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A budget impact analysis of a home-based colorectal cancer screening programme in Malaysia

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3 **A budget impact analysis of a home-based colorectal cancer screening**
4 **programme in Malaysia**
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9 Tran Thu Ngan^{1*}, Kogila Ramanathan^{2,3}, Muhamad Raziq Bin Mohd Saleh³, Désirée
10 Schliemann¹, Nor Saleha Binti Ibrahim Tamin⁴, Tin Tin Su^{2,3}, Michael Donnelly¹, Ciaran
11 O'Neill¹
12
13
14

15
16 ¹ *Centre for Public Health, Queen's University Belfast, Belfast, UK*

17
18 ² *Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences, Monash*
19 *University Malaysia, Selangor, Malaysia*
20
21

22
23 ³ *South East Asia Community Observatory (SEACO), Jeffrey Cheah School of Medicine and*
24 *Health Sciences, Monash University Malaysia*
25
26

27
28 ⁴ *Ministry of Health Malaysia, Putrajaya, Malaysia*
29
30

31
32 * Correspondence to:

33
34 Tran Thu Ngan, PhD

35
36 Postal address: Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom

37
38 Email: n.t.tran@qub.ac.uk
39
40
41
42

43
44 ORCID of the authors

45
46 Tran Thu Ngan : 0000-0003-2771-9878

47
48 Désirée Schliemann : 0000-0002-8746-3002

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50 Ciaran O'Neill : 0000-0001-7668-3934
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1 A budget impact analysis of a home-based colorectal cancer screening 2 programme in Malaysia

3 4 **Abstract**

5 **Objectives:** The 2020-2022 research project ‘Colorectal Cancer Screening Intervention for
6 Malaysia’ (CRC-SIM) evaluated the implementation of a home-based CRC screening pilot in
7 Segamat District. This budget impact analysis (BIA) assessed the expected changes in health
8 expenditure of the Malaysian Ministry of Health budget in the scenario where the pilot
9 programme was implemented nationwide versus current opportunistic screening.

10 **Methods:** Assumptions and costs in the opportunistic and novel CRC screening scenarios were
11 derived from a previous evaluation of opportunistic CRC screening in community health clinics
12 across Malaysia and the CRC-SIM research project, respectively. The BIA was conducted from
13 the viewpoint of the federal government and estimated the annual financial impact over a
14 period of five years.

15 **Results:** The total annual cost of the current practice of opportunistic screening was
16 RM1,584,321 of which 80% (RM1,274,690) was expended on the provision of opportunistic
17 CRC to adults who availed of the service. Regarding the implementation of national CRC
18 screening programme, the net budget impact in the 1st year was estimated to be RM107,631,959
19 and to reach RM148,485,812 in the 5th year based on an assumed increased uptake of 5%
20 annually. The costs were calculated to be sensitive to the probability of adults who were
21 contactable, eligible, and agreeable to participating in the programme.

22 **Conclusions:** The findings highlighted the net budget impact of implementing a population-
23 based national CRC screening programme in Malaysia. Together with the modelling
24 estimations, the results illustrate how a BIA may be used to improve informed decision-making
25 by health authorities about the affordability of programme implementation as well as aid
26 budgetary planning and decisions generally about implementation.

27
28 **Keywords:** Colorectal cancer screening, budget impact analysis, home-based testing, global
29 health, Malaysia

Strengths and limitations of this study

- A budget impact analysis (BIA) aids decision making by health service planners and commissioners about whether an intervention or programme is affordable within given budget constraints
- BIA and its pragmatic approach is an ideal method when a situation calls for an evaluation of 'affordability' which is of central importance in low and middle income countries (LMICs)
- A BIA is not intended to provide answers to questions about whether or not the screening programme is good value for money (which can be answered by cost-effectiveness analysis)

INTRODUCTION

Colorectal cancer (CRC) has the second highest incidence and mortality rate among all types of cancer in both sexes in Malaysia.¹ The age standardised incidence rate in 2012-2016 was 14.8 per 100,000 males and 11.1 per 100,000 females which appears to be stable compared to 2007-2011.² In contrast, the proportion of CRC patients who are diagnosed at a late stage (i.e., stage III or IV) is increasing. The proportion of males with late stage CRC increased from 65.9% during 2007-2011 to 72.4% during 2012-2016; and from 65.2% to 73.1% for females.² Late stage diagnosis negatively impacts survival rate; thus, it is unsurprising that the 5-year survival of CRC patients in Malaysia is much lower compared to high-income countries (e.g., less than 50% of Malaysians compared to 92% of the population in the United States).^{3 4} Improved survival can be achieved by early detection through screening and the removal of premalignant polyps.⁴ However, Malaysia currently does not have a population-based national CRC screening programme.

The Ministry of Health of Malaysia (MoHM) adopted the use of immunochemical faecal occult blood test (iFOBT) for opportunistic CRC screening at public health clinics since 2014.⁵ MoHM guidelines recommend screening for asymptomatic individuals aged 50-75 years old with average risk of CRC.⁶ The uptake of this opportunistic screening tends to be very low. For

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3 49 example, the annual average uptake during 2014-2018 was 0.5% while the 5-year cumulative
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5 50 uptake was 2.29 %.⁵ Home-based iFOBT has been implemented in many high-income
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7 51 countries (HICs) to improve the accessibility and uptake of CRC screening.⁷ In this context,
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9 52 the Southeast Asia Community Observatory (SEACO) at Monash University Malaysia and
10
11 53 Queen's University Belfast (Northern Ireland) collaborated to conduct the research project,
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13 54 'Colorectal Cancer Screening Intervention for Malaysia' (CRC-SIM) in 2020-2022. This
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15 55 project evaluated the implementation of a home-based CRC screening pilot in Segamat District.
16
17 56 The uptake of the novel screening programme was 22%. The significantly higher uptake
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19 57 indicates the potential population wide impact if this screening approach (i.e., using home-
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21 58 based iFOBT and self-reporting test results) was scaled up. However, in order to aid public
22
23 59 health decision making, there is a need to model a scaled-up version of the research-tested
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25 60 screening programme and, more specifically, gather insights about the total costs of programme
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27 61 implementation and how it might impact the MoHM budget. Therefore, this budget impact
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29 62 analysis (BIA) assessed the expected changes in the health expenditure of MoHM budget as a
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31 63 result of implementing a population-based national CRC screening programme versus current
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33 64 opportunistic screening (or 'usual care'). It assessed the affordability of the screening
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35 65 programme given potential budget constraints.
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43 66 **METHODS**

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46 67 The conduct of this BIA and presentation of this paper followed the guidelines developed by
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48 68 the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task
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50 69 Force.^{8 9} All costs are presented in local currency -the Malaysian Ringgit (RM)- and
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52 70 International Dollar (I\$). RM was converted to I\$ using purchasing power parity (PPP)
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54 71 conversion factors instead of market exchange rates.
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72 **Health service under assessment and its comparator**

73 The specific health service that was the focus of the BIA was a population-based screening
74 programme for colorectal cancer using a self-rapid response iFOBT. The comparator was
75 current or 'usual care' - opportunistic screening.

76

77 The BIA is predicated on the opportunistic screening programme being replaced by the new
78 population-based screening programme (i.e., the two programmes would not be run in
79 conjunction or in other words, the two scenarios in assessment are mutually exclusive). In each
80 scenario, the patient pathway from the point when patients were invited for screening to receipt
81 of a definitive diagnosis were identified and described. The screening procedure ends at the
82 point of a patient receiving their iFOBT result with encouragement to attend hospital for a
83 colonoscopy (if iFOBT is positive). It is important to note that the BIA included costs of
84 screening and diagnosis (e.g., colonoscopy, biopsy) but not treatment. The BIA also did not
85 address issues with respect to equity of access and uptake of services in either screening
86 scenarios.

87

88 The patient pathways for the 'usual care' practice and the novel CRC screening programme are
89 presented in Figure 1 and 2, respectively. In opportunistic screening practice, it is recommended
90 or expected that individuals who are aged 50-75 years will be screened for CRC symptoms
91 when they attend their local health clinic (for any health condition or problem). If they are
92 asymptomatic and have an average risk of having CRC (based on family history), they are
93 offered an iFOBT, followed by a colonoscopy if the iFOBT test was positive. If CRC is
94 detected following a colonoscopy, the result is conveyed to a patient along with an explanation
95 of the treatment plan or referral arrangement.

96 (Figure 1 is about here)

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3 97 Details of the home-based screening intervention in CRC-SIM were published elsewhere.¹⁰
4
5 98 Briefly, in the novel CRC screening programme, individuals aged 50-75 years were contacted,
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8 99 checked for eligibility, and invited to participate. A home-screening 'pack' was posted to
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10 100 eligible participants followed by two reminders. The test was performed at home by
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12 101 participants who took a photograph of the completed test and texted it to trained medical
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14 102 professionals who interpreted the photograph. Participants with positive iFOBT were referred
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17 103 for a colonoscopy at hospital.

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19 104 (Figure 2 is about here)

20
21 105 There were two main differences between these patient pathways. Firstly, individuals within
22
23 106 the target age group for screening were contacted directly and invited to participate in the novel
24
25 107 CRC screening programme while in the situation of 'usual care', CRC screening was offered
26
27 108 (if screening guideline recommendations were followed) only when members of the target
28
29 109 group visited their clinic for some other health condition or problem. Secondly, the iFOBT was
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31 110 performed by doctors at health clinics in the 'usual care' pathway while in the novel CRC
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33 111 screening programme, participants self-tested in their home. Home-based testing generated
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35 112 additional stages in the pathways in relation to sending a test, reminding participants, taking a
36
37 113 photo of a completed test, and sending it to programme officers and vice versa. The remaining
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39 114 stages of each pathway (e.g., being screened for eligibility, receiving a colonoscopy, and
40
41 115 receiving a treatment plan) were the same across the two scenarios.
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49 117 **Eligible population and input assumptions**

50
51 118 The target population for current opportunistic screening in Malaysia is individuals aged 50-
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53 119 75 years, regardless of sex. Due to the nature of home-based screening, the target population
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55 120 for the CRC screening programme was required to meet some additional inclusion criteria as
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3 121 presented in Figure 2. The number of individuals who presented and completed each stage was
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5 122 estimated using input assumptions.
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10 124 Data about the population of Malaysia by age was taken from government reports (i.e.,
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12 125 Department of Statistics, Malaysia) and from World Population Review. The total population
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14 126 was reported to be 32,676,786 in 2021, of which, 19% or 6,228,195 were aged 50-75 years
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16
17 127 old.^{11 12}
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21 129 **In the ‘usual care’ – opportunistic screening pathway or scenario**, all assumptions were
22
23 130 derived from a study by Tamin NSI (2020) which was a 5-year evaluation of opportunistic CRC
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25 131 screening (and the use of stool-based tests) in community health clinics across Malaysia.⁵ It was
26
27 132 assumed that 0.482% of the eligible population would avail of CRC screening when they
28
29 133 attended local health clinics for other conditions; and 9.21% of this proportion of tested patients
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31 134 would receive a positive result. Only 55.9% of patients in the study by Tamin availed of a
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33 135 colonoscopy after a positive iFOBT. CRC detection after colonoscopy investigation was 4.04%.
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39 137 **In the novel CRC screening programme**, all assumptions were derived from the CRC-SIM
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41 138 research project. It was assumed that 50.51% of the eligible population would be contactable
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43 139 and meet all inclusion criteria to participate in the home-based screening programme; 52.27%
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45 140 of people who were eligible would agree to participate; 41.63% would perform the iFOBT and
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47 141 send a photo of a completed test to the programme officers; 18.01% of people who would be
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49 142 tested would receive a positive result; 41.07% would avail of colonoscopy after a positive
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51 143 iFOBT result; and CRC detection after colonoscopy investigation would be 4.35%.
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3 145 Table 1 summarises details about the input assumptions that were used to estimate the number
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5 146 of individuals at each stage of the respective pathway: the opportunistic screening pathway and
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7 147 the CRC screening programme pathway.
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12 149 **Table 1: Input assumptions used to estimate the population at each stage of the patient**
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15 150 **pathways**

Stage in pathway	Opportunistic screening scenario (Current practice)		Population-based CRC programme screening scenario (Proposed practice)	
	Assumption*	No. of individuals	Assumption**	No. of individuals
Total population (all ages)	NA	32,676,786	NA	32,676,786
Target population (aged 50-75)	19.06%	6,228,195	19.06%	6,228,195
Eligible population (met all inclusion criteria)	100%	6,228,195	50.51%	3,146,020
Availed of/agreed to take CRC screening	0.482%	30,020	52.27%	1,644,561
Needed 1 st reminder to return the iFOBT result (among those agreed to participate)	NA	NA	78.71%	1,294,514
Needed 2 nd reminder to return the iFOBT result (among those received 1 st reminder)	NA	NA	88.10%	1,140,405
Returned iFOBT result (among those agreed to participate)	100%	30,020	41.63%	684,683
Received iFOBT positive result	9.21%	2,765	18.01%	123,287
Availed of colonoscopy after positive iFOBT	55.9%	1,546	41.07%	50,636
CRC detection after colonoscopy investigation	4.04%	62	4.35%	2,202

51 *CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test; NA: Not applicable; No: Number*

52 * *The assumptions were derived from a study of Tamin NSI (2020) which was a 5-year evaluation of using stool-based test for opportunistic CRC screening in primary health institutions across Malaysia ⁵.*

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55 ** *The assumptions were derived from the Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021.*

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3 152 **Cost input and data sources**
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5 153 In the opportunistic screening scenario, the total cost comprised the cost of:
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7 154 (i) performing screening (e.g., asking for symptoms, family history, and collecting the sample)
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9 155 (ii) processing stool specimens
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11 156 (iii) interpreting test results and
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13 157 (iv) conveying a definitive diagnosis to patients (include explaining treatment plan or referral
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15 158 arrangements)
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17 159
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19 160 In the CRC programme screening scenario, the total cost comprised the costs of:
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21 161 (i) contacting potential participants
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23 162 (ii) delivering iFOBT test kits (including cost of the test, postage, print materials, and sending
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25 163 video instruction)
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27 164 (iii) sending a reminder to participants (up to 2 times, by text message and phone call)
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29 165 (iv) interpreting and conveying results to participants and
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31 166 (v) following-up patients with positive iFOBT but did not take colonoscopy in order to
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33 167 encourage them to avail of the colonoscopy
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37 169 These costs were calculated by multiplying the time allocated for the completion of each task
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39 170 with the salary cost of the person who undertakes each task plus cost of consumables. Table 2
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41 171 shows the unit cost for each cost element, related assumptions, and data sources.
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174 **Table 2: Resources and unit costs**

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
<i>Current practice (opportunistic screening)</i>			
Performing screening (asking for symptoms, family history, referral) and taking sample	5.58	20 min x salary RM2947/month	1
Processing stool specimens	1.70	10 min x salary RM1797/month	2
Interpreting the test results	2.79	10 min x salary RM2947/month	1
Conveying a definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	30 min x salary RM2947/month	1
<i>Proposed practice (Population-based CRC screening programme)</i>			
Contact eligible individuals - agreed to participate	0.98	7.1 min x (salary RM1440/month + mobile package RM20/month)	3
Contact eligible individuals - rejected/excluded to participate	0.47	3.4 min x (same as above)	3
iFOBT rapid test kit	6.90		3
Print materials (instruction leaflet, explanatory statement)	1.10	90 cents for colour print + 20 cent for black & white print	3
Postage (stamps, etc.)	5.35		3
Sending video through WhatsApp	0.41	3 min x (salary RM1440/month + mobile package RM20/month)	3
Sending reminder text message	0.41	3 min x (same as above)	3
Reminder call	0.28	2 min x (same as above)	3
Interpreting the test kit result	1.70	10 min x salary RM1797/month	3
Sending text message to inform patient of negative result	0.45	2 min x (salary RM2350/month + mobile package RM20/month)	3
Calling patient to inform him/her of positive result	0.67	3 min x (same as above)	3
Preparing and sending referral letter to patient/clinic	1.12	5 min x (same as above)	3
Follow up effort	6.73	30 min x (same as above)	3
Developing communication materials, one-off cost	6,063	Communication materials do not change in 5 years	3

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
Training for data collectors*, one-off cost <i>* Data collectors are those employed by the programme to (i) contact potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants</i>	109,703	+ 1 day training (virtual using Zoom) + 1 trainer for maximum 25 trainees + 1 data collector* is needed for every target population of 400 + Cost=1-day-salary of trainer/trainees x number of trainer/trainees + No retraining in 5 years	3
Same in both scenarios/practices			
Colonoscopy (including polyps removal and/or biopsy if needed)	200		
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	RM8636.7/800 sets	3

iFOBT: Immunochemical faecal occult blood test; RM: Malaysian ringgit

Source:

1. Public Services Commission of Malaysia. Medical Officer Grade UD41. Accessed at <https://www.spa.gov.my/spa/laman-utama/gaji-syarat-lantikan-deskripsi-tugas/ijazah-sarjana-phd/pegawai-perubatan-gred-ud41>
2. Public Services Commission of Malaysia. Medical laboratory technologist Grade U29. Accessed at https://www.interactive.jpa.gov.my/ezskim/klasifikasi/perbikalanskim.asp?id_skim=3LU03
3. Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021

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176 In the current practice of opportunistic screening, doctors were consulted about the estimated
177 time to perform each stage in the pathway. The monthly salary of a general doctor and a medical
178 laboratory technologist was based on the rate published by the Public Services Commission of
179 Malaysia.^{13 14} These rates were RM2,947 (~I\$2,045) and RM1,797 (~I\$1,247), respectively.

180 In the novel CRC screening programme, the time to perform each stage in the pathway, salary
181 of personnel, and costs of material resources (e.g., rapid kit test, consumables, postage, printing
182 materials) were based on the time and expenditure observed in the CRC-SIM research project.
183 All costs were calculated per screen except the cost of training and the cost of developing
184 communication materials which were one-off costs based on the assumption that
185 communication materials would not change, and no re-training would be needed within 5 years.

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3 186 It was assumed (based on the experience of operating the screening programme during the
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5 187 CRC-SIM project) that one data collector (i.e., those employed by the programme to (i) contact
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7 188 potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants)
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10 189 would be needed for every 400 people in the target population. Training would last one day
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12 190 and would be delivered virtually; thus, the cost of training equalled (1-day-salary of trainer x
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14 191 number of trainer) + (1-day-salary of trainees x number of trainees/data collectors).
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19 193 **Perspective and time horizon**

21 194 The BIA was conducted from the viewpoint of the federal government which finances
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23 195 Malaysia's public health system.¹⁵ Only those costs and resource requirements relevant to the
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25 196 budget holder were included in the analysis. For example, the out-of-pocket expenditure
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27 197 incurred by patients were excluded.
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33 199 The analysis estimated the annual financial impact over a period of five years as recommended
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35 200 in the guidelines.⁹ ¹⁶ Costs were not discounted given that the BIA methodology reports the
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37 201 costs for each year in which they occur rather than a net present value.⁹
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41 203 **Budget impact analyses**

42 204 *Computing framework and base-case analysis*

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45 205 The BIA used a cost calculator programmed in Microsoft Excel, following the costing template¹
46
47 206 produced by the National Institute for Health and Care Excellence in the UK (NICE). The template
48
49 207 was modified to fit the programme under assessment. The cost calculator approach is
50
51 208 recommended by guidelines as it is easy for stakeholders to understand and replicate the results.⁹
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59 ¹ The template can be freely downloaded at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/budget-impact-template.xlsx>
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3 209 First, the number of individuals who completed each stage was estimated (Table 1). The
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5 210 resources that were used at each stage of the respective pathways (in opportunistic screening
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7 211 and the novel CRC screening programme) were listed along with their unit costs (i.e., cost of
8
9 212 each resource per person) (Table 2). Unit costs were multiplied by number of users to give the
10
11 213 total cost of resources for each scenario. The net budget impact was calculated as the difference
12
13 214 in cost between opportunistic screening and the CRC screening programme. Visual depiction
14
15 215 of the cost calculator is shown in Supplementary Material, Figure S1.
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217 *Uncertainty and scenario analyses*

24 218 The input assumptions (that were used to estimate the number of individuals at each stage of
25
26 219 the respective pathway) and the cost inputs were varied, and then the impact of these changes
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28 220 in relation to the results was analysed to investigate the sensitivity of the budget impact results
29
30 221 to variations in individual input. As recommended by Gray et al. (2011), the range of variation
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32 222 regarding parameters for which data sources about dispersion were unavailable were $\pm 20\%$ of
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34 223 the base case.¹⁷
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42 **Patient and public involvement**

43 226 It was not appropriate or possible to involve patients or the public in the design, or conduct, or
44
45 227 reporting, or dissemination plans of our research as this type of study is a secondary analysis
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47 228 of data from a payer perspective (Ministry of Health Malaysia).
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3 230 **RESULTS**
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6 231 **Base-case analysis**
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8 232 The total annual cost of the current practice of opportunistic screening is RM1,584,321
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10 233 (~I\$1,099,460), of which 80% (RM1,274,690 ~ I\$884,587) was for providing opportunistic
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12 234 CRC to adults who availed of the service. Costs of providing colonoscopy (including polyps
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14 235 removal and/or biopsy if needed) after receipt of a positive iFOBT and conveying definitive
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16 236 diagnosis to patients (along with explaining treatment plan or referral etc.) after the outcome
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18 237 of the colonoscopy were RM309,108 (~I\$214,509) and RM523 (~I\$363), respectively.
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24 239 The total annual cost over a 5-year period of the proposed practice (i.e., CRC screening
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26 240 programme) is shown in Table 3. It was assumed that the number of people who would agree
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28 241 to participate in the programme would increase by 5% each year (in consideration of health
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30 242 promotion activities as well as information flows including word of mouth between
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32 243 participants). Therefore, the financial impact would also increase accordingly.
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246 **Table 3: Annual cost of proposed practice (i.e., CRC screening programme)**

Currency: Malaysian ringgit (RM) and International Dollar (I\$)

Proposed practice	Year 1 RM (I\$)	Year 2 RM (I\$)	Year 3 RM (I\$)	Year 4 RM (I\$)	Year 5 RM (I\$)
Contacting adults who are eligible for CRC screening programme (i.e., aged 50-75) and screen for eligibility of participating	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)
Providing iFOBT test to adults who agreed to participate in CRC screening programme after being invited	93,654,886 (64,992,981)	102,612,907 (71,209,512)	111,570,928 (77,426,043)	120,528,949 (83,642,574)	129,486,970 (89,859,105)
Providing 1 st reminder to participants	536,929 (372,609)	588,286 (408,248)	639,643 (443,888)	690,999 (479,527)	742,356 (515,167)
Providing 2 nd reminder to participants	315,339 (218,833)	345,501 (239,765)	375,663 (260,696)	405,825 (281,627)	435,987 (302,559)
Interpreting returned iFOBT samples	1,165,129 (808,556)	1,276,572 (885,893)	1,388,016 (963,231)	1,499,460 (1,040,569)	1,610,903 (1,117,906)
Conveying result through message to participants with iFOBT negative result	251,990 (174,872)	276,093 (191,598)	300,196 (208,324)	324,298 (225,050)	348,401 (241,777)
Preparing and sending referral letter and calling participants with iFOBT POSITIVE result	221,356 (153,613)	242,529 (168,306)	263,701 (182,999)	284,874 (197,692)	306,046 (212,384)
Following up participants who DID NOT take colonoscopy after positive iFOBT	489,158 (339,457)	535,945 (371,926)	582,733 (404,394)	629,520 (436,863)	676,308 (469,332)
Providing colonoscopy (including polyps removal and/or biopsy if needed) to participants with positive iFOBT	10,127,147 (7,027,861)	11,095,801 (7,700,070)	12,064,455 (8,372,280)	13,033,109 (9,044,489)	14,001,764 (9,716,700)
Conveying definitive diagnosis to patients (along with explaining treatment plan or referral etc.) after the colonoscopy	18,432 (12,791)	20,195 (14,015)	21,958 (15,238)	23,721 (16,461)	25,484 (17,685)
Capital costs (Developing communication materials + Training for data collectors)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)
Total cost of proposed practice	109,216,279 (75,792,005)	119,429,743 (82,879,766)	129,643,206 (89,967,527)	139,856,670 (97,055,288)	150,070,133 (104,143,049)

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test

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3 248 Similar to opportunistic screening, the cost to provide iFOBT to the eligible population who availed
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5 249 of the service accounted for 86% of the total cost of the proposed CRC screening programme. The
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7 250 second most costly component was the provision of colonoscopy (including polyps removal and/or
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9 251 biopsy if needed) to patients with an iFOBT positive result, at 9% of the total cost. The remaining
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11 252 nine cost components such as contacting potential participants, reminding participants to send
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13 253 photograph of iFOBT result, conveying diagnosis to participants and the follow-up effort added
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15 254 only up to 5% of the total cost.
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21 256 The net budget impact in the 1st year of implementing CRC screening programme would be
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23 257 RM107,631,959 (~I\$74,692,546 which equalled the total cost of future practice minus the total
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25 258 cost of current practice). The impact increases each year as the number of people who agree to
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27 259 participate in the programme increase, reaching RM117,845,422 (~I\$81,780,307) in year 2,
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29 260 RM128,058,885 (~I\$88,868,067) in year 3, RM138,272,349 (~I\$ 95,955,829) in year 4, and
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31 261 RM148,485,812 (~I\$103,043,589) in year 5.
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38 263 The net budget impact of providing and delivering the CRC screening programme over the 5-year
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40 264 timeframe for each state in Malaysia (calculated according to the population size of each state) can
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42 265 be accessed in Supplementary Material, Table S1. These estimates aid service planning decisions
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44 266 if the novel pilot programme is implemented in one or more of these states before being scaled up
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46 267 into nationwide programme.
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51 269 **Uncertainty and scenario analyses**

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53 270 The tornado diagram in Figure 3 shows the change to net budget impact when assumptions and
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55 271 cost inputs were varied. It presents the results of multiple univariate sensitive analyses on key
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57 272 inputs that exert the most influence on the net budget impact. These inputs include the probability
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3 273 of (i) making successful contact with adults about the CRC screening programme, (ii) adults
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5 274 agreeing to participate, (iii) adults being eligible to participate in the programme, and (iv) the
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8 275 cost of consumables that are required to take a stool sample. The first three inputs influence the
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10 276 number of individuals who are present at each stage of the patient pathway.

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12 277 (Figure 3 is about here)

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14 278 The net budget impact would increase from RM107 million to RM130 million (~I\$74-90
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16 279 million) if there was a 20% increase in (i) the probability of adults who were contactable (from
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18 280 a contact list of people aged 50-75 years old) or (ii) the probability of adults agreeing to
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20 281 participate in the CRC screening programme or (iii) the probability of adults being eligible for
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22 282 the programme (i.e., aged 50-75 years old; having no symptoms of CRC, a smartphone, and
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24 283 WhatsApp; resident within programme area; and did not have colonoscopy this year). In other
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26 284 words, a 20% increase in each one of these factors would require an additional RM23 million
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28 285 (~I\$16 million) to be budgeted for the programme. Likewise, a 20% increase in the cost of the
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30 286 consumables that are required for taking stool samples would mean that the programme would
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32 287 cost RM15 million (~I\$10 million) more than the originally calculated total cost.
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41 289 **DISCUSSION**

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44 290 The result of this analysis provides information to guide public health service planners and
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46 291 commissioners in their decisions about an alternative CRC screening strategy i.e., a population-
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48 292 based CRC screening programme using home-based iFOBT compared to current opportunistic
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50 293 screening. It concluded that the net budget impact in the 1st year of implementing a CRC
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52 294 screening programme of this kind would be RM107,631,959 (~I\$74,692,546). The impact
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54 295 would increase by year due to increase in uptake and would reach RM148,485,812
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56 296 (~I\$103,043,589) in the 5th year of implementation. This analytical approach and the results of
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58 297 this analysis are presented as aids to better decision making by MoHs and stakeholders in
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3 298 lower-middle-income countries (LMICs) about health programme planning and in this
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5 299 particular illustrative case to the MoHM regarding the degree to which the proposed CRC
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7 300 screening programme is affordable.
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12 302 The total budget that was allocated to the MoHM in 2022 was RM32.4 billion (~I\$22.5
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14 303 million).¹⁸ Spending on prevention and public health services in 2009 was reported to be
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16 304 RM1.6 billion (~I\$1.1 million).¹⁵ More recent data and information about the size of the budget
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18 305 that is allocated to cancer screening is not available. As such, it is estimated that the net budget
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20 306 impact of implementing a CRC screening programme would account for between 7-10% of the
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22 307 total budget for prevention and public health services. This sum is a considerable amount of
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24 308 money relative to the budget allocation for prevention programmes/interventions, a budget that
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26 309 has to be spread across several health conditions or domains.
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33 311 The key factor in the implementation of a population-based screening programme/service or the
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35 312 factor that has biggest impact on the budget is the size of the population who use the service. The
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37 313 degree of accuracy regarding population size estimates is related closely to the cost estimates in
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39 314 the budget. It is important for service planners to keep this point in mind and to take into account
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41 315 an increase in uptake and the impact of such an increase. Therefore, in the case of the CRC
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43 316 programme presented here, we assumed a 5% increase annually in uptake and calculated the net
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45 317 budget impact. The net budget impact can be recalculated according to the actual change in uptake
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47 318 after the programme is implemented.
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53 320 Budget impact analysis is an economic assessment that is used to estimate the changes in
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55 321 expenditure of a specific budget holder if a new health technology/programme is implemented.⁹
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57 322 As such, BIA complements other health economic evaluation methods such as cost-
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3 323 effectiveness analysis (CEA) to provide a comprehensive economic assessment of a health care
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5 324 intervention to decision makers.⁹ A BIA aids decision making by health service planners and
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7 325 commissioners about whether an intervention or programme is affordable within given budget
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9 326 constraints while a CEA informs decisions about whether an intervention is good value for
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11 327 money.^{9 19} BIA and its pragmatic approach is an ideal method when a situation calls for an
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13 328 evaluation of ‘affordability’ which is of central importance in LMICs and, arguably, is the key
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15 329 concern of whoever is in charge of managing a health care budget.^{20 21}

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21 331 It could well be that savings in earlier treatment would counterbalance the additional budget
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23 332 impact. However, a BIA is not intended to provide answers to questions about whether or not,
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25 333 in this context, the screening programme is good value for money as it does not take into
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27 334 account the potential improvements in outcomes (e.g., increase quality-related life years) and
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29 335 savings from lower treatment costs for CRC diagnosed at earlier stages. The conduct of other
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31 336 types of economic evaluations such as a cost-effectiveness analysis would be required to
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33 337 provide a complete and comprehensive set of evidence for decision makers.
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40 339 Finally, the conduct of BIA in this paper has some limitations. First, assumptions and cost
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42 340 inputs for the CRC screening programme were based on the costs and rates that were observed
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44 341 in the CRC-SIM research project. The project was conducted in only one district (Segamat);
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46 342 and the distribution of three main ethnic groups (i.e., Malay, Chinese, Indian) in the project
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48 343 differed from the proportions that have been reported nation-wide (72%:24%:3% vs
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50 344 62%:21%:6%, respectively). Therefore, it is important to be mindful of the possibility that the
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52 345 assumptions and inputs (based on the project) may not be representative for, or read across to,
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54 346 the whole population of Malaysia. Likewise, it is important to bear in mind that our findings
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56 347 do not include the perspective of other payers and may not generalise to other settings. The
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348 results are related directly to the context of the Malaysian health system and the epidemiology
 349 of CRC in the country though they are illustrative of the positive contribution of the BIA
 350 methodology and approach.

351 **CONCLUSIONS**

352 This study employed a BIA methodology to analyse the costs of a novel CRC screening
 353 programme using home-based iFOBT and mHealth versus the current opportunistic screening.
 354 The findings estimated the net budget impact of implementing a population-based national
 355 CRC screening programme in Malaysia. The modelling estimations are important
 356 considerations for health authorities when they are required to decide the affordability of
 357 implementing a programme and to aid budgetary planning as well as decision making,
 358 generally, about implementation. Our study illustrates the use and value of the BIA approach
 359 in LMICs and resource-constrained settings.

360 **Abbreviations**

BIA	Budget impact analysis
CEA	Cost-effectiveness analysis
CRC	Colorectal cancer
CRC-SIM	Colorectal Cancer Screening Intervention for Malaysia
iFOBT	Immunochemical faecal occult blood test
I\$	International Dollar
ISPOR	The Professional Society for Health Economics and Outcomes Research
MoHM	Ministry of Health of Malaysia
NICE	National Institute for Health and Care Excellence
RM	Malaysian ringgit

SEACO Southeast Asia Community Observatory

UK The United Kingdom

361 **DECLARATIONS**

362 **Research ethics approval.** Not applicable (This study does not involve human participants).

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366 data collection, data analysis, data interpretation, or writing of the report.

367 **Competing interests.** The authors have no conflicts of interest to declare that are relevant to
368 the content of this article.

369 **Availability of data and material.** All data generated or analysed during this study are
370 included in this published article.

371 **Authors' contributions.** TTN: Methodology, Formal Analysis, Writing – Original draft, Writing –
372 Review & Editing. KG, MRS, and DS: Data Curation, Investigation, Writing – Review & Editing. ST:
373 Resources, Writing – Review & Editing. TTS, and MD: Conceptualization, Funding acquisition,
374 Writing – Review & Editing, Supervision. CON: Methodology, Formal Analysis, Writing – Review &
375 Editing, Supervision.

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3 432 **Figure Legends and Tables**
4

5 433 Table 1 Input assumptions used to estimate the population at each stage of the patient pathways
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7 434 Table 2 Resources and unit costs
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9 435 Table 3 Annual cost of proposed practice (i.e., CRC screening programme)
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11 436 Figure 1 Patient pathways in ‘usual care’ practice - opportunistic screening for CRC
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13 437 Figure 2 Patient pathway in population-based CRC screening programme
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15 438 Figure 3 Results of multiple univariate sensitive analyses showing key factors that exert most
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17 influence the net budget impact
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23 441 **Supplementary material**
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25 442 Figure S1 Visual depiction of the budget impact cost calculator
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28 443 Table S1 Net budget impact of CRC screening programme over 5-year timeframe, by state
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Figure 1: Patient pathway in 'usual care' practice - opportunistic screening for CRC

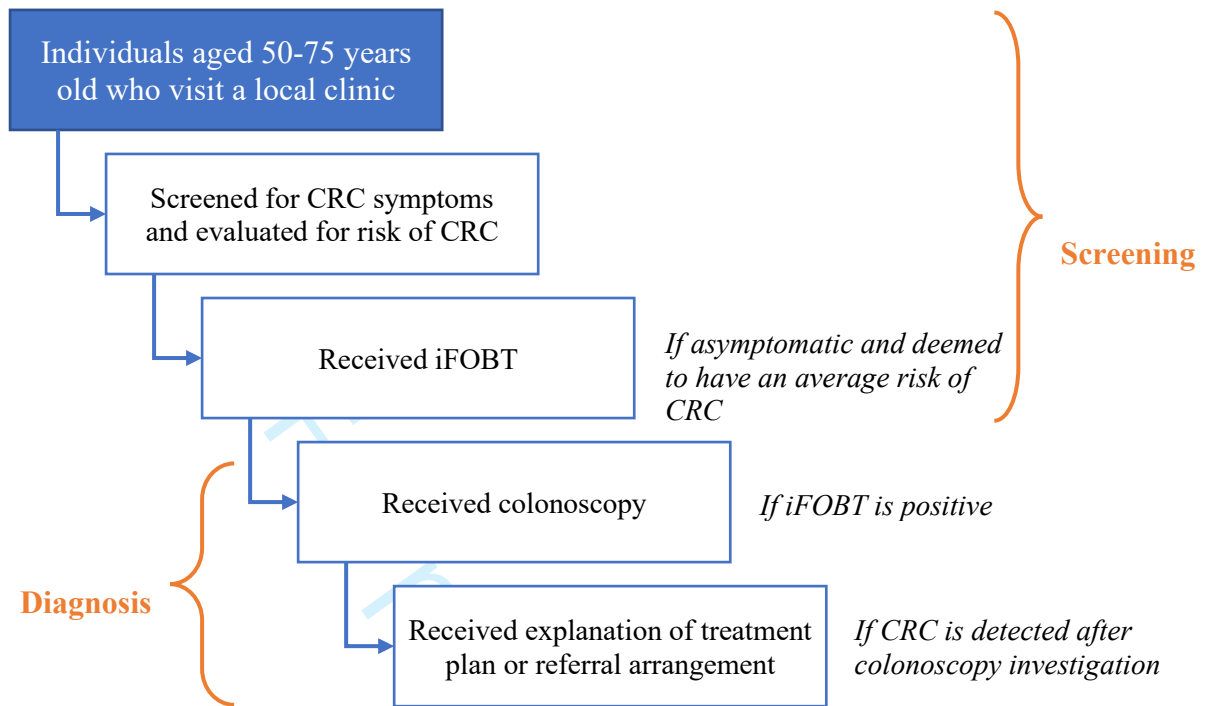


Figure 2: Patient pathway in population-based CRC screening programme

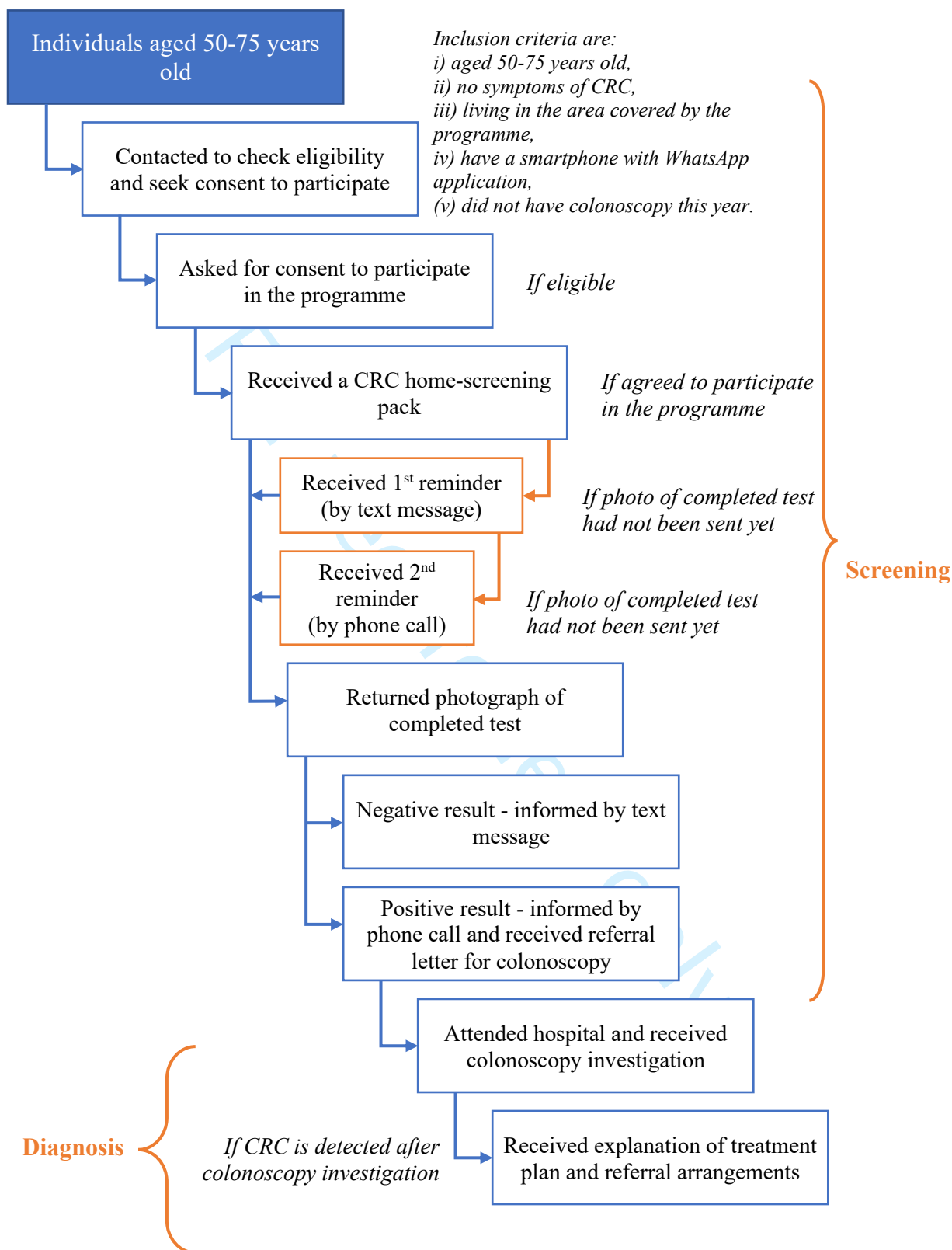
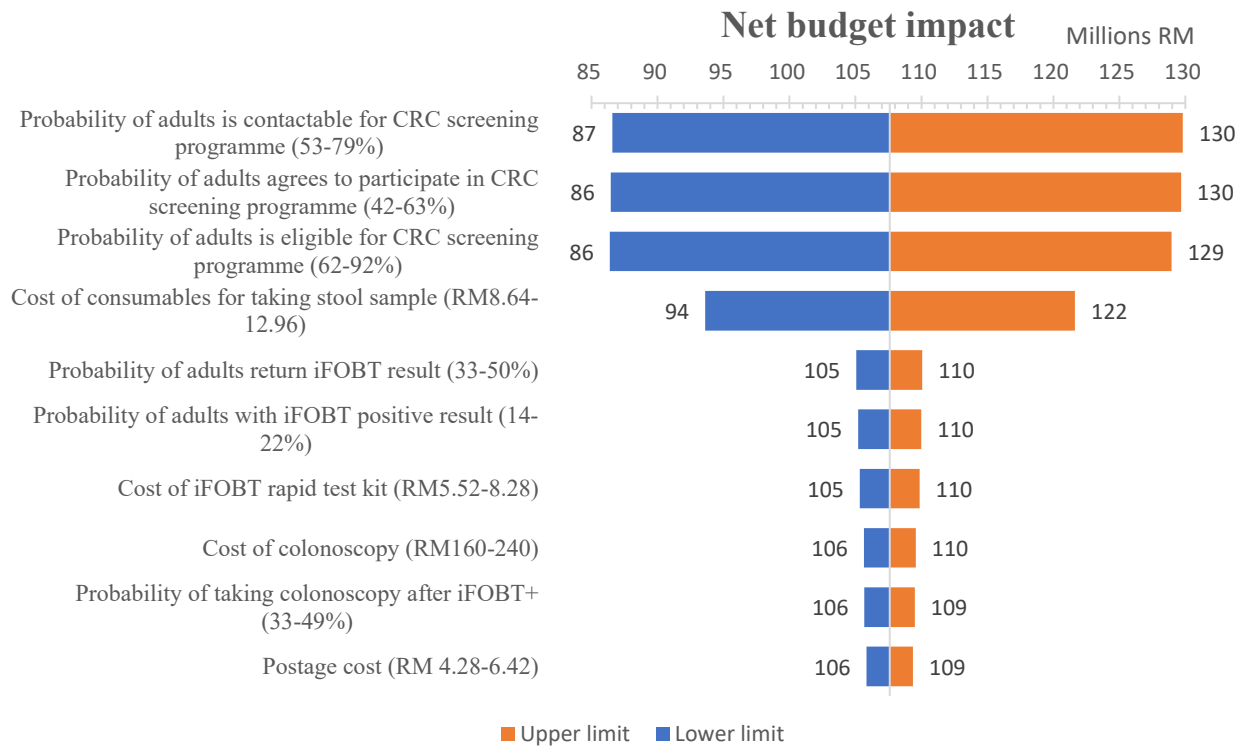
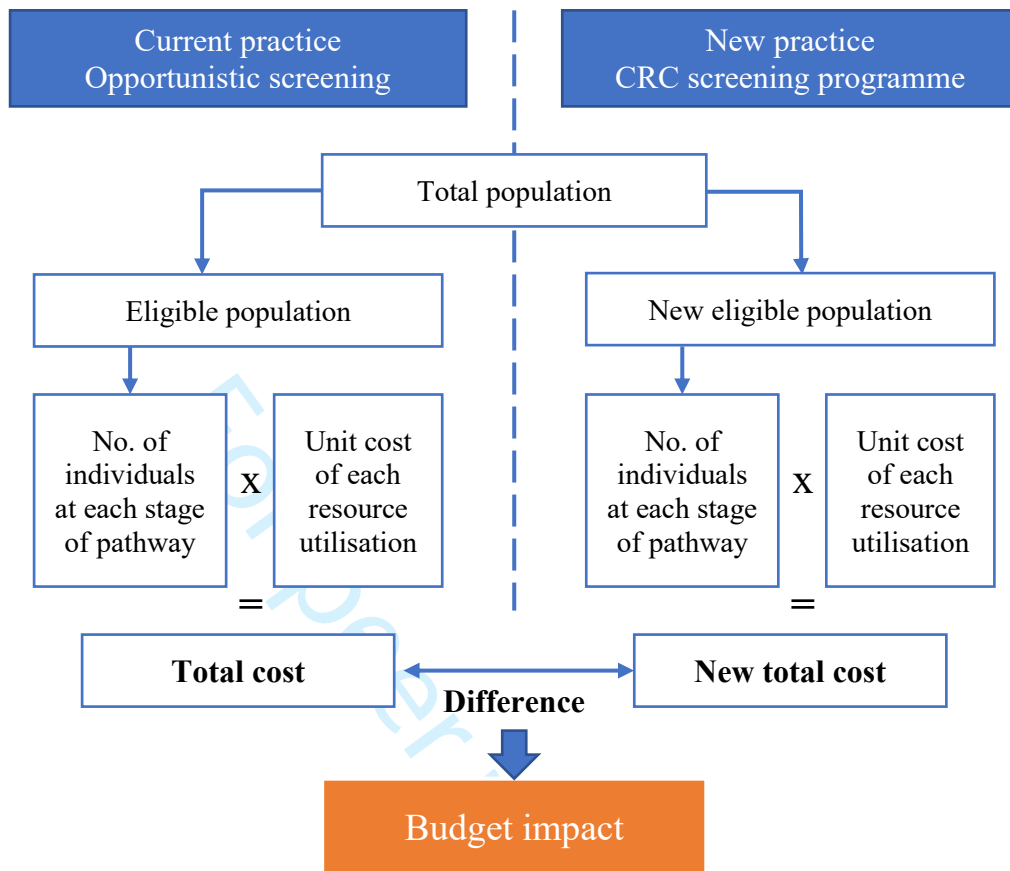


Figure 3: Results of multiple univariate sensitive analyses showing key factors that exert most influence the net budget impact



Supplementary material

Figure S1: Visual depiction of the budget impact cost calculator



Supplementary material

Table S1: Net budget impact of CRC screening programme over 5-year timeframe, by state

Currency: Malaysian ringgit

State	Population	Year 1	Year 2	Year 3	Year 4	Year 5
Johor	3,822,800	12,597,041	13,791,897	14,986,752	16,181,607	17,376,462
Kedah	2,206,200	7,272,541	7,962,112	8,651,682	9,341,252	10,030,823
Kelantan	1,884,300	6,212,311	6,801,268	7,390,225	7,979,183	8,568,140
Melaka	934,700	3,084,637	3,376,787	3,668,937	3,961,087	4,253,238
Negeri Sembilan	1,141,000	3,764,122	4,120,753	4,477,384	4,834,016	5,190,647
Pahang	1,702,900	5,614,833	6,147,092	6,679,351	7,211,609	7,743,868
Perak	2,569,300	8,468,450	9,271,511	10,074,572	10,877,633	11,680,693
Pulau Pinang	1,767,100	5,826,301	6,378,626	6,930,951	7,483,276	8,035,601
Sabah	3,919,600	12,915,864	14,140,975	15,366,086	16,591,197	17,816,308
Sarawak	2,829,400	9,325,144	10,209,501	11,093,859	11,978,217	12,862,575
Terengganu	1,245,300	4,107,648	4,496,879	4,886,111	5,275,342	5,664,573
Perlis	253,500	841,028	920,262	999,496	1,078,730	1,157,964
W.P. Kuala Lumpur	1,790,100	5,902,043	6,461,557	7,021,071	7,580,585	8,140,099
W.P. Labuan	99,000	332,138	363,081	394,024	424,968	455,911
W.P. Putrajaya	97,100	325,886	356,236	386,585	416,935	447,284
Nation-wide	32,676,786	107,631,959	117,845,422	128,058,885	138,272,349	148,485,812

CRC: Colorectal cancer | W.P.: The Federal Territories (Malay: Wilayah Persekutuan)

Readers can convert from Malaysian Ringgit to their currency of interest (e.g., International Dollar, US Dollar, British Pound, Euro etc.) using the free web-based tool ‘CCEMG – EPPI-Centre Cost Converter’ (<https://eppi.ioe.ac.uk/costconversion/default.aspx>). This tool help adjusting estimates of cost expressed in one currency and price year to a specific target currency and price year.

ISPOR—The Professional Society for Health Economics and Outcomes Research

Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force

Citation: Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, Orlewska E, Penna P, Rodriguez Barrios JM, Shau WY. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014 Jan-Feb;17(1):5-14. doi: <https://doi.org/10.1016/j.jval.2013.08.2291>

Recommendations for Reporting Format

Section/topic	Guidance for reporting	Reported in section
Introduction		
Objectives	The objective of the BIA should be clearly stated and tied to the study perspectives	Introduction
Epidemiology and management of health problem	Present information about the prevalence and incidence of the particular disease, disease severity, disease progression, undiagnosed or undertreated cases, and risk factors pertinent to estimating the budget impact	Introduction
Clinical impact	Consist of a brief description of the eligible population and existing management options and their efficacy and safety that are relevant to the design of the study of the BIA	Introduction
Economic impact	Include a brief description of previous BIAs in the condition of interest for another intervention and condition-specific treatment patterns and cost-of-care studies	Not applicable (No previous BIA)
Study Design and Methods		
Patient population	Specify the eligible population for the new intervention	Methods Sub-section: Eligible population and input assumptions Table 1
Intervention mix	Contain a detailed description of the use and characteristics of each intervention in the current intervention mix and in the expected intervention mix after the introduction of the new intervention	Methods Sub-section: Health service under assessment and its comparator Figure 1 and 2
Time horizon	Should be presented and the choice(s) justified	Methods Sub-section: Perspective and time horizon
Perspective	Identify the BIAs' perspective(s), the cost categories included, and the intended audience	Methods Perspective and time horizon

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Section/topic	Guidance for reporting	Reported in section
Analytic framework description	Complete description of the structure of the BIA cost calculator or condition-specific cohort or individual simulation model	Methods Sub-section: Eligible population and input assumptions
Input data	Input values used for the reported analyses, including alternative scenarios, should be presented	Methods Sub-section: Cost input and data sources Table 2
Data sources	The sources of data inputs should be described in detail	Methods Sub-section: Cost input and data sources Table 2
Data collection	The methods and processes for any primary data collection and data abstraction tasks not reported elsewhere should be described and explained.	Not applicable (secondary data)
Analyses	A description of the calculations used to complete the BIA should be provided. The choice of all the scenarios presented in the results should be documented and justified.	Methods Sub-section: Computing framework and base-case analysis under budget impact analyses
Uncertainty	Uncertainty analysis methods should be described and justified	Methods Sub-sections: Uncertainty and scenario analyses under budget impact analyses
Results	The budget impact should be presented for each budget period over the time horizon. Both budget period resource use and costs should be presented. The estimates of resource use should be listed in a table that shows the change in use for each time period reported in the BIA The results of the uncertainty analyses and scenarios analyzed should be described and presented in figures or tables	Results Table 3 Results Figure 2
Conclusions and Limitations	State the main conclusions on the basis of the results of the BIA. Report the main limitations regarding key issues such as design aspects including off-label use and adherence assumptions and the completeness and quality of data inputs and sources.	Discussion Conclusion
Inclusion of Graphics and Tables		
Figure of the analytical framework	Flow diagrams or other visual depictions of the cost calculator or condition-specific cohort or individual simulation model are recommended to be included with the analytical framework description.	Supplementary material Figure S1

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Section/topic	Guidance for reporting	Reported in section
Table of assumptions	All the major assumptions should be listed in a tabular form	Table 1
Tables of inputs	All the input parameter values and their data sources and derivations should be presented in a tabular form	Table 2
Tables of outputs	All outputs should be presented in a tabular and/or graphical Form	Table 3
Schematic representation of uncertainty analyses	Diagrams such as Tornado diagrams should be included along with the text on the results of the scenario analyses	Figure 3
Appendices and References	The appendices may cover literature search strategies, evidence summaries, intermediate results (e.g., of individual Delphi panel rounds), and the names and addresses of participating experts and investigators, for example.	Reference

BMJ Open

A budget impact analysis of a home-based colorectal cancer screening programme in Malaysia

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-066925.R1
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Complete List of Authors:	Ngan, Tran; Queen's University Belfast, Centre for Public Health Ramanathan, Kogila; Monash University Malaysia, Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences; Monash University Malaysia, South East Asia Community Observatory Saleh, Muhamad; Monash University Malaysia, South East Asia Community Observatory Schliemann, Desiree ; Queen's University Belfast, Centre for Public Health Ibrahim Tamin, Nor Saleha ; Ministry of Health Malaysia Su, Tin ; Monash University Malaysia, Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences; Monash University Malaysia, South East Asia Community Observatory Donnelly, Michael; Queen's University Belfast, Centre for Public Health O'Neill, Ciaran; Queen's University Belfast, Centre for Public Health
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3 **A budget impact analysis of a home-based colorectal cancer screening**
4 **programme in Malaysia**
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9 Tran Thu Ngan^{1*}, Kogila Ramanathan^{2,3}, Muhamad Raziq Bin Mohd Saleh³, Désirée
10 Schliemann¹, Nor Saleha Binti Ibrahim Tamin⁴, Tin Tin Su^{2,3}, Michael Donnelly¹, Ciaran
11 O'Neill¹
12
13

14
15
16 ¹ *Centre for Public Health, Queen's University Belfast, Belfast, UK*

17
18 ² *Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences, Monash*
19 *University Malaysia, Selangor, Malaysia*
20

21
22 ³ *South East Asia Community Observatory (SEACO), Jeffrey Cheah School of Medicine and*
23 *Health Sciences, Monash University Malaysia*
24

25
26 ⁴ *Ministry of Health Malaysia, Putrajaya, Malaysia*
27
28

29
30
31
32 * Correspondence to:

33
34 Tran Thu Ngan, PhD

35
36 Postal address: Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom

37
38 Email: n.t.tran@qub.ac.uk
39
40
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42

43
44 ORCID of the authors

45
46 Tran Thu Ngan : 0000-0003-2771-9878

47
48 Désirée Schliemann : 0000-0002-8746-3002

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50 Ciaran O'Neill : 0000-0001-7668-3934
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1 A budget impact analysis of a home-based colorectal cancer screening 2 programme in Malaysia

3 Abstract

4 **Objectives:** The 2020-2022 research project ‘Colorectal Cancer Screening Intervention for
5 Malaysia’ (CRC-SIM) evaluated the implementation of a home-based CRC screening pilot in
6 Segamat District. This budget impact analysis (BIA) assessed the expected changes in health
7 expenditure of the Malaysian Ministry of Health budget in the scenario where the pilot
8 programme was implemented nationwide versus current opportunistic screening.

9 **Design:** Budget impact analysis. Assumptions and costs in the opportunistic and novel CRC
10 screening scenarios were derived from a previous evaluation of opportunistic CRC screening in
11 community health clinics across Malaysia and the CRC-SIM research project, respectively.

12 **Setting:** National level (with supplement analysis for district level). The BIA was conducted
13 from the viewpoint of the federal government and estimated the annual financial impact over
14 a period of five years.

15 **Results:** The total annual cost of the current practice of opportunistic screening was
16 RM1,584,321 (~I\$1,099,460; RM=Ringgit Malaysia; I\$=International dollar) of which 80%
17 (RM1,274,690 or ~I\$884,587) was expended on the provision of opportunistic CRC to adults
18 who availed of the service. Regarding the implementation of national CRC screening
19 programme, the net budget impact in the 1st year was estimated to be RM107,631,959
20 (~I\$74,692,546) and to reach RM148,485,812 (~I\$103,043,589) in the 5th year based on an
21 assumed increased uptake of 5% annually. The costs were calculated to be sensitive to the
22 probability of adults who were contactable, eligible, and agreeable to participating in the
23 programme.

24 **Conclusions:** Results from the BIA aids decision making by health services planners and
25 commissioners in Malaysia about whether a population-based national CRC screening
26 programme is affordable within given budget constraint. The study also illustrates the use and
27 value of the BIA approach in LMICs and resource-constrained settings.

28
29 **Keywords:** Colorectal cancer screening, budget impact analysis, home-based testing, global
30 health, Malaysia

Strengths and limitations of this study

- The budget impact analysis (BIA) was used to evaluate the ‘affordability’ of colorectal cancer (CRC) screening programme in Malaysia within given budget constraint.
- Assumptions and cost inputs for modelling the budget impact were based on the actual costs and rates observed in Malaysia.
- The total cost of resources (=unit costs * number of users) for opportunistic screening and the CRC screening programme were compared to calculate the net budget impact.
- The BIA was conducted from the viewpoint of the federal government and only included costs and resource requirements relevant to this particular budget holder.
- The BIA could not and was not intended to provide answers to questions about whether or not the screening programme is good value for money (which can be answered by a cost-effectiveness analysis).

INTRODUCTION

Colorectal cancer (CRC) has the second highest incidence and mortality rate among all types of cancer in both sexes in Malaysia [1]. The age standardised incidence rate in 2012-2016 was 14.8 per 100,000 males and 11.1 per 100,000 females which appears to be stable compared to 2007-2011 [2]. In contrast, the proportion of CRC patients who are diagnosed at a late stage (i.e., stage III or IV) is increasing. Report from Ministry of Health Malaysia (MoHM) showed that the proportion of males with late stage CRC increased from 65.9% during 2007-2011 to 72.4% during 2012-2016; and from 65.2% to 73.1% for females [2]. The report did not give an explanation about this increasing trend though [2]. Late stage diagnosis negatively impacts survival rate; for example, the 5-year survival rates for cases diagnosed at stage I, II, III, and IV in 2002-2004 in Kuala Lumpur were 78.6%, 52.9%, 44.3%, and 9.3%, respectively [3]. Improved survival can be achieved by early detection through screening and the removal of premalignant polyps [4]. However, Malaysia currently does not have a population-based national CRC screening programme.

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3 47 The Ministry of Health of Malaysia (MoHM) adopted the use of immunochemical faecal occult
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5 48 blood test (iFOBT) for opportunistic CRC screening at public health clinics since 2014 [5].
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7 49 MoHM guidelines recommend screening for asymptomatic individuals aged 50-75 years old
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9 50 with average risk of CRC [6]. The uptake (number of patients screened/total eligible
10
11 51 population) of this opportunistic screening tends to be very low. The annual average uptake
12
13 52 during 2014-2018 was 0.5% while the 5-year cumulative uptake was 2.29% due to low
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15 53 awareness about CRC in general and CRC tests in particular, fear of the result, concern about
16
17 54 the cost, and absence of a doctor's recommendation [5, 7]. Home-based iFOBT has been
18
19 55 implemented in many high-income countries (HICs) to improve the accessibility and uptake of
20
21 56 CRC screening [8]. In this context, the Southeast Asia Community Observatory (SEACO) at
22
23 57 Monash University Malaysia and Queen's University Belfast (Northern Ireland) collaborated
24
25 58 to conduct the research project, 'Colorectal Cancer Screening Intervention for Malaysia'
26
27 59 (CRC-SIM) in 2020-2022. This project evaluated the implementation of a home-based CRC
28
29 60 screening pilot in Segamat District. The uptake of the novel screening programme was 22%.
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31 61 The significantly higher uptake indicates the potential population wide impact if this screening
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33 62 approach (i.e., using home-based iFOBT and self-reporting test results) was scaled up.
34
35 63 However, in order to aid public health decision making, there is a need to model a scaled-up
36
37 64 version of the research-tested screening programme and, more specifically, gather insights
38
39 65 about the total costs of programme implementation and how it might impact the MoHM budget.
40
41 66 Therefore, this budget impact analysis (BIA) assessed the expected changes in the health
42
43 67 expenditure of MoHM budget as a result of implementing a population-based national CRC
44
45 68 screening programme versus current opportunistic screening (or 'usual care'). It assessed the
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47 69 affordability of the screening programme given potential budget constraints.
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70 **METHODS**

71 The conduct of this BIA and presentation of this paper followed the guidelines developed by
72 the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force
73 [9, 10]. All costs are presented in local currency -the Malaysian Ringgit (RM)- and
74 International Dollar (I\$). RM was converted to I\$ using purchasing power parity (PPP)
75 conversion factors instead of market exchange rates. The PPP conversion rate of 1.441 was
76 obtained from the IMF World Economic Outlook Database [11].

78 **Health service under assessment and its comparator**

79 The specific health service that was the focus of the BIA was a population-based screening
80 programme for colorectal cancer using a self-rapid response iFOBT. The comparator was
81 current or 'usual care' - opportunistic screening.

82
83 The BIA is predicated on the opportunistic screening programme being replaced by the new
84 population-based screening programme (i.e., the two programmes would not be run in
85 conjunction or in other words, the two scenarios in assessment are mutually exclusive). In each
86 scenario, the patient pathway from the point when patients were invited for screening to receipt
87 of a definitive diagnosis were identified and described. The screening procedure ends at the
88 point of a patient receiving their iFOBT result with encouragement to attend hospital for a
89 colonoscopy (if iFOBT is positive). It is important to note that the BIA included costs of
90 screening and diagnosis (e.g., colonoscopy, biopsy) but not treatment. The BIA also did not
91 address issues with respect to equity of access and uptake of services in either screening
92 scenarios.

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3 94 The patient pathways for the 'usual care' practice and the novel CRC screening programme are
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5 95 presented in Figure 1 and 2, respectively. In opportunistic screening practice, it is recommended
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7
8 96 or expected that individuals who are aged 50-75 years will be screened for CRC symptoms
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10 97 when they attend their local health clinic (for any health condition or problem). If they are
11
12 98 asymptomatic and have an average risk of having CRC (based on family history), they are
13
14 99 offered an iFOBT, followed by a colonoscopy if the iFOBT test was positive. If CRC is
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16
17 100 detected following a colonoscopy, the result is conveyed to a patient along with an explanation
18
19 101 of the treatment plan or referral arrangement.

20
21
22 102 (Figure 1 is about here)

23
24 103 Details of the home-based screening intervention in CRC-SIM were published elsewhere [12].
25
26 104 Briefly, in the novel CRC screening programme, individuals aged 50-75 years were contacted,
27
28 105 checked for eligibility, and invited to participate. A home-screening 'pack' was posted to
29
30 106 eligible participants followed by two reminders. The test was performed at home by
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32
33 107 participants who took a photograph of the completed test and texted it to trained medical
34
35 108 professionals who interpreted the photograph. Participants with positive iFOBT were referred
36
37 109 for a colonoscopy at hospital.

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40 110 (Figure 2 is about here)

41
42 111 There were two main differences between these patient pathways. Firstly, individuals within
43
44 112 the target age group for screening were contacted directly and invited to participate in the novel
45
46 113 CRC screening programme while in the situation of 'usual care', CRC screening was offered
47
48 114 (if screening guideline recommendations were followed) only when members of the target
49
50 115 group visited their clinic for some other health condition or problem. Secondly, the iFOBT was
51
52 116 performed by doctors at health clinics in the 'usual care' pathway while in the novel CRC
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54 117 screening programme, participants self-tested in their home. Home-based testing generated
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56 118 additional stages in the pathways in relation to sending a test, reminding participants, taking a
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3 119 photo of a completed test, and sending it to programme officers and vice versa. The remaining
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5 120 stages of each pathway (e.g., being screened for eligibility, receiving a colonoscopy, and
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7
8 121 receiving a treatment plan) were the same across the two scenarios.
9

10 122

12 123 **Eligible population and input assumptions**

14 124 The target population for current opportunistic screening in Malaysia is individuals aged 50-
15
16
17 125 75 years, regardless of sex. Due to the nature of home-based screening, the target population
18
19 126 for the CRC screening programme was required to meet some additional inclusion criteria as
20
21
22 127 presented in Figure 2. The number of individuals who presented and completed each stage was
23
24 128 estimated using input assumptions.
25

26 129

28 130 Data about the population of Malaysia by age was taken from government reports (i.e.,
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30
31 131 Department of Statistics, Malaysia) and from World Population Review [13, 14]. The total
32
33 132 population was reported to be 32,676,786 in 2021, of which, 19% or 6,228,195 were aged 50-
34
35 133 75 years old [13, 14].
36

37 134

40 135 **In the ‘usual care’ – opportunistic screening pathway or scenario**, all assumptions were
41
42 136 derived from a study by Tamin NSI (2020) which was a 5-year evaluation of opportunistic CRC
43
44 137 screening (and the use of stool-based tests) in community health clinics across Malaysia [5]. It
45
46
47 138 was assumed that 0.482% of the eligible population would avail of CRC screening when they
48
49 139 attended local health clinics for other conditions; and 9.21% of this proportion of tested patients
50
51 140 would receive a positive result. Only 55.9% of patients in the study by Tamin availed of a
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53 141 colonoscopy after a positive iFOBT. CRC detection after colonoscopy investigation was 4.04%.
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3 143 **In the novel CRC screening programme**, all assumptions were derived from the CRC-SIM
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5 144 research project. It was assumed that 50.51% of the eligible population would be contactable
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8 145 and meet all inclusion criteria to participate in the home-based screening programme; 52.27%
9
10 146 of people who were eligible would agree to participate; 41.63% would perform the iFOBT and
11
12 147 send a photo of a completed test to the programme officers; 18.01% of people who would be
13
14
15 148 tested would receive a positive result; 41.07% would avail of colonoscopy after a positive
16
17 149 iFOBT result; and CRC detection after colonoscopy investigation would be 4.35%.

150

151 Table 1 summarises details about the input assumptions that were used to estimate the number
152 of individuals at each stage of the respective pathway: the opportunistic screening pathway and
153 the CRC screening programme pathway.

154

155 **Table 1: Input assumptions used to estimate the population at each stage of the patient**
156 **pathways**

Stage in pathway	Opportunistic screening scenario (Current practice)		Population-based CRC programme screening scenario (Proposed practice)	
	Assumption*	No. of individuals	Assumption**	No. of individuals
Total population (all ages)	NA	32,676,786	NA	32,676,786
Target population (aged 50-75)	19.06%	6,228,195	19.06%	6,228,195
Eligible population (met all inclusion criteria)	100%	6,228,195	50.51%	3,146,020
Availed of/agreed to take CRC screening	0.482%	30,020	52.27%	1,644,561
Needed 1 st reminder to return the iFOBT result (among those agreed to participate)	NA	NA	78.71%	1,294,514
Needed 2 nd reminder to return the iFOBT result (among those received 1 st reminder)	NA	NA	88.10%	1,140,405

Returned iFOBT result (among those agreed to participate)	100%	30,020	41.63%	684,683
Received iFOBT positive result	9.21%	2,765	18.01%	123,287
Availed of colonoscopy after positive iFOBT	55.9%	1,546	41.07%	50,636
CRC detection after colonoscopy investigation	4.04%	62	4.35%	2,202

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test; NA: Not applicable; No: Number
** The assumptions were derived from a study of Tamin NSI (2020) which was a 5-year evaluation of using stool-based test for opportunistic CRC screening in primary health institutions across Malaysia [5].*

*** The assumptions were derived from the Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021.*

157

158 **Cost input and data sources**

159 In the opportunistic screening scenario, the total cost comprised the cost of:

160 (i) performing screening (e.g., asking for symptoms, family history, and collecting the sample)

161 (ii) processing stool specimens

162 (iii) interpreting test results and

163 (iv) conveying a definitive diagnosis to patients (include explaining treatment plan or referral
 164 arrangements)

165

166 In the CRC programme screening scenario, the total cost comprised the costs of:

167 (i) contacting potential participants

168 (ii) delivering iFOBT test kits (including cost of the test, postage, print materials, and sending
 169 video instruction)

170 (iii) sending a reminder to participants (up to 2 times, by text message and phone call)

171 (iv) interpreting and conveying results to participants and

172 (v) following-up patients with positive iFOBT but did not take colonoscopy in order to
 173 encourage them to avail of the colonoscopy

174

175 These costs were calculated by multiplying the time allocated for the completion of each task
 176 with the salary cost of the person who undertakes each task plus cost of consumables. Table 2
 177 shows the unit cost for each cost element, related assumptions, and data sources.

178

179 **Table 2: Resources and unit costs**

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
<i>Current practice (opportunistic screening)</i>			
Performing screening (asking for symptoms, family history, referral) and taking sample	5.58	20 min x salary RM2947/month	1
Processing stool specimens	1.70	10 min x salary RM1797/month	2
Interpreting the test results	2.79	10 min x salary RM2947/month	1
Conveying a definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	30 min x salary RM2947/month	1
<i>Proposed practice (Population-based CRC screening programme)</i>			
Contact eligible individuals - agreed to participate	0.98	7.1 min x (salary RM1440/month + mobile package RM20/month)	3
Contact eligible individuals - rejected/excluded to participate	0.47	3.4 min x (same as above)	3
iFOBT rapid test kit	6.90		3
Print materials (instruction leaflet, explanatory statement)	1.10	90 cents for colour print + 20 cent for black & white print	3
Postage (stamps, etc.)	5.35		3
Sending video through WhatsApp	0.41	3 min x (salary RM1440/month + mobile package RM20/month)	3
Sending reminder text message	0.41	3 min x (same as above)	3
Reminder call	0.28	2 min x (same as above)	3
Interpreting the test kit result	1.70	10 min x salary RM1797/month	3
Sending text message to inform patient of negative result	0.45	2 min x (salary RM2350/month + mobile package RM20/month)	3
Calling patient to inform him/her of positive result	0.67	3 min x (same as above)	3

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
Preparing and sending referral letter to patient/clinic	1.12	5 min x (same as above)	3
Follow up effort	6.73	30 min x (same as above)	3
Developing communication materials, one-off cost	6,063	Communication materials do not change in 5 years	3
Training for data collectors*, one-off cost	109,703	+ 1 day training (virtual using Zoom) + 1 trainer for maximum 25 trainees + 1 data collector* is needed for every target population of 400 + Cost=1-day-salary of trainer/trainees x number of trainer/trainees + No retraining in 5 years	3
<i>* Data collectors are those employed by the programme to (i) contact potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants</i>			
Same in both scenarios/practices			
Colonoscopy (including polyps removal and/or biopsy if needed)	200		
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	RM8636.7/800 sets	3

iFOBT: Immunochemical faecal occult blood test; RM: Malaysian ringgit

Source:

1. Public Services Commission of Malaysia. Medical Officer Grade UD41. Accessed at <https://www.spa.gov.my/spa/laman-utama/gaji-syarat-lantikan-deskripsi-tugas/ijazah-sarjana-phd/pegawai-perubatan-gred-ud41>
2. Public Services Commission of Malaysia. Medical laboratory technologist Grade U29. Accessed at https://www.interactive.jpa.gov.my/ezskim/klasifikasi/perbekalanskim.asp?id_skim=3LU03
3. Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021

180

181 In the current practice of opportunistic screening, doctors were consulted about the estimated

182 time to perform each stage in the pathway. The monthly salary of a general doctor and a medical

183 laboratory technologist was based on the rate published by the Public Services Commission of

184 Malaysia [15, 16]. These rates were RM2,947 (~I\$2,045) and RM1,797 (~I\$1,247), respectively.

185 In the novel CRC screening programme, the time to perform each stage in the pathway, salary

186 of personnel, and costs of material resources (e.g., rapid kit test, consumables, postage, printing

187 materials) were based on the time and expenditure observed in the CRC-SIM research project.

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3 188 All costs were calculated per screen except the cost of training and the cost of developing
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5 189 communication materials which were one-off costs based on the assumption that
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7 190 communication materials would not change, and no re-training would be needed within 5 years.
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10 191 It was assumed (based on the experience of operating the screening programme during the
11
12 192 CRC-SIM project) that one data collector (i.e., those employed by the programme to (i) contact
13
14 193 potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants)
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16 194 would be needed for every 400 people in the target population. Training would last one day
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18 195 and would be delivered virtually; thus, the cost of training equalled (1-day-salary of trainer x
19
20 196 number of trainer) + (1-day-salary of trainees x number of trainees/data collectors).
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198 **Perspective and time horizon**

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28 199 The BIA was conducted from the viewpoint of the federal government which finances
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30 200 Malaysia's public health system [17]. Only those costs and resource requirements relevant to
31
32 201 the budget holder were included in the analysis. For example, the out-of-pocket expenditure
33
34 202 incurred by patients were excluded.
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40 204 The analysis estimated the annual financial impact over a period of five years as recommended
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42 205 in the guidelines [10, 18]. Costs were not discounted given that the BIA methodology reports
43
44 206 the costs for each year in which they occur rather than a net present value [10].
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3 209 **Budget impact analyses**
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5 210 *Computing framework and base-case analysis*
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7
8 211 The BIA used a cost calculator programmed in Microsoft Excel, following the costing
9
10 212 template¹ produced by the National Institute for Health and Care Excellence in the UK (NICE).
11
12 213 The template was modified to fit the programme under assessment. The cost calculator
13
14 214 approach is recommended by guidelines as it is easy for stakeholders to understand and
15
16 215 replicate the results [10].
17
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19 216
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21 217 First, the number of individuals who completed each stage was estimated (Table 1). The
22
23 218 resources that were used at each stage of the respective pathways (in opportunistic screening
24
25 219 and the novel CRC screening programme) were listed along with their unit costs (i.e., cost of
26
27 220 each resource per person) (Table 2). Unit costs were multiplied by number of users to give the
28
29 221 total cost of resources for each scenario. The net budget impact was calculated as the difference
30
31 222 in cost between opportunistic screening and the CRC screening programme. Visual depiction
32
33 223 of the cost calculator is shown in Supplementary Material, Figure S1.
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40 225 *Uncertainty and scenario analyses*
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42 226 The input assumptions (that were used to estimate the number of individuals at each stage of
43
44 227 the respective pathway) and the cost inputs were varied, and then the impact of these changes
45
46 228 in relation to the results was analysed to investigate the sensitivity of the budget impact results
47
48 229 to variations in individual input. As recommended by Gray et al. (2011), the range of variation
49
50 230 regarding parameters for which data sources about dispersion were unavailable were $\pm 20\%$ of
51
52 231 the base case [19].
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59 ¹ The template can be freely downloaded at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/budget-impact-template.xlsx>
60

232 **Patient and public involvement**

233 It was not appropriate or possible to involve patients or the public in the design, or conduct, or
234 reporting, or dissemination plans of our research as this type of study is a secondary analysis
235 of data from a payer perspective (Ministry of Health Malaysia).

236

237 **RESULTS**

238 **Base-case analysis**

239 The total annual cost of the current practice of opportunistic screening is RM1,584,321
240 (~I\$1,099,460), of which 80% (RM1,274,690 ~ I\$884,587) was for providing opportunistic
241 CRC to adults who availed of the service. Costs of providing colonoscopy (including polyps
242 removal and/or biopsy if needed) after receipt of a positive iFOBT and conveying definitive
243 diagnosis to patients (along with explaining treatment plan or referral etc.) after the outcome
244 of the colonoscopy were RM309,108 (~I\$214,509) and RM523 (~I\$363), respectively.

245

246 The total annual cost over a 5-year period of the proposed practice (i.e., CRC screening
247 programme) is shown in Table 3. It was assumed that the number of people who would agree
248 to participate in the programme would increase by 5% each year (in consideration of health
249 promotion activities as well as information flows including word of mouth between
250 participants). Therefore, the financial impact would also increase accordingly.

251

252

253 **Table 3: Annual cost of proposed practice (i.e., CRC screening programme)**

Currency: Malaysian ringgit (RM) and International Dollar (I\$)

Proposed practice	Year 1 RM (I\$)	Year 2 RM (I\$)	Year 3 RM (I\$)	Year 4 RM (I\$)	Year 5 RM (I\$)
Contacting adults who are eligible for CRC screening programme (i.e., aged 50-75) and screen for eligibility of participating	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)
Providing iFOBT test to adults who agreed to participate in CRC screening programme after being invited	93,654,886 (64,992,981)	102,612,907 (71,209,512)	111,570,928 (77,426,043)	120,528,949 (83,642,574)	129,486,970 (89,859,105)
Providing 1 st reminder to participants	536,929 (372,609)	588,286 (408,248)	639,643 (443,888)	690,999 (479,527)	742,356 (515,167)
Providing 2 nd reminder to participants	315,339 (218,833)	345,501 (239,765)	375,663 (260,696)	405,825 (281,627)	435,987 (302,559)
Interpreting returned iFOBT samples	1,165,129 (808,556)	1,276,572 (885,893)	1,388,016 (963,231)	1,499,460 (1,040,569)	1,610,903 (1,117,906)
Conveying result through message to participants with iFOBT negative result	251,990 (174,872)	276,093 (191,598)	300,196 (208,324)	324,298 (225,050)	348,401 (241,777)
Preparing and sending referral letter and calling participants with iFOBT POSITIVE result	221,356 (153,613)	242,529 (168,306)	263,701 (182,999)	284,874 (197,692)	306,046 (212,384)
Following up participants who DID NOT take colonoscopy after positive iFOBT	489,158 (339,457)	535,945 (371,926)	582,733 (404,394)	629,520 (436,863)	676,308 (469,332)
Providing colonoscopy (including polyps removal and/or biopsy if needed) to participants with positive iFOBT	10,127,147 (7,027,861)	11,095,801 (7,700,070)	12,064,455 (8,372,280)	13,033,109 (9,044,489)	14,001,764 (9,716,700)
Conveying definitive diagnosis to patients (along with explaining treatment plan or referral etc.) after the colonoscopy	18,432 (12,791)	20,195 (14,015)	21,958 (15,238)	23,721 (16,461)	25,484 (17,685)
Capital costs (Developing communication materials + Training for data collectors)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)
Total cost of proposed practice	109,216,279 (75,792,005)	119,429,743 (82,879,766)	129,643,206 (89,967,527)	139,856,670 (97,055,288)	150,070,133 (104,143,049)

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test

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3 255 Similar to opportunistic screening, the cost to provide iFOBT to the eligible population who availed
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5 256 of the service accounted for 86% of the total cost of the proposed CRC screening programme. The
6
7 257 second most costly component was the provision of colonoscopy (including polyps removal and/or
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9 258 biopsy if needed) to patients with an iFOBT positive result, at 9% of the total cost. The remaining
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11 259 nine cost components such as contacting potential participants, reminding participants to send
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13 260 photograph of iFOBT result, conveying diagnosis to participants and the follow-up effort added
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15 261 only up to 5% of the total cost.
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21 263 The net budget impact in the 1st year of implementing CRC screening programme would be
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23 264 RM107,631,959 (~I\$74,692,546 which equalled the total cost of future practice minus the total
24
25 265 cost of current practice). The impact increases each year as the number of people who agree to
26
27 266 participate in the programme increase, reaching RM117,845,422 (~I\$81,780,307) in year 2,
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29 267 RM128,058,885 (~I\$88,868,067) in year 3, RM138,272,349 (~I\$ 95,955,829) in year 4, and
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31 268 RM148,485,812 (~I\$103,043,589) in year 5.
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37 270 The net budget impact of providing and delivering the CRC screening programme over the 5-year
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39 271 timeframe for each state in Malaysia (calculated according to the population size of each state) can
40
41 272 be accessed in Supplementary Material, Table S1. These estimates aid service planning decisions
42
43 273 if the novel pilot programme is implemented in one or more of these states before being scaled up
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45 274 into nationwide programme.
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51 276 **Uncertainty and scenario analyses**

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53 277 The tornado diagram in Figure 3 shows the change to net budget impact when assumptions and
54
55 278 cost inputs were varied. It presents the results of multiple univariate sensitive analyses on key
56
57 279 inputs that exert the most influence on the net budget impact (See Table S2, Supplementary
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3 280 Material for results of multiple univariate sensitive analysis on all inputs). These inputs include
4
5 281 the probability of (i) making successful contact with adults about the CRC screening programme,
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7 282 (ii) adults agreeing to participate, (iii) adults being eligible to participate in the programme, and
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9 283 (iv) the cost of consumables that are required to take a stool sample. The first three inputs
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11
12 284 influence the number of individuals who are present at each stage of the patient pathway.

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15 285 (Figure 3 is about here)

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17 286 The net budget impact would increase from RM107 million to RM130 million (~I\$74-90
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19 287 million) if there was a 20% increase in (i) the probability of adults who were contactable (from
20
21 288 a contact list of people aged 50-75 years old) or (ii) the probability of adults agreeing to
22
23 289 participate in the CRC screening programme or (iii) the probability of adults being eligible for
24
25 290 the programme (i.e., aged 50-75 years old; having no symptoms of CRC, a smartphone, and
26
27 291 WhatsApp; resident within programme area; and did not have colonoscopy this year). In other
28
29 292 words, a 20% increase in each one of these factors would require an additional RM23 million
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31 293 (~I\$16 million) to be budgeted for the programme. Likewise, a 20% increase in the cost of the
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33 294 consumables that are required for taking stool samples would mean that the programme would
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35 295 cost RM15 million (~I\$10 million) more than the originally calculated total cost.
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41 42 43 297 **DICUSSION**

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46 298 The result of this analysis provides information to guide public health service planners and
47
48 299 commissioners in their decisions about an alternative CRC screening strategy i.e., a population-
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50 300 based CRC screening programme using home-based iFOBT compared to current opportunistic
51
52 301 screening. It concluded that the net budget impact in the 1st year of implementing a CRC
53
54 302 screening programme of this kind would be RM107,631,959 (~I\$74,692,546). The impact
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56 303 would increase by year due to increase in uptake and would reach RM148,485,812
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58 304 (~I\$103,043,589) in the 5th year of implementation. This analytical approach and the results of
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2
3 305 this analysis are presented as aids to better decision making by MoHs and stakeholders in
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5 306 lower-middle-income countries (LMICs) about health programme planning and in this
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7 307 particular illustrative case to the MoHM regarding the degree to which the proposed CRC
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9 308 screening programme is affordable.

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14 310 The total budget that was allocated to the MoHM in 2022 was RM32.4 billion (~I\$22.5 million)
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16 311 [20]. Spending on prevention and public health services in 2009 was reported to be RM1.6
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18 312 billion (~I\$1.1 million) [17]. More recent data and information about the size of the budget that
19
20 313 is allocated to cancer screening is not available. As such, it is estimated that the net budget
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22 314 impact of implementing a CRC screening programme would account for between 7-10% of the
23
24 315 total budget for prevention and public health services. This represents a significant proportion
25
26 316 of the overall budget allocated for prevention programmes/interventions.

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31 318 The key factor in the implementation of a population-based screening programme/service or the
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33 319 factor that has biggest impact on the budget is the size of the population who use the service. The
34
35 320 degree of accuracy regarding population size estimates is related closely to the cost estimates in
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37 321 the budget. It is important for service planners to keep this point in mind and to take into account
38
39 322 an increase in uptake and the impact of such an increase. Therefore, in the case of the CRC
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41 323 programme presented here, we assumed a 5% increase annually in uptake and calculated the net
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43 324 budget impact. The net budget impact can be recalculated according to the actual change in uptake
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45 325 after the programme is implemented.

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51 327 Budget impact analysis is an economic assessment that is used to estimate the changes in
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53 328 expenditure of a specific budget holder if a new health technology/programme is implemented
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55 329 [10]. As such, BIA complements other health economic evaluation methods such as cost-

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3 330 effectiveness analysis (CEA) to provide a comprehensive economic assessment of a health care
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5 331 intervention to decision makers [10]. A BIA aids decision making by health service planners
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7 332 and commissioners about whether an intervention or programme is affordable within given
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9 333 budget constraints while a CEA informs decisions about whether an intervention is good value
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11 334 for money [10, 21]. BIA and its pragmatic approach is an ideal method when a situation calls
12
13 335 for an evaluation of 'affordability' which is of central importance in LMICs and, arguably, is
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15 336 the key concern of whoever is in charge of managing a health care budget [22, 23].
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21 338 It could well be that savings in earlier treatment would counterbalance the additional budget
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23 339 impact. However, a BIA is not intended to provide answers to questions about whether or not,
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25 340 in this context, the screening programme is good value for money as it does not take into
26
27 341 account the potential improvements in outcomes (e.g., increase quality-related life years) and
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29 342 savings from lower treatment costs for CRC diagnosed at earlier stages. The conduct of other
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31 343 types of economic evaluations such as a cost-effectiveness analysis would be required to
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33 344 provide a complete and comprehensive set of evidence for decision makers.
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40 346 Finally, the conduct of BIA in this paper has some limitations. First, assumptions and cost
41
42 347 inputs for the CRC screening programme were based on the costs and rates that were observed
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44 348 in the CRC-SIM research project. The project was conducted in only one district (Segamat);
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46 349 and the distribution of three main ethnic groups (i.e., Malay, Chinese, Indian) in the project
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48 350 differed from the proportions that have been reported nation-wide (72%:24%:3% vs
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50 351 62%:21%:6%, respectively). Therefore, it is important to be mindful of the possibility that the
51
52 352 assumptions and inputs (based on the project) may not be representative for, or read across to,
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54 353 the whole population of Malaysia. Likewise, it is important to bear in mind that our findings
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56 354 do not include the perspective of other payers and may not generalise to other settings. The
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3 355 results are related directly to the context of the Malaysian health system and the epidemiology
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5 356 of CRC in the country though they are illustrative of the positive contribution of the BIA
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8 357 methodology and approach.
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10 11 358 **CONCLUSIONS**

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14 359 This study employed a BIA methodology to analyse the costs of a novel CRC screening
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16 360 programme using home-based iFOBT and mHealth versus the current opportunistic screening.
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18 361 The findings estimated the net budget impact of implementing a population-based national
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20 362 CRC screening programme in Malaysia. The modelling estimations are important
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22 363 considerations for health authorities when they are required to decide the affordability of
23
24 364 implementing a programme and to aid budgetary planning as well as decision making,
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26 365 generally, about implementation. Our study illustrates the use and value of the BIA approach
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28
29 366 in LMICs and resource-constrained settings.
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31

32 33 367 **Abbreviations**

34	BIA	Budget impact analysis
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36	CEA	Cost-effectiveness analysis
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38	CRC	Colorectal cancer
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40	CRC-SIM	Colorectal Cancer Screening Intervention for Malaysia
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42	iFOBT	Immunochemical faecal occult blood test
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44	I\$	International Dollar
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46	ISPOR	The Professional Society for Health Economics and Outcomes Research
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48	MoHM	Ministry of Health of Malaysia
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50	NICE	National Institute for Health and Care Excellence
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52	RM	Malaysian ringgit
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SEACO Southeast Asia Community Observatory

UK The United Kingdom

368 **DECLARATIONS**

369 **Research ethics approval.** Not applicable (This study does not involve human participants).

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375 the content of this article.

376 **Availability of data and material.** All data generated or analysed during this study are
377 included in this published article.

378 **Authors' contributions.** TTN: Methodology, Formal Analysis, Writing – Original draft, Writing –
379 Review & Editing. KR, MRS, and DS: Data Curation, Investigation, Writing – Review & Editing. ST:
380 Resources, Writing – Review & Editing. TTS, and MD: Conceptualization, Funding acquisition,
381 Writing – Review & Editing, Supervision. CON: Methodology, Formal Analysis, Writing – Review &
382 Editing, Supervision.

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3 446 **Figure Legends and Tables**
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5
6 447 Table 1 Input assumptions used to estimate the population at each stage of the patient pathways
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8 448 Table 2 Resources and unit costs
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10 449 Table 3 Annual cost of proposed practice (i.e., CRC screening programme)
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14
15 451 Figure 1 Patient pathways in 'usual care' practice - opportunistic screening for CRC
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17 452 Figure 2 Patient pathway in population-based CRC screening programme
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19 453 Figure 3 Results of multiple univariate sensitive analyses showing key factors that exert most
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21 influence the net budget impact
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24 455

25
26 456 **Supplementary material**
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28 457 Figure S1 Visual depiction of the budget impact cost calculator
29

30 458 Table S1 Net budget impact of CRC screening programme over 5-year timeframe, by state
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33 459 Table S2 Sensitivity of the total budget impact of CRC screening programme to changes in
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35 each variable individually
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Figure 1: Patient pathway in 'usual care' practice - opportunistic screening for CRC

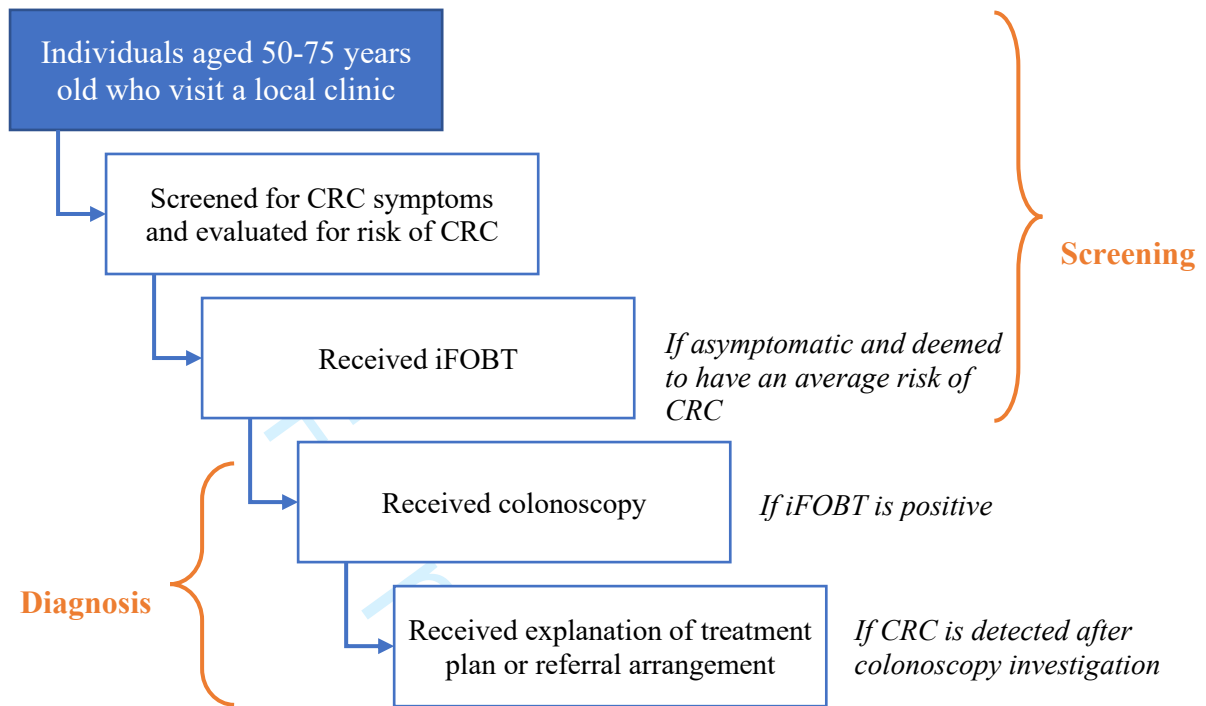


Figure 2: Patient pathway in population-based CRC screening programme

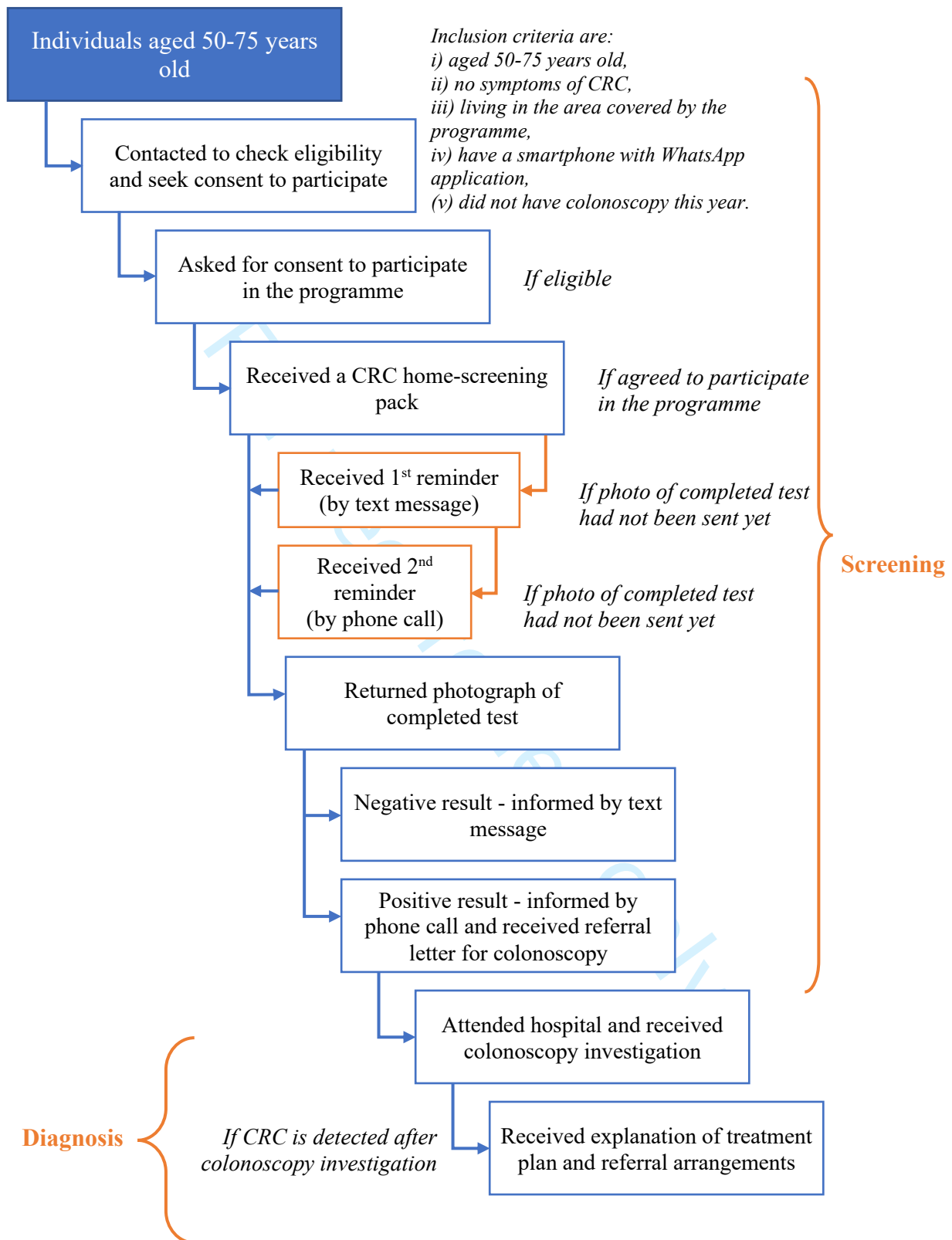
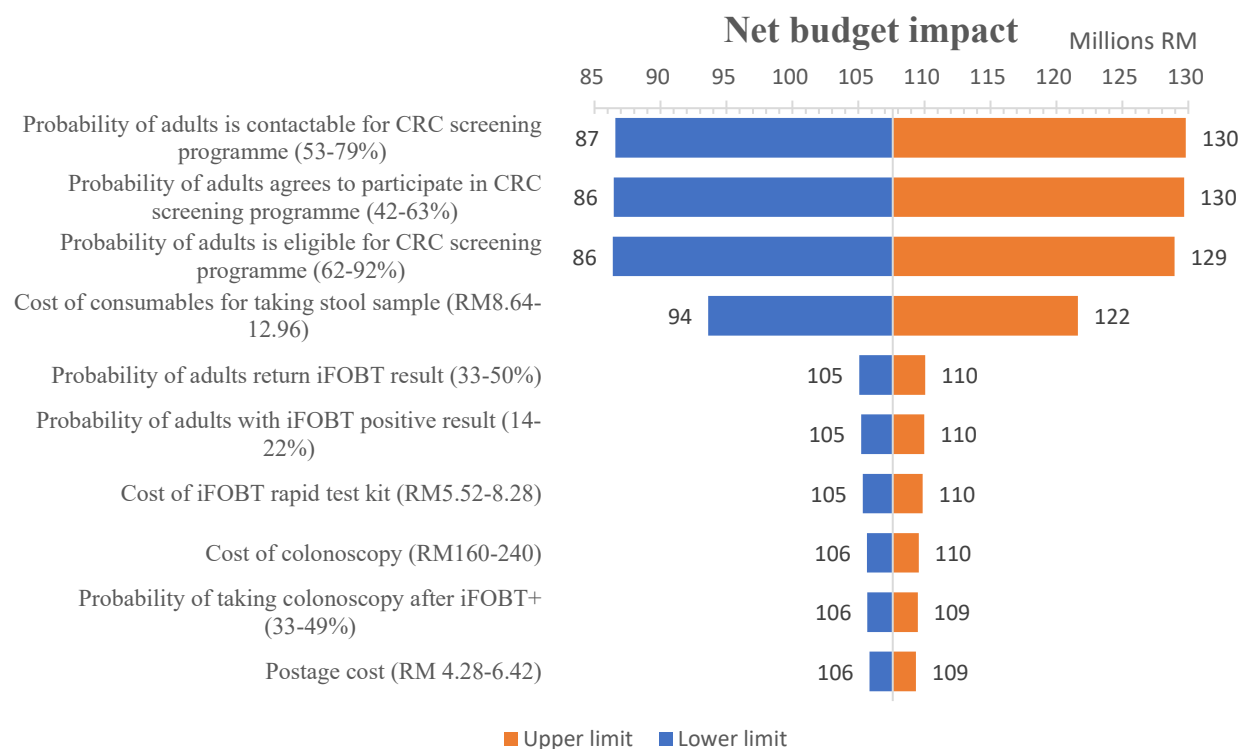


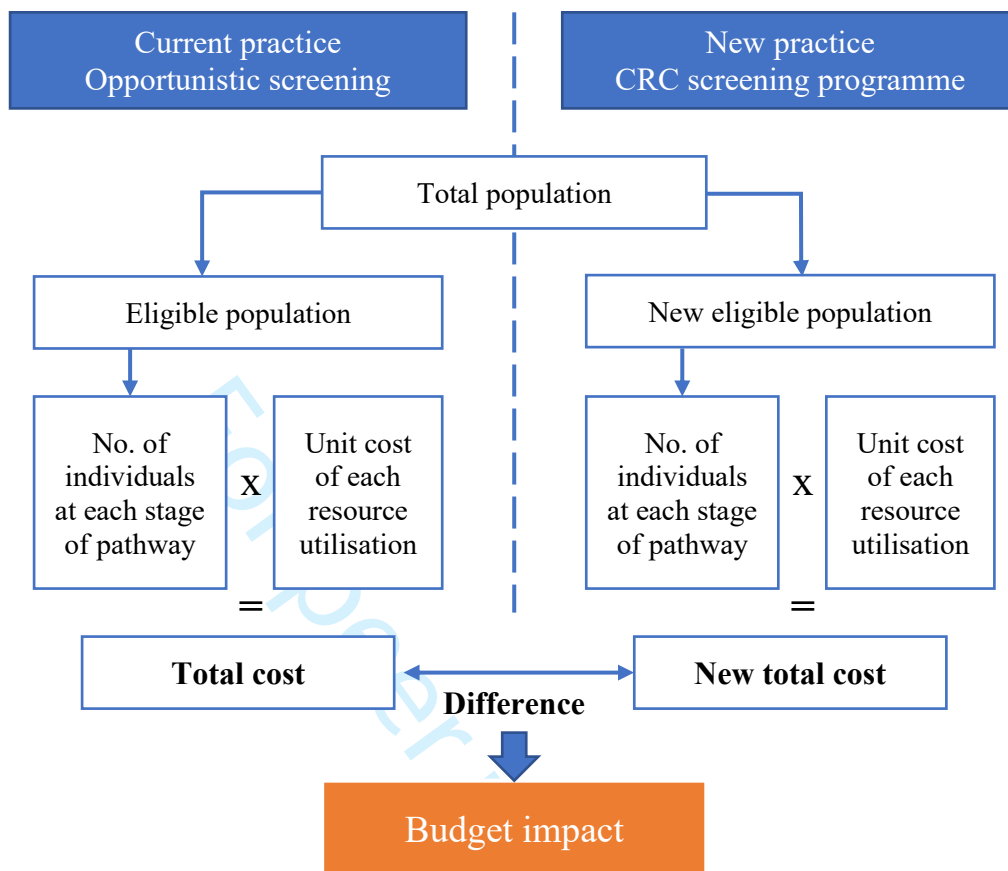
Figure 3: Results of multiple univariate sensitive analyses showing key factors that exert most influence the net budget impact



Review only

Supplementary material

Figure S1: Visual depiction of the budget impact cost calculator



Supplementary material

Table S1: Net budget impact of CRC screening programme over 5-year timeframe, by state

Currency: Malaysian ringgit

State	Population	Year 1	Year 2	Year 3	Year 4	Year 5
Johor	3,822,800	12,597,041	13,791,897	14,986,752	16,181,607	17,376,462
Kedah	2,206,200	7,272,541	7,962,112	8,651,682	9,341,252	10,030,823
Kelantan	1,884,300	6,212,311	6,801,268	7,390,225	7,979,183	8,568,140
Melaka	934,700	3,084,637	3,376,787	3,668,937	3,961,087	4,253,238
Negeri Sembilan	1,141,000	3,764,122	4,120,753	4,477,384	4,834,016	5,190,647
Pahang	1,702,900	5,614,833	6,147,092	6,679,351	7,211,609	7,743,868
Perak	2,569,300	8,468,450	9,271,511	10,074,572	10,877,633	11,680,693
Pulau Pinang	1,767,100	5,826,301	6,378,626	6,930,951	7,483,276	8,035,601
Sabah	3,919,600	12,915,864	14,140,975	15,366,086	16,591,197	17,816,308
Sarawak	2,829,400	9,325,144	10,209,501	11,093,859	11,978,217	12,862,575
Terengganu	1,245,300	4,107,648	4,496,879	4,886,111	5,275,342	5,664,573
Perlis	253,500	841,028	920,262	999,496	1,078,730	1,157,964
W.P. Kuala Lumpur	1,790,100	5,902,043	6,461,557	7,021,071	7,580,585	8,140,099
W.P. Labuan	99,000	332,138	363,081	394,024	424,968	455,911
W.P. Putrajaya	97,100	325,886	356,236	386,585	416,935	447,284
Nation-wide	32,676,786	107,631,959	117,845,422	128,058,885	138,272,349	148,485,812

CRC: Colorectal cancer | W.P.: The Federal Territories (Malay: Wilayah Persekutuan)

Readers can convert from Malaysian Ringgit to their currency of interest (e.g., International Dollar, US Dollar, British Pound, Euro etc.) using the free web-based tool ‘CCEMG – EPPI-Centre Cost Converter’ (<https://eppi.ioe.ac.uk/costconversion/default.aspx>). This tool help adjusting estimates of cost expressed in one currency and price year to a specific target currency and price year.

Supplementary material

Table S2: Sensitivity of the total budget impact of CRC screening programme to changes in each variable individually

Baseline budget impact=RM107,631,959

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Probability of adults is contactable for CRC screening programme	66%	53%	79%	86,574	129,818	43,244
Probability of adults is included (eligible for CRC screening programme)	77%	62%	92%	86,386	128,950	42,564
Probability of adults agree to participate in CRC screening programme after being invited	52%	42%	63%	86,454	129,675	43,221
Probability of adults needing 1st reminder	79%	63%	94%	107,430	107,766	336
Probability of adults needing 2nd reminder	88%	70%	100%	107,535	107,643	108
Probability of adults return iFOBT result	42%	33%	50%	105,062	110,060	4,998
Probability of adults with iFOBT positive result	18%	14%	22%	105,204	109,988	4,784
Probability of adults taking colonoscopy after positive iFOBT	41%	33%	49%	105,673	109,493	3,820
Probability of adults with CRC detection after getting colonoscopy	4%	3%	5%	107,594	107,603	9
Cost to perform the screening (asking for symptoms, family history, referral)	5.58	4.47	6.70	107,633	107,567	-66
Cost of stool specimen processing	1.70	1.36	2.04	107,610	107,590	-20
Interpretation of results	2.79	2.23	3.35	107,617	107,583	-34
Cost to convey definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	6.70	10.05	107,597	107,604	7
Contact eligible individuals - agreed to participate	0.98	0.79	1.18	107,285	107,926	641
Contact eligible individuals - rejected/excluded to participate	0.47	0.38	0.56	107,465	107,735	270
iFOBT rapid test kit (only the rapid test kit itself)	6.90	5.52	8.28	105,331	109,870	4,539
Print materials (instruction leaflet, explanatory statement)	1.10	0.88	1.32	107,238	107,962	724
Postage (stamp etc.)	5.35	4.28	6.42	105,840	109,360	3,520
Sending video through Whatapp	0.41	0.33	0.50	107,461	107,740	279
Sending reminder text message	0.41	0.33	0.50	107,490	107,710	220
Reminder call	0.28	0.22	0.33	107,536	107,661	125
Interpret the test kit result	1.70	1.36	2.04	107,366	107,832	466

Supplementary material

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Sending text message informing negative result	0.45	0.36	0.54	107,550	107,651	101
Call to inform positive result	0.41	0.33	0.50	107,590	107,611	21
Prepare and send referral letter	1.12	0.90	1.35	107,573	107,628	55
Follow up effort	6.73	5.39	8.08	107,503	107,698	195
Colonoscopy	200	160	240	105,638	109,564	3,926
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	8.64	12.96	93,612	121,641	28,029

1 ISPOR—The Professional Society for Health Economics and Outcomes Research

2
3 **Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR**
4 **2012 Budget Impact Analysis Good Practice II Task Force**
5

6
7 Citation: Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, Orlewska E, Penna
8 P, Rodriguez Barrios JM, Shau WY. Budget impact analysis-principles of good practice: report of the
9 ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014 Jan-Feb;17(1):5-
10 14. doi: <https://doi.org/10.1016/j.jval.2013.08.2291>
11
12

13 **Recommendations for Reporting Format**
14

Section/topic	Guidance for reporting	Reported in section
Introduction		
Objectives	The objective of the BIA should be clearly stated and tied to the study perspectives	Introduction
Epidemiology and management of health problem	Present information about the prevalence and incidence of the particular disease, disease severity, disease progression, undiagnosed or undertreated cases, and risk factors pertinent to estimating the budget impact	Introduction
Clinical impact	Consist of a brief description of the eligible population and existing management options and their efficacy and safety that are relevant to the design of the study of the BIA	Introduction
Economic impact	Include a brief description of previous BIAs in the condition of interest for another intervention and condition-specific treatment patterns and cost-of-care studies	Not applicable (No previous BIA)
Study Design and Methods		
Patient population	Specify the eligible population for the new intervention	Methods Sub-section: Eligible population and input assumptions Table 1
Intervention mix	Contain a detailed description of the use and characteristics of each intervention in the current intervention mix and in the expected intervention mix after the introduction of the new intervention	Methods Sub-section: Health service under assessment and its comparator Figure 1 and 2
Time horizon	Should be presented and the choice(s) justified	Methods Sub-section: Perspective and time horizon
Perspective	Identify the BIAs' perspective(s), the cost categories included, and the intended audience	Methods Perspective and time horizon

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Section/topic	Guidance for reporting	Reported in section
Analytic framework description	Complete description of the structure of the BIA cost calculator or condition-specific cohort or individual simulation model	Methods Sub-section: Eligible population and input assumptions
Input data	Input values used for the reported analyses, including alternative scenarios, should be presented	Methods Sub-section: Cost input and data sources Table 2
Data sources	The sources of data inputs should be described in detail	Methods Sub-section: Cost input and data sources Table 2
Data collection	The methods and processes for any primary data collection and data abstraction tasks not reported elsewhere should be described and explained.	Not applicable (secondary data)
Analyses	A description of the calculations used to complete the BIA should be provided. The choice of all the scenarios presented in the results should be documented and justified.	Methods Sub-section: Computing framework and base-case analysis under budget impact analyses
Uncertainty	Uncertainty analysis methods should be described and justified	Methods Sub-sections: Uncertainty and scenario analyses under budget impact analyses
Results	The budget impact should be presented for each budget period over the time horizon. Both budget period resource use and costs should be presented. The estimates of resource use should be listed in a table that shows the change in use for each time period reported in the BIA The results of the uncertainty analyses and scenarios analyzed should be described and presented in figures or tables	Results Table 3 Results Figure 2
Conclusions and Limitations	State the main conclusions on the basis of the results of the BIA. Report the main limitations regarding key issues such as design aspects including off-label use and adherence assumptions and the completeness and quality of data inputs and sources.	Discussion Conclusion
Inclusion of Graphics and Tables		
Figure of the analytical framework	Flow diagrams or other visual depictions of the cost calculator or condition-specific cohort or individual simulation model are recommended to be included with the analytical framework description.	Supplementary material Figure S1

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Section/topic	Guidance for reporting	Reported in section
Table of assumptions	All the major assumptions should be listed in a tabular form	Table 1
Tables of inputs	All the input parameter values and their data sources and derivations should be presented in a tabular form	Table 2
Tables of outputs	All outputs should be presented in a tabular and/or graphical Form	Table 3
Schematic representation of uncertainty analyses	Diagrams such as Tornado diagrams should be included along with the text on the results of the scenario analyses	Figure 3
Appendices and References	The appendices may cover literature search strategies, evidence summaries, intermediate results (e.g., of individual Delphi panel rounds), and the names and addresses of participating experts and investigators, for example.	Reference

CHEERS 2022 Checklist

Topic	No.	Item	Location where item is reported
Title			
	1	Identify the study as an economic evaluation and specify the interventions being compared.	Title page, Page 1
Abstract			
	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	Abstract, Page 1
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Introduction, Line 65-69
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Not applicable
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Methods, Line 123-152, Table 1
Setting and location	6	Provide relevant contextual information that may influence findings.	Methods, Line 79-92
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Methods, Line 79-121, Figure 1 and 2
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Methods, Line 199-202
Time horizon	9	State the time horizon for the study and why appropriate.	Methods, Line 204-205
Discount rate	10	Report the discount rate(s) and reason chosen.	Methods, Line 205-206
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Not applicable

Topic	No.	Item	Location where item is reported
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Not applicable
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Not applicable
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Methods, Line 159-196
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Methods, Line 73-76
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	Not applicable
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	Methods, Line 211-221, Figure S1 (Supplementary Material)
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Not applicable
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	Not applicable
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis.	Methods, Line 224-229, Figure S2 (Supplementary Material)
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	Methods, Line 233-235
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Table 1 and 2, Table S2 (Supplementary Material)
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Results, Line 239-274, Table 3

Topic	No.	Item	Location where item is reported
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Results, Line 277-295, Figure 3
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	Not applicable
Discussion			
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Discussion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	End of manuscript
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	End of manuscript

From: Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value Health 2022;25. doi:10.1016/j.jval.2021.10.008

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A budget impact analysis of a home-based colorectal cancer screening programme in Malaysia

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Keywords:	Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, HEALTH ECONOMICS, PUBLIC HEALTH

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3 **A budget impact analysis of a home-based colorectal cancer screening**
4 **programme in Malaysia**
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9 Tran Thu Ngan^{1*}, Kogila Ramanathan^{2,3}, Muhamad Raziq Bin Mohd Saleh³, Désirée
10 Schliemann¹, Nor Saleha Binti Ibrahim Tamin⁴, Tin Tin Su^{2,3}, Michael Donnelly¹, Ciaran
11 O'Neill¹
12
13

14
15
16 ¹ *Centre for Public Health, Queen's University Belfast, Belfast, UK*

17
18 ² *Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences, Monash*
19 *University Malaysia, Selangor, Malaysia*
20

21
22 ³ *South East Asia Community Observatory (SEACO), Jeffrey Cheah School of Medicine and*
23 *Health Sciences, Monash University Malaysia*
24

25
26 ⁴ *Ministry of Health Malaysia, Putrajaya, Malaysia*
27
28

29
30
31
32 * Correspondence to:

33
34 Tran Thu Ngan, PhD

35
36 Postal address: Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom

37
38 Email: n.t.tran@qub.ac.uk
39
40
41
42

43
44 ORCID of the authors

45
46 Tran Thu Ngan : 0000-0003-2771-9878

47
48 Désirée Schliemann : 0000-0002-8746-3002

49
50 Ciaran O'Neill : 0000-0001-7668-3934
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1 A budget impact analysis of a home-based colorectal cancer screening 2 programme in Malaysia

3 Abstract

4 **Objectives:** The 2020-2022 research project ‘Colorectal Cancer Screening Intervention for
5 Malaysia’ (CRC-SIM) evaluated the implementation of a home-based CRC screening pilot in
6 Segamat District. This budget impact analysis (BIA) assessed the expected changes in health
7 expenditure of the Malaysian Ministry of Health budget in the scenario where the pilot
8 programme was implemented nationwide versus current opportunistic screening.

9 **Design:** Budget impact analysis. Assumptions and costs in the opportunistic and novel CRC
10 screening scenarios were derived from a previous evaluation of opportunistic CRC screening in
11 community health clinics across Malaysia and the CRC-SIM research project, respectively.

12 **Setting:** National level (with supplement analysis for district level). The BIA was conducted
13 from the viewpoint of the federal government and estimated the annual financial impact over
14 a period of five years.

15 **Results:** The total annual cost of the current practice of opportunistic screening was RM1,584,321
16 (~I\$1,099,460; RM=Ringgit Malaysia; I\$=International dollar) of which 80% (RM1,274,690 or
17 ~I\$884,587) was expended on the provision of opportunistic CRC to adults who availed of the
18 service. Regarding the implementation of national CRC screening programme, the net budget
19 impact in the 1st year was estimated to be RM107,631,959 (~I\$74,692,546) and to reach
20 RM148,485,812 (~I\$103,043,589) in the 5th year based on an assumed increased uptake of 5%
21 annually. The costs were calculated to be sensitive to the probability of adults who were
22 contactable, eligible, and agreeable to participating in the programme.

23 **Conclusions:** Results from the BIA provided direct and explicit estimates of the budget
24 changes to when implementing a population-based national CRC screening programme to aid
25 decision making by health services planners and commissioners in Malaysia about whether
26 such programme is affordable within given their budget constraint. The study also illustrates
27 the use and value of the BIA approach in LMICs and resource-constrained settings.

28 **Keywords:** Colorectal cancer screening, budget impact analysis, home-based testing, global
29 health, Malaysia

Strengths and limitations of this study

- The budget impact analysis (BIA) was used to evaluate the ‘affordability’ of colorectal cancer (CRC) screening programme in Malaysia within given budget constraint.
- Assumptions and cost inputs for modelling the budget impact were based on the actual costs and rates observed in Malaysia.
- The total cost of resources (=unit costs * number of users) for opportunistic screening and the CRC screening programme were compared to calculate the net budget impact.
- The BIA was conducted from the viewpoint of the federal government and only included costs and resource requirements relevant to this particular budget holder.
- The BIA could not and was not intended to provide answers to questions about whether or not the screening programme is good value for money (which can be answered by a cost-effectiveness analysis).

INTRODUCTION

Colorectal cancer (CRC) has the second highest incidence and mortality rate among all types of cancer in both sexes in Malaysia [1]. The age standardised incidence rate in 2012-2016 was 14.8 per 100,000 males and 11.1 per 100,000 females which appears to be stable compared to 2007-2011 [2]. In contrast, the proportion of CRC patients who are diagnosed at a late stage (i.e., stage III or IV) is increasing. Report from Ministry of Health Malaysia (MoHM) showed that the proportion of males with late stage CRC increased from 65.9% during 2007-2011 to 72.4% during 2012-2016; and from 65.2% to 73.1% for females [2]. The report did not give an explanation about this increasing trend though [2]. Late stage diagnosis negatively impacts survival rate; for example, the 5-year survival rates for cases diagnosed at stage I, II, III, and IV in 2002-2004 in Kuala Lumpur were 78.6%, 52.9%, 44.3%, and 9.3%, respectively [3]. Improved survival can be achieved by early detection through screening and the removal of premalignant polyps [4]. However, Malaysia currently does not have a population-based national CRC screening programme.

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3 46 The Ministry of Health of Malaysia (MoHM) adopted the use of immunochemical faecal occult
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5 47 blood test (iFOBT) for opportunistic CRC screening at public health clinics since 2014 [5].
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7 48 MoHM guidelines recommend screening for asymptomatic individuals aged 50-75 years old
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9 49 with average risk of CRC [6]. The uptake (number of patients screened/total eligible
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11 50 population) of this opportunistic screening tends to be very low. The annual average uptake
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13 51 during 2014-2018 was 0.5% while the 5-year cumulative uptake was 2.29% due to low
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15 52 awareness about CRC in general and CRC tests in particular, fear of the result, concern about
16
17 53 the cost, and absence of a doctor's recommendation [5, 7]. Home-based iFOBT has been
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19 54 implemented in many high-income countries (HICs) to improve the accessibility and uptake of
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21 55 CRC screening [8]. In this context, the Southeast Asia Community Observatory (SEACO) at
22
23 56 Monash University Malaysia and Queen's University Belfast (Northern Ireland) collaborated
24
25 57 to conduct the research project, 'Colorectal Cancer Screening Intervention for Malaysia'
26
27 58 (CRC-SIM) in 2020-2022. This project evaluated the implementation of a home-based CRC
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29 59 screening pilot in Segamat District. The uptake of the novel screening programme was 22%.
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31 60 The significantly higher uptake indicates the potential population wide impact if this screening
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33 61 approach (i.e., using home-based iFOBT and self-reporting test results) was scaled up.
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35 62 However, in order to aid public health decision making, there is a need to model a scaled-up
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37 63 version of the research-tested screening programme and, more specifically, gather insights
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39 64 about the total costs of programme implementation and how it might impact the MoHM budget.
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41 65 In other words, there is a need for a budget impact analysis (BIA).
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51 67 Budget impact analysis was first introduced in 1998 by Mauskopf [9, 10]. Since then, BIA is
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53 68 gradually requested as a part of the health technology assessment (HTA) procedure by a few
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55 69 countries around the world such as Australia, Canada, the United States (the US), England,
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57 70 Ireland, Spain, Belgium, Poland, Israel, and Thailand [11]. Regarding BIA for colorectal cancer
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3 71 (CRC) screening, a recent systematic review found six studies conducted in the UK, US,
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5 72 Belgium, and Australia [12]. We found two additional studies published in 2018 and 2019 from
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7 73 Spain and Thailand, respectively [13, 14]. Although results from these studies are not
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9 74 comparable as they were specific to each studied country, all studies were conducted to answer
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11 75 the question ‘What is the budget impact of implementing a colorectal cancer
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13 76 screening/prevention programme compared with current usual care’. It is also the research
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15 77 question that the BIA in this study aims to answer. Specifically, the BIA assessed the expected
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17 78 changes in the health expenditure of MoHM budget as a result of implementing a population-
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19 79 based national CRC screening programme versus current opportunistic screening (or ‘usual
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21 80 care’). It assessed the affordability of the screening programme given potential budget
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23 81 constraints.
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32 **METHODS**

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34 84 The conduct of this BIA and presentation of this paper followed the guidelines developed by
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36 85 the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force
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38 86 [11, 15]. All costs are presented in local currency -the Malaysian Ringgit (RM)- and
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40 87 International Dollar (I\$). RM was converted to I\$ using purchasing power parity (PPP)
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42 88 conversion factors instead of market exchange rates. The PPP conversion rate of 1.441 was
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44 89 obtained from the IMF World Economic Outlook Database [16].
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51 **Health service under assessment and its comparator**

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53 92 The specific health service that was the focus of the BIA was a population-based screening
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55 93 programme for colorectal cancer using a self-rapid response iFOBT. The comparator was
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57 94 current or ‘usual care’ - opportunistic screening.
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3 96 The BIA is predicated on the opportunistic screening programme being replaced by the new
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5 97 population-based screening programme (i.e., the two programmes would not be run in
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7 98 conjunction or in other words, the two scenarios in assessment are mutually exclusive). In each
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10 99 scenario, the patient pathway from the point when patients were invited for screening to receipt
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12 100 of a definitive diagnosis were identified and described. The screening procedure ends at the point
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14 101 of a patient receiving their iFOBT result with encouragement to attend hospital for a colonoscopy
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16 102 (if iFOBT is positive). It is important to note that the BIA included costs of screening and
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18 103 diagnosis (e.g., colonoscopy, biopsy) but not treatment. The BIA also did not address issues with
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20 104 respect to equity of access and uptake of services in either screening scenarios.
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26 106 The patient pathways for the 'usual care' practice and the novel CRC screening programme are
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28 107 presented in Figure 1 and 2, respectively. In opportunistic screening practice, it is recommended
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30 108 or expected that individuals who are aged 50-75 years will be screened for CRC symptoms
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32 109 when they attend their local health clinic (for any health condition or problem). If they are
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34 110 asymptomatic and have an average risk of having CRC (based on family history), they are
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36 111 offered an iFOBT, followed by a colonoscopy if the iFOBT test was positive. If CRC is
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38 112 detected following a colonoscopy, the result is conveyed to a patient along with an explanation
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40 113 of the treatment plan or referral arrangement.
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44 114 (Figure 1 is about here)

46 115 Details of the home-based screening intervention in CRC-SIM were published elsewhere [17].
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48 116 Briefly, in the novel CRC screening programme, individuals aged 50-75 years were contacted,
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50 117 checked for eligibility, and invited to participate. A home-screening 'pack' was posted to eligible
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52 118 participants followed by two reminders. The test was performed at home by participants who took
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54 119 a photograph of the completed test and texted it to trained medical professionals who interpreted
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56 120 the photograph. Participants with positive iFOBT were referred for a colonoscopy at hospital.
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3 121 (Figure 2 is about here)
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5 122 There were two main differences between these patient pathways. Firstly, individuals within
6
7 123 the target age group for screening were contacted directly and invited to participate in the novel
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9 124 CRC screening programme while in the situation of 'usual care', CRC screening was offered
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11 125 (if screening guideline recommendations were followed) only when members of the target
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13 126 group visited their clinic for some other health condition or problem. Secondly, the iFOBT was
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15 127 performed by doctors at health clinics in the 'usual care' pathway while in the novel CRC
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17 128 screening programme, participants self-tested in their home. Home-based testing generated
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19 129 additional stages in the pathways in relation to sending a test, reminding participants, taking a
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21 130 photo of a completed test, and sending it to programme officers and vice versa. The remaining
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23 131 stages of each pathway (e.g., being screened for eligibility, receiving a colonoscopy, and
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25 132 receiving a treatment plan) were the same across the two scenarios.
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32 33 134 **Eligible population and input assumptions**

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35 135 The target population for current opportunistic screening in Malaysia is individuals aged 50-
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37 136 75 years, regardless of sex. Due to the nature of home-based screening, the target population
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39 137 for the CRC screening programme was required to meet some additional inclusion criteria as
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41 138 presented in Figure 2. The number of individuals who presented and completed each stage was
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43 139 estimated using input assumptions.
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49 141 Data about the population of Malaysia by age was taken from government reports (i.e.,
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51 142 Department of Statistics, Malaysia) and from World Population Review [18, 19]. The total
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53 143 population was reported to be 32,676,786 in 2021, of which, 19% or 6,228,195 were aged 50-
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55 144 75 years old [18, 19].
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3 146 **In the ‘usual care’ – opportunistic screening pathway or scenario**, all assumptions were
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5 147 derived from a study by Tamin NSI (2020) which was a 5-year evaluation of opportunistic CRC
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7 148 screening (and the use of stool-based tests) in community health clinics across Malaysia [5]. It
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9 149 was assumed that 0.482% of the eligible population would avail of CRC screening when they
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11 150 attended local health clinics for other conditions; and 9.21% of this proportion of tested patients
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13 151 would receive a positive result. Only 55.9% of patients in the study by Tamin availed of a
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15 152 colonoscopy after a positive iFOBT. CRC detection after colonoscopy investigation was 4.04%.
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21 154 **In the novel CRC screening programme**, all assumptions were derived from the CRC-SIM
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23 155 research project. It was assumed that 50.51% of the eligible population would be contactable
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25 156 and meet all inclusion criteria to participate in the home-based screening programme; 52.27%
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27 157 of people who were eligible would agree to participate; 41.63% would perform the iFOBT and
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29 158 send a photo of a completed test to the programme officers; 18.01% of people who would be
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31 159 tested would receive a positive result; 41.07% would avail of colonoscopy after a positive
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33 160 iFOBT result; and CRC detection after colonoscopy investigation would be 4.35%.
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40 162 Table 1 summarises details about the input assumptions that were used to estimate the number
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42 163 of individuals at each stage of the respective pathway: the opportunistic screening pathway and
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44 164 the CRC screening programme pathway.
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168 **Table 1: Input assumptions used to estimate the population at each stage of the patient**
 169 **pathways**

Stage in pathway	Opportunistic screening scenario (Current practice)		Population-based CRC programme screening scenario (Proposed practice)	
	Assumption*	No. of individuals	Assumption**	No. of individuals
Total population (all ages)	NA	32,676,786	NA	32,676,786
Target population (aged 50-75)	19.06%	6,228,195	19.06%	6,228,195
Eligible population (met all inclusion criteria)	100%	6,228,195	50.51%	3,146,020
Availed of/agreed to take CRC screening	0.482%	30,020	52.27%	1,644,561
Needed 1 st reminder to return the iFOBT result (among those agreed to participate)	NA	NA	78.71%	1,294,514
Needed 2 nd reminder to return the iFOBT result (among those received 1 st reminder)	NA	NA	88.10%	1,140,405
Returned iFOBT result (among those agreed to participate)	100%	30,020	41.63%	684,683
Received iFOBT positive result	9.21%	2,765	18.01%	123,287
Availed of colonoscopy after positive iFOBT	55.9%	1,546	41.07%	50,636
CRC detection after colonoscopy investigation	4.04%	62	4.35%	2,202

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test; NA: Not applicable; No: Number
 * The assumptions were derived from a study of Tamin NSI (2020) which was a 5-year evaluation of using stool-based test for opportunistic CRC screening in primary health institutions across Malaysia [5].

** The assumptions were derived from the Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021.

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3 172 **Cost input and data sources**
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5 173 In the opportunistic screening scenario, the total cost comprised the cost of:
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7 174 (i) performing screening (e.g., asking for symptoms, family history, and collecting the sample)
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9 175 (ii) processing stool specimens
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11 176 (iii) interpreting test results and
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13 177 (iv) conveying a definitive diagnosis to patients (include explaining treatment plan or referral
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15 178 arrangements)
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19 180 In the CRC programme screening scenario, the total cost comprised the costs of:
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21 181 (i) contacting potential participants
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23 182 (ii) delivering iFOBT test kits (including cost of the test, postage, print materials, and sending
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25 183 video instruction)
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27 184 (iii) sending a reminder to participants (up to 2 times, by text message and phone call)
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29 185 (iv) interpreting and conveying results to participants and
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31 186 (v) following-up patients with positive iFOBT but did not take colonoscopy in order to
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33 187 encourage them to avail of the colonoscopy
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37 189 These costs were calculated by multiplying the time allocated for the completion of each task
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39 190 with the salary cost of the person who undertakes each task plus cost of consumables. Table 2
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41 191 shows the unit cost for each cost element, related assumptions, and data sources.
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194 **Table 2: Resources and unit costs**

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
<i>Current practice (opportunistic screening)</i>			
Performing screening (asking for symptoms, family history, referral) and taking sample	5.58	20 min x salary RM2947/month	1
Processing stool specimens	1.70	10 min x salary RM1797/month	2
Interpreting the test results	2.79	10 min x salary RM2947/month	1
Conveying a definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	30 min x salary RM2947/month	1
<i>Proposed practice (Population-based CRC screening programme)</i>			
Contact eligible individuals - agreed to participate	0.98	7.1 min x (salary RM1440/month + mobile package RM20/month)	3
Contact eligible individuals - rejected/excluded to participate	0.47	3.4 min x (same as above)	3
iFOBT rapid test kit	6.90		3
Print materials (instruction leaflet, explanatory statement)	1.10	90 cents for colour print + 20 cent for black & white print	3
Postage (stamps, etc.)	5.35		3
Sending video through WhatsApp	0.41	3 min x (salary RM1440/month + mobile package RM20/month)	3
Sending reminder text message	0.41	3 min x (same as above)	3
Reminder call	0.28	2 min x (same as above)	3
Interpreting the test kit result	1.70	10 min x salary RM1797/month	3
Sending text message to inform patient of negative result	0.45	2 min x (salary RM2350/month + mobile package RM20/month)	3
Calling patient to inform him/her of positive result	0.67	3 min x (same as above)	3
Preparing and sending referral letter to patient/clinic	1.12	5 min x (same as above)	3
Follow up effort	6.73	30 min x (same as above)	3
Developing communication materials, one-off cost	6,063	Communication materials do not change in 5 years	3

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
Training for data collectors*, one-off cost * Data collectors are those employed by the programme to (i) contact potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants	109,703	+ 1 day training (virtual using Zoom) + 1 trainer for maximum 25 trainees + 1 data collector* is needed for every target population of 400 + Cost=1-day-salary of trainer/trainees x number of trainer/trainees + No retraining in 5 years	3
Same in both scenarios/practices			
Colonoscopy (including polyps removal and/or biopsy if needed)	200		
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	RM8636.7/800 sets	3

iFOBT: Immunochemical faecal occult blood test; RM: Malaysian ringgit

Source:

1. Public Services Commission of Malaysia. Medical Officer Grade UD41. Accessed at <https://www.spa.gov.my/spa/laman-utama/gaji-syarat-lantikan-deskripsi-tugas/ijazah-sarjana-phd/pegawai-perubatan-gred-ud41>
2. Public Services Commission of Malaysia. Medical laboratory technologist Grade U29. Accessed at https://www.interactive.jpa.gov.my/ezskim/klasifikasi/perbikalanskim.asp?id_skim=3LU03
3. Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021

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196 In the current practice of opportunistic screening, doctors were consulted about the estimated

197 time to perform each stage in the pathway. The monthly salary of a general doctor and a medical

198 laboratory technologist was based on the rate published by the Public Services Commission of

199 Malaysia [20, 21]. These rates were RM2,947 (~I\$2,045) and RM1,797 (~I\$1,247), respectively.

200 In the novel CRC screening programme, the time to perform each stage in the pathway, salary

201 of personnel, and costs of material resources (e.g., rapid kit test, consumables, postage, printing

202 materials) were based on the time and expenditure observed in the CRC-SIM research project.

203 All costs were calculated per screen except the cost of training and the cost of developing

204 communication materials which were one-off costs based on the assumption that

205 communication materials would not change, and no re-training would be needed within 5 years.

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3 206 It was assumed (based on the experience of operating the screening programme during the
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5 207 CRC-SIM project) that one data collector (i.e., those employed by the programme to (i) contact
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7 208 potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants)
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9 209 would be needed for every 400 people in the target population. Training would last one day
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11 210 and would be delivered virtually; thus, the cost of training equalled (1-day-salary of trainer x
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13 211 number of trainer) + (1-day-salary of trainees x number of trainees/data collectors).
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19 213 **Perspective and time horizon**

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21 214 The BIA was conducted from the viewpoint of the federal government which finances
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23 215 Malaysia's public health system [22]. Only those costs and resource requirements relevant to
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25 216 the budget holder were included in the analysis. For example, the out-of-pocket expenditure
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27 217 incurred by patients were excluded.
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33 219 The analysis estimated the annual financial impact over a period of five years as recommended
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35 220 in the guidelines [11, 23]. Costs were not discounted given that the BIA methodology reports
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37 221 the costs for each year in which they occur rather than a net present value [11].
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42 223 **Budget impact analyses**

43 44 224 *Computing framework and base-case analysis*

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46 225 The BIA used a cost calculator programmed in Microsoft Excel, following the costing
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48 226 template¹ produced by the National Institute for Health and Care Excellence in the UK (NICE).
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50 227 The template was modified to fit the programme under assessment. The cost calculator
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¹ The template can be freely downloaded at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/budget-impact-template.xlsx>

228 approach is recommended by guidelines as it is easy for stakeholders to understand and
229 replicate the results [11].

230

231 First, the number of individuals who completed each stage was estimated (Table 1). The
232 resources that were used at each stage of the respective pathways (in opportunistic screening
233 and the novel CRC screening programme) were listed along with their unit costs (i.e., cost of
234 each resource per person) (Table 2). Unit costs were multiplied by number of users to give the
235 total cost of resources for each scenario. The net budget impact was calculated as the difference
236 in cost between opportunistic screening and the CRC screening programme. Visual depiction
237 of the cost calculator is shown in Supplementary Material, Figure S1.

238

239 *Uncertainty and scenario analyses*

240 The input assumptions (that were used to estimate the number of individuals at each stage of
241 the respective pathway) and the cost inputs were varied, and then the impact of these changes
242 in relation to the results was analysed to investigate the sensitivity of the budget impact results
243 to variations in individual input. As recommended by Gray et al. (2011), the range of variation
244 regarding parameters for which data sources about dispersion were unavailable were $\pm 20\%$ of
245 the base case [24].

246

247 **Patient and public involvement**

248 It was not appropriate or possible to involve patients or the public in the design, or conduct, or
249 reporting, or dissemination plans of our research as this type of study is a secondary analysis
250 of data from a payer perspective (Ministry of Health Malaysia).

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3 252 **RESULTS**
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6 253 **Base-case analysis**
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8 254 The total annual cost of the current practice of opportunistic screening is RM1,584,321
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10 255 (~I\$1,099,460), of which 80% (RM1,274,690 ~ I\$884,587) was for providing opportunistic
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12 256 CRC to adults who availed of the service. Costs of providing colonoscopy (including polyps
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14 257 removal and/or biopsy if needed) after receipt of a positive iFOBT and conveying definitive
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16 258 diagnosis to patients (along with explaining treatment plan or referral etc.) after the outcome
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18 259 of the colonoscopy were RM309,108 (~I\$214,509) and RM523 (~I\$363), respectively.
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24 261 The total annual cost over a 5-year period of the proposed practice (i.e., CRC screening
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26 262 programme) is shown in Table 3. It was assumed that the number of people who would agree
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28 263 to participate in the programme would increase by 5% each year (in consideration of health
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30 264 promotion activities as well as information flows including word of mouth between
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32 265 participants). Therefore, the financial impact would also increase accordingly.
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268 **Table 3: Annual cost of proposed practice (i.e., CRC screening programme)**

Currency: Malaysian ringgit (RM) and International Dollar (I\$)

Proposed practice	Year 1 RM (I\$)	Year 2 RM (I\$)	Year 3 RM (I\$)	Year 4 RM (I\$)	Year 5 RM (I\$)
Contacting adults who are eligible for CRC screening programme (i.e., aged 50-75) and screen for eligibility of participating	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)	2,320,148 (1,610,096)
Providing iFOBT test to adults who agreed to participate in CRC screening programme after being invited	93,654,886 (64,992,981)	102,612,907 (71,209,512)	111,570,928 (77,426,043)	120,528,949 (83,642,574)	129,486,970 (89,859,105)
Providing 1 st reminder to participants	536,929 (372,609)	588,286 (408,248)	639,643 (443,888)	690,999 (479,527)	742,356 (515,167)
Providing 2 nd reminder to participants	315,339 (218,833)	345,501 (239,765)	375,663 (260,696)	405,825 (281,627)	435,987 (302,559)
Interpreting returned iFOBT samples	1,165,129 (808,556)	1,276,572 (885,893)	1,388,016 (963,231)	1,499,460 (1,040,569)	1,610,903 (1,117,906)
Conveying result through message to participants with iFOBT negative result	251,990 (174,872)	276,093 (191,598)	300,196 (208,324)	324,298 (225,050)	348,401 (241,777)
Preparing and sending referral letter and calling participants with iFOBT POSITIVE result	221,356 (153,613)	242,529 (168,306)	263,701 (182,999)	284,874 (197,692)	306,046 (212,384)
Following up participants who DID NOT take colonoscopy after positive iFOBT	489,158 (339,457)	535,945 (371,926)	582,733 (404,394)	629,520 (436,863)	676,308 (469,332)
Providing colonoscopy (including polyps removal and/or biopsy if needed) to participants with positive iFOBT	10,127,147 (7,027,861)	11,095,801 (7,700,070)	12,064,455 (8,372,280)	13,033,109 (9,044,489)	14,001,764 (9,716,700)
Conveying definitive diagnosis to patients (along with explaining treatment plan or referral etc.) after the colonoscopy	18,432 (12,791)	20,195 (14,015)	21,958 (15,238)	23,721 (16,461)	25,484 (17,685)
Capital costs (Developing communication materials + Training for data collectors)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)	115,766 (80,337)
Total cost of proposed practice	109,216,279 (75,792,005)	119,429,743 (82,879,766)	129,643,206 (89,967,527)	139,856,670 (97,055,288)	150,070,133 (104,143,049)

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test

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3 270 Similar to opportunistic screening, the cost to provide iFOBT to the eligible population who availed
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5 271 of the service accounted for 86% of the total cost of the proposed CRC screening programme. The
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7 272 second most costly component was the provision of colonoscopy (including polyps removal and/or
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9 273 biopsy if needed) to patients with an iFOBT positive result, at 9% of the total cost. The remaining
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11 274 nine cost components such as contacting potential participants, reminding participants to send
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13 275 photograph of iFOBT result, conveying diagnosis to participants and the follow-up effort added
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15 276 only up to 5% of the total cost.
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21 278 The net budget impact in the 1st year of implementing CRC screening programme would be
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23 279 RM107,631,959 (~I\$74,692,546 which equalled the total cost of future practice minus the total
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25 280 cost of current practice). The impact increases each year as the number of people who agree to
26
27 281 participate in the programme increase, reaching RM117,845,422 (~I\$81,780,307) in year 2,
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29 282 RM128,058,885 (~I\$88,868,067) in year 3, RM138,272,349 (~I\$ 95,955,829) in year 4, and
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31 283 RM148,485,812 (~I\$103,043,589) in year 5.
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37 285 The net budget impact of providing and delivering the CRC screening programme over the 5-year
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39 286 timeframe for each state in Malaysia (calculated according to the population size of each state) can
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41 287 be accessed in Supplementary Material, Table S1. These estimates aid service planning decisions
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43 288 if the novel pilot programme is implemented in one or more of these states before being scaled up
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45 289 into nationwide programme.
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50 51 291 **Uncertainty and scenario analyses**

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53 292 The tornado diagram in Figure 3 shows the change to net budget impact when assumptions and
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55 293 cost inputs were varied. It presents the results of multiple univariate sensitive analyses on key
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57 294 inputs that exert the most influence on the net budget impact (See Table S2, Supplementary
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3 295 Material for results of multiple univariate sensitive analysis on all inputs). These inputs include
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5 296 the probability of (i) making successful contact with adults about the CRC screening programme,
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7 297 (ii) adults agreeing to participate, (iii) adults being eligible to participate in the programme, and
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9 298 (iv) the cost of consumables that are required to take a stool sample. The first three inputs
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11
12 299 influence the number of individuals who are present at each stage of the patient pathway.

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15 300 (Figure 3 is about here)

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17 301 The net budget impact would increase from RM107 million to RM130 million (~I\$74-90
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19 302 million) if there was a 20% increase in (i) the probability of adults who were contactable (from
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21 303 a contact list of people aged 50-75 years old) or (ii) the probability of adults agreeing to
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23 304 participate in the CRC screening programme or (iii) the probability of adults being eligible for
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25 305 the programme (i.e., aged 50-75 years old; having no symptoms of CRC, a smartphone, and
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27 306 WhatsApp; resident within programme area; and did not have colonoscopy this year). In other
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29 307 words, a 20% increase in each one of these factors would require an additional RM23 million
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31 308 (~I\$16 million) to be budgeted for the programme. Likewise, a 20% increase in the cost of the
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33 309 consumables that are required for taking stool samples would mean that the programme would
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35 310 cost RM15 million (~I\$10 million) more than the originally calculated total cost.
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41 42 43 312 **DICUSSION**

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46 313 The result of this analysis provides information to guide public health service planners and
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48 314 commissioners in their decisions about an alternative CRC screening strategy i.e., a population-
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50 315 based CRC screening programme using home-based iFOBT compared to current opportunistic
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52 316 screening. It concluded that the net budget impact in the 1st year of implementing a CRC
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54 317 screening programme of this kind would be RM107,631,959 (~I\$74,692,546). The impact
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56 318 would increase by year due to increase in uptake and would reach RM148,485,812
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58 319 (~I\$103,043,589) in the 5th year of implementation. This analytical approach and the results of
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3 320 this analysis are presented as aids to better decision making by MoHs and stakeholders in
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5 321 lower-middle-income countries (LMICs) about health programme planning and in this
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7 322 particular illustrative case to the MoHM regarding the degree to which the proposed CRC
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9 323 screening programme is affordable.

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14 325 The total budget that was allocated to the MoHM in 2022 was RM32.4 billion (~I\$22.5 million)
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16 326 [25]. Spending on prevention and public health services in 2009 was reported to be RM1.6
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18 327 billion (~I\$1.1 million) [22]. More recent data and information about the size of the budget that
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20 328 is allocated to cancer screening is not available. As such, it is estimated that the net budget
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22 329 impact of implementing a CRC screening programme would account for between 7-10% of the
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24 330 total budget for prevention and public health services. This represents a significant proportion
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26 331 of the overall budget allocated for prevention programmes/interventions.

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31 333 The key factor in the implementation of a population-based screening programme/service or the
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33 334 factor that has biggest impact on the budget is the size of the population who use the service. The
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35 335 degree of accuracy regarding population size estimates is related closely to the cost estimates in
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37 336 the budget. It is important for service planners to keep this point in mind and to take into account
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39 337 an increase in uptake and the impact of such an increase. Therefore, in the case of the CRC
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41 338 programme presented here, we assumed a 5% increase annually in uptake and calculated the net
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43 339 budget impact. The net budget impact can be recalculated according to the actual change in uptake
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45 340 after the programme is implemented.

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50 342 Budget impact analysis is an economic assessment that is used to estimate the changes in
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52 343 expenditure of a specific budget holder if a new health technology/programme is implemented
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54 344 [11]. As such, BIA complements other health economic evaluation methods such as cost-

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3 345 effectiveness analysis (CEA) to provide a comprehensive economic assessment of a health care
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5 346 intervention to decision makers [11]. A BIA aids decision making by health service planners
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7 347 and commissioners about whether an intervention or programme is affordable within given
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9 348 budget constraints while a CEA informs decisions about whether an intervention is good value
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11 349 for money [11, 26]. BIA and its pragmatic approach is an ideal method when a situation calls
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13 350 for an evaluation of 'affordability' which is of central importance in LMICs and, arguably, is
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15 351 the key concern of whoever is in charge of managing a health care budget [27, 28].
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22 353 It could well be that savings in earlier treatment would counterbalance the additional budget
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24 354 impact. Likewise, reduction in travel and time costs of participant while using home-based
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26 355 screening would reduce the total costs of the screening programme from a societal perspective.
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28 356 However, a BIA is not intended to provide answers to questions about whether or not, in this
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30 357 context, the screening programme is good value for money as it does not take into account the
31
32 358 potential improvements in outcomes (e.g., increase quality-related life years) and savings from
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34 359 lower treatment costs for CRC diagnosed at earlier stages. The conduct of other types of
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36 360 economic evaluations such as a cost-effectiveness analysis would be required to provide a
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38 361 complete and comprehensive set of evidence for decision makers.
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45 363 Finally, the conduct of BIA in this paper has some limitations. First, assumptions and cost
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47 364 inputs for the CRC screening programme were based on the costs and rates that were observed
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49 365 in the CRC-SIM research project. Due to unavailability of data about dispersion of the
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51 366 parameters, the used range of variation ($\pm 20\%$ of the base case) may overestimate the
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53 367 uncertainty and suggests that the next step for further research is a CEA where parameter
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55 368 uncertainty is investigated with actual data. The project was conducted in only one district
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57 369 (Segamat); and the distribution of three main ethnic groups (i.e., Malay, Chinese, Indian) in
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3 370 the project differed from the proportions that have been reported nation-wide (72%:24%:3%
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5 371 vs 62%:21%:6%, respectively). Therefore, it is important to be mindful of the possibility that
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7 372 the assumptions and inputs (based on the project) may not be representative for, or read across
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10 373 to, the whole population of Malaysia. Likewise, it is important to bear in mind that our findings
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12 374 do not include the perspective of other payers and may not generalise to other settings. The
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14 375 results are related directly to the context of the Malaysian health system and the epidemiology
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16 376 of CRC in the country though they are illustrative of the positive contribution of the BIA
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18 377 methodology and approach.
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23 24 25 379 **CONCLUSIONS**

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27 380 This study employed a BIA methodology to analyse the costs of a novel CRC screening
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29 381 programme using home-based iFOBT and mHealth versus the current opportunistic screening.
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31 382 The findings estimated the net budget impact of implementing a population-based national
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33 383 CRC screening programme in Malaysia. The modelling estimations are important
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35 384 considerations for health authorities when they are required to decide the affordability of
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37 385 implementing a programme and to aid budgetary planning as well as decision making,
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39 386 generally, about implementation. Our study illustrates the use and value of the BIA approach
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41 387 in LMICs and resource-constrained settings.
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47 388 **Abbreviations**

48	BIA	Budget impact analysis
49	CEA	Cost-effectiveness analysis
50	CRC	Colorectal cancer
51	CRC-SIM	Colorectal Cancer Screening Intervention for Malaysia
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3	iFOBT	Immunochemical faecal occult blood test
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5	I\$	International Dollar
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8	ISPOR	The Professional Society for Health Economics and Outcomes Research
9		
10	MoHM	Ministry of Health of Malaysia
11		
12	NICE	National Institute for Health and Care Excellence
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15	RM	Malaysian ringgit
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17	SEACO	Southeast Asia Community Observatory
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19	UK	The United Kingdom
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389

390 **DECLARATIONS**

391 **Research ethics approval.** Not applicable (This study does not involve human participants).

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 393 Challenges Research Fund (MR/S014349/1) and the National Medical Research Register
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 395 data collection, data analysis, data interpretation, or writing of the report.

396 **Competing interests.** The authors have no conflicts of interest to declare that are relevant to
 397 the content of this article.

398 **Availability of data and material.** All data generated or analysed during this study are
 399 included in this published article.

400 **Authors' contributions.** TTN: Methodology, Formal Analysis, Writing – Original draft, Writing –
 401 Review & Editing. KR, MRS, and DS: Data Curation, Investigation, Writing – Review & Editing. ST:
 402 Resources, Writing – Review & Editing. TTS, and MD: Conceptualization, Funding acquisition,
 403 Writing – Review & Editing, Supervision. CON: Methodology, Formal Analysis, Writing – Review &
 404 Editing, Supervision.

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484 **Figure Legends and Tables**

485 Table 1 Input assumptions used to estimate the population at each stage of the patient pathways

486 Table 2 Resources and unit costs

487 Table 3 Annual cost of proposed practice (i.e., CRC screening programme)

488
489 Figure 1 Patient pathways in 'usual care' practice - opportunistic screening for CRC

490 Figure 2 Patient pathway in population-based CRC screening programme

491 Figure 3 Results of multiple univariate sensitive analyses showing key factors that exert most
492 influence the net budget impact

1
2
3 493 **Supplementary material**
4

5 494 Figure S1 Visual depiction of the budget impact cost calculator
6

7
8 495 Table S1 Net budget impact of CRC screening programme over 5-year timeframe, by state
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10 496 Table S2 Sensitivity of the total budget impact of CRC screening programme to changes in
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12 497 each variable individually
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Figure 1: Patient pathway in 'usual care' practice - opportunistic screening for CRC

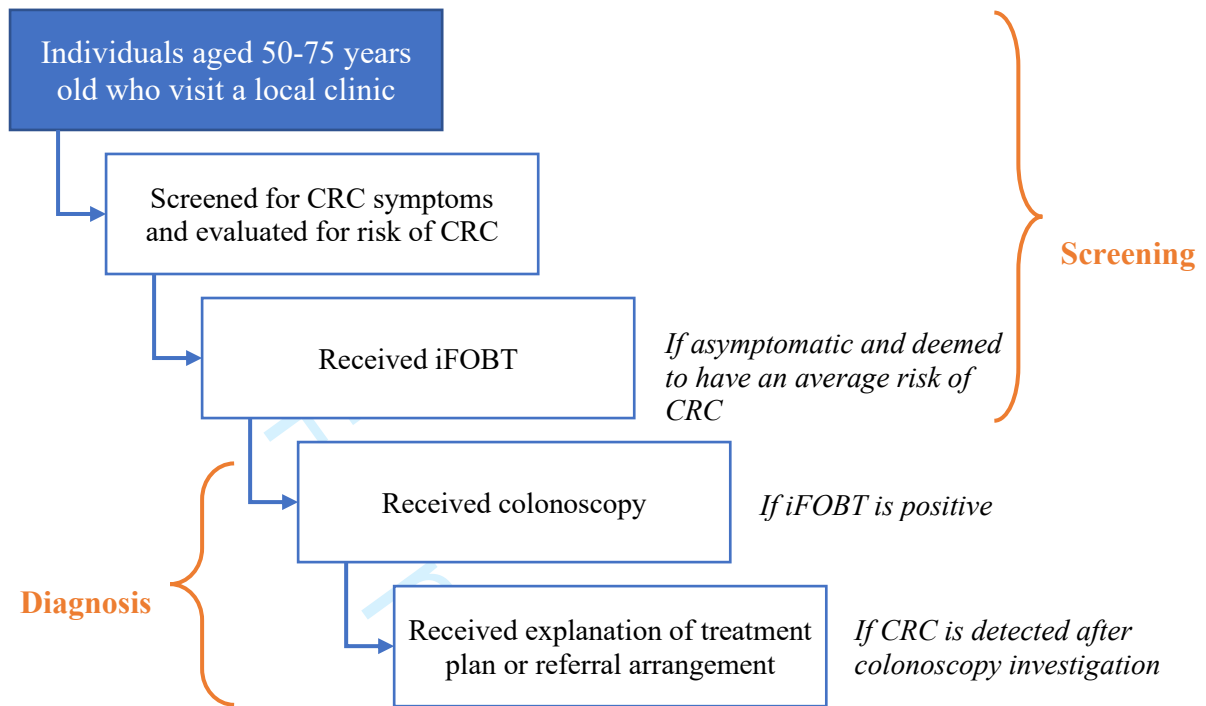


Figure 2: Patient pathway in population-based CRC screening programme

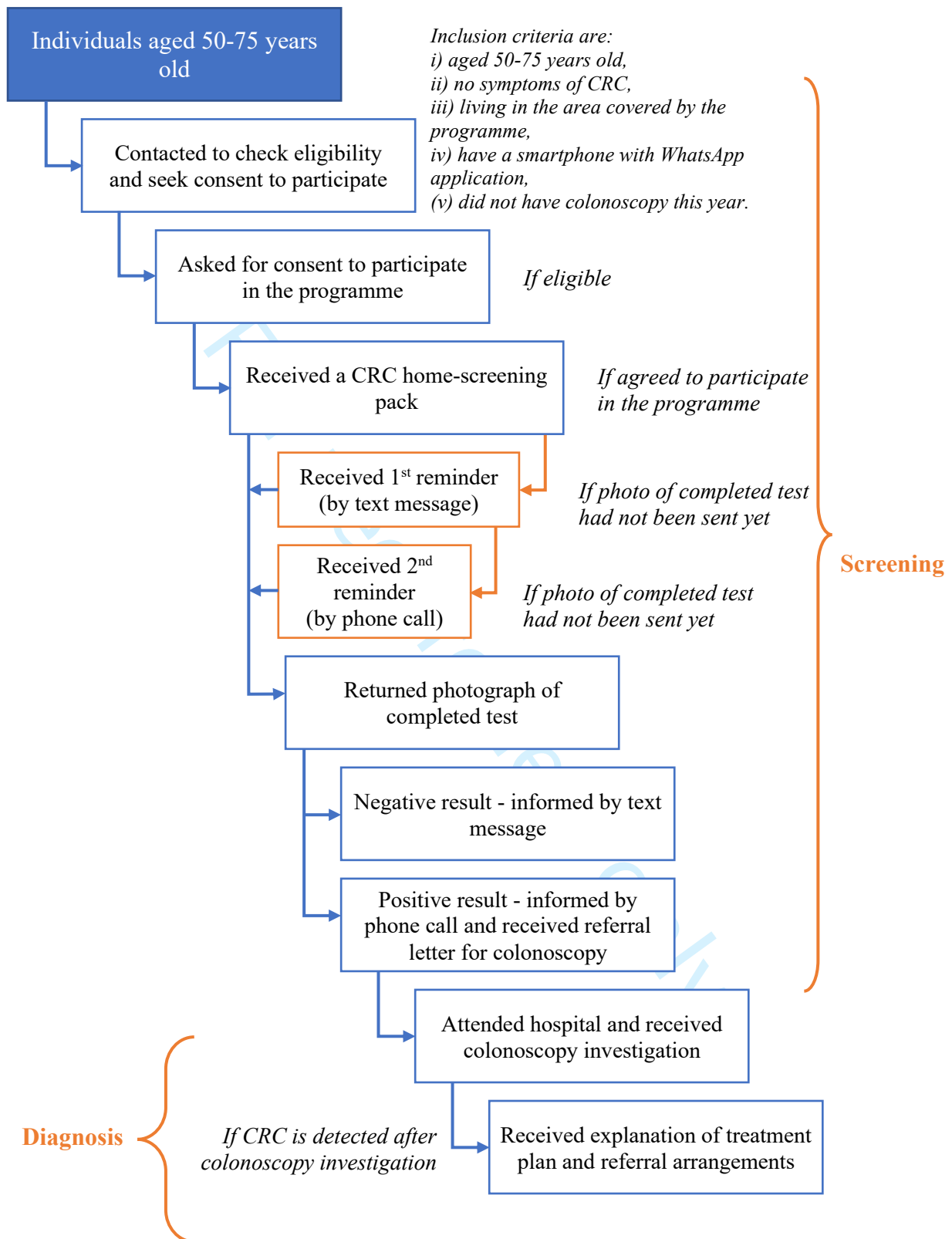
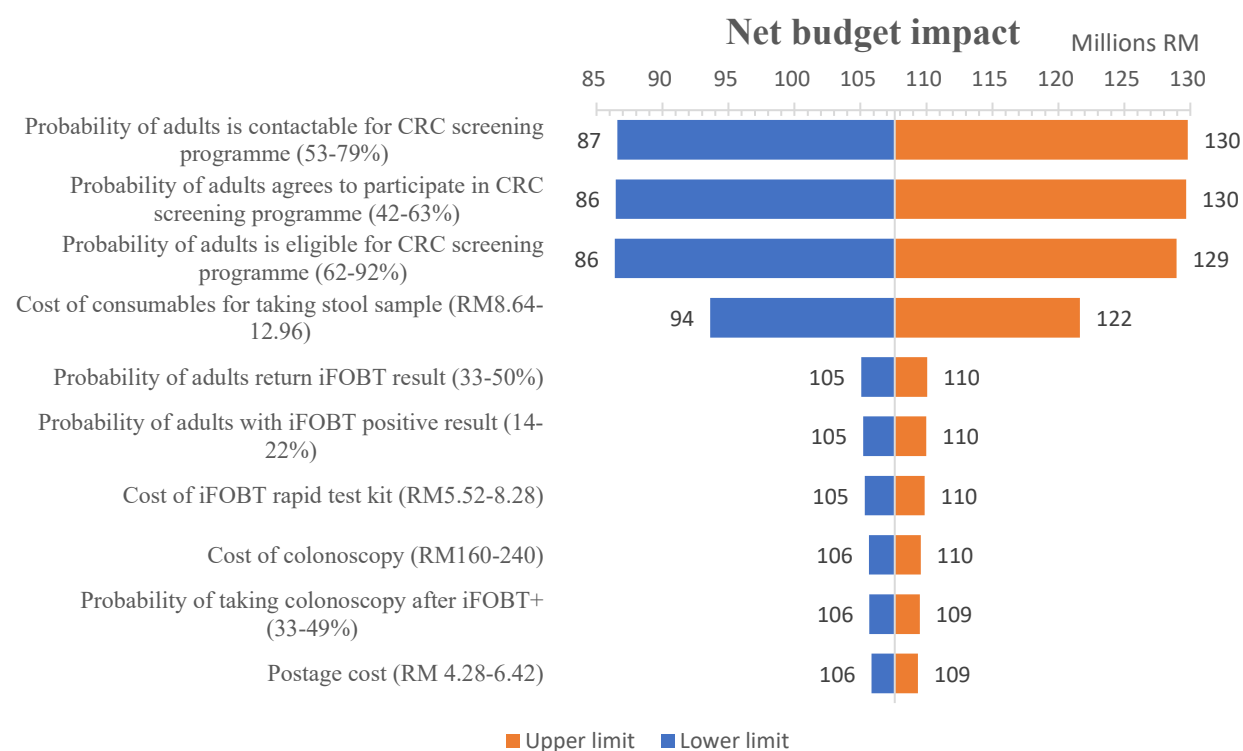
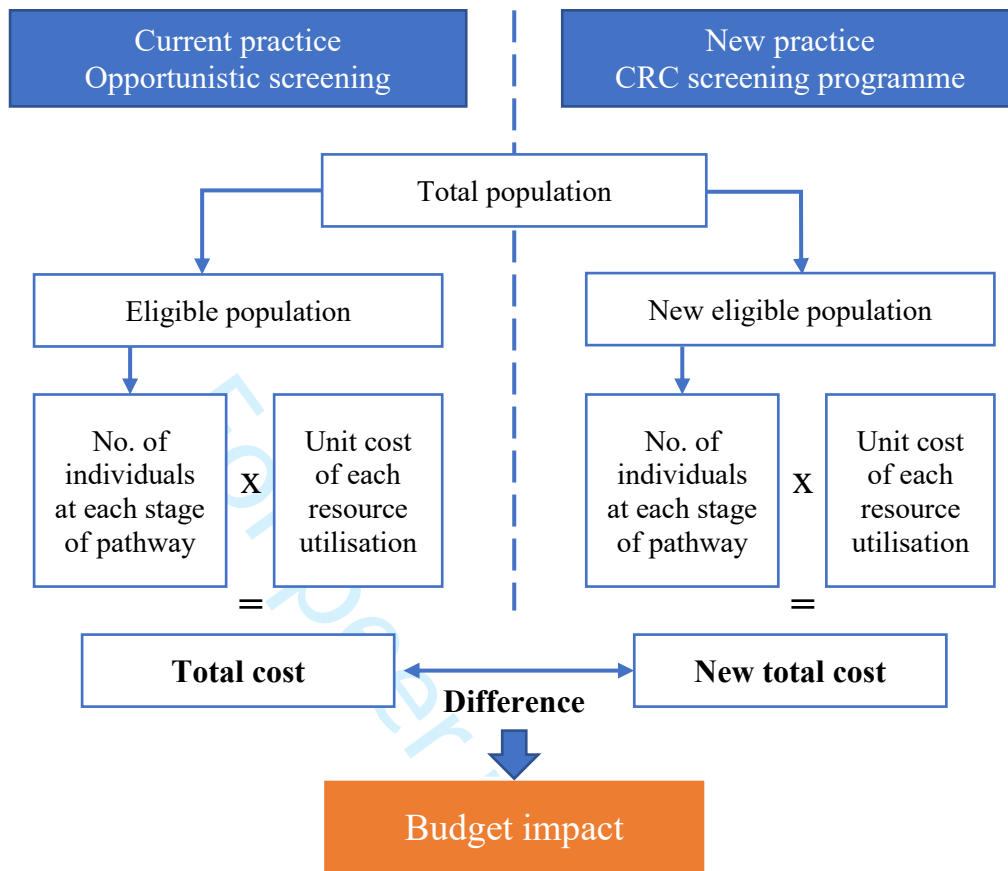


Figure 3: Results of multiple univariate sensitive analyses showing key factors that exert most influence the net budget impact



Supplementary material

Figure S1: Visual depiction of the budget impact cost calculator



Supplementary material

Table S1: Net budget impact of CRC screening programme over 5-year timeframe, by state

Currency: Malaysian ringgit

State	Population	Year 1	Year 2	Year 3	Year 4	Year 5
Johor	3,822,800	12,597,041	13,791,897	14,986,752	16,181,607	17,376,462
Kedah	2,206,200	7,272,541	7,962,112	8,651,682	9,341,252	10,030,823
Kelantan	1,884,300	6,212,311	6,801,268	7,390,225	7,979,183	8,568,140
Melaka	934,700	3,084,637	3,376,787	3,668,937	3,961,087	4,253,238
Negeri Sembilan	1,141,000	3,764,122	4,120,753	4,477,384	4,834,016	5,190,647
Pahang	1,702,900	5,614,833	6,147,092	6,679,351	7,211,609	7,743,868
Perak	2,569,300	8,468,450	9,271,511	10,074,572	10,877,633	11,680,693
Pulau Pinang	1,767,100	5,826,301	6,378,626	6,930,951	7,483,276	8,035,601
Sabah	3,919,600	12,915,864	14,140,975	15,366,086	16,591,197	17,816,308
Sarawak	2,829,400	9,325,144	10,209,501	11,093,859	11,978,217	12,862,575
Terengganu	1,245,300	4,107,648	4,496,879	4,886,111	5,275,342	5,664,573
Perlis	253,500	841,028	920,262	999,496	1,078,730	1,157,964
W.P. Kuala Lumpur	1,790,100	5,902,043	6,461,557	7,021,071	7,580,585	8,140,099
W.P. Labuan	99,000	332,138	363,081	394,024	424,968	455,911
W.P. Putrajaya	97,100	325,886	356,236	386,585	416,935	447,284
Nation-wide	32,676,786	107,631,959	117,845,422	128,058,885	138,272,349	148,485,812

CRC: Colorectal cancer | W.P.: The Federal Territories (Malay: Wilayah Persekutuan)

Readers can convert from Malaysian Ringgit to their currency of interest (e.g., International Dollar, US Dollar, British Pound, Euro etc.) using the free web-based tool ‘CCEMG – EPPI-Centre Cost Converter’ (<https://eppi.ioe.ac.uk/costconversion/default.aspx>). This tool help adjusting estimates of cost expressed in one currency and price year to a specific target currency and price year.

Supplementary material

Table S2: Sensitivity of the total budget impact of CRC screening programme to changes in each variable individually

Baseline budget impact=RM107,631,959

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Probability of adults is contactable for CRC screening programme	66%	53%	79%	86,574	129,818	43,244
Probability of adults is included (eligible for CRC screening programme)	77%	62%	92%	86,386	128,950	42,564
Probability of adults agree to participate in CRC screening programme after being invited	52%	42%	63%	86,454	129,675	43,221
Probability of adults needing 1st reminder	79%	63%	94%	107,430	107,766	336
Probability of adults needing 2nd reminder	88%	70%	100%	107,535	107,643	108
Probability of adults return iFOBT result	42%	33%	50%	105,062	110,060	4,998
Probability of adults with iFOBT positive result	18%	14%	22%	105,204	109,988	4,784
Probability of adults taking colonoscopy after positive iFOBT	41%	33%	49%	105,673	109,493	3,820
Probability of adults with CRC detection after getting colonoscopy	4%	3%	5%	107,594	107,603	9
Cost to perform the screening (asking for symptoms, family history, referral)	5.58	4.47	6.70	107,633	107,567	-66
Cost of stool specimen processing	1.70	1.36	2.04	107,610	107,590	-20
Interpretation of results	2.79	2.23	3.35	107,617	107,583	-34
Cost to convey definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	6.70	10.05	107,597	107,604	7
Contact eligible individuals - agreed to participate	0.98	0.79	1.18	107,285	107,926	641
Contact eligible individuals - rejected/excluded to participate	0.47	0.38	0.56	107,465	107,735	270
iFOBT rapid test kit (only the rapid test kit itself)	6.90	5.52	8.28	105,331	109,870	4,539
Print materials (instruction leaflet, explanatory statement)	1.10	0.88	1.32	107,238	107,962	724
Postage (stamp etc.)	5.35	4.28	6.42	105,840	109,360	3,520
Sending video through Whatapp	0.41	0.33	0.50	107,461	107,740	279
Sending reminder text message	0.41	0.33	0.50	107,490	107,710	220
Reminder call	0.28	0.22	0.33	107,536	107,661	125
Interpret the test kit result	1.70	1.36	2.04	107,366	107,832	466

Supplementary material

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Sending text message informing negative result	0.45	0.36	0.54	107,550	107,651	101
Call to inform positive result	0.41	0.33	0.50	107,590	107,611	21
Prepare and send referral letter	1.12	0.90	1.35	107,573	107,628	55
Follow up effort	6.73	5.39	8.08	107,503	107,698	195
Colonoscopy	200	160	240	105,638	109,564	3,926
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	8.64	12.96	93,612	121,641	28,029

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ISPOR—The Professional Society for Health Economics and Outcomes Research

Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force

Citation: Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, Orlewska E, Penna P, Rodriguez Barrios JM, Shau WY. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014 Jan-Feb;17(1):5-14. doi: <https://doi.org/10.1016/j.jval.2013.08.2291>

Recommendations for Reporting Format

Section/topic	Guidance for reporting	Reported in section
Introduction		
Objectives	The objective of the BIA should be clearly stated and tied to the study perspectives	Introduction
Epidemiology and management of health problem	Present information about the prevalence and incidence of the particular disease, disease severity, disease progression, undiagnosed or undertreated cases, and risk factors pertinent to estimating the budget impact	Introduction
Clinical impact	Consist of a brief description of the eligible population and existing management options and their efficacy and safety that are relevant to the design of the study of the BIA	Introduction
Economic impact	Include a brief description of previous BIAs in the condition of interest for another intervention and condition-specific treatment patterns and cost-of-care studies	Not applicable (No previous BIA)
Study Design and Methods		
Patient population	Specify the eligible population for the new intervention	Methods Sub-section: Eligible population and input assumptions Table 1
Intervention mix	Contain a detailed description of the use and characteristics of each intervention in the current intervention mix and in the expected intervention mix after the introduction of the new intervention	Methods Sub-section: Health service under assessment and its comparator Figure 1 and 2
Time horizon	Should be presented and the choice(s) justified	Methods Sub-section: Perspective and time horizon
Perspective	Identify the BIAs' perspective(s), the cost categories included, and the intended audience	Methods Perspective and time horizon

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Section/topic	Guidance for reporting	Reported in section
Analytic framework description	Complete description of the structure of the BIA cost calculator or condition-specific cohort or individual simulation model	Methods Sub-section: Eligible population and input assumptions
Input data	Input values used for the reported analyses, including alternative scenarios, should be presented	Methods Sub-section: Cost input and data sources Table 2
Data sources	The sources of data inputs should be described in detail	Methods Sub-section: Cost input and data sources Table 2
Data collection	The methods and processes for any primary data collection and data abstraction tasks not reported elsewhere should be described and explained.	Not applicable (secondary data)
Analyses	A description of the calculations used to complete the BIA should be provided. The choice of all the scenarios presented in the results should be documented and justified.	Methods Sub-section: Computing framework and base-case analysis under budget impact analyses
Uncertainty	Uncertainty analysis methods should be described and justified	Methods Sub-sections: Uncertainty and scenario analyses under budget impact analyses
Results	The budget impact should be presented for each budget period over the time horizon. Both budget period resource use and costs should be presented. The estimates of resource use should be listed in a table that shows the change in use for each time period reported in the BIA The results of the uncertainty analyses and scenarios analyzed should be described and presented in figures or tables	Results Table 3 Results Figure 2
Conclusions and Limitations	State the main conclusions on the basis of the results of the BIA. Report the main limitations regarding key issues such as design aspects including off-label use and adherence assumptions and the completeness and quality of data inputs and sources.	Discussion Conclusion
Inclusion of Graphics and Tables		
Figure of the analytical framework	Flow diagrams or other visual depictions of the cost calculator or condition-specific cohort or individual simulation model are recommended to be included with the analytical framework description.	Supplementary material Figure S1

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Section/topic	Guidance for reporting	Reported in section
Table of assumptions	All the major assumptions should be listed in a tabular form	Table 1
Tables of inputs	All the input parameter values and their data sources and derivations should be presented in a tabular form	Table 2
Tables of outputs	All outputs should be presented in a tabular and/or graphical Form	Table 3
Schematic representation of uncertainty analyses	Diagrams such as Tornado diagrams should be included along with the text on the results of the scenario analyses	Figure 3
Appendices and References	The appendices may cover literature search strategies, evidence summaries, intermediate results (e.g., of individual Delphi panel rounds), and the names and addresses of participating experts and investigators, for example.	Reference

CHEERS 2022 Checklist

Topic	No.	Item	Location where item is reported
Title			
	1	Identify the study as an economic evaluation and specify the interventions being compared.	Title page, Page 1
Abstract			
	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	Abstract, Page 1
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Introduction, Line 65-69
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Not applicable
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Methods, Line 123-152, Table 1
Setting and location	6	Provide relevant contextual information that may influence findings.	Methods, Line 79-92
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Methods, Line 79-121, Figure 1 and 2
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Methods, Line 199-202
Time horizon	9	State the time horizon for the study and why appropriate.	Methods, Line 204-205
Discount rate	10	Report the discount rate(s) and reason chosen.	Methods, Line 205-206
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Not applicable

Topic	No.	Item	Location where item is reported
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Not applicable
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Not applicable
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Methods, Line 159-196
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Methods, Line 73-76
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	Not applicable
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	Methods, Line 211-221, Figure S1 (Supplementary Material)
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Not applicable
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	Not applicable
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis.	Methods, Line 224-229, Figure S2 (Supplementary Material)
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	Methods, Line 233-235
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Table 1 and 2, Table S2 (Supplementary Material)
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Results, Line 239-274, Table 3

Topic	No.	Item	Location where item is reported
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Results, Line 277-295, Figure 3
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	Not applicable
Discussion			
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Discussion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	End of manuscript
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	End of manuscript

From: Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value Health 2022;25. doi:10.1016/j.jval.2021.10.008

BMJ Open

A budget impact analysis of a home-based colorectal cancer screening programme in Malaysia

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Complete List of Authors:	Ngan, Tran; Queen's University Belfast, Centre for Public Health Ramanathan, Kogila; Monash University Malaysia, Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences; Monash University Malaysia, South East Asia Community Observatory Saleh, Muhamad; Monash University Malaysia, South East Asia Community Observatory Schliemann, Desiree ; Queen's University Belfast, Centre for Public Health Ibrahim Tamin, Nor Saleha ; Ministry of Health Malaysia Su, Tin ; Monash University Malaysia, Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences; Monash University Malaysia, South East Asia Community Observatory Donnelly, Michael; Queen's University Belfast, Centre for Public Health O'Neill, Ciaran; Queen's University Belfast, Centre for Public Health
Primary Subject Heading:	Health economics
Secondary Subject Heading:	Global health, Public health, Oncology
Keywords:	Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, HEALTH ECONOMICS, PUBLIC HEALTH

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3 **A budget impact analysis of a home-based colorectal cancer screening**
4 **programme in Malaysia**
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9 Tran Thu Ngan^{1*}, Kogila Ramanathan^{2,3}, Muhamad Raziq Bin Mohd Saleh³, Désirée
10 Schliemann¹, Nor Saleha Binti Ibrahim Tamin⁴, Tin Tin Su^{2,3}, Michael Donnelly¹, Ciaran
11 O'Neill¹
12
13

14
15
16 ¹ *Centre for Public Health, Queen's University Belfast, Belfast, UK*

17
18 ² *Global Public Health, Jeffrey Cheah School of Medicine and Health Sciences, Monash*
19 *University Malaysia, Selangor, Malaysia*
20

21
22 ³ *South East Asia Community Observatory (SEACO), Jeffrey Cheah School of Medicine and*
23 *Health Sciences, Monash University Malaysia*
24

25
26 ⁴ *Ministry of Health Malaysia, Putrajaya, Malaysia*
27
28

29
30
31
32 * Correspondence to:

33
34 Tran Thu Ngan, PhD

35
36 Postal address: Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom

37
38 Email: n.t.tran@qub.ac.uk
39
40
41

42
43 ORCID of the authors

44
45 Tran Thu Ngan : 0000-0003-2771-9878

46
47 Désirée Schliemann : 0000-0002-8746-3002

48
49 Ciaran O'Neill : 0000-0001-7668-3934
50
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52
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1 A budget impact analysis of a home-based colorectal cancer screening 2 programme in Malaysia

3 Abstract

4 **Objectives:** The 2020-2022 research project ‘Colorectal Cancer Screening Intervention for
5 Malaysia’ (CRC-SIM) evaluated the implementation of a home-based CRC screening pilot in
6 Segamat District. This budget impact analysis (BIA) assessed the expected changes in health
7 expenditure of the Malaysian Ministry of Health budget in the scenario where the pilot
8 programme was implemented nationwide versus current opportunistic screening.

9 **Design:** Budget impact analysis. Assumptions and costs in the opportunistic and novel CRC
10 screening scenarios were derived from a previous evaluation of opportunistic CRC screening in
11 community health clinics across Malaysia and the CRC-SIM research project, respectively.

12 **Setting:** National level (with supplement analysis for district level). The BIA was conducted
13 from the viewpoint of the federal government and estimated the annual financial impact over
14 a period of five years.

15 **Results:** The total annual cost of the current practice of opportunistic screening was RM1,584,321
16 (~I\$1,099,460; RM=Ringgit Malaysia; I\$=International dollar) of which 80% (RM1,274,690 or
17 ~I\$884,587) was expended on the provision of opportunistic CRC to adults who availed of the
18 service. Regarding the implementation of national CRC screening programme, the net budget
19 impact in the 1st year was estimated to be RM107,631,959 (~I\$74,692,546) and to reach
20 RM148,485,812 (~I\$103,043,589) in the 5th year based on an assumed increased uptake of 5%
21 annually. The costs were calculated to be sensitive to the probability of adults who were
22 contactable, eligible, and agreeable to participating in the programme.

23 **Conclusions:** Results from the BIA provided direct and explicit estimates of the budget
24 changes to when implementing a population-based national CRC screening programme to aid
25 decision making by health services planners and commissioners in Malaysia about whether
26 such programme is affordable within given their budget constraint. The study also illustrates
27 the use and value of the BIA approach in LMICs and resource-constrained settings.

28 **Keywords:** Colorectal cancer screening, budget impact analysis, home-based testing, global
29 health, Malaysia

Strengths and limitations of this study

- The budget impact analysis (BIA) was used to evaluate the ‘affordability’ of colorectal cancer (CRC) screening programme in Malaysia within given budget constraint.
- Assumptions and cost inputs for modelling the budget impact were based on the actual costs and rates observed in Malaysia.
- The total cost of resources (=unit costs * number of users) for opportunistic screening and the CRC screening programme were compared to calculate the net budget impact.
- The BIA was conducted from the viewpoint of the federal government and only included costs and resource requirements relevant to this particular budget holder.
- The BIA could not and was not intended to provide answers to questions about whether or not the screening programme is good value for money (which can be answered by a cost-effectiveness analysis).

INTRODUCTION

Colorectal cancer (CRC) has the second highest incidence and mortality rate among all types of cancer in both sexes in Malaysia [1]. The age standardised incidence rate in 2012-2016 was 14.8 per 100,000 males and 11.1 per 100,000 females which appears to be stable compared to 2007-2011 [2]. In contrast, the proportion of CRC patients who are diagnosed at a late stage (i.e., stage III or IV) is increasing. Report from Ministry of Health Malaysia (MoHM) showed that the proportion of males with late stage CRC increased from 65.9% during 2007-2011 to 72.4% during 2012-2016; and from 65.2% to 73.1% for females [2]. The report did not give an explanation about this increasing trend though [2]. Late stage diagnosis negatively impacts survival rate; for example, the 5-year survival rates for cases diagnosed at stage I, II, III, and IV in 2002-2004 in Kuala Lumpur were 78.6%, 52.9%, 44.3%, and 9.3%, respectively [3]. Improved survival can be achieved by early detection through screening and the removal of premalignant polyps [4]. However, Malaysia currently does not have a population-based national CRC screening programme.

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3 46 The Ministry of Health of Malaysia (MoHM) adopted the use of immunochemical faecal occult
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5 47 blood test (iFOBT) for opportunistic CRC screening at public health clinics since 2014 [5].
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7 48 MoHM guidelines recommend screening for asymptomatic individuals aged 50-75 years old
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9 49 with average risk of CRC [6]. The uptake (number of patients screened/total eligible
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11 50 population) of this opportunistic screening tends to be very low. The annual average uptake
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13 51 during 2014-2018 was 0.5% while the 5-year cumulative uptake was 2.29% due to low
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15 52 awareness about CRC in general and CRC tests in particular, fear of the result, concern about
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17 53 the cost, and absence of a doctor's recommendation [5, 7]. Home-based iFOBT has been
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19 54 implemented in many high-income countries (HICs) to improve the accessibility and uptake of
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21 55 CRC screening [8]. In this context, the Southeast Asia Community Observatory (SEACO) at
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23 56 Monash University Malaysia and Queen's University Belfast (Northern Ireland) collaborated
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25 57 to conduct the research project, 'Colorectal Cancer Screening Intervention for Malaysia'
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27 58 (CRC-SIM) in 2020-2022. This project evaluated the implementation of a home-based CRC
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29 59 screening pilot in Segamat District. The uptake of the novel screening programme was 22%.
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31 60 The significantly higher uptake indicates the potential population wide impact if this screening
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33 61 approach (i.e., using home-based iFOBT and self-reporting test results) was scaled up.
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35 62 However, in order to aid public health decision making, there is a need to model a scaled-up
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37 63 version of the research-tested screening programme and, more specifically, gather insights
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39 64 about the total costs of programme implementation and how it might impact the MoHM budget.
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41 65 In other words, there is a need for a budget impact analysis (BIA).
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51 67 Budget impact analysis was first introduced in 1998 by Mauskopf [9, 10]. Since then, BIA is
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53 68 gradually requested as a part of the health technology assessment (HTA) procedure by a few
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55 69 countries around the world such as Australia, Canada, the United States (the US), England,
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57 70 Ireland, Spain, Belgium, Poland, Israel, and Thailand [11]. Regarding BIA for colorectal cancer
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3 71 (CRC) screening, a recent systematic review found six studies conducted in the UK, US,
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5 72 Belgium, and Australia [12]. We found two additional studies published in 2018 and 2019 from
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7 73 Spain and Thailand, respectively [13, 14]. Although results from these studies are not
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9 74 comparable as they were specific to each studied country, all studies were conducted to answer
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11 75 the question ‘What is the budget impact of implementing a colorectal cancer
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13 76 screening/prevention programme compared with current usual care’. It is also the research
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15 77 question that the BIA in this study aims to answer. Specifically, the BIA assessed the expected
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17 78 changes in the health expenditure of MoHM budget as a result of implementing a population-
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19 79 based national CRC screening programme versus current opportunistic screening (or ‘usual
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21 80 care’). It assessed the affordability of the screening programme given potential budget
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23 81 constraints.
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32 **METHODS**

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34 84 The conduct of this BIA and presentation of this paper followed the guidelines developed by
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36 85 the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force
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38 86 [11, 15]. All costs are presented in local currency -the Malaysian Ringgit (RM)- and
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40 87 International Dollar (I\$). RM was converted to I\$ using purchasing power parity (PPP)
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42 88 conversion factors instead of market exchange rates. The PPP conversion rate of 1.441 was
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44 89 obtained from the IMF World Economic Outlook Database [16].
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51 **Health service under assessment and its comparator**

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53 92 The specific health service that was the focus of the BIA was a population-based screening
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55 93 programme for colorectal cancer using a self-rapid response iFOBT. The comparator was
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57 94 current or ‘usual care’ - opportunistic screening.
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3 96 The BIA is predicated on the opportunistic screening programme being replaced by the new
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5 97 population-based screening programme (i.e., the two programmes would not be run in
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7 98 conjunction or in other words, the two scenarios in assessment are mutually exclusive). In each
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10 99 scenario, the patient pathway from the point when patients were invited for screening to receipt
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12 100 of a definitive diagnosis were identified and described. The screening procedure ends at the point
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14 101 of a patient receiving their iFOBT result with encouragement to attend hospital for a colonoscopy
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16 102 (if iFOBT is positive). It is important to note that the BIA included costs of screening and
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18 103 diagnosis (e.g., colonoscopy, biopsy) but not treatment. The BIA also did not address issues with
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20 104 respect to equity of access and uptake of services in either screening scenarios.
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26 106 The patient pathways for the 'usual care' practice and the novel CRC screening programme are
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28 107 presented in Figure 1 and 2, respectively. In opportunistic screening practice, it is recommended
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30 108 or expected that individuals who are aged 50-75 years will be screened for CRC symptoms
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32 109 when they attend their local health clinic (for any health condition or problem). If they are
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34 110 asymptomatic and have an average risk of having CRC (based on family history), they are
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36 111 offered an iFOBT, followed by a colonoscopy if the iFOBT test was positive. If CRC is
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38 112 detected following a colonoscopy, the result is conveyed to a patient along with an explanation
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40 113 of the treatment plan or referral arrangement.
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44 114 (Figure 1 is about here)

46 115 Details of the home-based screening intervention in CRC-SIM were published elsewhere [17].
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48 116 Briefly, in the novel CRC screening programme, individuals aged 50-75 years were contacted,
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50 117 checked for eligibility, and invited to participate. A home-screening 'pack' was posted to eligible
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52 118 participants followed by two reminders. The test was performed at home by participants who took
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54 119 a photograph of the completed test and texted it to trained medical professionals who interpreted
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56 120 the photograph. Participants with positive iFOBT were referred for a colonoscopy at hospital.
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3 121 (Figure 2 is about here)
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5 122 There were two main differences between these patient pathways. Firstly, individuals within
6
7 123 the target age group for screening were contacted directly and invited to participate in the novel
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9 124 CRC screening programme while in the situation of 'usual care', CRC screening was offered
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11 125 (if screening guideline recommendations were followed) only when members of the target
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13 126 group visited their clinic for some other health condition or problem. Secondly, the iFOBT was
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15 127 performed by doctors at health clinics in the 'usual care' pathway while in the novel CRC
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17 128 screening programme, participants self-tested in their home. Home-based testing generated
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19 129 additional stages in the pathways in relation to sending a test, reminding participants, taking a
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21 130 photo of a completed test, and sending it to programme officers and vice versa. The remaining
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23 131 stages of each pathway (e.g., being screened for eligibility, receiving a colonoscopy, and
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25 132 receiving a treatment plan) were the same across the two scenarios.
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32 33 134 **Eligible population and input assumptions**

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35 135 The target population for current opportunistic screening in Malaysia is individuals aged 50-
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37 136 75 years, regardless of sex. Due to the nature of home-based screening, the target population
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39 137 for the CRC screening programme was required to meet some additional inclusion criteria as
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41 138 presented in Figure 2. The number of individuals who presented and completed each stage was
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43 139 estimated using input assumptions.
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49 141 Data about the population of Malaysia by age was taken from government reports (i.e.,
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51 142 Department of Statistics, Malaysia) and from World Population Review [18, 19]. The total
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53 143 population was reported to be 32,676,786 in 2021, of which, 19% or 6,228,195 were aged 50-
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55 144 75 years old [18, 19].
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3 146 **In the ‘usual care’ – opportunistic screening pathway or scenario**, all assumptions were
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5 147 derived from a study by Tamin NSI (2020) which was a 5-year evaluation of opportunistic CRC
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7 148 screening (and the use of stool-based tests) in community health clinics across Malaysia [5]. It
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10 149 was assumed that 0.482% of the eligible population would avail of CRC screening when they
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12 150 attended local health clinics for other conditions; and 9.21% of this proportion of tested patients
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14
15 151 would receive a positive result. Only 55.9% of patients in the study by Tamin availed of a
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17 152 colonoscopy after a positive iFOBT. CRC detection after colonoscopy investigation was 4.04%.
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21 154 **In the novel CRC screening programme**, all assumptions were derived from the CRC-SIM
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23 155 research project. It was assumed that 50.51% of the eligible population would be contactable
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25 156 and meet all inclusion criteria to participate in the home-based screening programme; 52.27%
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27 157 of people who were eligible would agree to participate; 41.63% would perform the iFOBT and
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29 158 send a photo of a completed test to the programme officers; 18.01% of people who would be
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31 159 tested would receive a positive result; 41.07% would avail of colonoscopy after a positive
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33 160 iFOBT result; and CRC detection after colonoscopy investigation would be 4.35%.
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38 162 Table 1 summarises details about the input assumptions that were used to estimate the number
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40 163 of individuals at each stage of the respective pathway: the opportunistic screening pathway and
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42 164 the CRC screening programme pathway.
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168 **Table 1: Input assumptions used to estimate the population at each stage of the patient**
 169 **pathways**

Stage in pathway	Opportunistic screening scenario (Current practice)		Population-based CRC programme screening scenario (Proposed practice)	
	Assumption*	No. of individuals	Assumption**	No. of individuals
Total population (all ages)	NA	32,676,786	NA	32,676,786
Target population (aged 50-75)	19.06%	6,228,195	19.06%	6,228,195
Eligible population (met all inclusion criteria)	100%	6,228,195	50.51%	3,146,020
Availed of/agreed to take CRC screening	0.482%	30,020	52.27%	1,644,561
Needed 1 st reminder to return the iFOBT result (among those agreed to participate)	NA	NA	78.71%	1,294,514
Needed 2 nd reminder to return the iFOBT result (among those received 1 st reminder)	NA	NA	88.10%	1,140,405
Returned iFOBT result (among those agreed to participate)	100%	30,020	41.63%	684,683
Received iFOBT positive result	9.21%	2,765	18.01%	123,287
Availed of colonoscopy after positive iFOBT	55.9%	1,546	41.07%	50,636
CRC detection after colonoscopy investigation	4.04%	62	4.35%	2,202

CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test; NA: Not applicable; No: Number
 * The assumptions were derived from a study of Tamin NSI (2020) which was a 5-year evaluation of using stool-based test for opportunistic CRC screening in primary health institutions across Malaysia [5].
 ** The assumptions were derived from the Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021.

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3 172 **Cost input and data sources**
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5 173 In the opportunistic screening scenario, the total cost comprised the cost of:
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7 174 (i) performing screening (e.g., asking for symptoms, family history, and collecting the sample)
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9 175 (ii) processing stool specimens
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11 176 (iii) interpreting test results and
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13 177 (iv) conveying a definitive diagnosis to patients (include explaining treatment plan or referral
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15 178 arrangements)
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19 180 In the CRC programme screening scenario, the total cost comprised the costs of:
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21 181 (i) contacting potential participants
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23 182 (ii) delivering iFOBT test kits (including cost of the test, postage, print materials, and sending
24

25 183 video instruction)
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27 184 (iii) sending a reminder to participants (up to 2 times, by text message and phone call)
28

29 185 (iv) interpreting and conveying results to participants and
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31 186 (v) following-up patients with positive iFOBT but did not take colonoscopy in order to
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33 187 encourage them to avail of the colonoscopy
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37 189 These costs were calculated by multiplying the time allocated for the completion of each task
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39 190 with the salary cost of the person who undertakes each task plus cost of consumables. Table 2
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41 191 shows the unit cost for each cost element, related assumptions, and data sources.
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194 **Table 2: Resources and unit costs**

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
Current practice (opportunistic screening)			
Performing screening (asking for symptoms, family history, referral) and taking sample	5.58	20 min x salary RM2947/month	1
Processing stool specimens	1.70	10 min x salary RM1797/month	2
Interpreting the test results	2.79	10 min x salary RM2947/month	1
Conveying a definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	30 min x salary RM2947/month	1
Proposed practice (Population-based CRC screening programme)			
Contact eligible individuals - agreed to participate	0.98	7.1 min x (salary RM1440/month + mobile package RM20/month)	3
Contact eligible individuals - rejected/excluded to participate	0.47	3.4 min x (same as above)	3
iFOBT rapid test kit	6.90		3
Print materials (instruction leaflet, explanatory statement)	1.10	90 cents for colour print + 20 cent for black & white print	3
Postage (stamps, etc.)	5.35		3
Sending video through WhatsApp	0.41	3 min x (salary RM1440/month + mobile package RM20/month)	3
Sending reminder text message	0.41	3 min x (same as above)	3
Reminder call	0.28	2 min x (same as above)	3
Interpreting the test kit result	1.70	10 min x salary RM1797/month	3
Sending text message to inform patient of negative result	0.45	2 min x (salary RM2350/month + mobile package RM20/month)	3
Calling patient to inform him/her of positive result	0.67	3 min x (same as above)	3
Preparing and sending referral letter to patient/clinic	1.12	5 min x (same as above)	3
Follow up effort	6.73	30 min x (same as above)	3
Developing communication materials, one-off cost	6,063	Communication materials do not change in 5 years	3

Currency: Malaysian ringgit (RM)

Cost element	Unit cost (Per screen) RM (I\$)	Assumptions	Source
Training for data collectors*, one-off cost <i>* Data collectors are those employed by the programme to (i) contact potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants</i>	109,703	+ 1 day training (virtual using Zoom) + 1 trainer for maximum 25 trainees + 1 data collector* is needed for every target population of 400 + Cost=1-day-salary of trainer/trainees x number of trainer/trainees + No retraining in 5 years	3
Same in both scenarios/practices			
Colonoscopy (including polyps removal and/or biopsy if needed)	200		
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	RM8636.7/800 sets	3

iFOBT: Immunochemical faecal occult blood test; RM: Malaysian ringgit

Source:

1. Public Services Commission of Malaysia. Medical Officer Grade UD41. Accessed at <https://www.spa.gov.my/spa/laman-utama/gaji-syarat-lantikan-deskripsi-tugas/ijazah-sarjana-phd/pegawai-perubatan-gred-ud41>
2. Public Services Commission of Malaysia. Medical laboratory technologist Grade U29. Accessed at https://www.interactive.jpa.gov.my/ezskim/klasifikasi/perbekalanskim.asp?id_skim=3LU03
3. Colorectal Cancer Screening Intervention for Malaysia (or CRC-SIM research project) in Segamat District, conducted by Queen's University Belfast, Monash University, and Southeast Asia Community Observatory (SEACO) in 2021

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196 In the current practice of opportunistic screening, doctors were consulted about the estimated

197 time to perform each stage in the pathway. The monthly salary of a general doctor and a medical

198 laboratory technologist was based on the rate published by the Public Services Commission of

199 Malaysia [20, 21]. These rates were RM2,947 (~I\$2,045) and RM1,797 (~I\$1,247), respectively.

200 In the novel CRC screening programme, the time to perform each stage in the pathway, salary

201 of personnel, and costs of material resources (e.g., rapid kit test, consumables, postage, printing

202 materials) were based on the time and expenditure observed in the CRC-SIM research project.

203 All costs were calculated per screen except the cost of training and the cost of developing

204 communication materials which were one-off costs based on the assumption that

205 communication materials would not change, and no re-training would be needed within 5 years.

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3 206 It was assumed (based on the experience of operating the screening programme during the
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5 207 CRC-SIM project) that one data collector (i.e., those employed by the programme to (i) contact
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7 208 potential participants, (ii) deliver iFOBT test kits, and (iii) send a reminder to participants)
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10 209 would be needed for every 400 people in the target population. Training would last one day
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12 210 and would be delivered virtually; thus, the cost of training equalled (1-day-salary of trainer x
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14 211 number of trainer) + (1-day-salary of trainees x number of trainees/data collectors).
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19 213 **Perspective and time horizon**

21 214 The BIA was conducted from the viewpoint of the federal government which finances
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23 215 Malaysia's public health system [22]. Only those costs and resource requirements relevant to
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25 216 the budget holder were included in the analysis. For example, the out-of-pocket expenditure
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27 217 incurred by patients were excluded.
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33 219 The analysis estimated the annual financial impact over a period of five years as recommended
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35 220 in the guidelines [11, 23]. Costs were not discounted given that the BIA methodology reports
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37 221 the costs for each year in which they occur rather than a net present value [11].
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42 223 **Budget impact analyses**

44 224 *Computing framework and base-case analysis*

46 225 The BIA used a cost calculator programmed in Microsoft Excel, following the costing
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48 226 template¹ produced by the National Institute for Health and Care Excellence in the UK (NICE).
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50 227 The template was modified to fit the programme under assessment. The cost calculator
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60 ¹ The template can be freely downloaded at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/budget-impact-template.xlsx>

228 approach is recommended by guidelines as it is easy for stakeholders to understand and
229 replicate the results [11].

230
231 First, the number of individuals who completed each stage was estimated (Table 1). The
232 resources that were used at each stage of the respective pathways (in opportunistic screening
233 and the novel CRC screening programme) were listed along with their unit costs (i.e., cost of
234 each resource per person) (Table 2). Unit costs were multiplied by number of users to give the
235 total cost of resources for each scenario. The net budget impact was calculated as the difference
236 in cost between opportunistic screening and the CRC screening programme. Visual depiction
237 of the cost calculator is shown in Supplementary Material, Figure S1.

238

239 *Uncertainty and scenario analyses*

240 The input assumptions (that were used to estimate the number of individuals at each stage of
241 the respective pathway) and the cost inputs were varied, and then the impact of these changes
242 in relation to the results was analysed to investigate the sensitivity of the budget impact results
243 to variations in individual input. As recommended by Gray et al. (2011), the range of variation
244 regarding parameters for which data sources about dispersion were unavailable were $\pm 20\%$ of
245 the base case [24].

246

247 **Patient and public involvement**

248 It was not appropriate or possible to involve patients or the public in the design, or conduct, or
249 reporting, or dissemination plans of our research as this type of study is a secondary analysis
250 of data from a payer perspective (Ministry of Health Malaysia).

251

252 RESULTS

253 Base-case analysis

254 The total annual cost of the current practice of opportunistic screening is RM1,584,321
255 (~I\$1,099,460), of which 80% (RM1,274,690 ~ I\$884,587) was for providing opportunistic
256 CRC to adults who availed of the service. Costs of providing colonoscopy (including polyps
257 removal and/or biopsy if needed) after receipt of a positive iFOBT and conveying definitive
258 diagnosis to patients (along with explaining treatment plan or referral etc.) after the outcome
259 of the colonoscopy were RM309,108 (~I\$214,509) and RM523 (~I\$363), respectively.

260

261 The total annual cost over a 5-year period of the proposed practice (i.e., CRC screening
262 programme) is shown in Table 3. It was assumed that the number of people who would agree
263 to participate in the programme would increase by 5% each year (in consideration of health
264 promotion activities as well as information flows including word of mouth between
265 participants). Therefore, the financial impact would also increase accordingly.

266

267

268 **Table 3: Annual cost of proposed practice (i.e., CRC screening programme)**

<i>Currency: Malaysian ringgit (RM) and International Dollar (I\$)</i>					
Proposed practice	Year 1 RM (I\$)	Year 2 RM (I\$)	Year 3 RM (I\$)	Year 4 RM (I\$)	Year 5 RM (I\$)
Contacting adults who are eligible for CRC screening programme (i.e., aged 50-75) and screen for eligibility of participating	2,320,148 <i>(1,610,096)</i>	2,320,148 <i>(1,610,096)</i>	2,320,148 <i>(1,610,096)</i>	2,320,148 <i>(1,610,096)</i>	2,320,148 <i>(1,610,096)</i>
Providing iFOBT test to adults who agreed to participate in CRC screening programme after being invited	93,654,886 <i>(64,992,981)</i>	102,612,907 <i>(71,209,512)</i>	111,570,928 <i>(77,426,043)</i>	120,528,949 <i>(83,642,574)</i>	129,486,970 <i>(89,859,105)</i>
Providing 1 st reminder to participants	536,929 <i>(372,609)</i>	588,286 <i>(408,248)</i>	639,643 <i>(443,888)</i>	690,999 <i>(479,527)</i>	742,356 <i>(515,167)</i>
Providing 2 nd reminder to participants	315,339 <i>(218,833)</i>	345,501 <i>(239,765)</i>	375,663 <i>(260,696)</i>	405,825 <i>(281,627)</i>	435,987 <i>(302,559)</i>
Interpreting returned iFOBT samples	1,165,129 <i>(808,556)</i>	1,276,572 <i>(885,893)</i>	1,388,016 <i>(963,231)</i>	1,499,460 <i>(1,040,569)</i>	1,610,903 <i>(1,117,906)</i>
Conveying result through message to participants with iFOBT negative result	251,990 <i>(174,872)</i>	276,093 <i>(191,598)</i>	300,196 <i>(208,324)</i>	324,298 <i>(225,050)</i>	348,401 <i>(241,777)</i>
Preparing and sending referral letter and calling participants with iFOBT POSITIVE result	221,356 <i>(153,613)</i>	242,529 <i>(168,306)</i>	263,701 <i>(182,999)</i>	284,874 <i>(197,692)</i>	306,046 <i>(212,384)</i>
Following up participants who DID NOT take colonoscopy after positive iFOBT	489,158 <i>(339,457)</i>	535,945 <i>(371,926)</i>	582,733 <i>(404,394)</i>	629,520 <i>(436,863)</i>	676,308 <i>(469,332)</i>
Providing colonoscopy (including polyps removal and/or biopsy if needed) to participants with positive iFOBT	10,127,147 <i>(7,027,861)</i>	11,095,801 <i>(7,700,070)</i>	12,064,455 <i>(8,372,280)</i>	13,033,109 <i>(9,044,489)</i>	14,001,764 <i>(9,716,700)</i>
Conveying definitive diagnosis to patients (along with explaining treatment plan or referral etc.) after the colonoscopy	18,432 <i>(12,791)</i>	20,195 <i>(14,015)</i>	21,958 <i>(15,238)</i>	23,721 <i>(16,461)</i>	25,484 <i>(17,685)</i>
Capital costs (Developing communication materials + Training for data collectors)	115,766 <i>(80,337)</i>	115,766 <i>(80,337)</i>	115,766 <i>(80,337)</i>	115,766 <i>(80,337)</i>	115,766 <i>(80,337)</i>
Total cost of proposed practice	109,216,279 <i>(75,792,005)</i>	119,429,743 <i>(82,879,766)</i>	129,643,206 <i>(89,967,527)</i>	139,856,670 <i>(97,055,288)</i>	150,070,133 <i>(104,143,049)</i>
<i>CRC: Colorectal cancer; iFOBT: Immunochemical faecal occult blood test</i>					

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5 270 Similar to opportunistic screening, the cost to provide iFOBT to the eligible population who availed
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7 271 of the service accounted for 86% of the total cost of the proposed CRC screening programme. The
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9 272 second most costly component was the provision of colonoscopy (including polyps removal and/or
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11 273 biopsy if needed) to patients with an iFOBT positive result, at 9% of the total cost. The remaining
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13 274 nine cost components such as contacting potential participants, reminding participants to send
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15 275 photograph of iFOBT result, conveying diagnosis to participants and the follow-up effort added
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17 276 only up to 5% of the total cost.
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23 278 The net budget impact in the 1st year of implementing CRC screening programme would be
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25 279 RM107,631,959 (~I\$74,692,546 which equalled the total cost of future practice minus the total
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27 280 cost of current practice). The impact increases each year as the number of people who agree to
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29 281 participate in the programme increase, reaching RM117,845,422 (~I\$81,780,307) in year 2,
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31 282 RM128,058,885 (~I\$88,868,067) in year 3, RM138,272,349 (~I\$ 95,955,829) in year 4, and
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33 283 RM148,485,812 (~I\$103,043,589) in year 5.
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39 285 The net budget impact of providing and delivering the CRC screening programme over the 5-year
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41 286 timeframe for each state in Malaysia (calculated according to the population size of each state) can
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43 287 be accessed in Supplementary Material, Table S1. These estimates aid service planning decisions
44
45 288 if the novel pilot programme is implemented in one or more of these states before being scaled up
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47 289 into nationwide programme.
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52 53 291 **Uncertainty and scenario analyses**

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55 292 The tornado diagram in Figure 3 shows the change to net budget impact when assumptions and
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57 293 cost inputs were varied. It presents the results of multiple univariate sensitive analyses on key
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3 294 inputs that exert the most influence on the net budget impact (See Table S2, Supplementary
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5 295 Material for results of multiple univariate sensitive analysis on all inputs). These inputs include
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7
8 296 the probability of (i) making successful contact with adults about the CRC screening programme,
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10 297 (ii) adults agreeing to participate, (iii) adults being eligible to participate in the programme, and
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12 298 (iv) the cost of consumables that are required to take a stool sample. The first three inputs
13
14 299 influence the number of individuals who are present at each stage of the patient pathway.

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17 300 (Figure 3 is about here)

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19 301 The net budget impact would increase from RM107 million to RM130 million (~I\$74-90
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21 302 million) if there was a 20% increase in (i) the probability of adults who were contactable (from
22
23 303 a contact list of people aged 50-75 years old) or (ii) the probability of adults agreeing to
24
25 304 participate in the CRC screening programme or (iii) the probability of adults being eligible for
26
27 305 the programme (i.e., aged 50-75 years old; having no symptoms of CRC, a smartphone, and
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29 306 WhatsApp; resident within programme area; and did not have colonoscopy this year). In other
30
31 307 words, a 20% increase in each one of these factors would require an additional RM23 million
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33 308 (~I\$16 million) to be budgeted for the programme. Likewise, a 20% increase in the cost of the
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35 309 consumables that are required for taking stool samples would mean that the programme would
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37 310 cost RM15 million (~I\$10 million) more than the originally calculated total cost.
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45 312 **DISCUSSION**

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48 313 The result of this analysis provides information to guide public health service planners and
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50 314 commissioners in their decisions about an alternative CRC screening strategy i.e., a population-
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52 315 based CRC screening programme using home-based iFOBT compared to current opportunistic
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54 316 screening. It concluded that the net budget impact in the 1st year of implementing a CRC
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56 317 screening programme of this kind would be RM107,631,959 (~I\$74,692,546). The impact
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58 318 would increase by year due to increase in uptake and would reach RM148,485,812
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3 319 (~I\$103,043,589) in the 5th year of implementation. This analytical approach and the results of
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5 320 this analysis are presented as aids to better decision making by MoHs and stakeholders in
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7 321 lower-middle-income countries (LMICs) about health programme planning and in this
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9 322 particular illustrative case to the MoHM regarding the degree to which the proposed CRC
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11 323 screening programme is affordable.
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17 325 The total budget that was allocated to the MoHM in 2022 was RM32.4 billion (~I\$22.5 million)
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19 326 [25]. Spending on prevention and public health services in 2009 was reported to be RM1.6
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21 327 billion (~I\$1.1 million) [22]. More recent data and information about the size of the budget that
22
23 328 is allocated to cancer screening is not available. As such, it is estimated that the net budget
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25 329 impact of implementing a CRC screening programme would account for between 7-10% of the
26
27 330 total budget for prevention and public health services. This represents a significant proportion
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29 331 of the overall budget allocated for prevention programmes/interventions.
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35 333 The key factor in the implementation of a population-based screening programme/service or the
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37 334 factor that has biggest impact on the budget is the size of the population who use the service. The
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39 335 degree of accuracy regarding population size estimates is related closely to the cost estimates in
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41 336 the budget. It is important for service planners to keep this point in mind and to take into account
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43 337 an increase in uptake and the impact of such an increase. Therefore, in the case of the CRC
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45 338 programme presented here, we assumed a 5% increase annually in uptake and calculated the net
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47 339 budget impact. The net budget impact can be recalculated according to the actual change in uptake
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49 340 after the programme is implemented.
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55 342 Budget impact analysis is an economic assessment that is used to estimate the changes in
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57 343 expenditure of a specific budget holder if a new health technology/programme is implemented
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3 344 [11]. As such, BIA complements other health economic evaluation methods such as cost-
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5 345 effectiveness analysis (CEA) to provide a comprehensive economic assessment of a health care
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7 346 intervention to decision makers [11]. A BIA aids decision making by health service planners
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9
10 347 and commissioners about whether an intervention or programme is affordable within given
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12 348 budget constraints while a CEA informs decisions about whether an intervention is good value
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14 349 for money [11, 26]. BIA and its pragmatic approach is an ideal method when a situation calls
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16
17 350 for an evaluation of 'affordability' which is of central importance in LMICs and, arguably, is
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19 351 the key concern of whoever is in charge of managing a health care budget [27, 28].
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24 353 It could well be that savings in earlier treatment would counterbalance the additional budget
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26 354 impact. Likewise, reduction in travel and time costs of participant while using home-based
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28 355 screening would reduce the total costs of the screening programme from a societal perspective.
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30 356 If we assume that travel distance to a clinic is 10km (77% of Malaysian live within 5km of a
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32 357 clinic [29]), travel time is 10 minutes (travel speed = 60km/hour), opportunistic screening takes
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34 358 40 minutes (Table 2), and performing iFOBT at home take 10 minutes, the reduction in travel
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36 359 and time costs will be 40 minutes. This can be monetised using Gross Domestic Product per
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38 360 capita at RM50,224 [30] to which is then added 10km x RM1 per km (i.e., tolls & fuel [31]) =
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40 361 RM14 per participant. Consistent with BIA best practice guidance these have not been included
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42 362 in our estimate of the BIA which focuses on costs to the provider. Further work in this area
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44 363 may though be useful or a health technology assessment given the potential for aspects of
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46 364 societal cost to influence cost-effectiveness and service uptake.
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53 366 Finally, the conduct of BIA in this paper has some limitations. First, assumptions and cost
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55 367 inputs for the CRC screening programme were based on the costs and rates that were observed
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57 368 in the CRC-SIM research project. Due to unavailability of data about dispersion of the
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3 369 parameters, the used range of variation ($\pm 20\%$ of the base case) may overestimate the
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5 370 uncertainty and suggests that the next step for further research is a CEA where parameter
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7 371 uncertainty is investigated with actual data. The project was conducted in only one district
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9 372 (Segamat); and the distribution of three main ethnic groups (i.e., Malay, Chinese, Indian) in
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11 373 the project differed from the proportions that have been reported nation-wide (72%:24%:3%
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13 374 vs 62%:21%:6%, respectively). Therefore, it is important to be mindful of the possibility that
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15 375 the assumptions and inputs (based on the project) may not be representative for, or read across
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17 376 to, the whole population of Malaysia. Likewise, it is important to bear in mind that our findings
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19 377 do not include the perspective of other payers and may not generalise to other settings. The
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21 378 results are related directly to the context of the Malaysian health system and the epidemiology
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23 379 of CRC in the country though they are illustrative of the positive contribution of the BIA
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25 380 methodology and approach.
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34 382 **CONCLUSIONS**

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37 383 This study employed a BIA methodology to analyse the costs of a novel CRC screening
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39 384 programme using home-based iFOBT and mHealth versus the current opportunistic screening.
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41 385 The findings estimated the net budget impact of implementing a population-based national
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43 386 CRC screening programme in Malaysia. The modelling estimations are important
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45 387 considerations for health authorities when they are required to decide the affordability of
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47 388 implementing a programme and to aid budgetary planning as well as decision making,
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49 389 generally, about implementation. Our study illustrates the use and value of the BIA approach
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51 390 in LMICs and resource-constrained settings.
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392 Abbreviations

6	BIA	Budget impact analysis
8	CEA	Cost-effectiveness analysis
10	CRC	Colorectal cancer
13	CRC-SIM	Colorectal Cancer Screening Intervention for Malaysia
15	iFOBT	Immunochemical faecal occult blood test
17	I\$	International Dollar
20	ISPOR	The Professional Society for Health Economics and Outcomes Research
22	MoHM	Ministry of Health of Malaysia
24	NICE	National Institute for Health and Care Excellence
26	RM	Malaysian ringgit
29	SEACO	Southeast Asia Community Observatory
31	UK	The United Kingdom

393

394 DECLARATIONS

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3 404 **Authors' contributions.** TTN: Methodology, Formal Analysis, Writing – Original draft, Writing –
4
5 405 Review & Editing. KR, MRS, and DS: Data Curation, Investigation, Writing – Review & Editing. ST:
6
7 406 Resources, Writing – Review & Editing. TTS, and MD: Conceptualization, Funding acquisition,
8
9 407 Writing – Review & Editing, Supervision. CON: Methodology, Formal Analysis, Writing – Review &
10
11 408 Editing, Supervision.

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3 496 **Figure Legends and Tables**
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5
6 497 Table 1 Input assumptions used to estimate the population at each stage of the patient pathways
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8 498 Table 2 Resources and unit costs
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10 499 Table 3 Annual cost of proposed practice (i.e., CRC screening programme)
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15 501 Figure 1 Patient pathways in 'usual care' practice - opportunistic screening for CRC
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17 502 Figure 2 Patient pathway in population-based CRC screening programme
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19 503 Figure 3 Results of multiple univariate sensitive analyses showing key factors that exert most
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21 504 influence the net budget impact
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25
26 506 **Supplementary material**
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28 507 Figure S1 Visual depiction of the budget impact cost calculator
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30 508 Table S1 Net budget impact of CRC screening programme over 5-year timeframe, by state
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32 509 Table S2 Sensitivity of the total budget impact of CRC screening programme to changes in
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35 510 each variable individually
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Figure 1: Patient pathway in 'usual care' practice - opportunistic screening for CRC

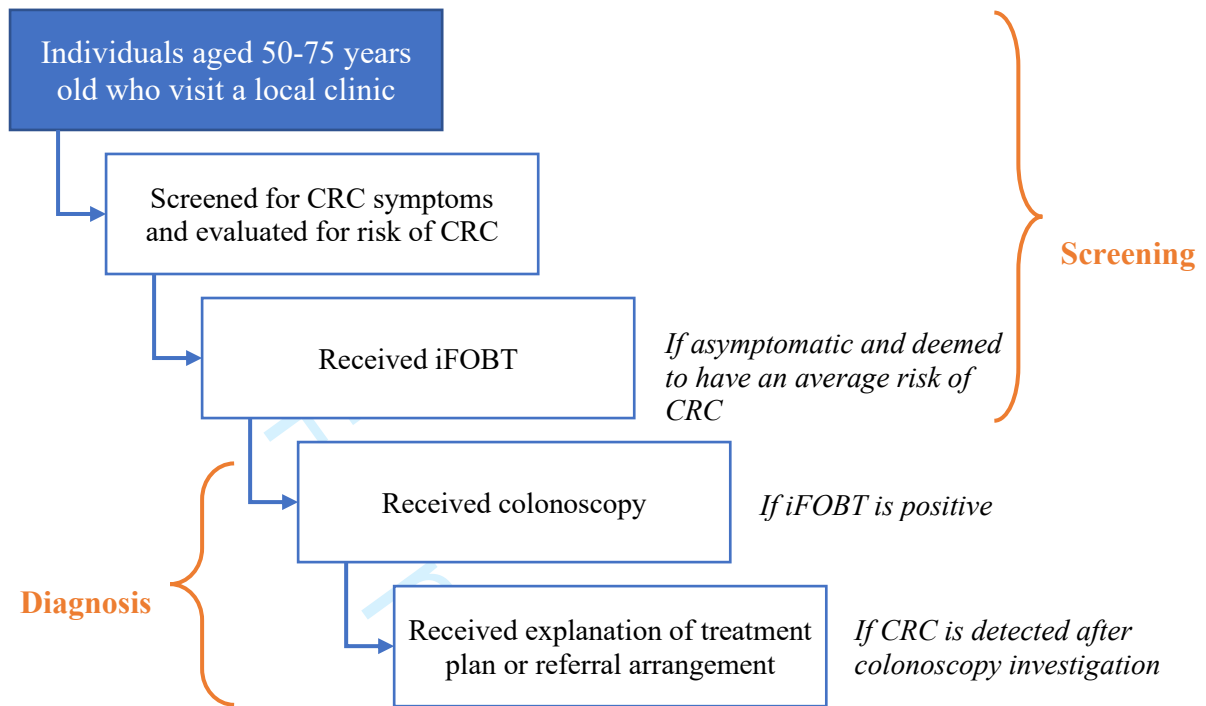


Figure 2: Patient pathway in population-based CRC screening programme

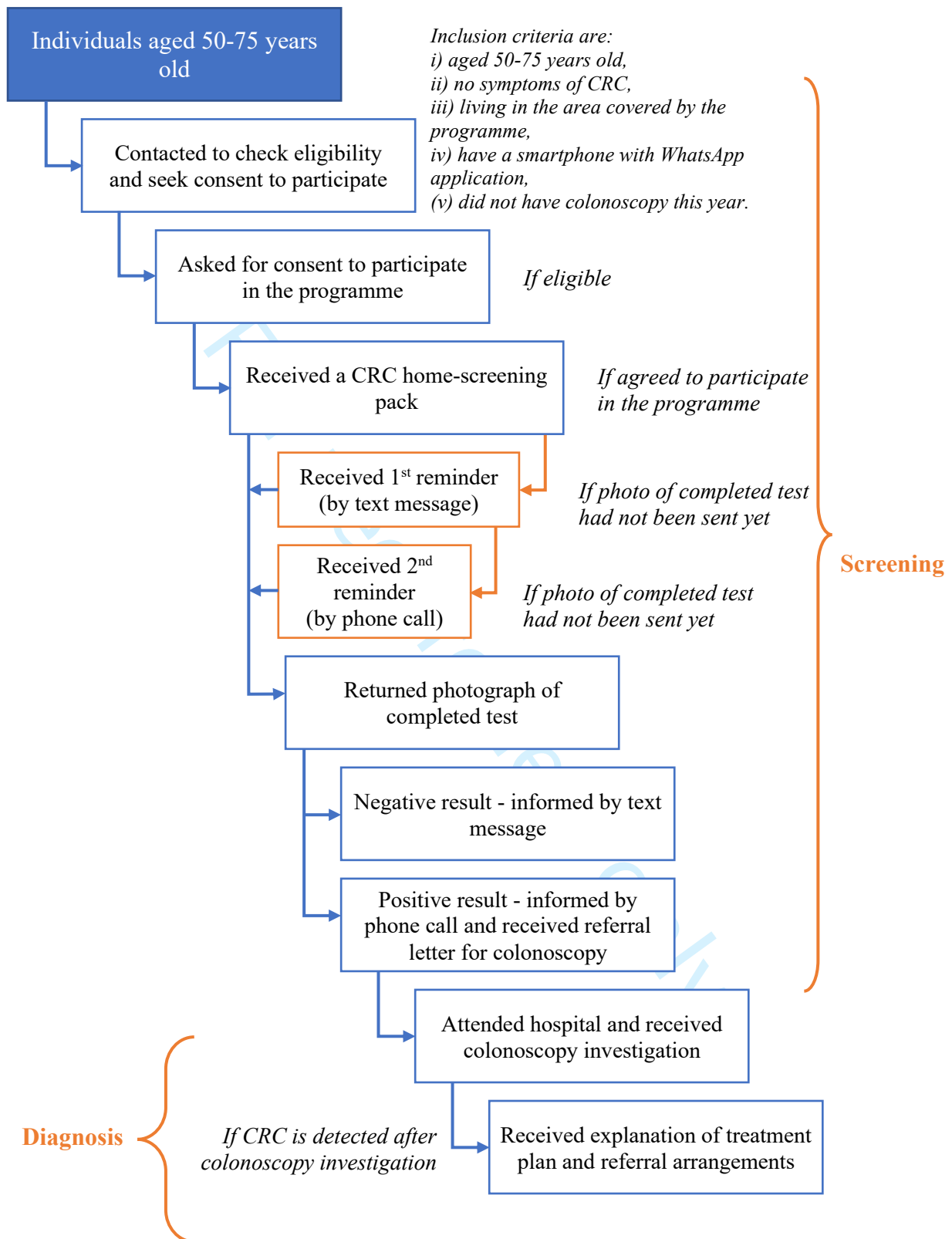
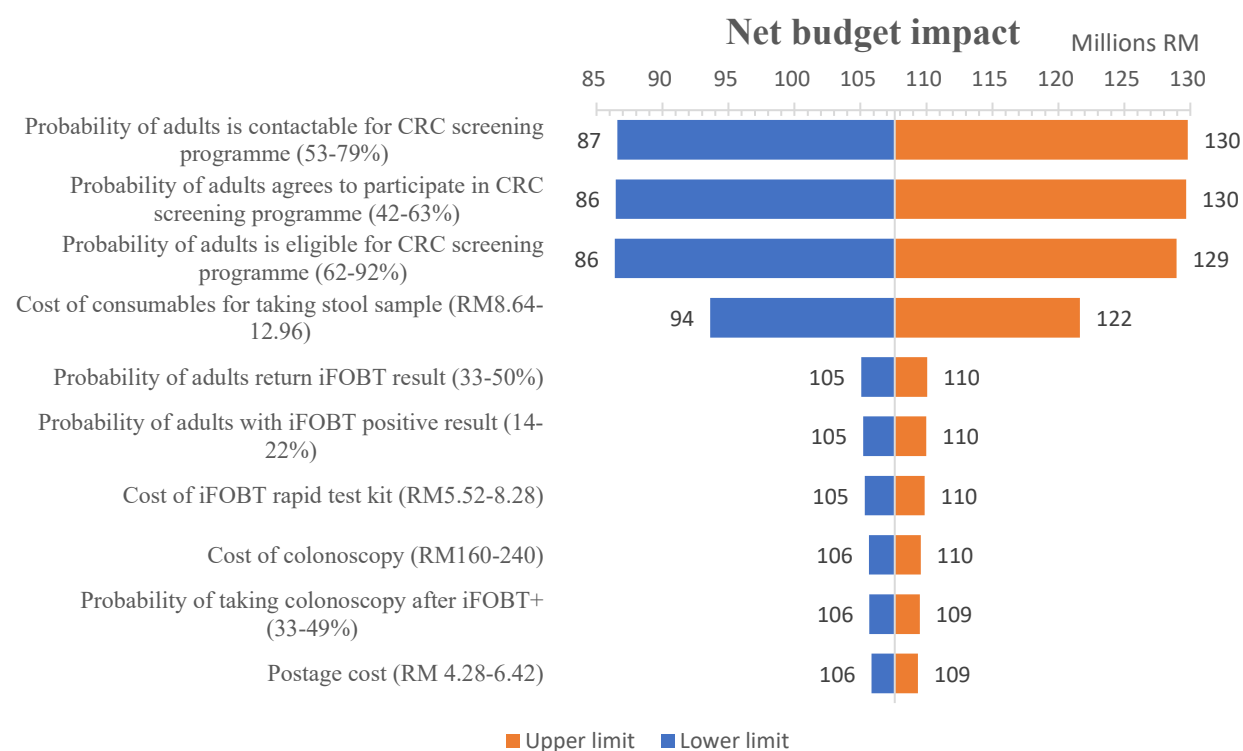
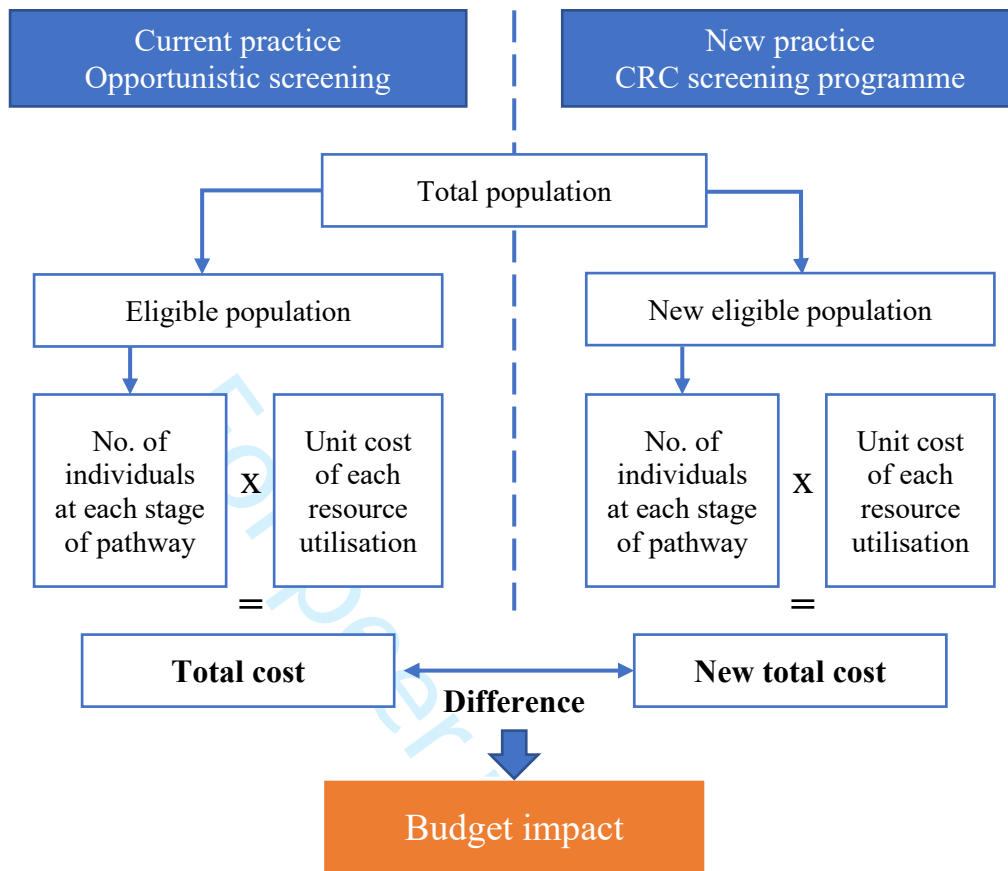


Figure 3: Results of multiple univariate sensitive analyses showing key factors that exert most influence the net budget impact



Supplementary material

Figure S1: Visual depiction of the budget impact cost calculator



Supplementary material

Table S1: Net budget impact of CRC screening programme over 5-year timeframe, by state

Currency: Malaysian ringgit

State	Population	Year 1	Year 2	Year 3	Year 4	Year 5
Johor	3,822,800	12,597,041	13,791,897	14,986,752	16,181,607	17,376,462
Kedah	2,206,200	7,272,541	7,962,112	8,651,682	9,341,252	10,030,823
Kelantan	1,884,300	6,212,311	6,801,268	7,390,225	7,979,183	8,568,140
Melaka	934,700	3,084,637	3,376,787	3,668,937	3,961,087	4,253,238
Negeri Sembilan	1,141,000	3,764,122	4,120,753	4,477,384	4,834,016	5,190,647
Pahang	1,702,900	5,614,833	6,147,092	6,679,351	7,211,609	7,743,868
Perak	2,569,300	8,468,450	9,271,511	10,074,572	10,877,633	11,680,693
Pulau Pinang	1,767,100	5,826,301	6,378,626	6,930,951	7,483,276	8,035,601
Sabah	3,919,600	12,915,864	14,140,975	15,366,086	16,591,197	17,816,308
Sarawak	2,829,400	9,325,144	10,209,501	11,093,859	11,978,217	12,862,575
Terengganu	1,245,300	4,107,648	4,496,879	4,886,111	5,275,342	5,664,573
Perlis	253,500	841,028	920,262	999,496	1,078,730	1,157,964
W.P. Kuala Lumpur	1,790,100	5,902,043	6,461,557	7,021,071	7,580,585	8,140,099
W.P. Labuan	99,000	332,138	363,081	394,024	424,968	455,911
W.P. Putrajaya	97,100	325,886	356,236	386,585	416,935	447,284
Nation-wide	32,676,786	107,631,959	117,845,422	128,058,885	138,272,349	148,485,812

CRC: Colorectal cancer | W.P.: The Federal Territories (Malay: Wilayah Persekutuan)

Readers can convert from Malaysian Ringgit to their currency of interest (e.g., International Dollar, US Dollar, British Pound, Euro etc.) using the free web-based tool ‘CCEMG – EPPI-Centre Cost Converter’ (<https://eppi.ioe.ac.uk/costconversion/default.aspx>). This tool help adjusting estimates of cost expressed in one currency and price year to a specific target currency and price year.

Supplementary material

Table S2: Sensitivity of the total budget impact of CRC screening programme to changes in each variable individually

Baseline budget impact=RM107,631,959

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Probability of adults is contactable for CRC screening programme	66%	53%	79%	86,574	129,818	43,244
Probability of adults is included (eligible for CRC screening programme)	77%	62%	92%	86,386	128,950	42,564
Probability of adults agree to participate in CRC screening programme after being invited	52%	42%	63%	86,454	129,675	43,221
Probability of adults needing 1st reminder	79%	63%	94%	107,430	107,766	336
Probability of adults needing 2nd reminder	88%	70%	100%	107,535	107,643	108
Probability of adults return iFOBT result	42%	33%	50%	105,062	110,060	4,998
Probability of adults with iFOBT positive result	18%	14%	22%	105,204	109,988	4,784
Probability of adults taking colonoscopy after positive iFOBT	41%	33%	49%	105,673	109,493	3,820
Probability of adults with CRC detection after getting colonoscopy	4%	3%	5%	107,594	107,603	9
Cost to perform the screening (asking for symptoms, family history, referral)	5.58	4.47	6.70	107,633	107,567	-66
Cost of stool specimen processing	1.70	1.36	2.04	107,610	107,590	-20
Interpretation of results	2.79	2.23	3.35	107,617	107,583	-34
Cost to convey definitive diagnosis to patients (along with explaining treatment plan or referral etc.)	8.37	6.70	10.05	107,597	107,604	7
Contact eligible individuals - agreed to participate	0.98	0.79	1.18	107,285	107,926	641
Contact eligible individuals - rejected/excluded to participate	0.47	0.38	0.56	107,465	107,735	270
iFOBT rapid test kit (only the rapid test kit itself)	6.90	5.52	8.28	105,331	109,870	4,539
Print materials (instruction leaflet, explanatory statement)	1.10	0.88	1.32	107,238	107,962	724
Postage (stamp etc.)	5.35	4.28	6.42	105,840	109,360	3,520
Sending video through Whatapp	0.41	0.33	0.50	107,461	107,740	279
Sending reminder text message	0.41	0.33	0.50	107,490	107,710	220
Reminder call	0.28	0.22	0.33	107,536	107,661	125
Interpret the test kit result	1.70	1.36	2.04	107,366	107,832	466

Supplementary material

Unit: Thousand Ringgit Malaysia

	Baseline value	Min value (-20% from baseline)	Max value (+20% from baseline)	Min budget impact	Max budget impact	Change
Sending text message informing negative result	0.45	0.36	0.54	107,550	107,651	101
Call to inform positive result	0.41	0.33	0.50	107,590	107,611	21
Prepare and send referral letter	1.12	0.90	1.35	107,573	107,628	55
Follow up effort	6.73	5.39	8.08	107,503	107,698	195
Colonoscopy	200	160	240	105,638	109,564	3,926
Consumables – stool container, gloves, mask, plastic waste bag and disposal of materials from the test	10.80	8.64	12.96	93,612	121,641	28,029

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ISPOR—The Professional Society for Health Economics and Outcomes Research

Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force

Citation: Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, Orlewska E, Penna P, Rodriguez Barrios JM, Shau WY. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014 Jan-Feb;17(1):5-14. doi: <https://doi.org/10.1016/j.jval.2013.08.2291>

Recommendations for Reporting Format

Section/topic	Guidance for reporting	Reported in section
Introduction		
Objectives	The objective of the BIA should be clearly stated and tied to the study perspectives	Introduction
Epidemiology and management of health problem	Present information about the prevalence and incidence of the particular disease, disease severity, disease progression, undiagnosed or undertreated cases, and risk factors pertinent to estimating the budget impact	Introduction
Clinical impact	Consist of a brief description of the eligible population and existing management options and their efficacy and safety that are relevant to the design of the study of the BIA	Introduction
Economic impact	Include a brief description of previous BIAs in the condition of interest for another intervention and condition-specific treatment patterns and cost-of-care studies	Not applicable (No previous BIA)
Study Design and Methods		
Patient population	Specify the eligible population for the new intervention	Methods Sub-section: Eligible population and input assumptions Table 1
Intervention mix	Contain a detailed description of the use and characteristics of each intervention in the current intervention mix and in the expected intervention mix after the introduction of the new intervention	Methods Sub-section: Health service under assessment and its comparator Figure 1 and 2
Time horizon	Should be presented and the choice(s) justified	Methods Sub-section: Perspective and time horizon
Perspective	Identify the BIAs' perspective(s), the cost categories included, and the intended audience	Methods Perspective and time horizon

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Section/topic	Guidance for reporting	Reported in section
Analytic framework description	Complete description of the structure of the BIA cost calculator or condition-specific cohort or individual simulation model	Methods Sub-section: Eligible population and input assumptions
Input data	Input values used for the reported analyses, including alternative scenarios, should be presented	Methods Sub-section: Cost input and data sources Table 2
Data sources	The sources of data inputs should be described in detail	Methods Sub-section: Cost input and data sources Table 2
Data collection	The methods and processes for any primary data collection and data abstraction tasks not reported elsewhere should be described and explained.	Not applicable (secondary data)
Analyses	A description of the calculations used to complete the BIA should be provided. The choice of all the scenarios presented in the results should be documented and justified.	Methods Sub-section: Computing framework and base-case analysis under budget impact analyses
Uncertainty	Uncertainty analysis methods should be described and justified	Methods Sub-sections: Uncertainty and scenario analyses under budget impact analyses
Results	The budget impact should be presented for each budget period over the time horizon. Both budget period resource use and costs should be presented. The estimates of resource use should be listed in a table that shows the change in use for each time period reported in the BIA The results of the uncertainty analyses and scenarios analyzed should be described and presented in figures or tables	Results Table 3 Results Figure 2
Conclusions and Limitations	State the main conclusions on the basis of the results of the BIA. Report the main limitations regarding key issues such as design aspects including off-label use and adherence assumptions and the completeness and quality of data inputs and sources.	Discussion Conclusion
Inclusion of Graphics and Tables		
Figure of the analytical framework	Flow diagrams or other visual depictions of the cost calculator or condition-specific cohort or individual simulation model are recommended to be included with the analytical framework description.	Supplementary material Figure S1

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Section/topic	Guidance for reporting	Reported in section
Table of assumptions	All the major assumptions should be listed in a tabular form	Table 1
Tables of inputs	All the input parameter values and their data sources and derivations should be presented in a tabular form	Table 2
Tables of outputs	All outputs should be presented in a tabular and/or graphical Form	Table 3
Schematic representation of uncertainty analyses	Diagrams such as Tornado diagrams should be included along with the text on the results of the scenario analyses	Figure 3
Appendices and References	The appendices may cover literature search strategies, evidence summaries, intermediate results (e.g., of individual Delphi panel rounds), and the names and addresses of participating experts and investigators, for example.	Reference

CHEERS 2022 Checklist

Topic	No.	Item	Location where item is reported
Title			
	1	Identify the study as an economic evaluation and specify the interventions being compared.	Title page, Page 1
Abstract			
	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	Abstract, Page 1
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Introduction, Line 65-69
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Not applicable
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Methods, Line 123-152, Table 1
Setting and location	6	Provide relevant contextual information that may influence findings.	Methods, Line 79-92
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Methods, Line 79-121, Figure 1 and 2
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Methods, Line 199-202
Time horizon	9	State the time horizon for the study and why appropriate.	Methods, Line 204-205
Discount rate	10	Report the discount rate(s) and reason chosen.	Methods, Line 205-206
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Not applicable

Topic	No.	Item	Location where item is reported
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Not applicable
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Not applicable
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Methods, Line 159-196
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Methods, Line 73-76
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	Not applicable
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	Methods, Line 211-221, Figure S1 (Supplementary Material)
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Not applicable
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	Not applicable
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis.	Methods, Line 224-229, Figure S2 (Supplementary Material)
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	Methods, Line 233-235
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Table 1 and 2, Table S2 (Supplementary Material)
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Results, Line 239-274, Table 3

Topic	No.	Item	Location where item is reported
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Results, Line 277-295, Figure 3
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	Not applicable
Discussion			
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Discussion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	End of manuscript
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	End of manuscript

From: Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value Health 2022;25. doi:10.1016/j.jval.2021.10.008