

# Determinants of colorectal carcinoma screening amongst patients attending a public primary care health centre in Johor Bahru

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## ABSTRACT

**Introduction:** Colorectal cancer (CRC) is one of the major causes of cancer-related mortality in Malaysia. Early screening has proven to be effective in reducing mortality due to CRC. The Malaysian CRC Clinical Practice Guidelines (2017) recommends that immunochemical faecal occult blood test (iFOBT) as the best non-invasive method for screening CRC in asymptomatic or average risk population. Outcome data on CRC screening program in the community is scarce. This study was to evaluate the prevalence and determinants of CRC among patients attending a public primary care health centre who underwent the screening program.

**Materials and Methods:** Reviews of CRC Screening Registry and medical case record were conducted on patients who underwent CRC screening program at Klinik Kesihatan Mahmoodiah, Johor Bahru (KKMJB) from 2016 to 2018 period. Sociodemographic data, clinical profile of patients, iFOBT results and colonoscopy outcomes were extracted for analysis. Descriptive and inferential statistics were performed using IBM SPSS version 25.

**Results:** Out of 591 registered patients, 584 were included for analysis. Majority of the screened individuals were males (2016-2017) compared to females (2018). Chinese were most screened individuals in 2016 [94 (46.8%)] and 2017 [87 (61.7%)]. Percentage of patients with appropriate indicators for screening and underwent colonoscopy for positive iFOBT were highest recorded in 2018 (74.7%, 58.8% respectively). Prevalence of CRC among those screened with iFOBT was 1 per cent for 2017 and 2018. Adherence to annual screening with iFOBT ranged between 1.1% (2016)-2.2% (2018). Significant association observed between gender and iFOBT results,  $\chi^2(df) = 4.747, p=0.029$  (2018). Median age and ethnicity were not significantly associated with iFOBT results ( $p>0.05$ )

**Conclusion:** Screening for CRC among average risk groups in primary care should focus on recruiting female patients/clients as an organised activity. Prevalence of CRC detected from screening with iFOBT was 1 per cent. CRC screening programs should focus on proportion of iFOBT positive patients progressing to receive definitive colonoscopy and complying to annual surveillance screening.

## KEYWORDS:

*Colorectal cancer, screening, iFOBT, Primary care*

## INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer-related death globally.<sup>1</sup> CRC is the second most commonly diagnosed cancer worldwide among females and the third in males. The global burden of CRC has been increasing consistently over the years, with approximately one to two million new diagnoses reported annually, and the majority are reported from Asian countries.<sup>2,3</sup> The Malaysian National Cancer Registry Report 2012-2016 (MNCRR) reported a 13.3% rise compared to the 2007-2011 period. The age-standardized incidence rate in men and women from 2012 to 2016 was reported as 14.8 and 11.1 per 100,000 population respectively. The incidence of colorectal cancer was noted to be the highest among the Chinese for both sexes in terms of differences among multi-ethnic Malaysians. Among men, the lifetime risk for Chinese was 1 in 43, significantly higher than that in other ethnic groups; 1 in 65 for Malays and 1 in 70 for Indians. The same lifetime risk was also reported in females, i.e., among Chinese 1 in 57, Malays 1 in 89 and Indians 1 in 95. The incidence of CRC is higher in both sexes and peak at the age of 70 and above.<sup>4</sup> The disease is accountable for 12.3% of all cancer-related mortality in Malaysia,<sup>5</sup> and contributes to 13% of cancer-associated disability-adjusted life year (DALY).<sup>6</sup>

Earlier studies have reported that the majority of Malaysians were diagnosed with late-stage CRC due to the absence of national CRC screening programs.<sup>7-9</sup> The disease causes an increase in Malaysian economic burden as the treatment costs increase with the advanced cancer stages. Thus, it was suggested that the implementation of screening programs may reduce the mortality through early detection of CRC, leveraging on screening in patients with no known risk or categorized as average risk at primary care facilities.<sup>10</sup> Screening using the immunochemical faecal occult blood test (iFOBT) is recommended at ages 50 to 70 years old, on an annual basis.<sup>11</sup> An early colonoscopy is recommended if screening with iFOBT is found to be positive.

The Malaysian Health Technology Assessment Section (MaHTAS), Ministry of Health Malaysia (MOH) reported that annual screening using iFOBT can be effective for preventing advanced CRC (i.e., reducing the risk of developing advanced

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CRC by 28-46% and reduce the mortality by 23-60%). Regular iFOBT can detect pre-cancerous lesions and when detected in early stages, will reduce CRC-related mortality. iFOBT followed by colonoscopy is the most cost-effective screening strategy compared with no screening or colonoscopy alone. The recommended screening program estimated an incremental cost-effectiveness ratio of RM9,377.65 compared to no screening.<sup>12</sup>

The sensitivity and specificity for iFOBT is 67% and 85% respectively.<sup>13</sup> Although the sensitivity and specificity are only moderate, the acceptability of iFOBT as a screening tool is still very high for detecting CRC owing to its noninvasive procedure and the ease in collection of specimens by patients. Furthermore, early diagnosis of CRC would potentially reduce the economic burden and mortality rates in the country.

The MOH implemented the CRC screening programs using iFOBT for screening of average risk population at public primary care health centres, since 2016. To date, studies assessing the outcomes of this screening program is scarce. This study was to evaluate the prevalence and factors associated with CRC among patients attending a public primary care health centre who underwent the screening programme.

## MATERIALS AND METHODS

### *Study design and setting*

This cross-sectional study was conducted at a public primary healthcare centre, the Klinik Kesihatan Mahmoodiah in Johor Bahru (KKMJB) district. The KKMJB CRC Screening Registry began when the CRC screening program was initiated in 2016 on the directive of the Johor Bahru District Health Office. The CRC screening program initially catered to patients' risk stratification profile by the primary care provider (PCP). The program is also available on a walk-in basis; where clients can request for this service (self-referral), with the staff nurse in charge at the clinic registration counter (Figure 1). The criteria for the latter included adults who are asymptomatic or no known risk for CRC. Hence, a clinic-based registry was formed. The clinic-based registry captured 11-items: socio-demographic data of clients (4 items), date of iFOBT test kit issued, reviewed by Clinician (medical officer or Family Medicine Specialist), iFOBT results, referral to Surgical Outpatient Department (SOPD) (i.e., patient agreed or refused), appointment date at SOPD, colonoscopy results, staging of CRC. The data of patients /clients registered during 1st January 2016 till 31st December 2018 were analysed.

### *Study tool*

A data extraction form was used to consolidate the information from CRC registry and information verified from Surgical Clinic, Hospital Sultanah Aminah Johor Bahru (HSAJB) (i.e., colonoscopy findings and histopathological examination reports). All patients/clients listed in the KKMJB CRC registry in the study period were included, while patients with non-traceable results or iFOBT samples rejected by laboratory for any particular reason (e.g., sample leakage) were excluded from analysis. All data were entered into SPSS spreadsheets, using pre-defined codes to ensure patients' anonymity was maintained throughout the study and the subsequent period.

### *Statistical Analysis*

Descriptive statistics was used to summarise the data. Frequencies and percentages were used to describe quantitative variables. Median and interquartile range were used to describe non-normally distributed data. Univariate non-parametric analysis such as Mann Whitney U and Fisher's exact tests were applied to determine differences and associations between sociodemographic variables and iFOBT results. Statistical Package for the Social Sciences (SPSS version 25) was used to perform analysis. The data from patients who had samples rejected by the clinical diagnostic laboratory due to technical /sampling errors were excluded from analysis.

Operational definition of terminologies used in this study include: Appropriate indication for CRC screening refers to asymptomatic patients aged 50-70 years old.<sup>11</sup> Compliant to annual CRC screening program refers to yearly CRC screening using iFOBT for asymptomatic patients.<sup>11</sup> Average risk population refers to a person who is asymptomatic and does not have family history of CRC, personal history of colorectal cancer or certain types of polyps or inflammatory bowel disease, confirmed or suspected hereditary colorectal cancer syndrome, e.g., familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC).<sup>11</sup>

Written consent from the patients was not obtained in the study since the study utilised secondary data from the primary care clinic records. However, all patients who registered at the clinic were notified during registration that the data collected during the clinic visits could potentially be used to improve the clinic services and performance, i.e., audit evaluations. Access to the database was restricted to the co-investigators only. The original electronic data was electronically encrypted, and password protected.

The ethical approval was obtained from Research Ethics Committee in Universiti Kebangsaan Malaysia (JEP-2019-554, FF-2019-403), Medical Research & Ethics Committee's (MREC) KKM/NIHSEC/P19- 1739 (5), Ministry of Health Malaysia and as well the Johor State Health Director. This study was self-funded by the research team.

## RESULTS

A total of 591 patients, were screened for CRC during the 2016-2018. However, seven (7) patients were omitted from the final analysis. Three (3) patients were excluded due to non-traceable iFOBT results. Four (4) patients were rejected due to leakage of samples. Altogether 584 patients were included for the final analysis. Overall, the median age of the patients who underwent CRC screening was 58 (10) years old (range 50.0-70.0 years). Most of the screening tests were performed in the year 2017 with 242 patients followed by 201 patients in 2016 and 141 in 2018. The profile of the patients screened are summarised in Table I.

Patients/clients meeting the recommended age-criteria for CRC screening were from 2018, (74.7%) compared to only 42.7% in 2017 and 46.8% in 2016.

Table I: Profile of CRC screened patients according to year

Characteristic	2016		2017		2018		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
<b>Gender</b>								
Male	121	60.2	129	53.3	64	45.4	314	53.8
Female	80	39.8	113	39.8	77	54.6	270	46.2
<b>Ethnicity</b>								
Malay	64	31.8	99	40.9	87	61.7	250	42.8
Chinese	94	46.8	108	44.6	35	24.8	237	40.6
Indian	40	19.9	34	14.0	19	13.5	93	15.9
Others	3	1.5	1	0.4	0	0.0	4	0.7
<b>iFOBT results</b>								
Negative	163	81.1	208	86.0	125	88.7	496	84.9
Positive	38	18.9	34	14.0	16	11.3	88	15.1
Completed colonoscopy*								
No	19	50.0	19	54.3	7	41.2	47	51.1
Yes	19	50.0	16	45.7	10	58.8	45	48.9
<b>Period prevalence (Prevalence of CRC/year)</b>		0		3/242=0.01		1/141=0.01		
<b>Compliant to annual CRC screening program</b>								
No	199	98.9	238	98.3	138	97.8	575	98.5
Yes	2	1.1	4	1.7	3	2.2	9	1.5

\*Confirmed from SOPD records

Table II: Association between sociodemographic variable and iFOBT test results.

Year	Variable	Negative	Positive	$\chi^2$	(df)	P value			
		n (%)	n (%)						
2016	<b>Age, Median (IQR)</b>	61 (12.0)	61 (16.0)	16075.5a		0.939			
	<b>Gender</b>								
	Male	101 (62.0)	20 (52.6)				1.120	(1)	0.290
	Female	62 (38.0)	18 (47.4)						
	<b>Ethnicity</b>						0.770b		
	Malay	53 (32.5)	11 (28.9)						
Chinese	75 (46.0)	19 (50.0)							
Indian	33 (20.2)	7 (18.4)							
Others	2 (1.2)	1 (2.6)							
2017	<b>Age, Median (IQR)</b>	58 (12.0)	60 (10.0)	3094.5 <sup>a</sup>		0.277			
	<b>Gender</b>								
	Male	105 (50.5)	24 (70.6)				4.747	(1)	0.029
	Female	103 (49.5)	10 (29.4)						
	<b>Ethnicity</b>						0.822b		
	Malay	86 (41.3)	13 (38.2)						
Chinese	93 (44.7)	15 (44.1)							
Indian	28 (13.5)	6 (17.6)							
Others	1 (0.5)	0 (0.0)							
2018	<b>Age, Median (IQR)</b>	58 (9.0)	57 (17.0)	988 <sup>a</sup>		0.938			
	<b>Gender</b>								
	Male	54 (43.2)	10 (62.5)				2.132	(1)	0.144
	Female	71 (56.8)	6 (37.5)						
	<b>Ethnicity</b>						0.182 <sup>b</sup>		
	Malay	80 (64.0)	7 (43.8)						
Chinese	28 (22.4)	7 (43.8)							
Indian	17 (13.6)	2 (12.5)							
Others	0 (0.0)	0 (0.0)							

a Mann Whitney U, b Fisher's exact test

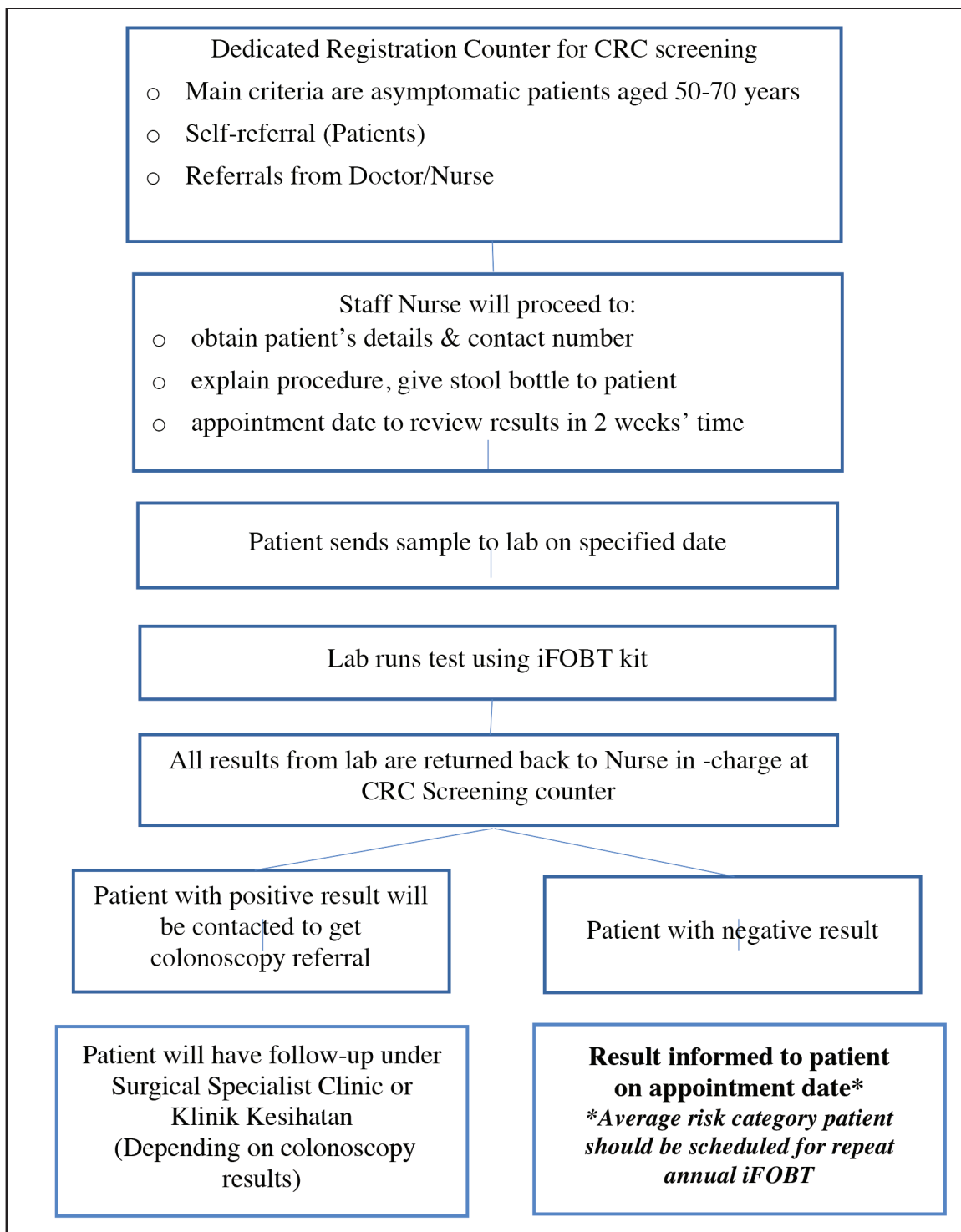


Fig. 1: CRC Screening Program at KK Mahmoodiah, Johor Bahru.

In general, 15.1% of patients/clients screened during the 2016-2018 period were iFOBT positive. The highest percentages of positive iFOBT test were in 2016, [38(18.9%)] and the count was lower over the years. Altogether, a total of 88 patients required referral for colonoscopy (Table 1). However, colonoscopy was performed for 43 out of 45 patients (95.6%). The histopathological examination results indicated that 29.7% had Adenomatous Polyps. The CRC screening program diagnosed four patients with CRC during

the study period. The number of cases confirmed with CRC from colonoscopy alone were 3 cases in 2017 and one in 2018. This makes the period prevalence, which is the proportion of patients with CRC in particular year, i.e., 0.01 in 2017 and 2018 respectively.

There was no significant difference in the median age of patients tested ( $p>0.05$ ). iFOBT results were not associated with ethnicity ( $0.182<p<0.822$ ). As for gender, no significant

association was observed with iFOBT result,  $\chi^2(df)= 1.120(1)$ ,  $p=0.290$  in 2016 and 2018,  $\chi^2(df)= 2.132(1)$ ,  $p=0.144$ . However, for 2017, gender was significantly associated with iFOBT result,  $\chi^2(df)= 4.747(1)$ ,  $p=0.029$ . Despite almost homogenous gender distribution of the patients screened in 2017, more males tested positive for iFOBT [24 (70.6%)] compared to female patients [10 (29.4%)].

## DISCUSSION

To our knowledge, this is a first study to evaluate the CRC screening program from a public primary care health centre in Malaysia. Our study provided an overview of the outcomes of a CRC screening program conducted at a public primary care healthcentre. For the 2016 – 2018 period, an overall of 15.1% of the patients screened had positive iFOBT test. However, only half of the patients who tested positive for iFOBT proceeded with colonoscopy for further investigation and diagnosis. Since the majority of patients tested 'negative' for iFOBT, we are unable to conclude if the screening in these individuals have been able to safely reassure both patients/clients and the primary care team have succeeded in ruling out CRC.

The Clinical Practice Guidelines on CRC management (2017) by the Malaysian Ministry of Health emulated the American and European CRC screening guidelines, recommends the age of 50 as the starting age for screening.<sup>14-15</sup> However, the consensus from the Malaysian Society of Gastroenterology and Hepatology, suggested that screening for colorectal cancer in Malaysia should start earlier than that of Europe and the United States of America.<sup>16</sup> This is based on Malaysian studies which reported approximately 90% of the CRC incidence occurred among those aged over 40 years old and geriatrics people above 60 years of age<sup>17</sup> Moreover, the Malaysian National Cancer Registry reported that adults younger than 40 diagnosed with CRC, accounted for only 7% of the CRC incidence in Malaysia.<sup>10</sup> Hence the recommendation was made for screening to be done among those aged 50-70 years only. However, in our study, slightly more than half of the patients were not in the recommended age range for the 2016-2017 period. This could be due to the fact that the CRC KKMJB Registry combined patients who were referred by the primary care team (i.e., symptomatic or had risk factors for CRC) as well as patients who may be from the asymptomatic or average risk. The proportion of age-appropriate patients screened in 2018 was higher at 74.7% and this could be due to the publication of the first CRC CPG in November 2017, offering a better guide to primary care team. The prevalence of CRC per year in our study was 1:100 among patients who had no or average risk for CRC based on our study.

Consequently, our study found the proportion of patients who returned for annual iFOBT screening was dismal, ranging from 1.1-2.2% compared to 34.6% in Canada.<sup>18</sup> Once tested negative for iFOBT for that year, Malaysian patients/clients are required to repeat the test annually, if they are in the 50 to 70-year-old age group. This suggests that the majority of the patients screened negative with iFOBT did not return to continue with the surveillance for CRC. Appropriate mechanisms should be put in place to educate

and re-enforce the staff as well as patients, that annual screening is advised even if the iFOBT screen is negative for that particular year. Methods to increase the screening rate such as sending out reminders to patients annually via post or short messaging service or one-to-one patient interaction when informing results.<sup>19</sup> The percentage of patients who comply with annual screening compliance should be the key performance index for the CRC screening program. Hence, it is our postulation that the screening program did not meet its objective for early detection of CRC in a cost-effective manner as per the original intention of this program. In terms of improving the CRC screening program at KKMJB, patients/clients in the average risk category should be given a reminder or assigned an annual repeat iFOBT appointment, after receiving results of the iFOBT for that particular year. The primary care team should also include safety netting measures for patients/clients should they develop symptoms of CRC at any time.

Due to diversity and ethnicity of the residents of Malaysia, the demography of CRC could differ from the developed countries. Despite this, the risk of CRC by gender is the same worldwide as the age-standardized incidence is higher among males than females.<sup>2,17</sup> However, the current recommendation by CPG does not differ by gender even though the screening outcome differs. This study demonstrated a slightly higher proportion of positive iFOBT in males than in females, although the association between gender and screening results is not significant except for in 2017. Contrastingly, studies from UK and US indicated that individuals subjected to CRC screening were higher in women than men.<sup>20-21</sup> Meanwhile, a study in Malaysia has suggested that women have a 59% higher chance of being screened for CRC than men when adjusted for age and ethnicity.<sup>22</sup> Although the possible reasons are inconclusive, improvement in the CRC mortality perception among male could be reflecting the result of this study.<sup>23</sup> Our study implies that perhaps CRC screening should be included among the female patients aged 50-70 years who attend primary care facilities, as an additional organised preventive health advise together with screening for cervical cancer (Papanicolaou test) and breast cancer screening (Mammogram).

In terms of ethnicity, the incidence of CRC is reported to be highest among the Chinese, followed by Malays and Indians in Malaysia.<sup>9,17</sup> In studies conducted in Malaysia and Canada, the utilisation of healthcare services is known to be low among the Chinese compared to other ethnicities, for various reasons such as refusal to seek specialist care for chronic or age-related conditions, socio-cultural taboos or due to under reporting.<sup>24-25</sup> On the contrary, in our study, the majority of the patients screened in the primary care clinic in 2016 and 2017 were Chinese. However, the proportion of Chinese patients was lower, almost 50% in 2018. There is no clear explanation for this finding. However, it must be taken into consideration that screening of CRC in private health care facilities may play a significant role in utilisation of healthcare facilities, as the demand for private healthcare services has increased in Malaysia, even though the cost of screening is significantly higher than in the public sector. Screening programs for malignancy may be offered as 'package deals' for wellness programs organised by private

hospitals or private clinical diagnostic labs. These screening packages may be conducted in better surroundings and include multiple cancer screening programs in one setting, at competitive prices. As opposed to screening programs conducted in public healthcare facilities, various factors may deter the patient from returning for annual CRC screening. Factors such as availability of test kits, laboratory facilities and long waiting time at the public primary care health centres are some of the significant barriers to CRC screening in Malaysia.<sup>26-27</sup>

The limitation of this study is the retrospective analysis of data obtained from the program, and the limited variables extracted for analysis from the KKMJB CRC screening program database. The results from this study may not be generalised to all public primary care healthcentres in Peninsular Malaysia. However, despite the introduction of screening campaigns, the CRC incidence in Malaysia is still on the rise with most cases still being diagnosed at late stages.<sup>4-6</sup> Hence, remedial measures are required to ensure the quality of CRC screening programs achieves its intended objectives and more importantly prevent wastage of resources. Our study suggests that the CRC screening program in asymptomatic or average risk population could be further improved with participation of positive iFOBT who proceeded for colonoscopy and the returning of negative iFOBT patients for annual screening. iFOBT positive patients must be encouraged to undergo colonoscopy for further diagnosis. As such, our study found close to one third of the patients who underwent colonoscopy had adenomatous polyps, which had potential for malignant change, hence requiring closer monitoring. By performing colonoscopic polypectomy for higher risk population, the incidence of CRC will be reduced and thus prevent mortality due to CRC. We recommend a more focused delivery of the pre iFOBT counselling on the interpretation of results should be included for all patients/clients undergoing screening for CRC to improve patients/client's compliance to the screening program.

Future studies should include data analyses from more public primary care health centres across Malaysia, representative of urban, suburban and rural facilities as well as private healthcare facilities. Serial analyses of CRC screening programs conducted after the release of the CPG CRC and its impact on the program should be assessed, especially in ensuring the better compliance to annual screening in the average risk group in the population who attend primary care health centres.

## CONCLUSION

Screening for CRC among average risk groups in primary care should focus on recruiting more female patients/clients as an organised activity. Prevalence of CRC detected from screening with iFOBT was 1 per cent. Evaluation of CRC screening programs should focus on proportion of iFOBT positive patients progressing to receive definitive colonoscopy and complying to annual surveillance screening.

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## CONFLICT OF INTEREST

The authors declare they have no competing interest.

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