



CALL FOR STAKEHOLDER COMMENTS ON THE <u>PRELIMINARY</u> RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON FECAL IMMUNOHISTOCHEMICAL TEST (FIT) FOR COLORECTAL CANCER IN APPARENTLY HEALTHY ADULTS AGED 50 YEARS AND ABOVE

Published as of 26 February 2025

As of 26 February 2025, the Health Technology Assessment (HTA) Council hereby makes public its <u>preliminary recommendation</u> on the possible financing of **Fecal immunohistochemical test (FIT)** as an annual screening test for colorectal cancer for apparently healthy adults aged 50 years and above by the Department of Health (DOH) and/or PhilHealth, <u>for stakeholder feedback/comments</u>.

The population, intervention, comparator, and outcomes (PICO) set by the HTA Council for the said evaluation are shown in the table below, for your reference:

	Fecal immunohistochemical test as screening tool for colorectal cancer		
Population	Apparently healthy adults aged 50 years and above		
Intervention	Annual screening using qualitative FIT (with confirmatory colonoscopy after a positive result)		
Comparator	Annual screening using guaiac-based fecal occult blood test (gFOBT) (with confirmatory colonoscopy after a positive result)		
Outcome	 Clinical Outcomes: Performance characteristics, effectiveness Economic Outcomes: Incremental cost-effectiveness ratio (ICER), budget impact, household financial impact Ethical, legal, social, and health systems implications (ELSHI) 		

Based on the reviewed evidence, the HTA Council recommends qualitative FIT as an annual screening test for colorectal cancer for apparently healthy adults aged 50 years and above for financing of DOH and/or PhilHealth. This preliminary recommendation was based on the following considerations:

C1. Burden of the Disease

- Colorectal cancer (CRC) is a major global and national health burden due to its rising incidence and mortality (<u>Globocan 2022/GBD 2019 Colorectal Cancer Collaborators, 2022</u>). It predominantly affects individuals aged 50 and above (<u>WHO, 2023</u>).
- Based on international literature (Novotny et al. 2024), patients who were diagnosed through screening have a higher prevalence of early stage CRC (stages 0 and I) at the point of diagnosis while patients who were diagnosed by their symptoms have a higher prevalence of late stage CRC (stages II, III, and IV). Moreover, before global implementation of screening tests for CRC, most cases of colorectal cancer were diagnosed at stages II and III (<u>IARC</u>, 2019). In terms of mortality, patients diagnosed through screening had lower risk for all-cause mortality (17.8% vs 28.5%) and risk for CRC mortality (65.22% vs 73.6%) compared to patients diagnosed through their symptoms (<u>IARC</u>, 2019).
- In the Philippines, CRC ranks third among all cancers in terms of incidence accounting for 12.6% of new cancer cases. Specifically, it is the second most common cancer among Filipino men (13.7%) and also the second most common cancer among women (8.8%), with age-standardized incidence rates of 25.6 and 17.0 per 100,000, respectively (Globocan, 2022).
- In terms of mortality, neoplasms were the second leading cause of death in the Philippines in 2023 and 2024 (<u>Philippine Statistics Authority, 2025</u>), with colorectal cancer ranking fourth among cancer-related deaths (<u>Globocan, 2022</u>).

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C2. Clinical Accuracy and Effectiveness

• <u>Performance Characteristics</u>

Evidence suggests FIT has higher sensitivity but similar specificity compared to gFOBT for detecting colorectal cancer in average-risk individuals. FIT's performance varies by brand and cut-off levels, but overall, it offers improved detection while maintaining comparable specificity.

• <u>Clinical effectiveness</u>

Both FIT and gFOBT are more effective than no screening in reducing colorectal cancer mortality and incidence. However, FIT significantly reduces the risk of colorectal cancer-specific mortality and the risk of developing colorectal cancer more than gFOBT. These findings suggest that FIT may be the superior screening method for reducing the burden of colorectal cancer.

- <u>Guideline recommendations</u>
 - Only one (Malaysian Health Technology Assessment Section) out of 10 scoped HTA agencies recommended fully automated quantitative FIT as a preferred screening strategy due to its efficiency. Of the 15 ministries of health (MoHs) and government agencies reviewed, nine recommended FIT only (South Korea, UK, Australia, Malaysia, China/China CDC, European Countries/European CDC, New Zealand, Thailand, and Japan), four recommended both FIT and gFOBT (US, Philippines, Canada, Singapore), one (Vietnam) recommended FOBT (type not specified), and one (Indonesia) had no recommendation.

C3. Cost-Effectiveness

- Annual FIT screening with confirmatory colonoscopy after a positive result is cost-saving (ICER: ₱-321,297.17/ QALY gained). compared to no screening. FIT screening has a lower cost compared to no screening by ₱2,483,627.16, but has higher effectiveness by 7.73 QALYs gained.
- Annual FIT screening has higher costs but higher QALYs compared to annual gFOBT screening (incremental cost: ₱15,982.93; incremental effectiveness: 2.00 QALYs). Therefore, shifting to annual FIT screening is estimated to be cost-effective (ICER: ₱7,991.47/ QALY gained) at all cost-effectiveness thresholds (CET), assuming CET at 0.5 GDP, 0.75 GDP, and 1.00 GDP.
- The one-way sensitivity analyses show that the ICERs of FIT vs no screening are most sensitive to the following parameters: (1) compliance to FIT, (2) transition probability from CRC stage IV to death, (3) treatment cost for CRC stage II, (4) treatment cost for CRC stage IV, and (5) sensitivity to FIT. Meanwhile, the ICERs of FIT vs gFOBT are most sensitive to (1) compliance to annual gFOBT and (2) compliance to FIT screening.

C4. Affordability and viability

Annual FIT with confirmatory colonoscopy after a positive result has a lower cost over a 5-year period at ₱44.65 billion, averaging ₱8.93 billion per year, compared to annual gFOBT with confirmatory colonoscopy after a positive result which has an estimated 5-year cost of ₱87 billion and an annual average cost of ₱17.40 billion.

C5. Household financial impact

The median hospitalization cost for colorectal cancer is ₱35,710.73 among adults aged 50 and above. PhilHealth covers a median cost of ₱14,200.00 for claims, leaving patients with a median out-of-pocket cost for hospitalization of ₱19,905.50. On average, PhilHealth covers 49.05% of hospitalization expenses for colorectal cancer among adults 50 years and above. However, there are outlier claims with hospitalization costs and out-of-pocket costs reaching up to millions of pesos.

The household financial impact of colorectal cancer justifies the adoption of a screening program for the detection of colorectal cancer for reducing the risks of unfavourable outcomes of colorectal cancer.

C6. Ethical, legal, social, health systems impact (ELSHI)

There is a need for a national screening program for CRC in the country to improve access to early detection and prevention of CRC, which would have a substantial impact on screening behavior. Literature comparing annual FIT with colonoscopy indicates that FIT is the preferred screening method. Leveraging this preference and promoting awareness are key to maximizing uptake of the screening programs at the early stage of disease.

There were no major ethical, legal, social, or health system concerns identified regarding the use of FIT for colorectal cancer screening in the country, but successful implementation requires data privacy protocols, informed consent procedures, additional healthcare personnel, and enhanced health promotion efforts.

For the evidence reviewed by the HTA Council, please refer to: https://bit.ly/HTACPrelimRecomFITforCRC

All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **12 March 2025**, for the consideration of the HTA Council, through email at <u>hta@dost.gov.ph</u>. Please use the prescribed form for appeals indicated on the official HTA Philippines website <u>https://hta.dost.gov.ph/appeals-2/</u>. Appeals not following the prescribed format, and those submitted beyond the deadline shall not be entertained.

Should you have any questions or concerns regarding the preliminary recommendation, please do not hesitate to contact us through the aforementioned email address or via telephone at (02) 8651-7800 loc 2410.

Thank you very much and best regards.

On behalf of the HTA Philippines:

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