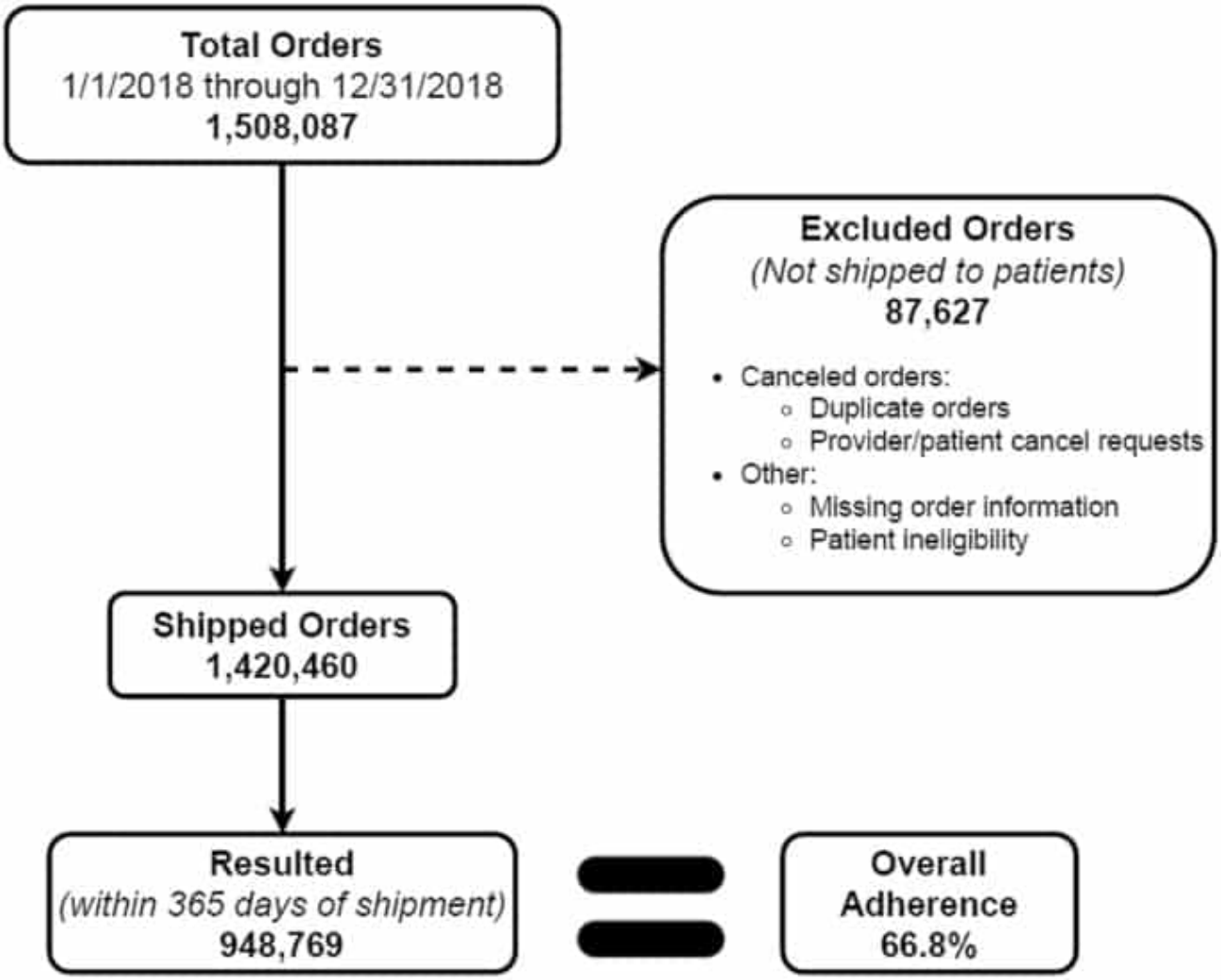
Aggregate laboratory data from Exact Sciences Laboratories LLC (ESL; Madison, WI), the sole-source national laboratory for mt-sDNA testing, were retrospectively reviewed as part of ongoing laboratory quality management processes and in compliance with the Health Insurance Portability and Accountability Act. Per Mayo Clinic Institutional Review Board (IRB) criteria, this study was deemed as exempt from review.

Study population, design, and data acquisition

Eligible study participants included individuals who met the following criteria: ages 50 years and older, covered by commercial insurance or Medicare, with a valid mt-sDNA test shipped to the order-specified address from ESL between January 1, 2018 and December 31, 2018. At the time of the study, the USPSTF recommendation was to start screening at 50 years old. Valid mt-sDNA test shipments were defined as having all information required for ESL to analyze the sample and report a positive or negative test result. Deidentified data referent to available patient (sex, age), provider (specialty, practice location), and test order features (testing status, time to completion) were sourced from the ESL internal data systems. Of note, patient race/ethnicity is listed as an optional field on the mt-sDNA order form and was additionally collected when available.

Information from ESL internal data systems regarding order characteristics was initially collected for 1,508,087 patients. Inclusion and exclusion criteria (including provider/patient cancellations, duplicate orders, missing information, and reasons for ineligibility) were utilized to comprise the final analysis cohort consisting of 1,420,460 patients. The cohort attrition flow chart outlines that cross-sectional adherence was defined as the percentage of eligible participants who successfully completed the test within 365 days of the shipment date (Fig. 1).

Fig. 1



Study cohort—attrition flowchart

Sociodemographic characteristics including income and education are not tracked in the ESL test order data system. Therefore, these data were ascertained at the residential zip code level from public data sources, including the United States Census and American Community Surveys database [21,22,23].

Statistical analysis

Descriptive statistics were used to describe the baseline characteristics of the study population overall and by insurance type. Counts and percentages were used to describe population-level statistics while distribution statistics (mean and median) were provided, where appropriate, to further describe the study populations' time to adherence, overall

adherence, and age. Descriptive statistics were principally stratified by patient insurance type. Distribution statistics relating to skewness and other appropriate tests (e.g., chi-square test) were used as needed to describe the study population.

Given that the study population comprises the entirety of mt-sDNA patients during this time ($N = 1{,}420{,}460$), point estimates and p-value testing do not provide necessary context or support better comparison. In essence, very small differences, even if significant, are likely to arise due to the population size though do not reflect meaningful differences among populations. In contrast to significance tests, effect size is independent of sample size, while statistical significance can be dependent upon both sample size and effect size [24, 25]. To avoid confounding the meaning of significance due to such a large sample size, we decided not to report two-sided 95% confidence intervals for point estimates or two-sided p-values for subgroup comparisons.

Results

Of 1,420,460 patients who met the study criteria (Fig. 1), 61.2% were female with a mean age of 64.9 years. Age distributions were 50–64 years (47.3%), 65–75 years (40.0%), and 76 + years (12.7%), with the majority of the cohort residing in urban areas (70.4%). Of those who specified a race/ethnic category, the majority of participants were white, although most participants (85.6%) did not provide this optional information (Table 1). Within the study population, 46.1% had commercial insurance coverage, 33.5% had Traditional Medicare coverage, and 20.4% were covered by Medicare Advantage (Table 2). Patients residing in zip codes with above average Bachelor's degree attainment rates (35.0% of all adults above 25 in the USA had a Bachelor's degree as of 2018) [22] accounted for 31.2% of all shipments. Patients in zip codes with a median income greater than the national median ($33,706 per the American Community Survey conducted in 2018) [23] accounted for 43.3% of mt-sDNA test orders. Geographically, the highest adherence in the study population was observed for those dwelling in highly rural locations: urban (66.0%), rural (68.5%), and highly rural (70.8%) (Table 3). Most mt-sDNA test orders were placed by primary care clinicians (72.2%), followed by nurse practitioners and physician assistants (19.3%), gastroenterologists (3.2%), and obstetrics and gynecologists (1.8%), with the remaining mt-sDNA test orders placed by other specialties (3.5%) (Table 4).

Table 1 Study population demographics by insurance coverage type

Table 2 Cross-sectional adherence by patient factors

Table 3 Cross-sectional adherence by zip code population factors

Table 4 Cross-sectional adherence by provider-level factors

The overall cross-sectional adherence rate for the entire study population was 66.8% (948,769/1,420,460 patients received and completed the mt-sDNA test and had a valid result) with a median time-to-adherence (TTA) of 22 days. The difference in adherence between males and females was small (67.2 vs. 66.5%, respectively). Cross-sectional adherence was highest in patients with Traditional Medicare coverage (72.1%) and lowest in patients with commercial insurance coverage (61.9%). Adherence increased with age: 50–64 years (60.8%), 65–75 years (71.3%), and 76 + years (74.7%) overall, and within each of the insurance types (Table 2). Relative to those with commercial insurance, increases in adherence by age were more pronounced among those with Traditional Medicare or Medicare Advantage plans, who demonstrated lower rates of adherence among those 50–64 compared to those with commercial insurance (Table 2). Moreover, adherence was 73.6% for Traditional Medicare patients ages 65–75.

Statistically, cross-sectional adherence with the mt-sDNA test was not shown to be associated with level of education or median income of the zip code wherein patients resided.

Adherence was 66.0% in zip codes with an above average Bachelor's degree attainment rate compared with 67.2% in zip codes with a below average Bachelor's degree attainment rate. Similarly, adherence was 68.2% compared to 65.7% in zip codes with median incomes above and below the national median, respectively (Table 3).

Adherence also varied among ordering provider specialty and practice location. Patients with mt-sDNA tests ordered by gastroenterologists exhibited a higher adherence rate (78.3%) than those with orders placed by primary care clinicians (67.2%), nurse practitioners and physician assistants (63.5%), obstetricians and gynecologists (63.1%), and other specialties (67.3%). Adherence rates were highest among patients with ordering providers in the Pacific region (71.4%) and West North Central region (70.1%). Contrastingly, the lowest adherence was observed in the Mid-Atlantic region (65.7%), New England (65.2%), West South-Central region (64.6%), and Puerto Rico/US Territories (60.7%) (Table 4).

Discussion

Results from this retrospective study of a large, insured population demonstrate relatively high cross-sectional adherence with the mt-sDNA test for CRC screening. Adherence rates were similar between males and females and increased with age. Of note, area-level education and median income of patients' residential zip codes were not significantly associated with differences in adherence rates. Consistent with previous observations in Medicare patients [19], adherence rates were also higher for orders placed by gastroenterologists compared to other provider specialties. Geographically, the greatest adherence was observed among those living in highly rural areas; however, that population was only 3% of the overall cohort. Although GIs ordered the fewest mt-sDNA tests, the rate of adherence to recommendations by disease specialists may relate in part to more detailed discussion during encounters regarding the importance of completing CRC screening; albeit, this speculative interpretation requires further evaluation.

With nearly 1.5 million participants included in the study population, our data contributes to the emerging literature regarding mt-sDNA test adherence in the clinical setting, although in a younger and larger cohort than seen previously [19]. Overall adherence approached 67%, with meaningful differences observed between age groups. The highest rate was seen in the 76 + years subgroup having Traditional Medicare coverage. Adherence also increased

with age, from 60.8% in those 50–64 to 74.7% in patients ≥ 76 + years, while Traditional Medicare patients ages 65–75 exhibited 73.6% adherence.

The mt-sDNA test is offered in conjunction with patient and provider navigation support (available 24 h per day, 365 days per year, with translation services in over 240 languages). Previous studies have shown that patient navigation has a beneficial effect on patient health behavior, demonstrating increased CRC screening rates [19, 26, 27]. The amalgamation of test and navigation services was shown to be successful in a separate study of Medicare beneficiaries where individuals who were previously non-adherent with CRC screening were offered the mt-sDNA test, resulting in 88% completion and 96% diagnostic colonoscopy exam follow-up for those with a positive mt-sDNA result [28]. This intricate feature adds inherent value to the mt-sDNA test at no additional cost to the payor, health system, patient, or provider, while also improving the probability of test completion compared with no intervention [19,20,21,22,23,24,25,26,27,28,29]. This information may be helpful to consider as a guiding input variation for CRC modeling studies to investigate comparative effectiveness between screening modalities.

There is general agreement concerning the effectiveness of colorectal cancer screening; however, in contrast to other organ sites, major guideline groups have endorsed more than one test option for average-risk CRC screening in order to maximize engagement. Informed health care provider discussions and screening decisions are better guided by implementation considerations that can help patients select the testing option they are most likely to complete, and this factor is essential for reducing the number of CRC-related deaths in the USA. Prior research has demonstrated low completion rates for other CRC screening tests [9, 10], and existing literature on repeat screening with other non-mt-sDNA stool-based screening tests suggests a need for improvement [9,10,11, 30]. A more sensitive test, such as mt-sDNA, is less susceptible to drops in adherences rates. Mt-sDNA has a higher single application sensitivity for all stages of CRC, which distinguishes it from single marker fecal occult blood tests (FIT/gFOBT) [31]. The 10,000-person mt-sDNA pivotal study by Imperiale et al. [31] reported 92% sensitivity for CRC (vs 74% for FIT). This performance difference held true in receiver operating characteristic (ROC) analysis, regardless of the cutoff chosen for FIT. Higher one-time test sensitivity is relevant given that FIT adherence

to recommended screening frequency can drop off substantially after the first cycle of annual testing [32].

As an integral part of the screening process, the follow-up colonoscopy to a positive non-colonoscopy CRC screening exam is becoming increasingly appreciated in the literature. Follow-up colonoscopy after a positive first-line test is necessary for complete and effective CRC screening [33, 34]. Failure to, and delay of follow-up after a positive stool-based test has been associated with increased risk of later stage CRC and CRC mortality [33, 35,36,37]. Doubeni et al. found that patients failing to follow-up on abnormal FIT results face a sevenfold higher risk of dying of CRC than those who complete the follow-up process [37].

Differences have also been revealed in CRC screening completion rates by modality [13, 14]. In a study by Rutten et al. [14] among residents of Olmsted County, MN, eligible and due for CRC screening, it was revealed that CRC screening incidence rates remained stable from 2016 to 2018, while test-specific rates for mt-sDNA significantly increased. Moreover, the study revealed that adherence with follow-up colonoscopy within 6 months after a positive stool-based test was significantly higher among patients who underwent mt-sDNA screening versus FIT/FOBT (84.9% vs 42.6%, respectively). At real-world (imperfect) adherence rates of 40% for annual FIT and 70% for triennial mt-sDNA derived from a critical assessment of meta-analyses and retrospective cross-sectional data [19, 38] (in systems using FIT without a navigation program) [39], modeling illustrates that the number of LYG and reductions in CRC incidence and mortality were higher for triennial mt-sDNA [40].

Several geographic variations in adherence aligned with the currently reported US percentage of adults being up-to-date with CRC screening tests by state [41], with the highest rates seen in the Pacific and West North Central regions in our study, although adherence was lower in the New England and Middle Atlantic regions where up-to-date screening hovers around ≥ 70% and ≥ 65%, respectively.

Additionally, practice specialty was associated with higher cross-sectional adherence. Although gastroenterologists ordered fewer tests, adherence was lower among primary care providers. The observed difference in adherence by specialty could be related to various

provider factors (strength of screening recommendation, patient perception of specialty-related knowledge), patient factors (attitude concerning referral/follow-up completion), or a combination. It is also likely that patients who present to a gastroenterologist bring with them specific concerns which may serve as motivation to screen. Although test adherence rates differed by practice, recent literature has shown widespread awareness of the 2018 ACS CRC guidelines among primary care providers [42]. A 2020 survey study by the Montana Cancer Control Program revealed that fecal DNA testing has become much more popular since 2016, with more than a third (35.2%) of primary care providers reporting discussing it with patients in 2020 compared to only 4% in 2016 [43]. The same report from the Montana Department of Public Health and Human Services highlighted that in 2020 the fecal DNA test was the 3rd highest ranked CRC screening test prescribed with 86% of ordering providers considering the test effective. Future CRC screening studies can be tailored to garner information on provider ordering characteristics to better inform screening strategy, assess prescription differences, and develop provider education initiatives.

We would like to acknowledge several limitations of our study. First, there was limited reporting of ethnicity in this study population, with less than 15% of patients specifying a racial category. The unavailability of such data prohibited us from examining an important demographic aspect associated with screening adherence; thus, the differences observed among race/ethnicity were not overly considered due to a large percentage of participants not providing the optional information. Patient and provider factors analyzed in our study were limited to those characteristics that could be captured from the existing laboratory database. A more detailed assessment of factors suspected to influence mt-sDNA screening adherence, such as socioeconomic status along with a closer look at social determinants of health, will benefit future investigations. Secondly, we relied on determination of the mt-sDNA ordering clinician to define CRC average-risk status. Although indicated for mt-sDNA, we assumed that each provider appropriately followed test eligibility indications before prescribing, and we did not have access to sufficient data to confirm risk status for all participants in this real-world study. Thus, a percentage of off-label use can be logically assumed. Lastly, given the relative recency of mt-sDNA availability and adoption in clinical practice, we did not assess longitudinal adherence for the current study. Mt-sDNA test adherence was only evaluated on a cross-sectional basis with a review of associated patient

and provider factors over a 1-year study period. Further evaluation of longitudinal adherence with triennial mt-sDNA screening is anticipated in future studies.

Conclusions

Novel data from this large retrospective cohort of both Medicare and commercially insured patients revealed favorable adherence to CRC screening with the mt-sDNA assay test among eligible patients who met the study criteria, having a valid mt-sDNA test shipped to their order-specified address from ESL between January 1, 2018, and December 31, 2018. Innovative features of the mt-sDNA test such as the accompanying patient navigation system, together with its noninvasive approach and feasibility, likely impacted test completion rates. The highest adherence rates were observed among those covered by Medicare and for tests ordered by gastroenterologists. Our findings contribute valuable real-world data to the existing evidence base and provide clinical decision-makers with supportive information to recommend a guideline-endorsed CRC screening strategy, with the goal of increasing adherence through test completion. Future investigations examining longitudinal completion rates in accordance with national guidelines, as well as more detailed analyses of associations with socioeconomic, race/ethnicity, and other demographic factors on mt-sDNA test completion rates, are anticipated to complement this study.

Availability of data and materials

Study data are available upon reasonable request.

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