Title:

A preliminary analysis of the cost-effectiveness of the National Bowel Cancer Screening Program – Demonstrating the potential value of comprehensive real world data

Manuscript Word Count: 2,797

Abstract Word Count: 248

Short Title:

Cost effectiveness analysis of the NBCSP

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This is an Accepted Article that has been peer-reviewed and approved for publication in the *Internal Medicine Journal*, but has yet to undergo copy-editing and proof correction. Please cite this article as an "Accepted Article"; doi: 10.1111/j.1445-5994.2011.02585.x

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Abstract:

Background

The complexity and cost of treating cancer patients is escalating rapidly and increasingly difficult decisions are being made regarding which interventions provide value for money. BioGrid Australia supports collection and analysis of comprehensive treatment and outcome data across multiple sites. Here we use preliminary data regarding the National Bowel Cancer Screening Program (NBCSP) and stage-specific treatment costs for colorectal cancer (CRC) to demonstrate the potential value of real world data for cost-effectiveness analyses (CEA).

Methods

Data regarding the impact of NBCSP on stage at diagnosis was combined with stage-specific CRC treatment costs and existing literature. An incremental CEA was undertaken from a government healthcare perspective, comparing NBCSP to no-screening. The 2008 invited population (n=681,915) was modelled in both scenarios. Effectiveness was expressed as CRC-related life years saved (LYS). Costs and benefits were discounted at 3% per annum.

Results

Over the lifetime and relative to no-screening, NBCSP was predicted to save 1,265 life-years, prevent 225 CRC cases and cost an additional $48.3 million, equivalent to a cost-effectiveness ratio of $38,217 per LYS. A scenario analysis assuming full participation improved this to $23,395.

Conclusions

This preliminary CEA based largely on contemporary real world data suggests population-based FOBT screening for CRC is attractive. Planned ongoing data collection will enable repeated analyses over time, using the same methodology in the same patient populations, permitting an accurate analysis of the impact of new therapies and changing practice. Similar CEA using real world data related to other disease types and interventions appears desirable.

Keywords: Colorectal Cancer, FOBT screening, Cost-effectiveness

Introduction

In Australia, colorectal cancer (CRC) is the second most common cancer and second most common cause of cancer-related mortality[1]. Three large randomised studies have demonstrated that biennial faecal occult blood test (FOBT) screening significantly reduces CRC mortality, largely due to diagnosis of CRC at earlier curable stages[2-4]. In Australia, biennial FOBT screening was deemed feasible, acceptable and cost-effective in a pilot study[5], leading to implementation of the National Bowel Cancer Screening Program (NBCSP) in 2006. The NBCSP was most recently inviting Australians aged 50, 55 and 65 years to undergo a FOBT[6]. Future expansion of the eligible population is being considered. The NBCSP recommends symptomatic persons and those with a family history seek medical advice rather than participate in screening[5].

Previous cost-effectiveness analyses (CEA) have concluded that population FOBT screening is cost-effective[5,7-8]. However, these had consistent and specific limitations, including an exclusive reliance on clinical trial data to determine the impact of FOBT testing in the general population. This is particularly relevant given the repeated demonstrations of wide variations when comparing outcomes achieved in fit and motivated patients within carefully conducted and monitored clinical trials, to the outcomes observed in real world patient populations[9]. Further limitations of these CEA include the absence of comprehensive hospital and community based costing data and patient survival; one study substituted Australian survival data with more modern survival data from the USA in a sensitivity analysis which moved the result to well above the acceptable cost-effectiveness threshold[8]. Finally, as practice evolves year by year, any analyses relying on published data to determine treatment costs[10] and survival rates[11] which are inevitably outdated by time of publication, becomes increasingly less relevant to current practice.

Using BioGrid data we have previously reported on the impact of the NBCSP on colorectal cancer stage at diagnosis[12], demonstrating within the community setting, that FOBT screening led to an increased number of early stage cancers and a marked fall in late stage cancers,

when compared to patients presenting with symptomatic disease. In a separate analysis of comprehensive treatment and outcome data from 4 Melbourne hospitals, we showed that the cost of treating CRC was rapidly escalating; the cost of treating CRC in Australia is likely to be around $1,210 Million in 2011 (2008 prices) [13], approximately four times the equivalent cost reported for 2001 [14].

Here we seek to demonstrate that comprehensive real world treatment data, where standardised data collection, and data collation and analysis is supported by BioGrid Australia (www.biogrid.org.au), can be used to reflect both the real impact of FOBT screening in the general population and the true stage specific cost of treating colorectal cancer. Another potential advantage, along with using real world data, is that analyses are as current as possible, and could be repeated and updated on a regular basis rather than being applied as a stand alone CEA.

Method

Research Design

An incremental cost-effectiveness analysis was undertaken from a government healthcare perspective. Net costs and effectiveness of the NBCSP were compared to a no-screening scenario. Costs analysed are associated with invitation and screening, diagnosis, adenoma surveillance and CRC treatment. Effectiveness results are expressed as life years saved from the NBSCP. The year 2008 was nominated as the reference year due to availability of detailed program data. Costs and benefits were discounted at 3% per annum.

Eligible Population

The population invited to participate in the NBCSP in 2008 included 681,915 Australians aged 50, 55 and 65[10]. This population was modelled in both scenarios.

Modelling

A decision analytic model **(Figure-1)** was developed to estimate lifetime costs and benefits associated with the NBCSP. The eligible population enters the model and screening and diagnostic pathways were estimated based on participation rates, diagnostic results and the incidence of adenomas and CRC. Seven health states are assigned to the eligible population (clear, low and high risk adenomas and CRC Stage 1 through 4). For those diagnosed with adenomas, surveillance colonoscopy costs were applied to all cases and treatment cost savings and life years saved due to CRC prevented were applied to a proportion of cases. Treatment costs and life years lost were applied to persons diagnosed with CRC based upon stage of disease. NBCSP invitees who do not participate in the recommended healthcare pathways were assumed to incur costs up to the point of drop-out and to have the same outcomes as the no-screening scenario.

The no-screening scenario assumed no FOBT screening and adopted incidence rates for adenoma and CRC from no-screening reference populations. Many variables are provided for "screened" and "unscreened" persons. People in the NBCSP scenario who chose not to participate are assigned the same values as the no-screening scenario.

Screening participation rates, outcomes and costs

Screening costs relate to FOBT invitation and screening. Costs include program administration, FOBT kits, pathology testing, telephone helplines and a National CRC register. The Australian Government allocated $87.4 million over 3 years for the NBCSP's second phase[6]. An estimate of $30.8 million for the program in 2008 is adopted within our analysis. For the NBCSP scenario, age-specific rates of FOBT screening participation and positive FOBT results were sourced from the NBCSP Monitoring Report[6] **(Figure-1)**. For the no-screening comparator, we assumed no opportunistic FOBT screening and therefore no-screening costs.

Diagnostic participation rates and costs

For screened persons, diagnostic costs were applied to individuals with positive FOBT results and include general practitioner (GP) consultation and colonoscopy costs. Rates of GP consultation and colonoscopy reported by the NBCSP Monitoring Report are presumed to be gross underestimations due to low rates of clinician feedback[6]. However, the report describes that 91.7% of those recorded as consulting their GP proceeded to have a colonoscopy. Our model assumes 90% of persons with positive FOBT consult their GP and 91.7% of those consulting a GP will complete a colonoscopy. For unscreened patients, diagnostic costs were applied to all persons diagnosed with adenoma or CRC. GP costs were sourced from the Medicare Benefits Schedule November 2008 (item 23) and colonoscopy costs (accounting for complication rates[15]) from the Victorian Public Hospital's casemix funding model. We assumed all diagnostic costs occurred in the year of screening.

Adenoma incidence and surveillance costs

For screened persons, low/high risk adenoma incidence rates were sourced from the NBCSP Monitoring Report[6]. For unscreened patients, incidence rates for "diagnosed" low/high risk adenoma were adopted from the control group of a pivotal FOBT screening study[2] **(Table-1)**. Most adenomas in unscreened populations are undetected. Both references defined high-risk adenomas as greater than 10mm. Following identification and resection of adenoma(s), patients undergo lifetime surveillance through regular colonoscopies. The NHMRC recommends 5 and 3 yearly surveillance colonoscopies for completely resected low and high risk adenomas respectively[16]. Consultation with experts have led us to assume that on average, surveillance colonoscopies are performed at half this frequency (10 and 6 yearly) due to poor patient/clinician compliance and many older patients being unfit for colonoscopy. Surveillance intervals, colonoscopy costs and life expectancy were combined to calculate age-specific, lifetime adenoma surveillance costs.

CRC incidence, stage at diagnosis and treatment costs

Our analysis assumes an equal incidence of CRC in both the NBCSP and no-screening scenarios. Recently published age-specific CRC incidence rates were adopted[1]. In the context of biennial screening, our model assumes the expected number of CRC cases is the sum of incidence over two consecutive years.

The stage distribution of CRC at diagnosis for both screened and unscreened patients was sourced from an analysis of the impact of the Australian NBCSP[12] **(Table-2)**. Screen-detected CRC stage distribution was only applied to patients completing the recommended healthcare pathway. The sensitivity of immunochemical FOBT and colonoscopy were also accounted for at 66%[17] and 95%[16] respectively. For screened patients with undetected CRC, the stage distribution of unscreened patients was applied.

Ananda et al. developed a model which calculated CRC treatment costs for stage 1 CRC, stage 2 colon cancer, stage 3 colon cancer, stage 2/3 rectal cancer and stage 4 CRC [13]. This model used data from 3,012 patients with CRC diagnosed between January 2003 and December 2008. For our study, this model was adjusted to determine treatment costs for stage 1 through 4 CRC. These stage specific treatment costs are listed in **Table-2**. Based on clinical experience, we assumed half the treatment costs fell in the screening year and the remainder in the following year.

Years of life lost (YLL) averted (earlier stage diagnosis)

YLL due to CRC were applied to participants diagnosed with CRC in 2008 based on stage of diagnosis in both scenarios. Stage-specific five-year survival rates (5YS) and median survival for non-survivors were sourced from the BioGrid Australia dataset used in the treatment cost model **(Table-2)**. The 5YS analysis was based upon patients in this cohort with available survival data (n=2,818), from which the median follow up was 6.9 years. YLL for non-survivors were calculated as the difference between median survival and age-specific life expectancy[18]. Analyses assumed that patients surviving beyond 5 years revert to normal life expectancy.

Survival benefits gained as a consequence of lead-time bias were accounted for using stage-specific sojourn times[19].

YLL averted (CRC prevention)

High-risk adenomas have the potential to progress to CRC. A study of the natural history of CRC describes 8% of high risk adenomas transforming to CRC at 10 years (increasing to 24% at 20 years)[20], whilst a review confirmed that resection and subsequent surveillance of high-risk adenomas can reduce colorectal cancer incidence by 76-90%[21]. Our analysis conservatively assumes that without intervention, 8% of high-risk adenomas diagnosed during the screening year (2008) would transition to CRC at 10 years and that 75% of these cases are prevented due to their resection/surveillance. We assumed that CRC cases prevented had the same stage distribution as unscreened patients. Treatment cost offsets and life years saved are captured for each CRC case prevented.

Scenario Analyses

We extrapolated costs and benefits to the future eligible NBCSP population to simulate the impact of introducing older age groups where different participation and incidence rates are observed[1,6]. The population was sourced from the Australian Bureau of Statistics[22]. Data for 50, 55 and 65 year olds was applied to age groups 50-54, 55-59 and 65-69, and a "line of best fit" was utilised to estimate the same data for 60-64 and 70-74 age groups. The NBCSP budget (screening costs) was increased proportionally with the number of persons screened. Other cost assumptions were the same as the primary model. Additional scenario analyses include increasing FOBT participation rates (25% increase, 50% increase and 100% participation), adopting alternative UK 5YS rates based on a larger patient cohort, but not age-specific to the target population[23], adopting NHMRC guidelines for adenoma surveillance frequencies, increasing the proportion of CRC prevented by adenoma resection/surveillance to the maximum rate (90%) observed in previous clinical trials, and adjusting the discount rate to 0%. We also simulated the impact of re-inviting 390,000 people who received defective FOBT kits, as reported by the Department of Health and Aging.

Results

In 2008, 681,915 people were invited to participate in the NBCSP. Modelling predicted that from this population, 1,664 CRC cases would be diagnosed in both scenarios, however, earlier stage diagnoses are seen in the NBCSP scenario. An additional 6,021 adenomas diagnosed in the NBCSP scenario was also projected. Relative to the no screening scenario, the lifetime benefits from screening included 1,265 life years saved (LYS) and 225 CRC cases prevented. The NBCSP scenario resulted in additional screening, diagnostic and surveillance costs, partly offset by savings in CRC treatment costs. The total additional cost for the NBCSP scenario was $48.3 million. The resulting cost-effectiveness ratio is $38,216 per LYS **(Table-3)**.

All scenario analyses improved cost-effectiveness with three exceptions: introducing the cost of re-invitations for faulty FOBT kits and the use of outdated stage specific costs led to a cost-effectiveness ratio marginally below the acceptable range, whilst adopting NHMRC guidelines for adenoma surveillance resulted in a ratio slightly above the acceptable range **(Table-4)**. The full participation and zero discounting scenarios had the greatest impact, each decreasing the cost-effectiveness ratio to below $25,000 per LYS.

Discussion

In Australia, an intervention is deemed sufficiently cost-effective for implementation if it costs less than $50,000 per LYS[8]. Approved screening programs for breast and cervical cancer are well within this range[8]. Our study suggests that the NBCSP, as implemented in 2008, is cost-effective at $38,216 per LYS.

Our methods are notable for several reasons. We adopted contemporary treatment costs derived from comprehensive treatment data across 4 hospitals that account for current treatment protocols. **Table-2** compares the costs adopted by our analysis to lower costs reported by O'Leary et al. that were adopted in previous cost effectiveness analyses[10]. Survival data is also current and representative of the Australian population. Calculated benefits from the NBCSP were based upon an up to date analysis of the impact of the Australian NBCSP on

stage at CRC diagnosis. Finally, we utilised observed NBCSP screening costs, rates of participation and positive FOBT[6].

Previous cost effectiveness analyses of the NBCSP followed cohorts through regular screening from invitation until death[8]. Our model is similar to that used by Stone et al (2000), where costs and benefits resulting from one representative year of the NBCSP are analysed[7]. The strengths of the annual model are that observed rather than modelled data is utilised and methods are often more transparent. However, factors related to repeat screening, such as the observation that repeated screening improves participation[2] could not be captured. Our model is conservative with regards to other timing related effects. We have excluded the anticipated higher number of CRC cases diagnosed early in a screening program. We have also assumed 2008 was the first year of screening and therefore cases of CRC prevented are well into the future and heavily discounted, whilst most costs are undiscounted. The large impact of discounting is illuminated by the 0% discount rate scenario analysis which almost halved the cost-effectiveness ratio.

Diagnostic costs were $15.7 million higher in the screening scenario because colonoscopies are recommended for all persons with a positive FOBT. Approximately half the colonoscopies were estimated to reveal adenoma or CRC. Similarly, costs of lifetime adenoma surveillance were $14.7 million higher in the screening scenario due to the higher rate of adenoma detection. Consistent with expert advice, our study assumed less frequent adenoma surveillance than the NHMRC recommendations. We believe our assumptions are an accurate reflection of actual practice, supported by previous cost effectiveness analyses[7]. A scenario analysis adopting the NHMRC guidelines resulted in the NBCSP being marginally above the acceptable cost-effectiveness threshold. However, our assumptions regarding CRC prevention due to adenoma resection/surveillance are very conservative which may counter any concerns regarding the frequency of colonoscopies adopted.

The 5YS adopted in this analysis, whilst calculated specifically for the Australian NBCSP target age group, is based upon a small number of patients. We believe the rates capture advances in CRC treatment as demonstrated by survival improvements for Stage 3 and 4 when compared to McLeish et al data[11] **(Table-2)**. Our data shows superior survival compared to more modern UK rates[23.] We believe this is due to our patient cohort being mostly treated in tertiary referral hospitals. A scenario analysis using the poorer UK survival rates improved the NBCSP cost-effectiveness because worse survival outcomes correlate to greater opportunities to save life years through screening **(Table-4)**. CRC survival is expected to improve further as survival benefits of recently funded treatments, such as bevacizumab and cetuximab, become evident. Therefore, we believe our superior survival rate assumptions are most appropriate.

Screening interventions are dependent upon participation to realise health benefits. The rates used in our study are observed data from the NBCSP in 2008 and are very poor, particularly for 50 year olds **(Figure-1)**. Substantially higher participation rates for FOBT screening have been achieved in other countries[2]. Results from our scenario analyses demonstrate that increased participation will lead to greater health benefits and cost-effectiveness. A movement from current to full participation will shift cost-effectiveness from $38,216 to $23,395 per life year saved. These results should be used as a further impetus to increase public education and awareness regarding both CRC and the NBCSP.

In summary our preliminary data suggests the NBCSP is currently cost effective, however there are multiple limitations to our analyses and we would not suggest that this is definitive. The intent of this study however was to demonstrate that comprehensive real world data can be used to support cost effectiveness analyses based on contemporary data. Such analyses could be employed across many other scenarios where the cost-effectiveness of treatment is of particular interest. As the BioGrid data continues to be updated over time, repeated real time analyses would be possible, and would be of particular interest as new treatment options are introduced. Importantly, following the effort to perform the initial analyses, the same

methodology can be used in repeated interrogations of the data over time to produce valid comparisons with modest additional effort.

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Tables

Table 1 CRC and Adenoma incidence rates for 2008

Age	**CRC Incidence rate** (per 100,000 person)	**Adenoma Incidence rate in NBCSP** (per 100,000 invitations using 2008 participation rates)		**Diagnosed Adenoma Incidence rate in unscreened population** (per 100,000)		**Discounted Lifetime Cost of Adenoma surveillance** (per adenoma)	
		Low Risk	High Risk	Low Risk	High Risk	Low Risk	High Risk
50-54	57.8	311	239	69	95	$2,268	$3,780
55-59	94.7	313	544	29	40	$1,600	$3,200
65-69	245.6	527	1144	58	81	$895	$2,686
Source	AIHW 2008[1]	NBCSP Monitoring Report 2009 [6]		Kronborg et al. [2]		Calculated	

Table 2 CRC stage distribution, lifetime costs and survival data

	Impact of NBCSP on stage at diagnosis (17) (%)		**Cost (AUD$)**		**5 Year Survival (%)**			**Median Survival for non-survivors (years)**
	*Screening (n=40)	*Unscreened (n=1588)	*BioGrid [13] (2011)*	O'Leary [10] (2004)	*BioGrid (2003-2008)	McLeish [11] (1987)	UK NCIN [23] (1996-2002)	*BioGrid (2003-2008)
Stage 1	43%	17%	$34,337	$17,148	84%	89%	93%	1.59
Stage 2	27%	27%	$53,487	$33,364	77%	79%	77%	2.12
Stage 3	27%	28%	$79,924	$25,771	64%	35%	48%	1.84
Stage 4	3%	18%	$71,156	$6,264	19%	1%	7%	0.94

Notes: * adopted in primary cost-effectiveness analyses. Remaining data were utilised for scenario analysis or are included for comparison purposes.

Table 3 Cost-Effectiveness Analysis results for the NBCSP in 2008

	NBCSP	No-Screening	Difference
Costs (million)			
Screening Costs (including recruitment)	30.8	0.0	30.8
Diagnostic Costs	19.9	4.2	15.7
Adenoma Surveillance Costs	19.1	4.4	14.7
CRC Treatment Costs (CRC patients)	97.0	99.8	-2.8
CRC Treatment Cost Savings (CRC prevented)	-12.7	-2.6	-10.1
Total Costs	154.0	105.7	48.3
Effectiveness			
Life years lived (CRC patients)	22,905	22,424	481
Life years saved (CRC prevented)	784	0	784
Total YLL averted	23,688	22,424	1,265
Cost-Effectiveness			
Cost per life year gained	38,216		

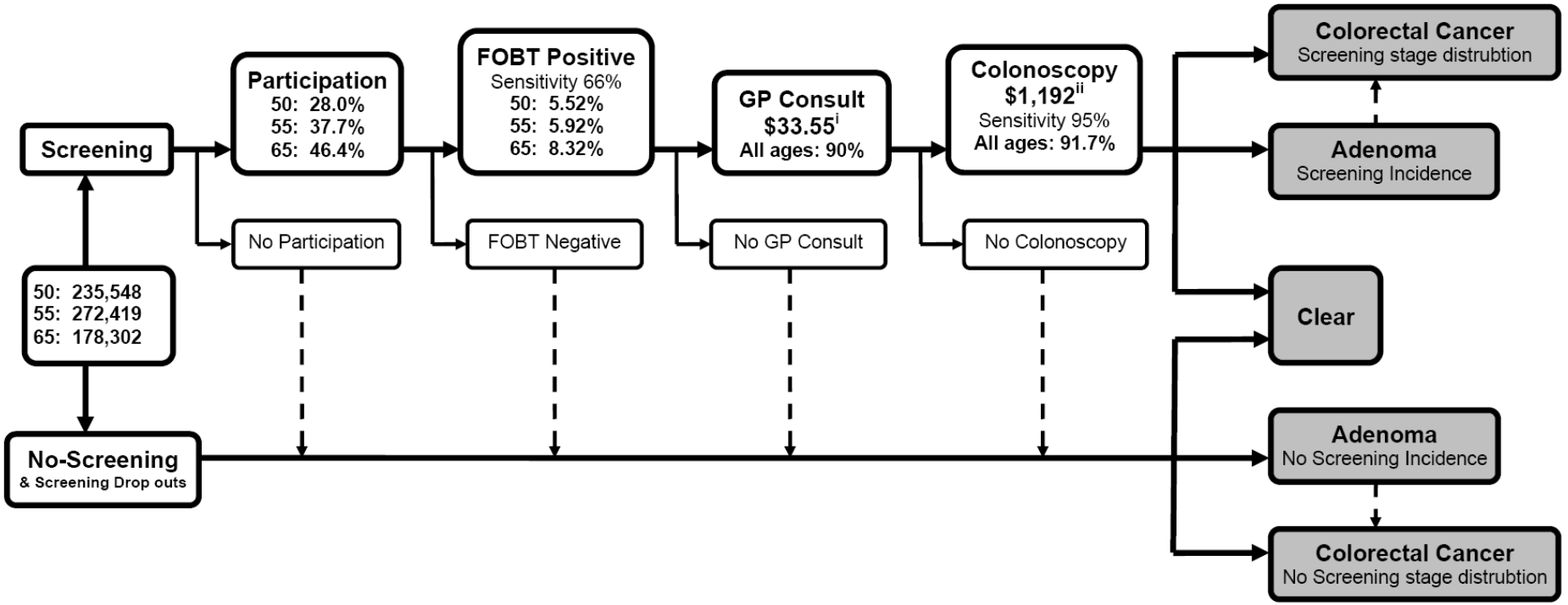
Table 4 Scenario analyses

		NBCSP additional cost	NBCSP additional LYS	Cost per life year saved
Primary analyses		48.3	1,265	$38,216
Outdated costs	Costs reported by O'Leary et al.	57.3	1,265	$45,341
Expanded population	Age 50-74 (n=5,317,282)	187.7	5,925	$31,686
Participation	25% increase (mean 47%)	52.7	1,622	$32,501
	50% increase (mean ~75%)	57.1	1,979	$28,849
	Full participation (100%)	79.3	3,388	$23,395
Survival	UK NCIN 5 Year survival rates	48.3	1,607	$30,076
Adenoma surveillance	NHMRC guidelines for adenoma surveillance	65.6	1,265	$51,850
Discounting	No Discounting	51.4	2,171	$23,656
CRC prevention	90% CRC prevented by adenoma resection	46.3	1,421	$32,572
Faulty FOBT	390,000 Re-invitations	56.8	1,265	$44,897

Note: all scenarios are univariate adjustments based on the primary analyses

Figures

Figure 1 NBCSP Healthcare utilisation and outcomes pathway



[i] Medical Benefits Schedule November 2008
[ii] Weighted colonoscopy cost using complication rates from Vialla et al. [15] and costs from Victoria Public Hospitals (99.69% uncomplicated $1,162, 0.21% bleeding $7,070, 0.10% perforation $19,102)

Figures

Figure 1 NBCSP Healthcare utilisation and outcomes pathway