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## Review Article

# Current status and future challenge of population-based organized colorectal cancer screening: Lesson from the first decade of Taiwanese program

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Colorectal cancer (CRC) is the most common cancer in Taiwan, and is the third leading cause of cancer-related death. Screening has been proven the most effective way to reduce CRC mortality, and stool-based screening is currently the most popular method of screening worldwide. In 2004, Taiwanese government launched a nationwide screening program and fecal immunochemical test (FIT) is offered biennially to individuals aged 50 to 75. The results from the program have demonstrated that FIT screening could effectively reduce the mortality from CRC.

Nevertheless, there were some problems needed to deal with. First, the occurrence of interval cancers, which are associated with the performance of screening tests or quality of colonoscopy, has affected the program sensitivity. Second, increasing participation in the program has increased the demand for colonoscopy and the burden on public health workers. Third, some individuals are non-compliant with FIT screening, and with the recommendation for colonoscopy after a positive FIT, which may be the result of insufficient awareness toward CRC and screening of the public. Fourth, long-lasting financial support for this program is necessary for its success. All of these problems need to be solved via collaboration between the screening organizer, screening distributor, and professional societies.

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## Introduction

Colorectal cancer (CRC) is currently the fourth leading cause of cancer death worldwide, and Asian countries have experienced a remarkable rise in both CRC incidence and mortality in the past few decades owing to the increasingly Westernized lifestyle and aging population. In Taiwan, CRC has been the most common cancer for the past 9 years, with an age-adjusted incidence of 44.7 per 10<sup>5</sup> persons, and mortality of 14.9 per 10<sup>5</sup> persons in 2015. It is now also the third leading cause of cancer death in Taiwan, and impacts greatly on the health care system.<sup>1</sup>

Screening for CRC has proven effective in reducing mortality from CRC, and pooled results of prior randomized trials with guaiac fecal occult blood test (gFOBT) screening have shown a reduction of CRC mortality of 15%.<sup>2</sup> Though endoscopy-based CRC screening has the advantages of higher sensitivity for detecting both cancer and precancerous lesions, and also the ability to remove benign neoplastic lesion at the same time, thereby greatly reducing the incidence and mortality of CRC, its high invasiveness, high cost, and manpower demanding characteristics limits its use in population screening, especially in regions with limited endoscopy capacity.<sup>3–6</sup> Currently, only a few countries adopted colonoscopy as the primary screening modality for CRC. In contrast, fecal occult blood tests, including the gFOBT and fecal immunochemical test (FIT), are capable of identifying high-risk individuals, and are currently the most widely used screening test worldwide.<sup>7,8</sup> FIT has superior sensitivity for detecting early-stage CRC and advanced adenoma, with similar specificity as compared with gFOBT, and it does not require dietary restriction prior to testing and thus may improve screening uptake.<sup>9–12</sup> Moreover, evaluation of the test is highly automated, and therefore can facilitate high-throughput management of fecal samples, and the screening organizer can also adjust the cutoff for a positive test based on the capacity for performing colonoscopies making it the most popular screening test worldwide.<sup>8</sup> In 2004 the Taiwanese government launched a nationwide CRC screening program with FIT screening, after a successful pilot program. This review will present our experience at different stages of the FIT-based population CRC screening program, from the pilot program to introduction of the nationwide full program, and address the future challenges of the program.

## Pilot stage

Prior to the commencement of the full program, in 1999 a pilot trial with FIT (Eiken OC Sensor) screening was conducted in Keelung, a city located in northern Taiwan with population of 0.38 million, as a part of an integrated multiple disease screening program.<sup>13</sup> In the pilot program, the screening uptake rate was 82%, positivity rate was 5.6%, and 70% of FIT-positive subjects were compliant with follow-up colonoscopy, which demonstrated the feasibility of FIT screening in community in terms of public acceptance and impact on clinical service capacity.<sup>14</sup> It also showed that of the cancers detected by screening, as high as 70% were localized, which was a strong contrast to

clinically (non-screening) detected cancers of which less than 40% were localized. Based on the results of the pilot program, serial studies were conducted which included a simulation study predicting the programs potential effectiveness on reducing CRC death, and also a modeling study showing that 20 µg hemoglobin/g of feces was the optimal cutoff in our population.<sup>14,15</sup> In addition, the simulation study also demonstrated that concurrent screening for several chronic diseases such as hypertension, obesity, diabetes, and metabolic syndrome may work additively with screening on reducing CRC mortality, which is attributable to the effect of primary prevention by identifying and controlling the abovementioned risk factors.<sup>14</sup> Based on the experience and encouraging results from the pilot program and subsequent simulations, FIT screening was considered a feasible and effective way for population CRC screening in Taiwan.

## Full program

### Target population and screening logistics

After the enactment of the Cancer Control Act in 2003, the Taiwanese government launched the nationwide CRC screening program in 2004 as a part of the National Cancer Control Program. Individuals 50–69 years old were eligible for biennial screening from 2004 to 2009, and then the upper age limit was increased to 75 years old in 2013. Participants with positive results were referred for follow-up examinations, either with colonoscopy or with double-contrast barium enema plus flexible sigmoidoscopy if colonoscopy was considered not feasible. Patients with a neoplasm identified at the follow-up examination were treated as appropriate, and those who were FIT-negative were encouraged to continue biennial FIT screening.

The method of offering the screening service differed in the inaugural stage and in the full roll-out period. In the inaugural stage, people were informed by mass media that they could visit regional health centers to obtain the FIT screening kits under the supervision of regional health bureaus (outreach approach). In the roll-out period, clinics and hospitals participated in the program, and screening kits were also available in clinics and dedicated cancer screening service window in hospitals (inreach approach) without the need of making appointment for outpatient clinic.<sup>16</sup> Detailed descriptions of these two approaches are further described later in this article.

Participant flow of the FIT screening program is illustrated in [Figure 1](#).

### Fecal immunochemical testing

Two FIT systems, OC-Sensor (Eiken Chemical Co. Ltd, Tokyo, Japan) and HM-JACK (Kyowa Medex Co. Ltd, Tokyo, Japan) were used in the program. Selection of the kit was based on the purchasing process and specific considerations of individual municipalities and hospitals. A cutoff of 20 µg hemoglobin/g feces was used to determine positivity with either kit, and only certified laboratories were allowed to process the submitted tests. The laboratories underwent regular audits and accreditation to ensure the quality of FIT

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