATUS

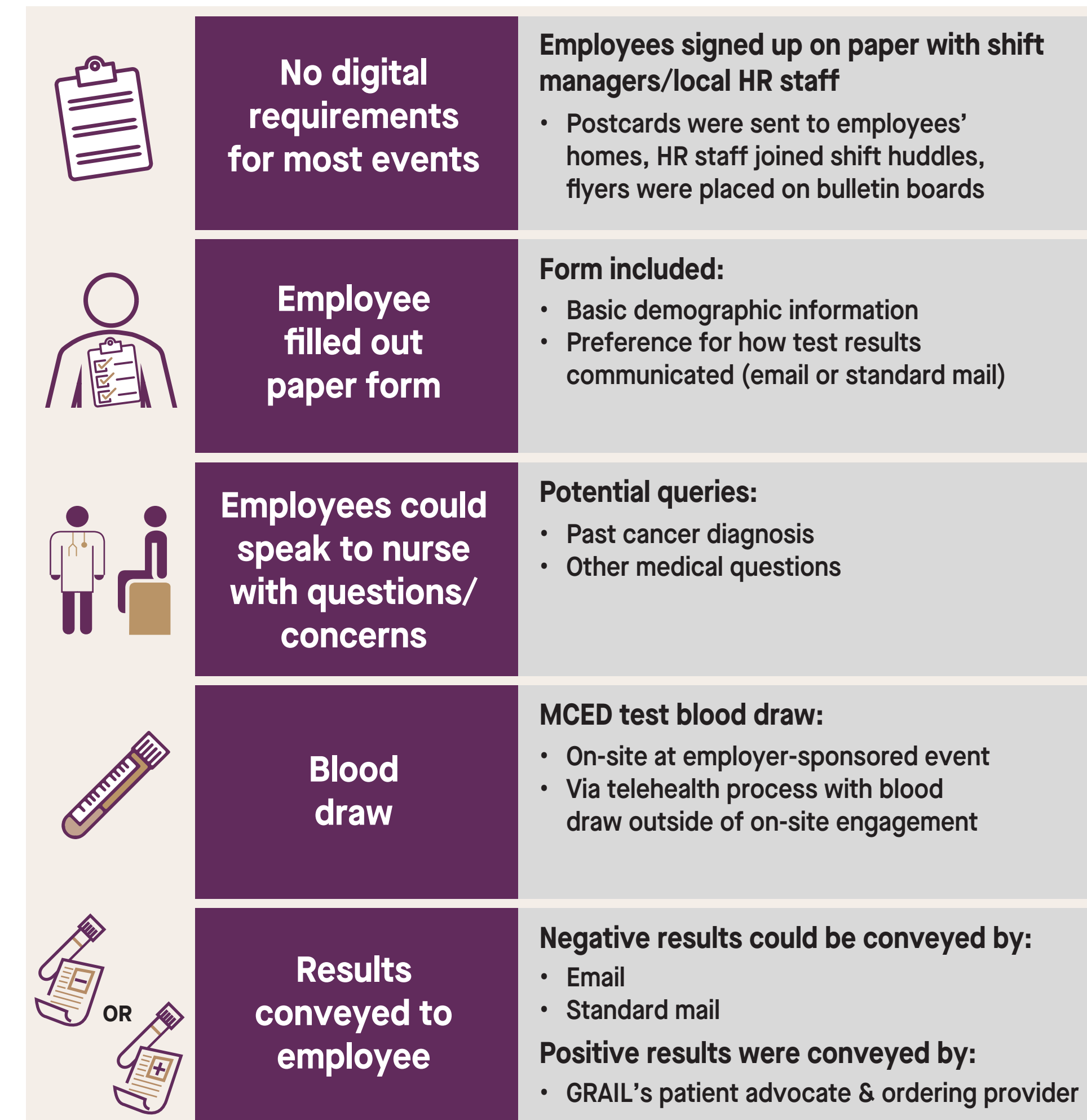
Implementation of MCED Testing

- The employee process for taking the MCED test is shown in Figure 1
- The vast majority of tests (83%) were administered at on-site events (Figure 2)
 - There were multiple on-site sessions at several of the employer sites, some very early in the morning or in the evening to accommodate shift work
- A mobile pod unit staffed by GRAIL was used for some of the on-site events (Figure 3)

Employees Who Were Administered the MCED Test

- A total of 812 industrial-based workers from three US companies were administered the MCED test
 - Workers were employed in manufacturing jobs that did not require a college degree
 - These employees were considered to have lower SES based on the approximation of educational attainment of ≤12 years, a metric established in prior publications^{1,7-9}
 - All employees had health insurance coverage as an employee benefit
- A majority of the 812 participating employees were male (Figure 4)
- Median age of participants was 54 years, and most were 50-64 years of age (Figure 4)

Figure 1. Employee Process for Taking the MCED Test



HR, human resources; MCED, multi-cancer early detection.

Figure 2. Most MCED Tests Were Administered to Employees at On-Site Events

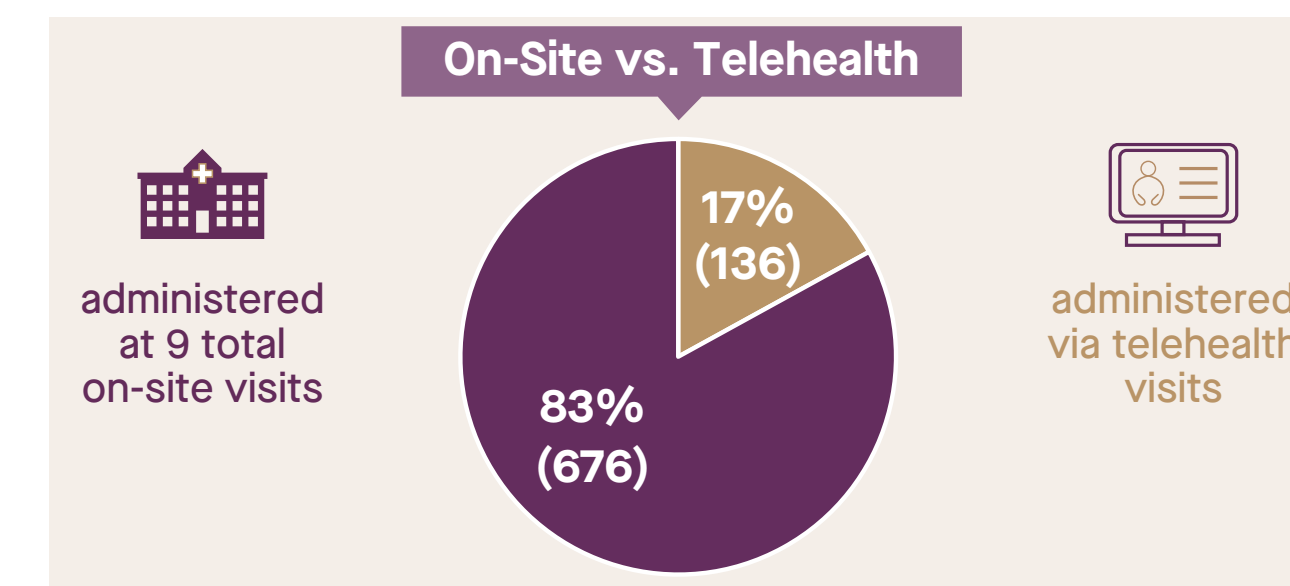
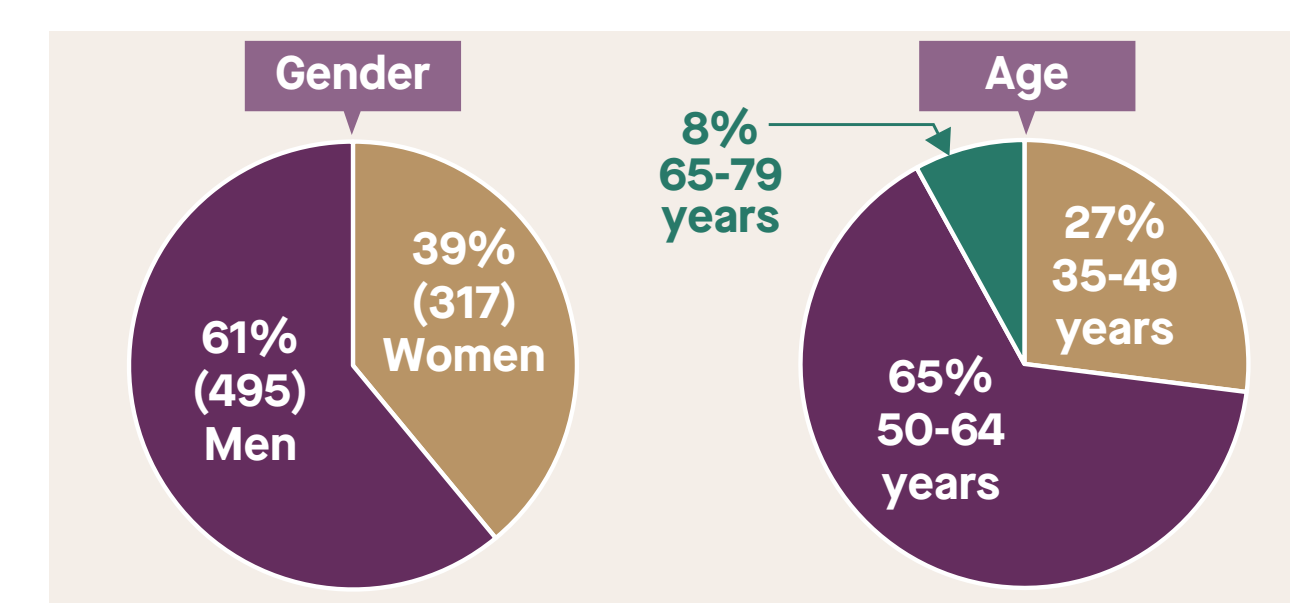


Figure 3. Mobile Pod Unit Used for Some On-Site Events



Figure 4. Employee Demographics (N=812)



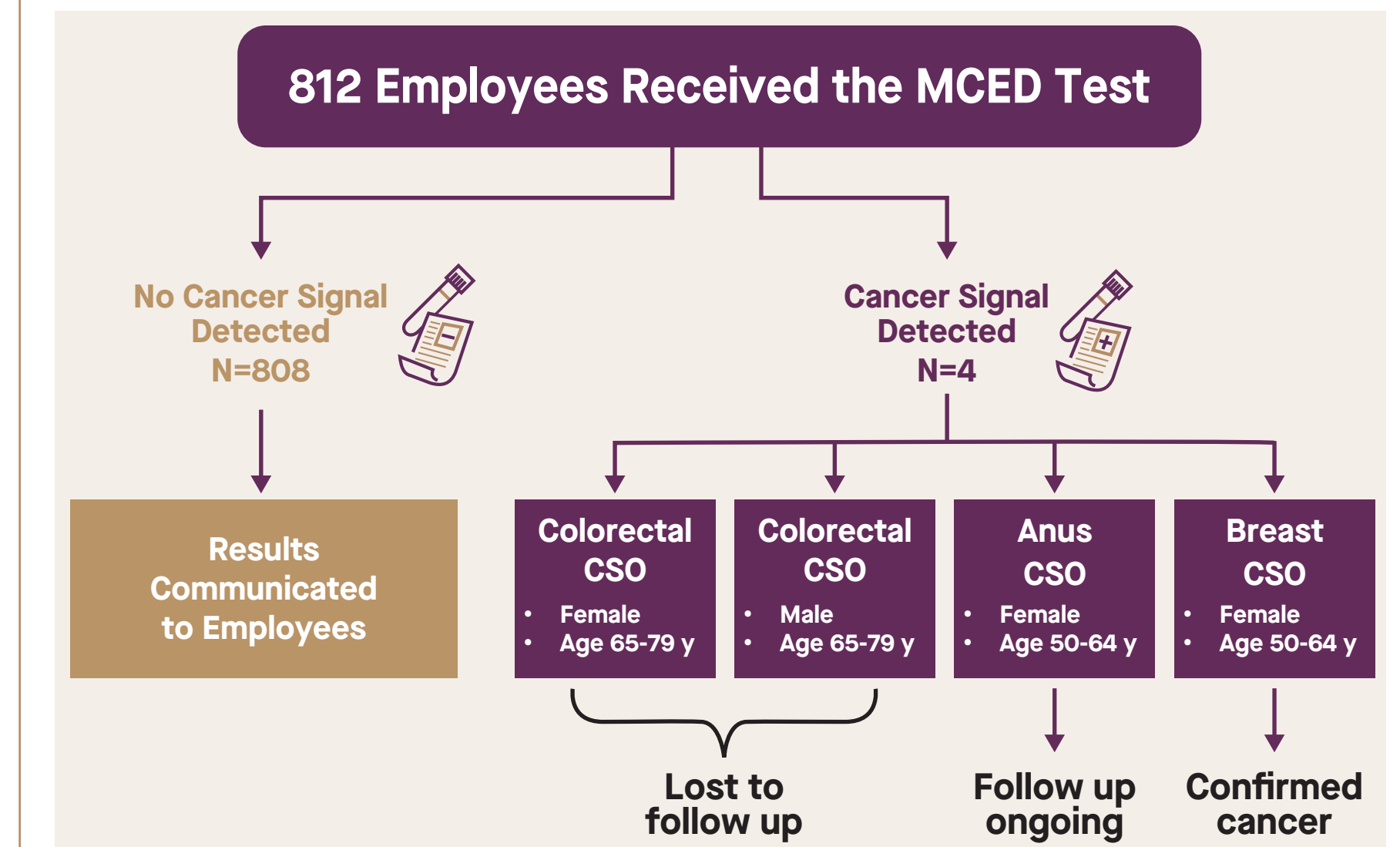
MCED Test Results

- A total of 808 tests returned a 'cancer signal not detected' result (Figure 5)
- A total of 4 tests returned a 'cancer signal detected' result with predicted top CSOs of colorectal (n=2), anus (n=1), and breast (n=1) (Figure 5)
 - The cancer signal detection rate was ~0.5%, which is in line with expectations based on the median age of participants
 - Of these employees, three were in the 50-64 age group, and one was in the 65-79 age group
 - Breast cancer case was confirmed in the employee who received a CSO of 'breast' as the employee had a diagnosis of breast cancer at the time of taking the test
 - The employee who received a CSO of 'anus' is undergoing follow up
 - The two employees who received a CSO of 'colorectal' failed to follow up, highlighting the need for a post-test navigation framework for those receiving a positive test
 - All employees had employer-sponsored health insurance coverage, and lack of insurance was unlikely to have been the cause of failure to follow up

Factors Important for MCED Test Uptake in the Employer Setting

- Factors that were important for participation in MCED testing were derived from employer insight into the employee population, employee feedback, and observations of GRAIL staff at on-site events (Figure 6)

Figure 5. MCED Test Results



CSO, cancer signal origin (top CSO is reported).

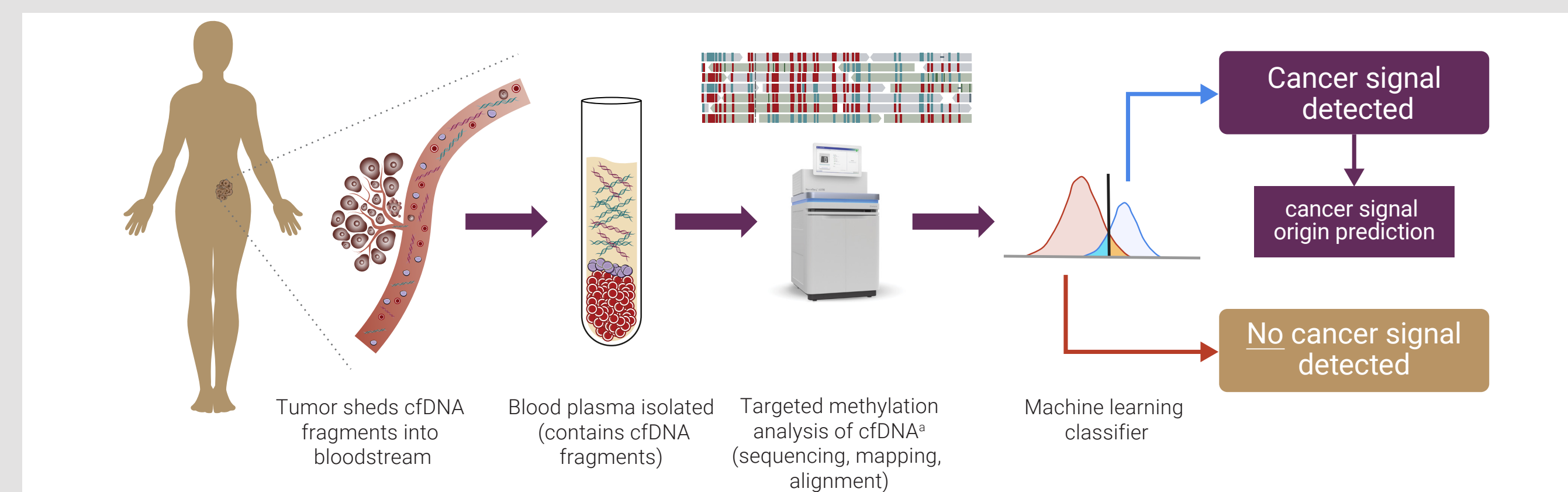
Figure 6. Factors Important for MCED Test Uptake From Employer Insights, Employee Feedback, and Staff Observations at On-Site Events



METHODS

How the MCED Test Works

Figure S1. Overview of Multi-Cancer Early Detection with Galleri MCED Test



cfDNA, cell-free DNA.
 *Bisulfite treatment; targeted probes pull out fragments matching regions of interest.
 The Galleri® test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider.
 Adapted from Liu MC et al. 2020.¹³ Galleri is a registered trademark of GRAIL, LLC.

Implementation of Galleri Test as an Employee Benefit

- From October 2021 to May 2023, Galleri MCED tests were administered in a population of industrial-based workers from three companies in the US
- Educational attainment (≤12 years vs >12 years) was approximated as a dichotomous measurement of socioeconomic status (SES) based on published work assessing cancer disparities^{1,7-9}
- The industrial locations with employees of lower SES were selected based on data provided by individual companies
- Of particular importance for site selection were:
 - Highly diverse employees
 - Low rates of preventive screenings
 - High healthcare costs
 - Low health literacy

Employee Population

- Employees spoke to an ordering provider/delegate (a nurse working on their behalf) if there was any concern about past cancer diagnosis or further medical questions

Enrollment and Testing Process

- Enrollment was accomplished through on-site events where consent and blood draws were available or via telehealth visits with subsequent blood draws off-site
- Employees filled out a paper form as part of the test request process
 - For most events there were no digital requirements, and employees signed up on paper with their shift managers/local human resources staff leading up to the events
 - For those who had no email available, postcards were sent to employees' homes in advance of events, human resources staff joined shift huddles, and fliers were placed on bulletin boards
- Employees spoke to an ordering provider/delegate (a nurse working on their behalf) if there was any concern about past cancer diagnosis or further medical questions

Conveyance of Test Results and Follow up

- For employees with a 'cancer signal not detected' test result, results were sent to employees via email unless they requested a mailed copy
- For employees with a 'cancer signal detected' test result, results and follow up were managed by GRAIL's patient advocate and the ordering provider

CONCLUSIONS

- MCED testing may be implemented more widely among individuals of lower SES when it is included as an employee benefit with in-person communication by trusted employee messengers, by providing forms/documents translated into first languages, and by limiting digital requirements
- Supporting the unique needs of individuals before administering an MCED test, and follow-up with those with a cancer signal detected result, are important steps for improving access and achieving diagnostic resolution
- Ongoing and future efforts will help optimize implementation strategies of MCED testing in people with socioeconomic disparities in receipt of screening

References

1. Singh GK, Jemal A. *J Environ Public Health*. 2017;2619372.
2. Cheng E et al. *JAMA Netw Open*. 2021;4:e2139593.
3. National Cancer Institute. *Cancer Disparities*. 2022.
4. O'Connor JM et al. *JAMA Netw Open*. 2018;1:e183146.
5. American Cancer Society. *Cancer Facts & Figures*. 2020.
6. Islami F et al. *CA Cancer J Clin*. 2022;72:112-43.
7. Albanro JD et al. *J Natl Cancer Inst*. 2007;99:1384-94.
8. American Cancer Society. *Making the Case for Health Equity*. 2020.
9. Ma J, Jemal A. *JNCI Cancer Spectrum* 2019;3:pkz087.
10. Alcaraz KI et al. *CA Cancer J Clin*. 2020;70:31-46.
11. Zavala VA et al. *Br J Cancer*. 2021;124:315-32.
12. Clarke CA et al. *Cancer Epidemiol Biomarkers Prev*. 2022;31:521-27.
13. Liu MC et al. *Ann Oncol*. 2020;31:745-59.
14. Klein EA et al. *Ann Oncol*. 2021;32:1167-77.
15. Tang WWH et al. *Prev Med*. 2023;167:107384.

Disclosures

Study funded by GRAIL, LLC. WC, LW, and TJ are current employees of GRAIL, LLC with equity in the company. The remaining authors are employed by their affiliated institutions and made no disclosures related to this study.

Acknowledgements

Funded by GRAIL, LLC. Writing, editorial, and graphic assistance provided by Prescott Medical Communications Group (Chicago, IL).

