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## When good evidence is not enough: The role of context in bowel cancer screening policy in New Zealand

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### Abstract

Bowel cancer is a serious health problem in developed countries. Australia, the United Kingdom (UK) and New Zealand (NZ) reviewed the same randomised controlled trial evidence on the benefits and harms of population-based bowel cancer screening. Yet only NZ, with the highest age standardised rate of bowel cancer mortality, decided against introducing a bowel cancer screening programme. This case study of policy making explores the unique resource, ethical, institutional and political environments in which the evidence was considered. It highlights the centrality of context in assessing the relative worth of evidence in policy making and raises questions about the suitability of knowledge utilisation strategies.

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# When good evidence is not enough: the role of context in bowel cancer screening policy in New Zealand

Kathy L Flitcroft, James A. Gillespie, Stacy M. Carter, Lyndal J. Trevena and Glenn P. Salkeld (2011)

Bowel cancer is a serious health problem in developed countries. Australia, the United Kingdom (UK) and New Zealand (NZ) reviewed the same randomised controlled trial evidence on the benefits and harms of population-based bowel cancer screening. Yet only NZ, with the highest age standardised rate of bowel cancer mortality, decided against introducing a bowel cancer screening programme. This case study of policy making explores the unique resource, ethical, institutional and political environments in which the evidence was considered. It highlights the centrality of context in assessing the relative worth of evidence in policy making and raises questions about the suitability of knowledge utilisation strategies.

## Introduction

Bowel cancer, also known as colorectal cancer, is the second largest cause of cancer death in men and women combined in Australia, the United Kingdom (UK) and New Zealand (NZ) (International Agency for Research on Cancer & World Health Organization, 2010a, 2010b, 2010c). There is solid evidence from meta-analysis of randomised controlled trials (RCTs) that screening for bowel cancer using faecal occult blood tests (FOBTs) can reduce the relative risk of dying from bowel cancer by up to 25% (Hewitson et al, 2007). Australia, the UK and NZ examined this same RCT evidence for the benefits and potential harms of population screening for bowel cancer using FOBTs. The UK and Australian governments subsequently piloted bowel cancer screening in 2000 and 2002 respectively, and began implementing national screening programmes in 2006.

In contrast, NZ, with the highest age standardised mortality rates of bowel cancer in the world (IARC and WHO, 2010c) decided against bowel cancer screening and has only recently announced a pilot programme to commence in 2011. This case study of bowel cancer screening policy in NZ explores two research questions: How has context shaped NZ's consideration of the evidence and affected policy decisions about bowel cancer screening? And what are the implications of our findings for the broader issue of getting research evidence into policy and practice? To position this case study of how evidence is used or not, we begin with a review of the research utilisation literature.

### **Getting evidence into policy and practice**

In 1979, Caplan outlined his 'two communities' theory, which described researchers and policy makers as inhabiting 'separate worlds with different and often conflicting values, different reward systems, and different languages' (1979: 459). Since then, the difficulties of getting research into policy and practice has become a central issue in public policy (Pawson, 2006; Nutley et al, 2007; Banks, 2010; Head, 2010a) and four types of models of research utilisation have been proposed.

The first of these, the 'knowledge transfer' model, viewed the solution to the problem in market terms and identified the need to increase the supply of evidence to policy makers (Lavis et al, 2003, 2004, 2005; Nutley et al, 2007). Proponents of this approach advocated capacity building for research in the form of methodology training, more targeted commissioned research and systematic reviews of evidence, as well as a focus on strategies to communicate the research findings in a way policy audiences would understand (Nutley et al, 2007). They argued that barriers to the use of research should be explored, based on the underlying assumption that research needs to be actively pushed to passive policy recipients (the producer-push model). This notion of 'knowledge transfer' assumed that the problem could be overcome by linking the stocks of existing knowledge with the potential users of this knowledge, so it was simply a matter of communicating and disseminating the objective, value-free and high-quality knowledge, which was then automatically accepted and utilised (Nutley et al, 2007)

The second model was a further development of the market-based approach, but with more emphasis on the demand side of the equation (Solesbury, 2001; Armstrong et al, 2008; Bowen and Hyde, 2008). It acknowledged that the process was two-way, and that providing good-quality research was not always enough. Hence, the term 'knowledge transfer' was expanded to 'knowledge transfer and exchange' (KTE) and the focus moved to increasing the demand for evidence, a user-pull approach. Strategies included training of staff in evidence use, facilitating the exposure of policy makers to evidence, offering

incentives to use research, the use of pilot programmes, and the establishment of a research culture within government organisations (Nutley et al, 2007).

The third model is a revival of Caplan's (1979) original 'two communities' theory. It views the problem not as an issue of inadequate supply of, or demand for, evidence, but rather as a lack of connection between the two. For example, Lomas (2000) talked of the need for establishing and maintaining ongoing links between the 'two communities' of researchers and policy makers. This literature focused on the diffusion of knowledge and what can be done to 'get research into policy and practice' by 'bridging the gap' (Elliott and Popay, 2000; Lavis et al, 2002; Nutley, 2003; Davies, 2004; Bowen and Zwi, 2005; Brownson et al, 2006; National Institute of Clinical Studies, 2006; Campbell et al, 2007; Poulos et al, 2007; Hector et al, 2008; Campbell et al, 2009; Mitchell et al, 2009; Schur et al, 2009). Nutley et al (2007) described the two major types of activities that followed from this view — those that sought to integrate researchers within the policy process (by establishing research units, staffed by researchers, within government, or by placing policy makers in research organisations) and the creation of intermediary institutions to act as brokers between these two communities. The latter is reflected by the establishment of health research organisations in the UK such as the National Institute for Health and Clinical Excellence and the National Treatment Agency (Nutley et al, 2007).

Although the interactive 'two communities' approach seems intuitively more likely to resemble policy making in the real world, its validity is yet to be established. Caplan (1979) cautioned that for meta-level problems, more and better contact between the two communities may not necessarily lead to improved understanding and greater utilisation, but may also breed contempt rather than respect: linkage may increase the quantity but not the quality of utilisation. This more cautious opinion is supported by a systematic review of interview studies with policy makers about their use of evidence. This review was limited by methodological problems relating to the incompatibility of many of the studies included in the review, and so did not produce any firm conclusions, but the authors warned that although two-way communication between policy makers and researchers may improve the use of research, it may also promote the selective use of research that suits the aims of the policy makers (Innvaer et al, 2002).

More recently, a retrospective survey of principal investigators in three established research funding agencies in Australia showed that full engagement of researchers and research users was not associated with research value or utility (Adily et al, 2009). Mitton et al (2007: 756), in their review of knowledge transfer and exchange literature, concluded 'that despite the rhetoric and growing perception in health services research

circles of the "value" of KTE ... there is insufficient evidence for conducting "evidence-based" KTE for health policy decision making'.

### **The need for a broader view**

Concerns about the limited success of research utilisation strategies have led to calls for more 'research about research use' (Adily et al, 2009; see also Innvaer et al, 2002; Lavis et al, 2002; Mitton et al, 2007; Armstrong et al, 2008; Head, 2010b). More specifically, Nutley et al (2007) argue that the dominant model of research use involves a relationship between individual researchers and policy makers and note that there is a need for further investigation into the potential roles that research may play at the organisational and system levels. A fourth model, 'knowledge integration', attempts to address the lack of organisational focus in this literature. Knowledge integration is defined as 'the effective incorporation of knowledge into decisions, practices and policies of organizations and systems' (Best et al, 2008: 322). While it acknowledges the importance of organisational-level factors in decision making, it still does not go beyond advocating 'the role of communications as a central strategy in providing the "glue" for connections between people and organisations' (Best et al, 2008: 325).

This paper addresses the literature's lack of focus on the wider context by considering how evidence was used by policy committees and government departments, and the broader context within which research is reviewed, used or not used. Dopson and Fitzgerald (2005: 79) have argued for a 'more sophisticated and active notion of context'. They conclude from their empirical findings of evidence use in healthcare organisations that 'local contexts are multifaceted, multidimensional configurations of forces which often interact in complex ways ... [and] that context is socially perceived and enacted, and is, therefore, actively brought into the processes of innovation' (2005: 102-3). While Dobrow et al (2006) considered the impact of context on evidence use by expert groups, their analysis did not go beyond the policy formulation stage to policy implementation. Pawson (2006: 24-5) stresses the role of context in policy implementation, noting that 'interventions, by definition, are always inserted into pre-existing conditions' and argues for the need to consider evidence in terms of not just 'what works, but what works for whom and in what circumstances'.

We argue here for a broader and more inclusive definition of context, which considers the resource, ethical, institutional and political environments that shape not just the development of policy options, but also their implementation. Using this definition, context becomes crucial to the consideration of evidence and cannot be regarded as just a mitigating, residual factor, to be summoned when other explanations fail. Furthermore, by conceptualising context as a central component of decision making, we demonstrate

the limitations of traditional knowledge translation theories — how one determines the benefit-to-harm trade-off of a population screening programme is context specific, and different policy outcomes are acceptable, even when based on the same evidence. It is the interpretation of that evidence in the local context that matters.

## Methodology

We used case study methodology, which emphasises the importance of describing and interpreting an event or series of related events and their context, in order to illuminate more general issues (Stake, 2005). Flyvbjerg (2006) argues for the value of specific cases and context-dependent knowledge, because of its ability to falsify existing theories and/or generate new theories: 'the advantage of the case study is that it can "close in" on real-life situations and test views directly in relation to phenomena as they unfold in practice' (Flyvbjerg, 2006: 225). Contandriopoulos et al (2011: 453), in their large-scale systematic review of knowledge exchange processes, argue that the breadth and complexity of this literature make it 'ontologically more suited to case studies than to any other method'.

## Methods

### Documents

Documents were analysed to clarify both the chronology of events and the arguments made throughout the policy process. The aim was to obtain all public-domain documents about bowel cancer screening policy in NZ, and the process began with KF examining the three major published reviews of bowel cancer screening in NZ (see Table 1). From these key documents we used snowballing techniques to identify other relevant document sources, including journal articles, commissioned reports, press releases, NZ government websites, committee minutes and screening criteria; interview respondents were also helpful in identifying and providing relevant documents that were not publicly available.

**Table I:** Major reviews of bowel cancer screening in NZ, 1998-2008

Date	Reviewers	Report title	Key recommendations
May 1998	Working Party on Screening for Colorectal Cancer (clinicians, academics, cancer organisation representative, consumer representative)	<i>Population screening for colorectal cancer</i> (National Advisory Committee on Health and Disability, 1998)	Given the modest potential benefit, the considerable commitment of health sector resources and the small but real potential for harm, population-based screening for colorectal cancer with FOBTs is not recommended in NZ. This decision should be reviewed as further evidence becomes available.
Nov 2006	Colorectal Cancer Screening Advisory Group (clinicians, academics, Ministry of Health representative, cancer	<i>Report of the Colorectal Cancer Screening Advisory Group</i> (CRCSAG, 2006)	A feasibility study is an essential prerequisite to a decision regarding a pilot study particularly in relationship to the provision of colonoscopy,

	organisation representative, consumer representative)		given the current capacity constraints in NZ. Planning for a feasibility study should be initiated.
Mar 2008	Caroline Shaw, Ruth Cunningham, Diana Sarfati (academics)	<i>Next steps towards a feasibility study for colorectal cancer in New Zealand: Report for the Ministry of Health (Shaw et al, 2008)</i>	A prevalence and incidence round of bowel cancer screening should be conducted within geographically defined populations to answer key questions. This feasibility/pilot study will require a seven-year timeframe.

### **Interviews**

Twelve face-to-face semi-structured interviews were conducted with key respondents between 23 September 2008 and 16 October 2008, with two subsequent telephone interviews, one in December 2008, the other in April 2010. Another respondent provided written answers to emailed questions on one specific issue. Interviews were semi-structured and lasted between 30 and 90 minutes. Questions varied according to the participant's role in bowel cancer screening policy, but generally covered questions about their personal involvement in the process, how the committees they were part of functioned, and questions on how important they believed particular factors were (research evidence, political and community support, cultural issues, etc). All respondents were asked the same final question: 'Are there any other factors that you think are important that we haven't covered?'

Respondents were selected on the basis of their involvement in policy formulation: purposive sampling was used to maximise the range of expertise of respondents, the variety of perspectives, as well as the type of contribution they had made over the duration of the policy development process. The 14 interviewees were major players in at least one stage of the evolution of bowel cancer screening policy and several were involved across all stages. Members of the three major government review committees (authors of publications in Table 1) were initially targeted, with additional respondents identified through further document analysis and opportunistic suggestions from respondents. Respondents included representatives from cancer organisations, academics, clinicians and former and current Ministry of Health bureaucrats. The Health Minister at the time was unable to attend his scheduled interview due to parliamentary commitments, and one member of the 1998 committee declined to be interviewed.

### ***Data management and qualitative analysis***

All interviews were digitally recorded and transcribed either by KF or a professional transcription service. Responses were coded by KF using NVivo 8 software to tag any part of the interview transcripts that referred in any way, directly or indirectly, to the use of evidence. We reviewed all data allocated to the 'use of evidence' code and inductively identified factors that participants accredited with influencing the use of evidence in decisions regarding bowel cancer screening in NZ. These factors were grouped into four categories, which were then used as the basis of our descriptive analysis. We compared interview responses from those with different experience and expertise, and considered how these views supported or differed from the relevant documents. Our aim was to develop a fuller understanding of the different perspectives of informants. To preserve confidentiality, respondents are referred to by an identification number (ID.), given in brackets after quotations or references attributable to them.

### **The role of context in policy decisions about bowel cancer screening**

Our analysis revealed four broad categories of factors that were important in shaping policy responses to the evidence: the resource, ethical, institutional and political contexts.

#### ***The resource context***

Population cancer screening is resource intensive. The document analysis and key informant interviews revealed serious shortfalls in the capacity of the health system for colonoscopy follow-up of people with positive FOBTs. A 2007 survey (Yeoman and Parry, 2007) revealed that one third of public endoscopy units were unable to offer a diagnostic colonoscopy to patients with possible bowel cancer symptoms within three months of referral, and that 2,225 patients at higher risk of bowel cancer were waiting more than six months for surveillance colonoscopies. Public facilities could not cope with the demand for symptomatic and surveillance colonoscopies and lacked spare capacity for additional colonoscopies generated by positive FOBTs on asymptomatic, average-risk individuals. These limitations stemmed from shortages of endoscopists and endoscopy nurses (Yeoman and Parry, 2007). "The colonoscopy capacity is the major issue. Absolutely.... If we have a faecal occult blood test, an immunochemical one that gives the same positivity rate as in Australia, God help us ... we would need an extra 40,000 colonoscopies. And we do 20,000 currently and don't manage" (ID09).

The lack of a reliable population register and inadequate information technology (IT) systems were also identified as major resource issues by respondents. Significant problems remain in these areas, although the situation is improving. Unlike Medicare Australia or the UK's National Health Service, NZ lacks a national population register to

issue invitations to screen and coordinate recall and follow-up of initial screenees. Since the introduction of the NZ primary healthcare strategy in 2001, general practitioners (GPs) have been required to join a primary health organisation (PHO) and have an enrolled population of patients. These changes have resulted in a dramatic improvement in register capability, with respondents in 2008 estimating that between 85 and 95% of people are now enrolled with a GP, and so are traceable through the PHO registers (ID03, ID07).

Despite these registry advances, suitable IT systems, which are required to enable connectivity between the PHO and cancer registers, and the electronic reporting of FOBT, colonoscopy and pathology results back to these registers, are still under development. Several respondents noted the importance of getting the IT systems in place before beginning the roll-out of a programme (ID09, ID10, ID12, ID13) because "it is really difficult to do it in retrospect and then you have a problem with not knowing what good or harm you are doing with your screening" (ID10).

The relative importance of resource constraints on policy decisions about bowel cancer screening is debatable. On the one hand, the resource context has clearly impacted on the timeline for a bowel cancer screening programme — there were major workforce, registry and IT issues that had to be addressed before the introduction of a programme was deemed possible. Yet, on the other hand, as one respondent noted, "you can argue about whether health system capacity is sort of the ultimate deciding factor, because if you put enough resources into improving health system capacity, you can have a screening programme. You know there's never spare capacity sitting around in the health system waiting for a screening programme to come and take it up" (ID09).

### ***The ethical context***

Concern over the ethical consequences of screening, at both the individual and societal levels, also played a major role in shaping the decision not to screen. Non-maleficence is one of the cornerstones of bioethics (Beauchamp and Childress, 2008). In 2003, the National Health Committee reviewed existing criteria for screening programmes and produced its own set of eight principles customised for NZ, devised to ensure that a screening programme is 'safe and effective' (National Advisory Committee on Health and Disability, 2003). These criteria specifically noted that 'the potential benefit from the screening program should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)' and that 'there should be consideration of social and ethical issues' (2003: 3).

### ***Concerns about individual harms***

Following publication of the RCTs on bowel cancer screening in late 1996 (Hardcastle et al, 1996; Kronberg et al, 1996), the National Advisory Committee on Health and Disability, known as the National Health Committee (NHC), established a Working Party on Screening for Colorectal Cancer in early 1997. Over an 18-month period, the Working Party undertook a thorough review of the bowel cancer screening literature and concluded that: '[O]ver the modest potential benefit, the considerable commitment of health sector resources and the small but real potential for harm, population-based screening for colorectal cancer with faecal occult blood tests is not recommended in New Zealand' (National Advisory Committee on Health and Disability, 1998: 7).

The focus on the potential harms of screening is understandable when placed in the context of NZ's recent history of adverse screening incidents. These included the deliberate experimental non-treatment of women identified with cervical carcinoma in situ at The National Women's Hospital in Auckland (Women's Health Action Trust, undated), under-reporting of cervical intra-epithelial invasion over several years in the Gisborne region (Gisborne Cervical Screening Inquiry), both of which resulted in women dying, and a repeated clerical error causing some women with mammographic abnormalities being allocated to routine follow-up in the Otago and Southland regions (Chamberlain, 2002). All three incidents led to formal investigations and a very public exposure of the potential harms of screening. The lessons learned had a major impact on the professionals running or planning screening programmes: "I think people who work in screening are very aware of the legacy of those things and ... we very much focus on harms of screening because, because we've, you know, we've had all these women die" (ID09). One former Ministry official commented they were there "in those early days with ministers, facing those women in Gisborne, and [I] was very aware of the failures and very aware of what needed to happen and also very aware of how, you know, screening is not like other health services you know, you can do great harm" (ID13).

The second review of bowel cancer screening by the Colorectal Cancer Screening Advisory Group (CRCSAG) reported its findings in November 2006 (CRCSAG, 2006). These specifically addressed the 2003 screening criteria (National Advisory Committee on Health and Disability, 2003) and contained a chapter on the potential harms of screening. This report had access to information on the longer-term follow-up of the original trials and evidence from the UK pilot programme, which included reassuring data on the safety of bowel cancer screening, with few major adverse events such as bleeding following biopsy, and no recorded deaths from screening colonoscopies (CRCSAG, 2006).

Closely related to the concerns over harms to the individual, is the issue of quality of the screening programme. The CRCSAG acknowledged that the extent of colonoscopy complication rates 'will always be dependent on the level of expertise of the operator' (CRCSAG, 2006:53). As one respondent stated: "New Zealand is very conscious about quality in screening ... New Zealanders expect quality in a screening programme and they get very mad if they don't get it" (ID03). The National Screening Unit (NSU) was specifically established in response to the lack of adequate quality assurance measures identified by the 2001 Gisborne Inquiry into cervical cancer screening, and according to one Ministry official has helped to "restore confidence of the ministers as well as of the public in screening."

### ***Concerns about societal harms***

The 2006 CRCSAG report also contained a chapter on the social and ethical issues relating to screening. This chapter specifically examined the cultural issues involved in bowel cancer screening for Maori and the potential for screening to increase inequalities among population subgroups, demonstrating that these issues are considered to be social and ethical issues in NZ. We have classified these issues as societal harms because they threaten a particular group in society, rather than individuals.

Approximately 15% of New Zealanders identify as Maori (Ministry of Social Development [NZ], 2009) and policy makers were concerned about increasing inequity, both in access to screening and in treatment outcomes. Inequitable access was highlighted in the 2005 report Access to cancer services for Maori (Cormack et al, 2005: iv), which noted the need to address the 'fundamental drivers of the differential distribution in New Zealand of the factors associated with access, such as racism and unequal power relations'. The subsequent publication of Unequal impact: Maori and non-Maori cancer statistics 1996-2001 (Robson et al, 2006) demonstrated the disparities in outcomes for bowel cancer specifically. Although bowel cancer is more common among non-Maori than Maori, mortality rates are similar for both populations. Maori were significantly less likely than non-Maori to be diagnosed at a localised stage, and once diagnosed with bowel cancer, Maori were two thirds more likely than non-Maori to die from their cancer.

An overlapping source of potential inequity is socioeconomic. Fewer than half the population has private health insurance, and although treatment in a public hospital is free, co-payments are required for most people to see their GP, resulting in comparatively high user charges for primary care. These costs have been identified as a significant barrier to GP access (Robinson, 2003).

Consideration of these societal harms made assessment of the benefit-to-harm trade-off of bowel cancer screening by policy makers more complicated and time consuming. The benefits of bowel cancer screening had to outweigh its harms, not only to the individuals taking part in screening, but also to society as a whole. Furthermore, the ethical imperative to avoid increasing socioeconomic inequities limited the delivery and pricing options for a bowel cancer screening programme, requiring public sector delivery (so placing an added burden on an already stretched system) and minimal out-of-pocket costs for participants.

### ***The institutional context***

Decisions about bowel cancer screening policy took place within a particular institutional context, which determined the constraints on the policy-making processes. We identified four types of institutional constraints.

### ***Shared responsibility for decision making***

The Treaty of Waitangi, a treaty between the Maori tribes and representatives of the British government, was signed in 1840 and formally (although not legally) recognised the Maori population as the traditional owners of NZ and entitled them to share in government. In 1999, the newly elected Clarke Labour Government pledged to implement structural reform of the health sector, and as part of this process, incorporated specific Treaty of Waitangi references in new health legislation (Earp, 2004). The New Zealand Health Strategy, also published in 2000, is based on the three treaty principles: participation of Maori at all levels; partnership in service delivery; and protection and improvement of Maori health status (Ministry of Health [NZ], 2000). From a policy development perspective, the treaty provisions ensured that policy makers considered the need to respect ethnic difference and avoid making one-size-fits-all policy decisions. Although this approach inevitably results in longer consultative processes and the need for more targeted implementation strategies, the delays could be readily justified on equity or social justice grounds. However, as one respondent noted, consultation is not always genuinely about power sharing, but may in some instances be about getting subsequent Maori approval of decisions that have already been made (ID05).

### ***Conflicting advice from advisory bodies***

In response to publication of follow-up data from the original RCTs of bowel cancer screening and evaluation reports by the UK and Australian pilot programmes, the NSU commenced a review of bowel cancer policy in late 2004. As part of this detailed review process, the NSU commissioned a wide range of additional reports into specific aspects of bowel cancer screening. These included a health technology assessment review to look at

different modalities of bowel cancer screening; a review of cancer registry data; a workforce capability study; a consumer acceptability study; an economic evaluation; a report on inequalities; a survey of colonoscopy capacity; and an international literature review by New Zealand Health Technology Assessment, a research unit of the University of Otago (ID13). The NSU also convened the CRCSAG to provide independent strategic advice and recommendations on the appropriateness and feasibility of bowel cancer screening. The NSU had originally planned to incorporate the CRCSAG findings into its own report, but this group insisted on producing a separate and totally independent report for the Minister of Health. The CRCSAG's final report, published in November 2006, stated that [a] feasibility study is an essential pre-requisite to a decision regarding a pilot study' (CRCSAG, 2006: 10).

Other policy advisers advocated a more proactive stance. In January 2007, the National Screening Advisory Committee (NSAC) prepared a report for the Director-General on the CRCSAG findings, recommending that 'consideration needs to be given to developing a detailed implementation plan' (NSAC, 2007: 2). In March 2007, the NSU hosted Dr Ellis Friedman, a regional director of public health in the UK, to advise on policy options and his report recommended 'the presumptive acceptance' of a bowel cancer screening programme if the minimum success criteria of the feasibility study are met (Friedman, 2007: 8). The Cancer Control Council had also independently advised the Minister of Health in early 2007 that a bowel cancer screening programme should be implemented (Towel cancer funding ...', 2008). The NSU compiled a policy briefing for the Minister of Health based on the results of the background papers and reports it had commissioned, including the CRCSAG report and the Friedman report, as well as on the NSAC report and consultation with the Cancer Control Council. This briefing recommended that "New Zealand should proceed with implementing a bowel cancer screening programme presumptive on the outcome of feasibility studies" (ID13).

There was a subtle but important difference between the CRCSAG and the NSU recommendations — the former implied that nothing needed to be done until the results of the feasibility study were available as that would determine whether NZ should proceed with a bowel cancer screening programme. The latter suggested that NZ should proceed with a bowel cancer screening programme and the feasibility study would test some certain key questions about how it might be organised. The NSU position implied that more action was necessary and it made further recommendations to the Minister of Health about the need to build capacity within the Ministry to both deliver a feasibility study (or pilot) and prepare for the eventual roll-out of the programme (ID13).

### ***Restructuring within the Ministry of Health***

Conflicting advice and lack of consensus on how to proceed coincided with major personnel changes at senior levels of the Ministry. A new chief executive and director-general of the Ministry of Health, appointed in July 2006, began a process of restructuring the directorates. The NSU was moved from the Public Health Directorate (which was disbanded) into the Health and Disability National Services Directorate. This move reflected a reframing of screening from a public health programme to a national service delivery programme (ID08). According to one respondent, the transfer of responsibility for bowel cancer screening policy also related to a more general view within the Ministry that policy advice could be done by anyone and did not require specific content knowledge (ID09). Because the main obstacle to bowel cancer screening was colonoscopy capacity, screening came to be seen as a health service issue and so was reassigned to the "part of the Ministry that deals with hospital services" (ID10).

The disbanding of the Public Health Directorate also meant that there was no longer anyone with public health or screening expertise on the Executive. Moved further to the periphery, the NSU had difficulty in securing Ministry support to build the capacity required to prepare for a bowel cancer screening programme (ID13). The Ministry transferred responsibility for the development of the bowel cancer screening programme from the NSU to the Cancer Control area of the Ministry, which is within the Sector Capability and Innovation Directorate. The rationale for this change was the need to "keep the screening programme very closely linked to the provision of bowel cancer services for high-risk people and also bowel cancer services for symptomatic people" (ID14).

### ***Lack of leadership***

Although bowel cancer screening had found a new home in the Cancer Control Team, no one was really driving the preparation for a bowel cancer screening programme. The process stalled amid a myriad of competing priorities (ID08) as "the Ministry of Health's ... internal process went strangely awry and nothing happened" (ID09). Delay led to irritation, particularly among clinicians. One respondent recalled their frustration

"that there was a recommendation now that we move forward with screening for colorectal cancer ... but that nothing was happening.... You know, people were working but there was no impetus or major leadership. It was all a bit clunk, clunk, clunk sort of stuff. It was hard to see how we were going to step up to the level that we were going to implement, even a feasibility study, without a major will and driver and funding for that." (1D03)

This institutional context set boundaries within which policy makers operated and helps explain the delay in progress: Maori perspectives had to be respected with consequent delays; conflicting sources of advice contributed to policy confusion, if not inertia; and effective decision making was difficult amid ministerial reshuffling and in the absence of strong leadership.

### ***The political context***

The lack of progress with bowel cancer screening policy was significantly influenced by the wider political context. Government commitments to expensive health programmes such as bowel cancer screening require not just evidence, but also political will. In March 2007, the-then Minister of Health approved a paper, 'which set up the groundwork for the feasibility study' (Cunliffe, 2008). However, according to one respondent, he did not follow up with the Ministry when its response had been "very slow" (ID08), while another commented that he "certainly did not have [bowel cancer screening] high on his agenda" (ID03).

The issue gained momentum when David Cunliffe was appointed Minister of Health on 31 October 2007. In early 2008, an Interim Colorectal Cancer Screening Reference Group was formed within the Ministry of Health (ID03). An informal group comprising Ministry staff and external experts, it advised the Ministry on how to move forward with bowel cancer screening recommendations made by the CRCSAG in 2006. The Ministry of Health commissioned a scoping study, giving the authors only a five-week timeframe, and this was presented to the Minister in March 2008 (Shaw et al, 2008). The report noted that the CRCSAG had 'specifically advised that a feasibility study rather than a pilot study be conducted, in order that it is explicit that a decision to proceed with a national programme has not been made' (2008: 57). It discussed the semantics of the terminology used, noting that 'there are no differences in design of feasibility and pilot studies, and so the decision between the two will be based on other considerations such as Government commitment to screening and public perception of the implications of the two terms' (2008: 57). This detailed scoping report noted that there was a 'huge amount of work' needed to prepare for any bowel cancer screening activity and proposed a two-year planning period for preparation of a feasibility/pilot study (2008: 95).

However, 1998 was an election year, and political considerations were beginning to overtake evidentiary ones. The short three-year electoral cycle was poorly synchronised with calls for a slow, evidence-based approach to bowel cancer screening as advocated in the scoping report: pressure was mounting on the government to act without delay. The Interim Colorectal Cancer Screening Reference Group assessed and commented on the scoping report in March 2008, also informing the Minister of Health that professional

groups were becoming impatient because no decision had been made and were planning to formally lobby the government (ID03). On 28 March 2008, the Opposition spokesperson on health, Tony Ryall, tabled a written question in Parliament asking Associate Minister O'Connor whether or not the government had undertaken a feasibility study for establishing a national bowel cancer screening programme (New Zealand Parliament, 2008).

Clinicians, also frustrated with the lack of progress, entered the political arena, and approached well-known television reporter Lorelei Mason (ID06) to ask Minister Cunliffe directly: "Why are we still waiting for bowel cancer screening in New Zealand?" (ID15). Cunliffe confounded his critics by using the television interview in May 2008 to announce the introduction of a bowel cancer screening programme (ID15).

The political context had revealed the limits on the use of evidence in policy making, particularly in an election period. After commissioning the scoping report to specifically consider the data necessary to inform an evidence-based bowel cancer screening programme, the same minister promptly ignored this expert advice in the face of growing political demands for immediate action. As one respondent commented: "because screening is so political and decisions always come down to politicians, really advisory groups can only have a very limited role because in the end it's a judgement call from a politician about whether they want to spend the money and whether it's going to get them votes" (ID09).

In August, the timetable for the programme was fast-tracked, with plans announced for a pilot to begin by the end of 2009, with the aim of commencing a roll-out of the programme from the end of 2011 (NZPA, 2008). The Labour Party had been behind in the polls and the announcement earned it some positive press, while at the same time trumping the Opposition's plans to announce a programme of its own. The announcement of an even tighter timeline for the programme alarmed those working in the Ministry of Health. Bowel cancer screening had been on "the possibility books" but "it wasn't a priority on our work programme" (ID11). Once the announcement was made, Ministry staff "were all hands to the pumps" (ID11) as the impromptu decision had not taken into account their competing priorities and existing workload.

Despite the NSU's experience in developing and running breast and cervical cancer screening programmes, the Cancer Control Team retained responsibility for fast-tracking the introduction of bowel cancer screening, and recruited additional staff to work in a specialist Bowel Cancer Programme in mid-2008. The minister also established a Bowel Cancer Taskforce in August 2008. It initially comprised six 'experts', but no specific district

health board or Maori representation, and was responsible for providing advice and recommendations to the minister on a programme to improve bowel cancer outcomes.

Associate Minister O'Connor noted that '[a] critical part of the Taskforce's operation will be to make sure there is a workforce ready to begin the screening programme' (O'Connor, 2008). Although some additional funding and training for colonoscopists had been allocated, training of colonoscopists takes time and this deadline was seen by all involved as unrealistic, especially given the enormous amount of work that still needed to be done on registry and IT issues. Ministry staff hoped that the independent

Bowel Cancer Taskforce would be able to persuade the minister of the impossibility of his timeline: "certainly the advice [the Ministry] had provided had indicated squarely the risks involved around trying to accelerate a programme" (ID14). As it happened, the Labour Party was defeated in the election on 8 November 2008 and the new National Party government, which now had three years to oversee the introduction of a bowel cancer screening programme, could take the time to consider the evidence properly. The Taskforce did not submit its final report to the Minister of Health, Tony Ryall, until early 2010. On 5 May 2010 Ryall, announced that NZ\$24 million had been allocated over four years for a bowel cancer screening pilot programme to run from 2011 to 2015. A decision on whether or not to proceed with a national bowel cancer screening programme will not be made until the pilot data have been analysed and the pilot programme evaluated (Ryall, 2010).

### **Lessons from the case study: (I) the role of context**

Our case study identified the resource, ethical, institutional and political environments within which evidence was considered and prioritised. All of these environments are interrelated and demonstrate the active and multifaceted qualities of context as described by Dopson and Fitzgerald (2005). In the NZ case, the role of context was crucial and extended beyond the Ministry of Health to broadly shared, national perspectives. The ethical context framed the way in which individual and societal harms were valued, so RCT evidence of benefits, which satisfied policy makers in the UK and Australia, was considered insufficient in NZ. Hence, the traditional evidence hierarchy, where high-quality RCT evidence trumps all, was moderated by ethical considerations, prioritising from the outset specific consideration of what was required to deliver a safe, high-quality and equitable national bowel cancer screening programme.

Screening decisions in NZ need to take into account not just the resource issues, which are of concern to all countries contemplating screening programmes, but also the

potential ethical consequences of a bowel cancer screening programme, which should be important in any jurisdiction but are not always considered, at least not explicitly. In addition to a pronounced focus on the more traditional potential physical and psychosocial harms for individuals, stemming from its history of other screening programmes, the NZ case was also particularly concerned with a much broader group of potential societal harms. These included screening's impact on ethnic and socioeconomic inequity. The addition of these societal harms made assessment of the benefit-to-harm trade-off of bowel cancer screening much more complicated and time consuming.

Furthermore, this already difficult process was compounded by the institutional and political context within which these assessments were taking place. The Treaty of Waitangi obligations meant that policy options considered the specific impact on Maori, thus displacing the traditional emphasis on the evidence for efficacy, and considering outcomes in terms of equality and social justice. Conflicting policy advice led to confusion over policy direction, which was in turn exacerbated by ministerial re-organisation of personnel, directorates and responsibilities for bowel cancer screening policy. A lack of ministerial leadership and the absence of a sense of urgency about preparing for the implementation of a bowel cancer screening programme left the Ministry ill-prepared to deal with the sudden political announcement by Minister Cunliffe that bowel cancer screening would go ahead as soon as possible. An imminent election had finally supplied the incentive for cementing bowel cancer screening on the policy agenda, but political pressure to act quickly led to the abandonment by Cunliffe of the evidence-based approach he had previously sanctioned when commissioning the scoping report. The new government was unencumbered by election commitments to bowel cancer screening and had the breathing space to undertake a more considered review of the evidence compiled by the Bowel Cancer Taskforce. The decision to pilot bowel cancer screening in New Zealand from 2011 will allow for the careful assessment of the benefit-to-harm trade-off in the local context, but means that NZ is still at least four years away from introducing a programme.

### **Lessons from the case study: (2) implications for research utilisation**

The NZ case has also demonstrated the impact of context on the policy process generally, beyond the specific confines of population screening policy. Our findings support the notion that conventional strategies for getting evidence into policy and practice, involving greater collaboration between researchers and policy makers, will not necessarily lead to more evidence-based policy, as the context within which policy decisions are made is crucial. Head (2010b: 77) contrasts this rational expectation of research utilisation with the 'practical limitations on the rational processes typical in the

real world of political decision-making, which is characterised by bargaining, entrenched commitments, and the interplay of diverse stakeholder values and interests'.

If the active role and broad nature of context is accepted, it suggests a potential difficulty with the argument that global methods can be used to apply evidence in different decision-making contexts, as Dobrow et al (2006) advocate. Similarly, the primacy of context in policy making calls into question the notion of 'global evidence' and 'global public goods' (Lavis et al, 2008). In this case study, academics, clinicians, bureaucrats and health professionals worked together on several committees and thoroughly reviewed the same evidence as experts in the UK and Australia. It was neither a lack of evidence, nor poor communication between researchers and policy makers, that led to different policy decisions. The decision to screen is no more or less inherently evidence based than a decision not to screen. The evidence was substantially the same, but the contexts in which the evidence was considered differed.

## **Conclusion**

Despite having the highest age standardised rate of bowel cancer in the world, NZ has taken a cautious approach to the introduction of bowel cancer screening. Our findings have demonstrated that context is crucial to the consideration and prioritisation of evidence. Furthermore, the complex relationship between context and evidence calls into question the assumptions of the traditional knowledge translation literature: greater collaboration between researchers and policy makers will not be sufficient to improve the uptake of the best available evidence if the resource, ethical, institutional and/or political contexts privilege other concerns over evidence. Rather than searching for global methods to increase the use of evidence in policy decisions, it may be more useful to look in detail at what evidence works for whom and in what circumstances (Pawson, 2006). Further case studies of the entire policy process — from problem identification to implementation and evaluation — may help to identify more successful strategies to increase the relative role of evidence in different contexts.

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