

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Organized colorectal cancer screening in Lampang Province, Thailand: Preliminary results from a pilot implementation programme
AUTHORS	Khuhaprema, Thiravud; Sangrajrang, Suleporn; Lalitwongsa, Somkiat; Chokvanitphong, Vanida; Raunroadroong, Tawarat; Ratanachu-ek, Tawee; Muwonge, Richard; Lucas, Eric; Wild, Christopher; Sankaranarayanan, Rengaswamy

VERSION 1 - REVIEW

REVIEWER	Dr Ryan Courtney Research Fellow NDARC UNSW Australia
REVIEW RETURNED	22-Aug-2013

GENERAL COMMENTS	<p>Thank you for asking me to review this paper. It is a well-crafted manuscript and important research which will help to guide the implementation of future colorectal cancer screening programmes in Thailand. The study findings highlight that the programme was feasible and points positively towards future scaling up of the program. This manuscript is seminal research and will be critical to inform future population-level approaches to CRC screening in Thailand. Scientifically, there are no problems with the study.</p> <p>Abstract</p> <p>A relatively high rate of CRC screening participation was found in this study. It is important that the authors explain that a face to face invitation was provided. Most pilot programs in developed countries have not adopted this approach and it does explain partly why the screening rate was high.</p> <p>Introduction</p> <p>The authors have clearly indicated in the introduction the strengths and weakness of various occult blood testing modalities and included information on the current evidence base surrounding FOBT and its effectiveness at increasing early detection and reducing CRC mortality.</p>
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	<p>Please amend the following sentence: "In this context, a decision was made.....safety in order to guide the subsequent national scaling up of the program through the existing public health services". This sentence is quite disjointed and hard to follow for the reader</p> <p>Method</p> <p>The authors indicate that the Lampang Province was used for the pilot project. However, no information is provided on how representative this area is compared to other parts of the country. The authors make the pertinent point this area was selected because of its high incidence of CRC, however, no information is provided on whether this area is representative of the wider Thai population i.e. age, gender, education level, income etc. Please provide information about the samples representativeness.</p> <p>Results</p> <p>The authors indicate that family history of CRC was assessed but do not specify whether this was asked for both first and second-degree relatives. This would help to define what is meant by "family history". Please insert this information for the reader.</p> <p>The authors use the classification of rural and urban for varying districts, however, no index or measurement tool has been used to classify these areas. Please include how and what measure was used to classify Districts as rural vs. urban.</p> <p>In Table 2 "setting" requires a capital letter.</p> <p>On page 13 the authors state "to date" however without any exact date this information is not meaningful. Please insert the exact date so the reader can ascertain in what exact period from study commencement the diagnostic results have been obtained.</p> <p>Discussion</p> <p>Australia's NBCSP and its pilot implementation is ignored in the discussion. A comparison of findings to the Australian context and its results are warranted.</p> <p>Cost-effectiveness of the program is not aired or mentioned. Please</p>
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	include this information or at least address this point in the discussion.
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REVIEWER	Carroll, June Mount Sinai Hospital
REVIEW RETURNED	28-Nov-2013

GENERAL COMMENTS	<p>Abstract:</p> <ul style="list-style-type: none"> - line 11 has a typo - should be "fecal" - Results should indicate screening over what time period - Consider including p values for the differences reported <p>Strengths section:</p> <ul style="list-style-type: none"> - This pilot study doesn't show the efficacy of CRC screening at 5-year intervals. It is a baseline study - future studies will show this. <p>Introduction:</p> <ul style="list-style-type: none"> - More information is needed on the context for this study both to understand it and consider generalizability. This includes information on the health care system generally in Thailand - how is health care delivered? Payment for services? What is usual general role of these health workers who are part of the intervention? - More needed on how CRC treatment was delivered prior to the intervention. were services readily available to those who were symptomatic so this screening program was value added? Or was this screening program a way to get treatment faster? If so, the program would catch incident cases. <p>Methods:</p> <ul style="list-style-type: none"> - Page 7 line 26 - why did you choose age 50-65 i.e. not older cut off? - How did you know the target population of 127, 301 people aged 50-65 with no CRC? - Page 8 line 1 - the Method implies that posters were displayed in all health care facilities, educational institutions, public offices and public places and distributed in person to all households in the province. This is a very broad sweeping statement. More detail is needed here about how the intervention was implemented. As well, was this a new function for the health workers - were they hired for this project - I would like to see some discussion of the cost of the program which is never addressed. - Page 8 line 28 - Was eligibility only age related and no CRC? What about symptomatic individuals? - Page 8 Line 31 - "proportion of households visited were much higher in rural than in urban areas" - this is actually a result. The proportion of households etc who received the intervention should be reported. More information on what "routine visits" mean would be helpful. Do you mean when people came in for medical problems or checkups. It would also be interesting to know what proportion of participation came from home distribution and what from coming in during regular visits - this is not described but would be helpful information if available, for implementation elsewhere - this would go in results section. - page 8 line 53 - I'm assuming "verbal informed consent" was
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	<p>obtained for the whole study before analyzing the sample?</p> <ul style="list-style-type: none"> - Page 10 line 15 - 0.7% had a reported Family History - many would argue that if they had a first degree relative, they should go straight to colonoscopy. Was there any different management of those with a FH? <p>Limitation Section:</p> <ul style="list-style-type: none"> - Only went to age 65 - do you anticipate implications if wanting to scale up to older individuals? - How would you suggest attracting urban population? - Are you able to report any differences between nonparticipants and participants? Do you have any demographic details on them? - Specifics to this province that might have affected uptake should be mentioned - as would have impact for the scale up of the intervention or applying it elsewhere i.e. SES, education, occupation, better organized health care system, community health care workers, availability of colonoscopy and CRC treatment <p>Table 1</p> <ul style="list-style-type: none"> - Please explain "Elementary occupations" - Income - would be helpful to provide context for international readers - Reported family history is low - any comments on this? - What was the definition of rural/urban - was it self-report? <p>Page 11</p> <ul style="list-style-type: none"> - I would like p-values and confidence intervals for the differences (urban/rural, male/female) <p>Table 2 - I think you have urban and rural mixed up as 21, 139 were urban</p> <p>page 13 - Table 3</p> <ul style="list-style-type: none"> - would suggest "number screened with iFOBT" - line 37 - again I'd like some p-values for differences between men and women - line 42 - if reporting serious adverse events - what those included and how obtained should be described in the Methods section <p>Page 14 Table 4 - bivariate analysis - did you consider logistic regression to see what was predictive in your model?</p> <p>Page 16 line 34 - You mention earlier that the intervention was quite different in rural and urban locations - some reporting on that in the results would be helpful and then discussed in discussion section line 38 "higher screening uptake in rural populations than in urban areas indicate that direct person to person..." - I don't think you have cause and effect here - agree they "suggest" this.</p> <p>More discussion on cost needed here - do Health workers normally visit at home - was this added into their normal work flow - if not, would affect implementation in other areas and cost of scale up</p> <p>Page 18 - Other countries have shown that there was a high pick up of CRC on the start-up of a CRC screening program due to incident cases - which lowers with time - ? part of discussion</p> <p>Page 19 - what do you think of the need for qualitative inquiry to determine how best to approach the urban population</p>
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	<p>Strength of this paper is that it describes a program of implementation of CRC screening that could potentially be scaled up for the entire country or used elsewhere. Excellent participation is demonstrated in the program.</p> <p>This program was very well executed and the description would be worth while to others considering such a program.</p> <p>More details regarding the implementation are required however.</p>
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VERSION 1 – AUTHOR RESPONSE

Thank you for asking me to review this paper. It is a well-crafted manuscript and important research which will help to guide the implementation of future colorectal cancer screening programmes in Thailand. The study findings highlight that the programme was feasible and points positively towards future scaling up of the program. This manuscript is seminal research and will be critical to inform future population-level approaches to CRC screening in Thailand. Scientifically, there are no problems with the study.

Thank you for your kind words. We have now addressed your valuable comments with more details in this revised version.

Abstract

A relatively high rate of CRC screening participation was found in this study. It is important that the authors explain that a face to face invitation was provided. Most pilot programs in developed countries have not adopted this approach and it does explain partly why the screening rate was high.

Agreed: We have indicated that target population was invited face to face (please see page 2, abstract, under “design”).

Introduction

The authors have clearly indicated in the introduction the strengths and weakness of various occult blood testing modalities and included information on the current evidence base surrounding FOBT and its effectiveness at increasing early detection and reducing CRC mortality.

Please amend the following sentence: “In this context, a decision was made.....safety in order to guide the subsequent national scaling up of the program through the existing public health services”. This sentence is quite disjointed and hard to follow for the reader

Agreed. We have amended the long sentence. Please see the last paragraph under “Introduction” (page 6-7): “In this context, a decision was made to implement a pilot CRC screening program with iFOBT followed by full colonoscopy for test positive persons using existing facilities and personnel in government health services in Lampang Province. This pilot study was implemented to assess the feasibility, acceptability, safety of CRC screening both in urban and rural settings and to inform whether and how to introduce a nationwide, organized CRC screening program through the existing public health services in a phased manner.”

Method

The authors indicate that the Lampang Province was used for the pilot project. However, no information is provided on how representative this area is compared to other parts of the country. The authors make the pertinent point this area was selected because of its high incidence of CRC, however, no information is provided on whether this area is representative of the wider Thai population i.e. age, gender, education level, income etc. Please provide information about the samples representativeness.

We have addressed the representativeness of Lampang province of wider Thai population in the 1st paragraph, page 7: “Lampang Province was chosen to implement the pilot project, due to its representativeness of the wider Thai population in terms of demographic, and socio-economic profiles, a relatively high incidence rate of CRC (14.7 per 100,000 in men and 10.1/100,000 in women), the availability of comprehensive cancer diagnosis, treatment and follow-up care facilities in general, and colonoscopy, histopathology and CRC treatment services in particular, at the Lampang provincial hospital and the Lampang Regional Comprehensive Cancer Center and the existing population-based cancer registry that will help to evaluate the impact of the pilot intervention on CRC incidence and mortality in the province.

Results

The authors indicate that family history of CRC was assessed but do not specify whether this was asked for both first and second-degree relatives. This would help to define what is meant by “family history”. Please insert this information for the reader.

We have indicated that the family history covers both first- and second degree relatives (see the 7th sentence under “training for screening...” on page 8 and Table 1 on page 11-12).

The authors use the classification of rural and urban for varying districts, however, no index or measurement tool has been used to classify these areas. Please include how and what measure was used to classify Districts as rural vs. urban.

The districts were classified as “rural” and “urban” by the National Statistics Office based on demography, economy, educational, occupation and migration criteria (see under “results,” page 12, second sentence): “.....categorized as defined by the National Statistics Office based on demography, economy, educational, occupational and migration criteria. “

In Table 2 “setting” requires a capital letter: Corrected; see Table 2, page 13.

On page 13 the authors state “to date” however without any exact date this information is not meaningful. Please insert the exact date so the reader can ascertain in what exact period from study commencement the diagnostic results have been obtained.: Corrected; please see page 15, second paragraph, first sentence: “As of 21 February 2013.....”

Discussion

Australia’s NBCSP and its pilot implementation is ignored in the discussion. A comparison of findings to the Australian context and its results are warranted.

We now refer to both the Australian pilot project and the National Bowel Cancer Screening Program in the “Discussion” section: See pages 18, 1st and 2nd paragraphs:” In the Australian pilot CRC screening project ,56,907 women aged 55 to 74 years were invited for iFOBT screening during November 2002 to June 2004. Of them 25,840 (45.4%) participated, 25,688 correctly completed iFOBT screening and 2,317 (9.0%) were positive on iFOBT. The pilot project detected 176 persons with advanced adenoma and 67 with suspected cancer yielding a positive predictive value of 19.2%; the estimated cost per additional life year saved in the Australian pilot project was 24,000 Australian \$. (reference: The Australian Bowel Cancer Screening Pilot Program and beyond, 2005. Screening monograph no 6/2005. Commonwealth of Australia. Accessed on 30 November at [Http://www.health.gov.au/internet/screening/publishing.nsf/Content/2DDFA95B20302107CA257](http://www.health.gov.au/internet/screening/publishing.nsf/Content/2DDFA95B20302107CA257)“

page 19, 2nd paragraph; page 20,2nd paragraph, last paragraph; etc.

page 21, last paragraph etc.: “The national scale up of screening following the pilot project in Australia

since 2006 occurs in a phased manner. It introduced national bowel cancer screening program (NBCSP) in 2006 as one off test for those turning 55 and 65 years and testing for 50 year-olds was added in 2008 and for 60 year-olds in 2013; 70 year-olds will be added in 2015. It would then progressively shift to 2-yearly screening of all Australians aged 50-74 years from 2017-18. Thus a full scale national scale up in Australia will take 13 years from introduction.”

Cost-effectiveness of the program is not aired or mentioned. Please include this information or at least address this point in the discussion.

We now briefly mention about the value of a formal cost-effectiveness evaluation in the context of the pilot study in further scaling up of CRC screening in Thailand: please see page 22, last sentence of first paragraph: “Based on the preliminary findings from our pilot study, we are planning a formal cost-effectiveness analysis to determine the costs of all services provided along the screening pathway to estimate screening cost-effectiveness and funding required for the national program.”

Reviewer: June Carroll, Mount Sinai Hospital

Abstract:

- line 11 has a typo - should be "fecal": Corrected
- Results should indicate screening over what time period: Agreed; done:”..... iFOBT between April 2011 and November 2012.”
- Consider including p values for the differences reported: Agreed, please see text and Tables.

Strengths section:

- This pilot study doesn't show the efficacy of CRC screening at 5-year intervals. It is a baseline study - future studies will show this.

Agreed: Please see 1st bullet point under “Strengths and limitations”: This pilot study documents the feasibility, acceptance and safety of CRC screening in a lower-middle income country. See other modifications as well

Introduction:

- More information is needed on the context for this study both to understand it and consider generalizability. This includes information on the health care system generally in Thailand - how is health care delivered? Payment for services? What is usual general role of these health workers who are part of the intervention?
- More needed on how CRC treatment was delivered prior to the intervention. were services readily available to those who were symptomatic so this screening program was value added? Or was this screening program a way to get treatment faster? If so, the program would catch incident cases.

Please see 2nd paragraph, page 6: Thailand has a well-developed public health services with an extensive primary care network well integrated with district, provincial hospitals and tertiary care centers such as several comprehensive regional cancer centers and advanced university hospitals. Four decades ago when Thailand was a low-income country, it invested early in health care and transportation infrastructure that has reached most remote rural communities and helped it to achieve health care at low costs, given the fact that 4.1% its gross domestic product (GDP) for health, a figure far lower than the 10% average in high-income countries. Thailand has been successful in training doctors, nurses, auxillary and paramedical health workers and technicians in large numbers for its health system, with innovative distribution of human resources to rural areas. In addition, health volunteers recruited from local communities play important support, prevention and early detection roles, thereby enhancing community involvement. The entire Thai population is covered through a comprehensive health care package through universal health coverage (UHC) for financing an

extensive range of preventive, diagnostic, treatment and follow-up care and hospitalisations due to any illness (Ref: Hanvoravongchai P. 2013. Thailand-Health financing reform in Thailand towards universal health coverage under fiscal constraints. UNICO study series: No.20 Washington DC; World Bank)

Also see the description, 1st paragraph, page 7: Lampang Province was chosen to implement the pilot project, due to its representativeness of the wider Thai population in terms of demographic, and socio-economic profiles, a relatively high incidence rate of CRC (14.7 per 100,000 in men and 10.1/100,000 in women), the availability of comprehensive cancer diagnosis, treatment and follow-up care facilities in general, and colonoscopy, histopathology and CRC treatment services in particular, at the Lampang provincial hospital and the Lampang Regional Comprehensive Cancer Center and the existing population-based cancer registry that will help to evaluate the impact of the pilot intervention on CRC incidence and mortality in the province.

Methods:

- Page 7 line 26 - why did you choose age 50-65 i.e. not older cut off?:

Nothing wrong with this cut off, although it may be counted as a "limitation"! Even the national program in Australia covers 50-65 years now: page 21, last paragraph etc.: "The national scale up of screening following the pilot project in Australia since 2006 occurs in a phased manner. It introduced national bowel cancer screening program (NBCSP) in 2006 as one off test for those turning 55 and 65 years and testing for 50 year- olds was added in 2008 and for 60 year-olds in 2013; 70 year-olds will be added in 2015. It would then progressively shift to 2-yearly screening of all Australians aged 50-74 years from 2017-18. Thus a full scale national scale up in Australia will take 13 years from introduction."

- How did you know the target population of 127, 301 people aged 50-65 with no CRC?:

The total number of target population was derived from the national statistics office and from the population list (target population of each health centre) maintained by the health centres in the province. We assume apparently healthy people as with no CRC. Please see under "Target population..." page 7.

- Page 8 line 1 - the Method implies that posters were displayed in all health care facilities, educational institutions, public offices and public places and distributed in person to all households in the province. This is a very broad sweeping statement. More detail is needed here about how the intervention was implemented. As well, was this a new function for the health workers - were they hired for this project:

More details now provided: page 7 & 8: "The Government healthcare infrastructure consisting of 154 primary care units (PCUs), 12 community hospitals (CHs), Lampang provincial hospital and Lampang cancer hospital (the Regional Cancer Centre of Lampang) and the doctors, nurses, HWs and technicians in these public facilities provided the various services voluntarily to the screening project as an additional responsibility assigned to them and no added financial incentives were provided to them for these additional tasks. No additional workers were hired for this project"

"The eligible subjects for CRC screening in this study were met, educated, invited and encouraged to participate in screening and the pamphlets and the fecal collection pots were distributed by HWs to eligible subjects during these routine house visits. Family history of CRC among first and second degree relatives was enquired into during the house visits."

- I would like to see some discussion of the cost of the program which is never addressed: We now briefly mention about the value of a formal cost-effectiveness evaluation in the context of the pilot study in further scaling up of CRC screening in Thailand: please see page 22, last sentence of first paragraph: "Based on the preliminary findings from our pilot study, we are conducting a formal cost-effectiveness analysis in collaboration with the Health Intervention and Technology Assessment Program of the Thailand Government to determine the costs of all services provided along the screening pathway to estimate screening cost-effectiveness and funding required for the national program."

- Page 8 line 28 - Was eligibility only age related and no CRC? What about symptomatic individuals?: Yes, eligibility only age related and apparently no CRC. Kindly understand the method of recruitment: we are not enquiring about symptoms!

- Page 8 Line 31 - "proportion of households visited were much higher in rural than in urban areas" - this is actually a result.: Agreed; moved this to the "discussion section"

The proportion of households etc. who received the intervention should be reported. More information on what "routine visits" mean would be helpful. Do you mean when people came in for medical problems or checkups. It would also be interesting to know what proportion of participation came from home distribution and what from coming in during regular visits - this is not described but would be helpful information if available, for implementation elsewhere - this would go in results section. Please see page 19, 2nd paragraph: ". The proportion of households visited were much higher in rural than in urban areas, where the sample collection kits were mostly collected by the eligible individuals during their routine and opportunistic visits to the health centers or community hospitals for health checkups for early detection of diabetes, hypertension and helminthiasis and for medical problems. Unfortunately we could not exactly quantify the proportion of participation from home visits or by visits to the PCUs/CHs as this was not documented in the database. The higher screening uptake in rural populations than in urban areas suggest that more direct person to person contacts and personalized invitations improved participation"

- page 8 line 53 - I'm assuming "verbal informed consent" was obtained for the whole study before analyzing the sample? Yes.

- Page 10 line 15 - 0.7% had a reported Family History - many would argue that if they had a first degree relative, they should go straight to colonoscopy. Was there any different management of those with a FH? No. Family history involved both first and second degree relatives, although the break up is not available. Our protocol did not imply immediate colonoscopy for first degree relatives. Our main objective was to evaluate the feasibility of a iFOBT screening in low-middle income setting.

Limitation Section:

- Only went to age 65 - do you anticipate implications if wanting to scale up to older individuals? We do not think this is a problem.

- How would you suggest attracting urban population? We need to do some qualitative studies to address this aspect.

- Are you able to report any differences between nonparticipants and participants? Do you have any demographic details on them? We have addressed whatever available demographic details in Table 2.

- Specifics to this province that might have affected uptake should be mentioned - as would have impact for the scale up of the intervention or applying it elsewhere i.e. SES, education, occupation, better organized health care system, community health care workers, availability of colonoscopy and CRC treatment:

Please see our response in the 2nd paragraph, page 22: The fact that Thailand has developed an

equitably accessible health care system with universal health coverage and has experienced an inclusive socioeconomic progress covering all regions of the country suggest that the pilot experience in Lampong can be translated to the national population in due course. However additional specific measures need to evolve by qualitative studies to ensure adequate participation in urban areas.

Table 1

- Please explain "Elementary occupations" Changed to "manual labour"
- Income - would be helpful to provide context for international readers: USD conversion is now provided
- Reported family history is low - any comments on this?: Indicates historically low risk of CRC in the past cohorts; CRC risk is increasing now due to increasing trend "western life styles" ; may also reflect some underreporting as well.
- What was the definition of rural/urban - was it self-report?: No; The districts were classified as "rural" and "urban" by the National Statistics Office based on demography, economy, educational, occupation and migration criteria (see under "results," page 12, second sentence): ".....categorized as defined by the National Statistics Office based on demography, economy, educational, occupational and migration criteria. "

Page 11

- I would like p-values and confidence intervals for the differences (urban/rural, male/female): Added now

Table 2 - I think you have urban and rural mixed up as 21, 139 were urban: Thank you, corrected now

page 13 - Table 3

- would suggest "number screened with iFOBT" : Changed as suggested
- line 37 - again I'd like some p-values for differences between men and women: Yes, added.
- line 42 - if reporting serious adverse events - what those included and how obtained should be described in the Methods section : Agreed: Please see page 9 (last paragraph)& 10 (1st paragraph): The findings of colonoscopy, any severe adverse events within 30 days following colonoscopy (such as bleeding, perforation, administration of blood transfusion, hospitalisations for severe abdominal pain, paralytic ileus, cardiovascular events, hypotension, syncope, shock, dehydration, anaphylactic reactions, cardiorespiratory arrest etc.), histology, stage, treatment and follow-up assessment were recorded in a diagnosis and treatment form and entered into the database.

Page 14 Table 4 - bivariate analysis - did you consider logistic regression to see what was predictive in your model? : Logistic regression was used to obtain the crude OR estimates. However, we are now providing the adjusted estimates obtained from including all characteristics in one model. Since Settings was derived from the District variable, we could not include both variables in the same model. Hence the adjusted estimates for the two variables were obtained separately from two different logistic regression models, one including Setting (main model) and the other including district.

Page 16 line 34 - You mention earlier that the intervention was quite different in rural and urban locations - some reporting on that in the results would be helpful and then discussed in discussion section line 38 "higher screening uptake in rural populations than in urban areas indicate that direct person to person..." - I don't think you have cause and effect here - agree they "suggest" this.

Agreed; Please see page 19, 2nd paragraph: ". The proportion of households visited were much higher in rural than in urban areas, where the sample collection kits were mostly collected by the eligible individuals during their routine and opportunistic visits to the health centers or community hospitals for health checkups and medical problems. Unfortunately we could not exactly quantify the proportion of participation from home visits or by visits to the PCUs/CHs as this was not documented

in the database. The higher screening uptake in rural populations than in urban areas suggests that more direct person to person contacts and personalized invitations improved participation”

More discussion on cost needed here - do Health workers normally visit at home - was this added into their normal work flow - if not, would affect implementation in other areas and cost of scale up:

Please see page 8, under “ Training for Screening...”: Health workers routinely visit all households as part of their work: The HWs routinely visit all households under the jurisdiction of each PCU once in 6 months to provide preventive care.

Page 18 - Other countries have shown that there was a high pick up of CRC on the start-up of a CRC screening program due to incident cases - which lowers with time - ? part of discussion: Agreed , but we are still at the start-up phase in Thailand!

Page 19 - what do you think of the need for qualitative inquiry to determine how best to approach the urban population I Yes, we need it.

Strength of this paper is that it describes a program of implementation of CRC screening that could potentially be scaled up for the entire country or used elsewhere. Excellent participation is demonstrated in the program.

This program was very well executed and the description would be worthwhile to others considering such a program.

More details regarding the implementation are required however. Thank you for your kind words. We have now provided more details on implementation.

VERSION 2 – REVIEW

REVIEWER	Dr Ryan Courtney NDARC, UNSW, Australia
REVIEW RETURNED	05-Dec-2013

- The reviewer completed the checklist but made no further comments.