

Cost-effectiveness of ColoSTAT for primary colorectal cancer screening in the United States.

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Background: Colorectal cancer (CRC) screening is at the cornerstone of strategies for reducing the mortality, healthcare and societal cost burden of CRC, the third most common cancer in the United States (US). ColoSTAT immunoassay is a simple, highly accurate, minimally invasive blood-based screening test for CRC that will be launched in the US market. Using a *de novo* decision analytic model, we compared the health benefits and cost-effectiveness of CRC screening with ColoSTAT with current screening offered by private insurers assuming a 5-yearly colonoscopy (COL) or biennial fecal immunochemical test (FIT) for the US population. **Methods:** For the three screening strategies, the expected number of CRC cases detected, and total screening program cost were estimated using a decision-analytic model based on: published CRC incidence in the US, tests performance characteristics, adherence rates to screening (61% for COL; 46% for FIT) and to diagnostic assessment via COL after a positive FIT or ColoSTAT test (80.4%). The gain in quality-adjusted life year (QALY) associated with every CRC case detected through screening, and confirmed by diagnostic assessment, was estimated by linking US-specific estimates of: CRC deaths by age-subgroups, life expectancies at the time of CRC death, quality of life projections for the general population and reduction in CRC mortality associated with screening. Healthcare cost savings associated with every CRC case detected through screening were estimated based on the distribution of CRC across disease stages by diagnosis method (screening versus symptomatically) and stage-specific CRC treatment costs. **Results:** Biennial screening with ColoSTAT, compared with 5-yearly COL screening offered by private insurers, is estimated to generate cost savings on screening programs of around \$40 million per 100,000 people of screening age (PoSA) per one-off screening. When scaled up to the total US population within screening age covered by private insurance (66%), the estimated cost savings with ColoSTAT exceed \$30 billion per one-off screening. The reduction in the number of CRC cases detected would generate a modest loss of 58 discounted QALYs per 100,000 people, that could be mitigated if ColoSTAT were to boost screening uptake. In the context of government-sponsored screening programs, replacing FIT with ColoSTAT is estimated to increase the number of CRC cases detected via screening by 9% (to 50 cases per 100,000 PoSA), assuming an unchanged screening uptake of 46%. At the commonly used value of \$100,000 per QALY, this would equate to a discounted benefit of \$834,820 per 100,000 PoSA per one-off screening. **Conclusions:** CRC screening with ColoSTAT as an alternative to COL could result in multi-billion-dollar cost savings to US private insurers while still detecting most CRC cases and generate population-health gains if used as an alternative to FIT in government-sponsored screening programs. Research Sponsor: Rhythm Biosciences.