Implementation of Blood-Based Colorectal Cancer (CRC) Screening: Real-World Clinical Experience

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Introduction

- Despite multiple colorectal cancer (CRC) screening options, screening adherence has plateaued well below the 80% goal set by leading health organizations
  - More than **one-third** of eligible individuals are not up to date with CRC screening
- Implementation of a blood-based CRC screening test can enhance effectiveness of population-based screening programs by achieving increased adherence, especially in those unscreened or not up to date.
- We report on real-world adherence rates of a blood-based CRC screening test.
  - A version of the test was recently validated in a large prospective CRC screening study (ECLIPSE, NCT04136002) and demonstrated 83% sensitivity for CRC and 90% specificity.

Methods

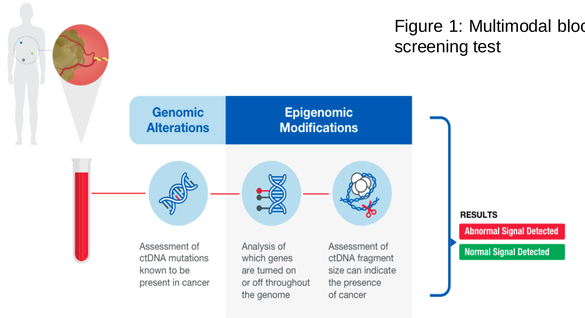


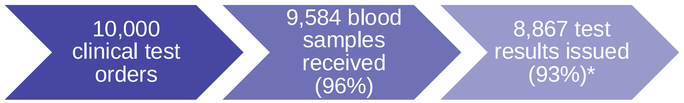
Figure 1: Multimodal blood-based CRC screening test

- The blood-based test, Shield, a qualitative Laboratory Developed Test (LDT) validated in a CLIA/CAP-accredited laboratory (Guardant Health, CA) for the detection of colorectal neoplasia associated biomarkers using a blood sample (Figure 1)
- Results are returned as “normal signal detected” or “abnormal signal detected” and not intended to be the sole basis for a CRC diagnosis.
  - Patients with an abnormal result should be referred for colonoscopy evaluation.
- Laboratory orders of the first 10,000 screening age-eligible patients were retrospectively reviewed to assess test completion rate, defined as both a clinical test order and blood sample received.
- A cross-sectional survey sent to ordering providers and staff (N = 1,524) collected data on ordering behaviors (e.g., pts unscreened, not up to date) and acceptance rate (defined by practice behavior to continue clinical use of the test).

Results

Table 1: Demographics of first 10,000 screening age eligible patients

		N	%
Biological Sex	Female	5,932	59%
	Male	4,033	40%
	Not Reported	35	0%
Age at test order (in years) Mean (min, max)		60 (45 - 99)	



* Reasons for results not reported include provider and/or patient factors (e.g., lack of insurance coverage, inaccurate sample labeling, subsequently deemed not at average risk) or laboratory related reasons (e.g., sample received was quantity not sufficient (QNS)).

Figure 2: Specialty of Survey Respondents

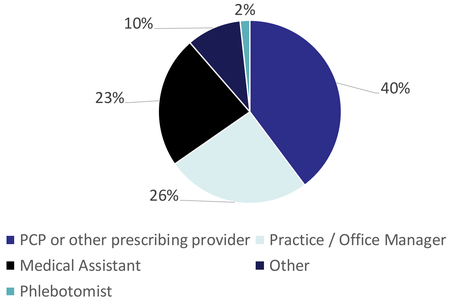


Figure 3: Screening status for typical patient

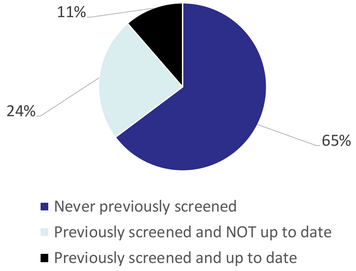
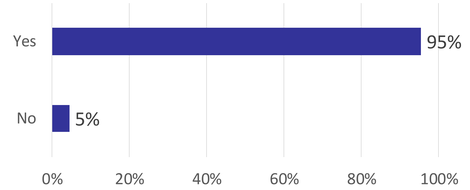


Figure 4: Do you plan to continue using Shield?



- The cross-sectional survey completed by ordering providers and staff (Figure 2) identified that 89% of respondents ordered the blood-based test for individuals never previously screened or not up to date with screening (Figure 2)
- A binary-response model investigating practice behavior yielded a 95% provider acceptance rate with the blood-based test (Figure 4).

Conclusions

- Implementation of this blood-based CRC screening test in 10,000 pts yields an adherence rate (96%) that exceeds rates with existing options (<67%).
- When surveyed, t