Protocol for the

Review of MBS colonoscopy items

Australian Government

Department of Health and Ageing

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1. Quality Framework reviews

1.1 Introduction

In the 2009-10 Budget the Australian Government agreed to put in place a new evidence-based framework for managing the Medicare Benefits Schedule (MBS) into the future through the measure *Medicare Benefits Schedule – A quality framework for reviewing services* (MBS Quality Framework). A key component of the MBS Quality Framework is implementing a systematic approach to reviewing existing MBS items to ensure they reflect contemporary evidence, offer improved health outcomes for patients and represent value for money.

DLA Phillips Fox has been engaged by the Department of Health and Ageing to undertake a review of the evidence relating to MBS colonoscopy item numbers 32090 and 32093. These item numbers are described in detail below.

1.2 Purpose of this document

This document outlines the methods that will be used to conduct an evidence-based analysis of literature relevant to MBS colonoscopy item numbers 32090 and 32093.

The objectives of the protocol are to:

- define the relevant clinical questions on which the review will focus;
- clarify the role of colonoscopy services described in item numbers 32090 and 32093 in current clinical practice;
- clarify the mechanisms for identifying evidence and provide an opportunity for discussion of clinical and methodological issues;
- clarify timelines associated with this project; and
- clarify roles and responsibilities of key stakeholders.

1.3 Objective of this review

The overarching objective of this review is to carry out an evidence-based assessment of MBS colonoscopy item numbers 32090 and 32093 to inform ongoing Government decisions in relation to Medicare support for these services.

1.4 Principles to guide MBS reviews

MBS Quality Framework reviews are underpinned by the following key principles:

- reviews have a primary focus on improving health outcomes and the financial sustainability of the MBS, through consideration of areas potentially representing:
    - patient safety risk;
    - uncertain health benefit; and/or
    - inappropriate use (under or over use);

- reviews are evidence-based, fit-for-purpose and consider all relevant data sources;
- reviews are conducted in consultation with key stakeholders including, but not limited to, the medical profession and consumers;
- review topics are made public, with identified opportunities for public submission and outcomes of reviews published;
- reviews are independent of Government financing decisions and may result in recommendations representing costs or savings to the MBS, as appropriate, based on the evidence;
- secondary investment strategies to facilitate evidence-based changes in clinical practice are considered; and
- review activity represents efficient use of Government resources.

2. Background on MBS colonoscopy item numbers 32090 and 32093

2.1 Description of current services

Colonoscopy is an endoscopic procedure for examination of the terminal ileal, colonic and rectal mucosa. It is used in the diagnosis, management and ongoing follow-up of patients with a range of clinical conditions, including neoplastic, inflammatory and familial conditions. Although colonoscopy services are predominantly provided to adult patients, the procedure is also performed in paediatric patients.

MBS item numbers relevant to colonoscopy services include:

- 32090: Fibreoptic colonoscopy examination of colon beyond the hepatic flexure with our without biopsy; and
- 32093: Endoscopic examination of the colon beyond the hepatic flexure by fibreoptic colonoscopy for the removal of 1 or more polyps, or the treatment of radiation proctitis, angiodysplasia or post-polypectomy bleeding by argon plasma coagulation.

Colonoscopy is currently the gold standard for the examination of the bowel lining. It allows direct mucosal inspection to the terminal ileum and biopsy of or definitive treatment by polypectomy. Patients generally adopt a liquid diet one or more days prior to examination, followed by ingestion of oral lavage solutions and / or use of laxatives to stimulate bowel movements. Patients receive sedation or an anaesthetic to make the procedure more comfortable[1 2].

A principal benefit of colonoscopy is that it allows for a full structural examination of the bowel in a single session and for the removal or biopsy of lesions identified during the procedure. Other forms of colon investigation, if positive, usually require colonoscopy as a follow up procedure[3].

Colonoscopy is widely available throughout both Australia's public and private sectors. Services are provided predominantly in public and private hospital settings. However, settings such as stand-alone day units may also be utilised. Clinicians who perform colonoscopy may

possess specialist gastroenterology, general medicine, surgical or primary care specialty qualifications.

There is an existing Australian process for formal recognition of training in colonoscopy by the Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy, a conjoint committee of the Royal Australasian College of Surgeons, the Gastrointestinal Society of Australia and the Royal Australasian College of Physicians[4]. Conjoint committee recognition is not a requirement for access to MBS items.

2.2 Context

There has been an increase in MBS utilisation between 2000/2001 and 2009/2010 financial years for both 32090 and 32093 item numbers. This increase has been observed in all States and Territories and for Australia as a whole (Table 1).

Table 1: MBS Utilisation for colonoscopy items, Australian States and Territories, 2000/01-2009/10

		State								Total	% annual change
		NSW	**VIC**	**QLD**	**SA**	**WA**	**TAS**	**ACT**	**NT**		
32090	2000/01	59,520	54,351	41,673	13,764	12,317	4,334	2,354	710	189,023	-
	2001/02	64,184	58,485	42,468	13,745	13,464	4,875	2,496	753	200,470	*6%*
	2002/03	68,227	60,051	44,235	14,581	14,249	5,176	2,738	877	210,134	*5%*
	2003/04	69,580	62,669	44,409	14,699	14,026	5,047	2,831	884	214,145	*2%*
	2004/05	72,588	63,335	47,300	15,014	15,663	4,831	2,849	848	222,428	*4%*
	2005/06	76,818	67,323	49,306	15,910	17,260	5,630	3,204	907	236,358	*6%*
	2006/07	81,914	72,682	50,275	16,511	19,448	5,977	3,271	890	250,968	*6%*
	2007/08	91,110	77,702	54,637	17,063	20,620	6,966	3,685	938	272,721	*9%*
	2008/09	92,173	83,074	55,804	19,267	22,121	7,068	4,086	1,162	284,755	*4%*
	2009/10	96,611	87,818	57,194	21,478	24,059	7,525	4,295	1,385	300,365	*5%*
	Total	**772,725**	**687,490**	**487,301**	**162,032**	**173,227**	**57,429**	**31,809**	**9,354**	**2,381,367**	***59%****
32093	2000/01	20,961	13,201	15,865	3,657	6,426	782	746	220	61,858	-
	2001/02	23,445	15,066	16,411	3,936	7,617	817	957	289	68,538	*11%*
	2002/03	26,099	16,527	18,611	4,620	8,768	968	1,039	268	76,900	*12%*
	2003/04	27,653	18,503	20,988	4,895	9,073	1,180	1,161	310	83,763	*9%*
	2004/05	31,296	19,239	23,342	5,187	10,450	1,178	1,347	249	92,288	*10%*
	2005/06	35,142	21,193	26,921	5,565	11,538	1,530	1,654	387	103,930	*13%*
	2006/07	40,831	25,442	29,486	6,587	13,809	1,616	1,666	360	119,797	*15%*
	2007/08	45,397	29,119	32,701	7,807	16,357	2,161	2,032	417	135,991	*14%*
	2008/09	47,996	31,776	35,554	9,618	17,153	2,214	2,102	457	146,870	*8%*
	2009/10	52,618	35,216	38,509	10,838	19,239	2,592	2,421	577	162,010	*10%*
	Total	**351,438**	**225,282**	**258,388**	**62,710**	**120,430**	**15,038**	**15,125**	**3,534**	**1,051,945**	***162%****

*% increase 2000-01 to 2009-10. Source: Medicare Australia (accessed 30/08/2010)

MBS utilisation for colonoscopy item numbers varies according to age category. Utilisation rates (per 1,000 population) increase with increasing age category to a maximum in persons aged 65 to 69 years. Utilisation progressively declines after the 65 to 69 year age category.

Increases in MBS utilisation between 1999/2000 and 2008/2009 have occurred across all patient age groups (Table 2). The crude percentage increases have been highest in patients aged between 55 and 69 years. However, the highest rate of increase (per 1,000 population) has been observed in patients aged 75 to 79 years.

Table 2: 10 year increase in MBS utilisation for colonoscopy items, Australian States and Territories, 2000/01 to 2009/10

Patient's age category in years	10 year increase in colonoscopy utilisation	% increase	Colonoscopy utilisation rate (per 1,000 population) 1999/00	Colonoscopy utilisation rate (per 1,000 population) 2008/09	Increase per 1,000 population over 10 yrs
0->20	1,689	94.2%	0.3	0.6	0.3
20->24	3,326	108.2%	2.4	4.0	1.6
25->29	3,621	71.3%	3.5	5.4	1.9
30->34	4,593	62.5%	5.1	7.9	2.8
35->39	6,938	58.9%	7.8	11.6	3.8
40->44	10,214	57.2%	12.3	18.4	6.0
45->49	16,961	74.0%	17.1	25.4	8.3
50->54	25,025	87.4%	22.8	37.3	14.5
55->59	33,008	125.1%	27.4	45.5	18.1
60->64	35,350	142.6%	31.1	51.4	20.3
65->69	29,611	128.9%	33.9	60.5	26.6
70->74	18,726	90.7%	32.6	57.4	24.8
75->79	17,291	143.4%	23.8	53.4	29.6
80->84	9,359	160.5%	18.9	35.2	16.3
85+	1,919	67.5%	11.2	12.5	1.3

Source: Medicare Australia (accessed 30/08/2010)

MBS claims for colonoscopies where a polyp was removed have increased over time relative to the total number of MBS claims for colonoscopy (Table 3).

Table 3: Relative MBS utilisation for items 32090 and 32093, 2003/04 to 2008/09

Financial Year / Colonoscopy Type		Number	Percent
2003/04	Colonoscopy where no polyp was removed - MBS item 32090	214,145	71.9
	Colonoscopy where polyp was removed - MBS item 32093	83,763	28.1
2004/05	Colonoscopy where no polyp was removed - MBS item 32090	222,428	70.7
	Colonoscopy where polyp was removed - MBS item 32093	92,288	29.3
2005/06	Colonoscopy where no polyp was removed - MBS item 32090	236,358	69.5
	Colonoscopy where polyp was removed - MBS item 32093	103,930	30.5
2006/07	Colonoscopy where no polyp was removed - MBS item 32090	250,968	67.7
	Colonoscopy where polyp was removed - MBS item 32093	119,797	32.3
2007/08	Colonoscopy where no polyp was removed - MBS item 32090	272,721	66.7
	Colonoscopy where polyp was removed - MBS item 32093	135,991	33.3
2008/09	Colonoscopy where no polyp was removed - MBS item 32090	284,755	66.0
	Colonoscopy where polyp was removed - MBS item 32093	146,870	34.0

Source: Medicare Australia (accessed 30/08/2010)

In contrast, MBS utilisation for rigid sigmoidoscopy (items 32072, 32075, 32078 & 32081) and barium enema (item 58921) has decreased between 2000/2001 and 2009/2010 and there has been little change in MBS utilisation for flexible sigmoidoscopy (items 32084+32087) (Table 4).

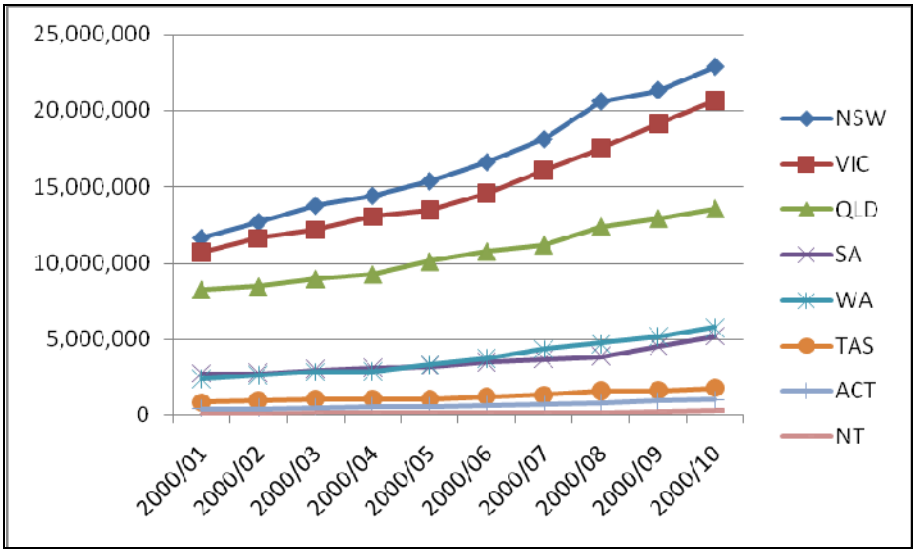
Table 4: 10 year change in MBS Utilisation for comparator procedures, 2000/01 to 2009/10

10 year change in MBS utilisation - 2000/01 to 2009/10			
	Rigid sigmoidoscopy	**Flexible sigmoidoscopy**	**Barium enema**
% change	-49.2	+1.9%	-77.7%

Source: Medicare Australia (accessed 30/08/2010)

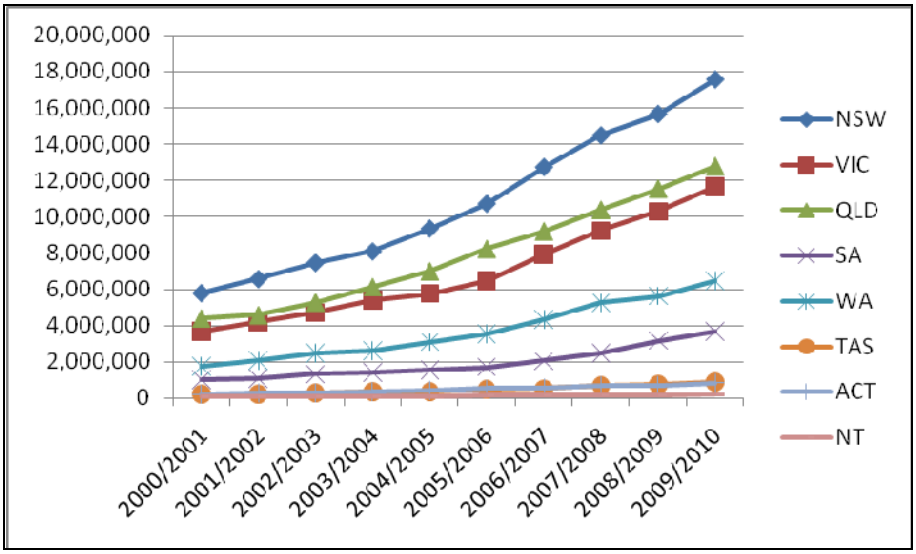
Benefits payable for MBS colonoscopy items 32090 and 32093 have increased between 2000/01 and 2009/10 in all States and Territories, and for Australia as a whole (Figures 1 and 2).

Figure 1: MBS benefits paid ($) for item 32090, Australian States and Territories, 2000/01 to 2009/10



Source: Medicare Australia (accessed 30/08/2010)

Figure 2: MBS benefits paid ($) for item 32093, Australian States and Territories, 2000/01 to 2009/10



Source: Medicare Australia (accessed 30/08/2010)

Of those patients who had a colonoscopy in the 10 years between 1999/2000 and 2008/09 (patients in whom a claim for MBS item 32090, or 32093, or both was made), 68% had one colonoscopy, 20% had two colonoscopies, 7.5% had three colonoscopies, 2.6% had four colonoscopies and 0.9% had five colonoscopies.

In some age groups the observed increase in MBS utilisation of colonoscopy items may in part be due to the commencement of the National Bowel Cancer Screening Program (NBCSP).

Phase 1 of the NBCSP commenced in 2006 following a successful pilot study. This phase of the program invited Australians turning 55 and 65 between 1 May 2006 and 30 June 2008 to participate in faecal occult blood test (FOBT) screening for bowel cancer. The second phase, which commenced on 1 July 2008, offers testing to people turning 50, 55 or 65 years of age between January 2008 and December 2010. Persons with a positive FOBT are generally referred by their usual medical practitioner for a colonoscopy.

It is unlikely the NBCSP is associated with the majority of the increase in MBS utilisation of colonoscopy item numbers as increases have been observed in age groups outside the NBCSP specific age targets; and increases in MBS utilisation of colonoscopy began before the NBCSP commenced[5].

2.3 Justification for review

The delivery of evidence-based care is an important goal of the MBS and is articulated in *Medicare Benefits Schedule – a quality framework for reviewing services* as essential to improve effectiveness of service delivery, enhance achievement of positive health outcomes for consumers and reduce wasteful or inefficient practices by health care providers.

As funding of services other than those provided to public patients by public hospitals depends to a large extent on the MBS, the Schedule can play an important role in integrating knowledge from clinical practice guidelines into health services delivery.

Where the MBS is inconsistent with evidence-based guidelines, significant barriers to provision of evidence-based care may result. Further, access to care that is of proven effectiveness may be inequitable. Persons experiencing economic and social disadvantage may be particularly vulnerable to the effects of inconsistencies between the Schedule and clinical practice guidelines because personal financial capacity, rather than considerations about the best available clinical care, are likely to have a substantial influence on the type of services they access.

There is, therefore, a need to align the MBS item numbers with the best available evidence regarding indications for colonoscopy.

There are no published national guidelines for the use of colonoscopy per se as there are numerous clinical indications to examine the lower gastrointestinal tract. Clinicians access a variety of sources of guidance regarding the use of colonoscopy in specific disease states e.g. for the management of inflammatory bowel syndrome.

The Australian *Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer* (2005) relate only to indications for colonoscopy associated with bowel cancer. The guidelines make the following recommendations[6]:

- organised screening for colorectal cancer with FOBT performed at least once every 2 years is recommended for the Australian population over 50 years of age is strongly recommended;
- in persons at category 1 risk (those with a positive family history who are at or slightly above average risk) FOBT performed at least once every 2 years is recommended in combination with a sigmoidoscopy (preferably flexible) every 5 years; and

- in persons at category 2 risk (those with a positive family history who are at moderately increased risk) colonoscopy every 5 years starting at age 50 or 10 years younger than the age of first diagnosis of bowel cancer in the family, whichever comes first, or sigmoidoscopy plus double contrast barium enema if colonoscopy is unavailable, is recommended.

Additional recommendations for genetic testing, surgical management and gastrointestinal surveillance are made for persons with high risk familial colorectal cancer syndromes.

The National Bowel Cancer Screening Program Quality Working Group report "*Improving Colonoscopy Services in Australia*" recognises the need to ensure MBS item numbers are aligned with best available evidence regarding indications for colonoscopy. Evidence-based clinical indications for colonoscopy are not provided in the report[7].

The Gastroenterological Society of Australia (GESA) and Gastroenterological Nurses College of Australia (GENCA) have published standards for endoscopic facilities and services that provide specifications for facilities, equipment, patient services, information, education and consent, organisation and administration, medical and nursing services, patient sedation, administrative services, medical records, environmental services, quality assurance and education[8 9]. However, indications for colonoscopy are not included in the standards.

As preparation for a colonoscopy is unpleasant and colonoscopy is associated with infrequent but significant complications, it is important to ensure the procedure is undertaken only in persons in whom it is indicated[10 11 12 13].

In addition to serious complications, there are a number of other issues that reinforce the need to ensure the use of the procedure only when indicated:

- the procedure usually requires administration of some form of sedation or anaesthesia which may be associated with further complications in a minority of individuals;
- colonoscopy requires one or more days of preparation and bowel cleansing which is unpleasant and may be associated with significant adverse events in a minority of individuals[14]; and
- patients usually prefer non-invasive alternatives to colonoscopy[15 16 17].

Appropriate training of colonoscopists is required to ensure high quality examinations and to minimise adverse events, including missed abnormal findings, associated with colonoscopy[18].

Assessment against prioritisation criteria outlined in the Medicare Benefits Schedule Quality Framework demonstrates the high priority for this review (Attachment 1).

3. Clinical / research questions

The PICO (Population, Intervention, Comparator, Outcomes) criteria have been used to develop clinical questions for the review[19]. The following are the four elements of the PICO criteria:

- the target population for the intervention;
- the intervention being considered;
- the comparator for the existing MBS service (where relevant); and
- the clinical outcomes that are most relevant to assess safety and effectiveness.

As the comparative effectiveness of various technologies for investigating bowel conditions such as faecal occult blood tests, sigmoidoscopy or CT colonography are outside the scope of this review, PICO 'Comparator' questions have not been developed.

Further, as the majority of colonoscopy services are provided to adult patients, the use of colonoscopy for the diagnosis and management of colorectal pathology in paediatric patients (defined for the purposes of this review as persons aged 16 years and under) is outside the scope of this review.

The specific clinical questions for relevant PICO criteria that will be the focus of this review are as follows:

1. When in the patient journey should colonoscopy commence and how frequently should colonoscopy be performed for clinical conditions where it is indicated?
2. What is the strength of evidence for the effectiveness of colonoscopy in improving outcomes in each target population across the patient journey?
    - What is the likelihood of a single colonoscopy leading to the detection of an adenoma and / or colorectal cancer?
3. What are the safety and quality implications (including morbidity, mortality and patient satisfaction) associated with colonoscopy in each target population?
    - How do safety and quality outcomes of colonoscopy vary according to:
        - the procedural volumes of colonoscopists?
        - certification / re-certification processes?
4. What is the evidence regarding the cost implications associated with colonoscopy in each target population across the patient journey?
5. What is the evidence regarding the socioeconomic implications associated with colonoscopy in each target population across the patient journey?

The review methods that will be used to enable literature relevant to these questions to be systematically identified are discussed below.

A number of organisations and professional bodies in Australia are currently conducting reviews of the literature and formulating guidelines that relate to the questions being addressed in this review. It is not the intention of this review to duplicate the work already being undertaken. Rather, these materials will be reviewed in the first instance and will be supplemented with additional analysis as required in order to comprehensively address the review questions.

4. Key stakeholders

The following organisations and groups represent the key stakeholders that may be impacted by alignment of the MBS item numbers with the best available evidence regarding indications for colonoscopy. These organisations and groups will be invited to participate in the consultation process:

- consumers;
- Commonwealth government;
- State and territory health departments;
- Gastroenterological Society of Australia;
- Colorectal Surgical Society of Australia and New Zealand;
- General Surgeons Australia;
- Australian Society of Anaesthetists;
- Gastroenterological Nurses College of Australia;
- Royal Australasian College of Physicians;
- Australian and New Zealand College of Anaesthetists;
- Royal Australasian College of Surgeons;
- Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy;
- Royal Australian College of General Practitioners;
- Australian College of Rural and Remote Medicine;
- Australian College of Operating Room Nurses;
- The National Bowel Cancer Screening Program Quality Working Group;
- Cancer Australia;
- The Cancer Council of Australia; and
- Australian Medical Association

4.1 Clinical Working Group

A Clinical Working Group has been established by the Department of Health and Ageing for the duration of the review. The role of the Clinical Working Group is to ensure the review reflects an understanding of current Australian clinical practice and draws valid conclusions from the available evidence. While this working group will be given the opportunity to comment on the review protocol and on the final report in their individual capacity, it is not able to make recommendations on future financing arrangements.

Members are experts in the field of colonoscopy service delivery. The following organisations have nominees on the Clinical Working Group:

- Department of Health and Ageing;
- Gastroenterological Society of Australia;
- Royal Australasian College of Physicians;
- General Surgeons Australia;
- Conjoint Committee for Certification of Training in Gastrointestinal Endoscopy (CCCTGE);
- Royal Australasian College of Surgeons (nominated by the Colorectal Surgical Society of Australia and New Zealand); and
- Quality Working Group of the National Bowel Cancer Screening Program.

The Clinical Working Group is chaired by an officer of the Department of Health and Ageing, and also includes a Medical Advisor from the Department.

4.2 Clinical craft groups

Clinical craft groups representing those that provide the MBS services under review are key stakeholders.

Clinical craft groups that will be invited to participate in the review include the following:

- Gastroenterological Society of Australia - the peak body for the disciplines of gastroenterology and hepatology in Australia, with members comprising medical graduates, scientists and trainees;
- Gastroenterological Nurses College of Australia – the Australian college of gastroenterology and endoscopy nursing whose role is to promote excellence in gastroenterology nursing practice through facilitating the provision of education, standards and credentialling;
- Royal Australasian College of Physicians – the medical college responsible for training those who wish to become physicians or paediatricians and for providing a program of continuing professional development for Fellows of the College, including gastroenterologists and physicians who provide colonoscopy services;
- Royal Australasian College of Surgeons – the medical college responsible for training those who wish to become surgeons and for providing a program of continuing professional development for Fellows of the College, including surgeons who provide colonoscopy services;
- Colorectal Surgical Society of Australia and New Zealand - the society that represents specialist colorectal surgeons in Australia and New Zealand. Members have undertaken advanced training in colorectal surgery and are dedicated to ongoing professional development to maintain their expertise in the diagnosis and

management of intestinal and anorectal problems. Most members are actively involved in research and teaching and all are committed to maintaining the highest standards in their practice. The Society and its members promote the best evidence-based practice in order to improve the treatment of patients. The society has a close relationship with the Royal Australasian College of Surgeons and maintains strong links with many other professional organisations, both nationally and internationally;

- Royal Australian College of General Practitioners – the medical college responsible for training those who wish to become general practitioners and for providing a program of continuing professional development for Fellows of the College, including general practitioners who provide colonoscopy services;

- General Surgeons Australia – an independent national body that, since January 2009, has assumed responsibility for General Surgical training, to the level of Fellowship of RACS. GSA provides administrative and executive support to the RACS Board in General Surgery, and manages the Surgical Education and Training (SET) program for General Surgery as it relates to training in Australia. GSA membership is offered to all duly qualified and recognised Specialist General Surgeons practicing in Australia, and all trainees in the SET General Surgery training program;

- Australian and New Zealand College of Anaesthetists - the medical college responsible for training those who wish to become anaesthetists and for providing a program of continuing professional development for Fellows of the College; and

- Conjoint Committee for Certification of Training in Gastrointestinal Endoscopy (CCCTGE) – a national body comprising representatives from the Gastroenterological Society of Australia, the Royal Australasian College of Physicians and the Royal Australasian College of Surgeons. The CCCTGE recognises training of endoscopists who have completed their training in Australia or who are now practising in Australia. The CCRTGE has set numbers of procedures which a trainee must carry out under supervision for each endoscopic procedure. Each trainee, no matter what there specialty has to submit log books to the CCCTGE. Full recognition is dependent on the completion of training, experience and supervision pursuant to those training programs. Trainees of other specialist medical colleges are assessed on a case-by-case basis.

4.3 Consumers and the general public

Consumers and the general public will be offered the opportunity to comment on the review.

The Department of Health and Ageing will make review materials available online for public comment, including the draft review report.

5. Roles of the consultants and the Department

5.1 DLA Phillips Fox

DLA Phillips Fox is responsible for drafting the review protocol and identifying, analysing and synthesising the evidence related to MBS colonoscopy item numbers 32090 and 32093 through the methodology identified below. DLA Phillips Fox will provide a review report at the

completion of the project that will help inform the Government's consideration of MBS subsidy of these services into the future.

Dr Heather Wellington

Heather is a medical practitioner and lawyer with extensive experience as a clinician, hospital manager, bureaucrat, director and policy advisor in health care. She has conducted a large number of service and program reviews, all requiring high level consultation with service providers, facilitation of workshops and preparation of reports and recommendations.

Heather is a national expert in health care safety and quality. She was a member of the Australian Council for Safety and Quality in Health Care for 5 years and for over a decade has conducted an active consultancy practice with a focus on health care safety, appropriateness, regulation, governance, service planning and reviews.

Dr Paul Woodhouse

Paul is a medical manager who has worked as a senior hospital manager as well as in the Victorian Department of Human Services. For ten years, he was the Director of Policy at AMA Victoria. Paul also has a Doctorate in Business Administration.

Paul's has undertaken a range of projects with DLA Phillips Fox in the areas of health care policy, planning and governance.

Paul has highly-developed analytical skills and is recognised for his ability to analyse clinical datasets with an insight which reflects his thorough understanding of clinical and administrative practice.

Dr Kelly Shaw

Kelly is a public health physician and general practitioner. She maintains academic roles as an Honorary Associate of the Menzies Research Institute and a Postdoctoral Research Fellow of Southern Cross University.

She has conducted a number of rigorous systematic reviews and meta-analyses of the literature, many of which are published in the peer review literature.

Professor John McNeil

To complement the skills and expertise of our team, we have recruited Professor John McNeil as an external consultant. He will provide senior professional advice and assistance to our team for the purposes of this project.

John is an accomplished public health specialist with extensive experience in evidence-based medicine, clinical practice guidelines, health policy and efficiency of health care service delivery.

John has been the head of the Monash University School of Public Health and Preventive Medicine based at the Alfred Hospital in Prahran since 1986. His research background is in epidemiology and clinical pharmacology. He is currently a member of the Boards of the Colonial Foundation, the International Society of Cardiovascular Pharmacotherapy and Austin

Health, Melbourne. He is a previous member of the Boards of Alfred Health, the Metropolitan Ambulance Service, Water Quality Research Australia and the Victorian Public Health Research and Education Foundation. He has been a member of ministerial committees reporting on renal failure services, organ transplantation and medical staff salaries. He also serves on scientific committees for the Red Cross Blood Transfusion Service, the National Blood Authority, the Therapeutics Goods Administration and the Australian Commission for Safety & Quality in Healthcare. He is a member of the executive of the Monash Faculty of Medicine, Nursing & Health Sciences.

5.2 The Department of Health and Ageing

The Department of Health and Ageing (the Department) is responsible for the ongoing management and oversight of the review process.

Following the finalisation of the review report, the Department will be responsible for providing advice to the Minister for Health and Ageing on future subsidy arrangement for MBS colonoscopy item numbers 32090 and 32093. This advice will be informed by the review report but will also draw on other information such as budget considerations.

6. Review methods

6.1 Literature review

A systematic review of the peer-reviewed and other relevant published literature will be conducted for the purposes of identifying published materials relevant to the specific clinical questions outlined above.

6.1.1 Types of studies considered for the review

Studies involving adult patients (defined as persons aged > 16 years) who receive colonoscopy for any purpose relevant to the specific clinical questions outlined above will be considered for inclusion.

The inclusion criteria for selection of specific studies will include the following:

- publication presents original data or reviews of original data;
- publication focuses on colonoscopy;
- publication addresses one or more of the specific research questions;
- research conducted in humans;
- publication in English language;
- publication between 1999 and 2010;
- selection of study participants was representative of the general population being studied; and
- research conducted in an appropriate population for the question being addressed.

Exclusion criteria for selection of relevant studies will include the following:

- studies where qualitative research methods were used;
- editorials, articles and reviews which present opinion rather than evidence;
- non-systematic reviews;
- studies where methods are not sufficiently described to enable appraisal of quality according to NHMRC criteria; and
- duplicate publications of the same research study.

6.1.2 Search strategies for identifying studies

The search strategies used to identify studies will be as follows:

1 Manuscripts will be sought for the years 1999 to 2010 in order to identify relevant publications based on contemporary colonoscopy practice.

2 Searches will be conducted in the MEDLINE, PsychINFO, CINAHL, EMBASE, Cochrane Library and will be supplemented with searches of proprietary search engines (including Google® and Google Scholar®).

3 Direct analysis of output from known centres of excellence, international, national and state-based government agencies will be conducted.

We will supplement our search strategies by approaching professional bodies for clinical guidelines, unpublished studies and reviews of relevance to this review. In particular, we will approach the National Health and Medical Research Council, the Australian Cancer Network, Cancer Australia and the National Bowel Cancer Screening Program Quality Working Group for additional materials relevant to this review.

6.1.3 Search terms for identifying studies

Relevant Medical Index Subject Heading (MeSH) terms and subject headings will be combined with key words of relevance to enable databases to be searched. Where there is a large amount of literature or a large volume of poor quality research, limits will be imposed according to experimental design to exclude less rigorous forms of research.

Searches will be conducted individually for each of the five review questions outlined above. An initial search strategy will be used to identify materials of broad relevance to the review. The results of this search will form the basis for five specific searches that will be conducted for each of the research questions using additional search terms that are relevant to each research question.

1 colonoscopy [MeSH]

2 colonoscopy.tw

3 or/1 and 2

4	meta-analysis.pt.
5	(meta-anal$ or metaanal$).tw.
6	(quantitativ$ review$ or quantitativ$ overview$).tw.
7	(systematic$ review$ or systematic$ overview$).tw.
8	review.pt.
9	guideline.pt
10	randomized controlled trial.pt.
11	controlled clinical trial.pt.
12	random allocation/
13	double blind method/
14	single blind method/
15	clinical trial.pt.
16	cross-over studies/
17	((singl$ or doubl$ or tebl$ or tripl$) adj25 (blind$ or mask$)).tw.
18	(randomi?ation or random allocation or random selection or random assignment or randomly allocated
19	randomly selected or randomly assigned or randomly divided or randomly distributed).tw.
20	cohort studies [MeSH]
21	case control studies [MeSH]
22	descriptive.sh
23	observational.sh
24	or/2-21
25	not (case report$ OR editorial$ OR comment$ or letter$)
26	animals/ not (animals/ and humans/)
27	24 and 25 and 26
28	3 and 27

The following search terms will form the basis for addressing the specific questions being addressed in the review. For each question, the search terms listed below will be supplemented with additional search terms of relevance as required.

Question 1

29 frequen$.tw

30 time interval$.tw

31 how often.tw

32 periodic$ test$.tw

33 or/27-30

34 28 and 33

Question 2

35 outcome assessment (health care) [MeSH]

36 outcome$.tw.

37 adenoma$.tw

38 neoplasms [MeSH]

39 or/35-38

40 28 and 39

Question 3

41 quality assurance, health care [MeSH]

42 morbidit$.tw.

43 mortalit$.tw.

44 (survival rate$ or survival time$).tw.

45 harm$.tw.

46 adverse effect$.tw.

47 adverse event$.tw.

48 consequence$.tw.

49 patient satisfaction [MeSH]

50 or/41-49

51 28 and 50

Question 4

52 "costs and cost analysis"/ or cost-benefit analysis/ or "cost of illness"/ or exp health care costs/ or health

53 expenditures/

54 (cost analysis or cost analyses).tw.

55 cost effect$.tw.

56 cost benefit$.tw.

57 (cost of illness$ or illness cost$).tw.

58 (cost$ of disease or disease cost$).tw.

59 (cost$ of sickness or sickness cost$).tw.

60 (health care cost$ or medical care cost$ or treatment cost$).tw.

61 health expenditure$.tw.

62 economic impact$.tw.

63 economic consideration$.tw.

64 or/52-63

65 28 and 64

Question 5

66 socioeconomic factors [MeSH]

67 health status disparities [MeSH]

68 population characteristics [MeSH]

69 or/66-68

70 28 and 69

6.1.4 Study selection

Two reviewers will sort through search results by scanning lists of titles and abstracts generated by the electronic database search, highlighting potentially relevant articles. Full articles will be retrieved if they address one or more of the specified review questions.

Articles with original data will be sorted according to study design. Articles with the most rigorous experimental designed will be reviewed in the first instance. Articles conducted to other study designed will be included if they add new information not found in the papers of highest levels of evidence. Relevant articles will be sorted as follows:

- Meta-analysis, systematic review of randomised controlled trials;
- Randomised controlled trials;
- Cohort studies;
- Case control studies;

- Case series, pre-post or post studies.

Abstracts that do not meet inclusion criteria will be coded according to reason for rejection. If there is any doubt regarding the details of the study from the information given in the title and abstract, the full article will be retrieved for clarification. A third party will resolve differences in opinion.

6.1.5 Data extraction

Data that will be extracted include the following:

1 general information: title, authors, country, year of publication;

2 study methods: study design, study location and setting, study duration;

3 participants: baseline characteristics of study groups, sampling method, sample size, inclusion and exclusion criteria, withdrawals / losses to follow-up, subgroups;

4 interventions: purposes for which colonoscopy performed, comparison interventions (if any);

5 outcomes: primary outcomes assessed, secondary outcomes assessed, length of follow-up of participants, patient satisfaction, technical performance of colonoscopy, rates of complications and adverse events.

6.1.6 Quality assessment of studies

Quality assessment will be undertaken to enable publications of poorer quality to be identified and accounted for in data synthesis.

The quality of reporting of each study will be assessed by quality criteria based on the National Health and Medical Research Council's "Levels of Evidence and Grades for Recommendations for Developers of Guidelines[20]".

Both reviewers will independently undertake quality assessment of published material. Differences of opinion will be resolved through discussion with a third party.

6.1.7 Data analysis

The search strategy (terms and limits) and yield will be documented for each review question, including the number of articles identified by each search, the number of articles relevant from that search, the number of relevant articles identified through other search processes, the number of articles obtained for review, the level of evidence of relevant articles and the highest level of evidence found for each question.

Overall assessment of individual studies will include, where appropriate, the level of evidence, quality rating, magnitude of effect and relevance rating according to checklists recommended by the NHMRC.

Data from publications will first be summarized narratively, by chronicling and ordering the evidence to produce an account of the evidence. This enables integration of quantitative and qualitative evidence[21].

Where objective outcomes data are provided, data will be extracted and reported for all relevant outcomes.

We will liaise with the Clinical Working Group to ensure their input into the review is ongoing over the course of the review. We will seek the clinical input of members regarding the results of the review as the review progresses.

6.2 MBS data

A detailed analysis of MBS data will be conducted for the purposes of this review. Results of preliminary data analysis are presented above. Data regarding MBS items 32090 and 32093 will be appraised independently and as a combined dataset. The time period of analysis will be between 1998/1999 and the most recent available data for the parameter under investigation.

Use of colonoscopy according to the following parameters will be appraised:

- provider group;
- geographical spread;
- age of patients; and
- utilisation patterns for relevant MBS comparators and items related to conditions investigated by colonoscopies.

The purpose of the analysis is to determine the changes in MBS utilisation of colonoscopy item numbers over time according to provider type and patient characteristics. The costs associated with MBS utilisation of colonoscopy item numbers will also be assessed.

The Department will facilitate access to necessary data as appropriate.

6.3 Stakeholder consultation

Consultation with stakeholders will be conducted via invitations to comment in writing on the protocol and draft project report. A list of key questions for consideration by stakeholders will be developed prior to the call for public submissions to ensure consistency of approach and continually focus on quality of the consultation process.

To ensure consumers are provided with an opportunity to comment, the Department of Health and Ageing will make review materials available online for public comment, including the draft review report.

7. Review outcomes

The conclusions regarding the colonoscopy services will be provided in a draft report. This report will be presented in chapters according to each service being reviewed. The report will be finalised following public consultation.

The evaluation method that is tested for this review will also be assessed and critiqued as part of the project, with suggestions for its modification/revision provided, along with the final report.

Reviews are expected to result in primary and supplementary review outcomes as shown below:

Primary review outcomes

Where an evaluation suggests that an item under review is supported by the evidence, the likely recommendation will be that the MBS listing will be retained in its current form. However, should an evaluation suggest that listed MBS items or services are inconsistent with contemporary evidence in relation to its clinical use or effectiveness, direct amendments to the MBS may be recommended. These may include one or more of the following changes:

- addition or removal of MBS items;
- changes to the Schedule fee;
- refinement of MBS item descriptors to better target patient groups, clinical indicators and/or promote the use of optimal clinical pathways; and/or
- potential for interim-listing pending the collection of item-specific data.

Potential amendments to the MBS arising from reviews will be undertaken through consultation with the relevant stakeholder groups.

Supplementary review outcomes - initiatives to facilitate evidence-based changes in clinical practice

In addition to primary review outcomes relating to MBS reimbursement, reviews may indicate the need for secondary investment strategies aimed at bridging the divide between current evidence, including clinical guidelines and current clinical practice. To achieve this, a number of strategies may be implemented following the evaluation of individual items or services. These may include, but are not limited to, the following:

- development or revision of clinical practice guidelines for evaluated services where there is an identified need;
- strengthening or targeting of auditing/compliance activities;
- education and training initiatives for practitioners and/or consumers;
- exploring incentive-based initiatives to promote improved clinical practices or linking education and training programs to access incentives; and
- the development of research opportunities where gaps in effective service provision are evident.

The identification of mechanisms to support evidence-based best practice will complement and reinforce any primary outcome MBS amendments to help improve health outcomes for patients, whilst ensuring the most efficient use of limited resources.

8. Review timeframe

The expected timeframes of the review process for each of the key milestones are as follows:

Timeframe	Milestone
November 2010	Draft review protocol available for public comment
February/March 2011	Draft review report available for public comment
April 2011	Finalisation of the Report and recommendations

The draft review report for four weeks from the time they are made available on the Department of Health and Ageing's website.

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