



Tables 1 & 2

These tables were part of the submitted manuscript and have been peer reviewed. They are posted as supplied by the authors.

Online-only tables for: Dear RF, Barratt AL, Evans A, et al. Identifying and prioritising gaps in colorectal cancer trials research in Australia. Med J Aust 2012; 197: 507-511. doi: 10.5694/mja12.10623.

Table 1: Areas of agreement: Gaps identified by ALL groups (consumers, health professionals, and researchers) and examples of trial proposals to address these gaps

Gaps identified	Trial proposals to fill the gaps identified
How to increase participation in bowel cancer screening, how to implement and evaluate a proper national program, and tailored screening for high risk people	<p>Strategies to increase uptake of screening for CRC (1) (HP and R)</p> <ul style="list-style-type: none"> • Participants- above-average risk individuals (eg patients with adenomas or a strong family history of CRC) who are not currently being screened. This needs to be recorded on a national database. Patients identified by an appropriate screening tool for general practice • Intervention- screening in a dedicated familial cancer clinic • Outcomes- screening uptake and mortality. <p>Strategies to increase uptake of screening for CRC (2) (C, HP, R)</p> <ul style="list-style-type: none"> • Participants- healthy adults aged 50 years and over • Intervention- development and testing of educational tools for general practitioners and patients to encourage participation in the National Bowel Cancer Screening program, and/or send a reminder letter to patients who were screened at 50 years of age prior to re-screening at 55 years • Outcomes- screening uptake and uptake of colonoscopy by patients with positive faecal occult blood test (FOBT) results <p>Is a GP-led model for bowel cancer screening superior (in terms of participation and cost) to a population-based model? (C)</p> <p>What interventions can increase awareness by GPs and the broader community about the benefits of screening? (C)</p>
Better understanding of biomarkers as measures of risk for colorectal cancer, predictors of response to treatment and predictors of disease recurrence	<p>Incorporate tissue collection as a standard component of clinical trials and use available tissue to develop biomarker-based therapies. Develop clinical trial designs that incorporate blood and tissue biomarkers to stratify interventions (R)</p>

Gaps identified	Trial proposals to fill the gaps identified
Testing chemoprevention to reduce polyp occurrence and recurrence	<p>Primary prevention of CRC with aspirin (HP)</p> <ul style="list-style-type: none"> • Participants- healthy individuals 50–79 years not taking aspirin. Exclude regular aspirin takers, people with ulcerative colitis, and those with heavy alcohol use • Intervention- decision aid for patients and GPs to decide whether patient will start daily low-dose aspirin. Include a reference to cardiovascular risk • Control- generic information booklet on CRC and aspirin use • Outcomes-decision to use or not use aspirin assessed using existing, validated outcome measures for informed decision making; adverse events at five years (eg gastrointestinal bleeding or withdrawal causing blood clots); compliance at five years assessed using blood tests for markers of aspirin activity and/or using multi-dimensional measures of informed choice, attitudes, knowledge and behaviour • Sub-study- sub-group of patients at high-risk of CRC followed up in a longitudinal cohort study to assess cancer outcomes • Notes- data linkage to Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data should be included as part of the study design. A large randomised controlled trial (ASPREE, www.aspree.org) is assessing risks and benefits of low dose aspirin versus placebo in older people and may inform this proposal. Collaborative trial with PC4 and AGITG
Consider the role of new imaging for diagnosis and staging	<p>PET and functional imaging (HP)</p> <ul style="list-style-type: none"> • Participants- people with rectal cancer • Intervention- all patients have a pre-treatment PET scan in addition to standard staging imaging. The multi-disciplinary meeting is blind to the result of the PET scan until after making a decision about management • Outcome- proportion of clinical decisions changed after finding out PET scan result
Identification of individualised/targeted therapies for colorectal cancer	<p>What factors affect a person's response to a particular treatment? (C)</p>
Effects of treatment on long-term quality of life	<p>What is the long-term impact of treatment for colorectal cancer on bowel symptoms, including incontinence frequency/urgency? (C)</p> <p>Does a long-term care plan that includes nutritional assessment and rehabilitation issues enhance patient quality of life? (C)</p> <p>Evaluate an intervention to reduce fear of cancer recurrence in patients who have a clinical level of anxiety (R)</p>

Gaps identified	Trial proposals to fill the gaps identified
Alternative models for follow-up after diagnosis and treatment of colorectal cancer	<p>Novel follow-up methods after adjuvant treatment (HP)</p> <p>Identify and test an alternative 'non-medical' model of follow-up care that considers psychosocial issues; Intervention likely to involve the GP as well as education for patients (R)</p>
Describe current patterns of care and identify new models of care for colorectal cancer and barriers to best practice	<p>Studies to increase uptake/implementation of known approaches to best practice treatment/care (R)</p> <p>Studies to improve quality of care (surgery/radiotherapy) (R)</p> <p>Studies to achieve equity across geographical areas (R)</p> <p>Design studies that identify and address the needs of particular population groups including the elderly, culturally and linguistically diverse groups and non-English speaking groups (R)</p>

CRC- Colorectal cancer

C- Consumers

HP- Health care professionals

R- Researchers

AGITG- Australasian Gastro-intestinal Trials Group

PC4- Primary Care Collaborative Cancer Clinical Trials Group

Table 2: Areas of difference: Gaps in colorectal cancer trials research identified by one or two groups (consumers, health professionals, and researchers)

Category	Consumers	Health care professionals	Researchers
Role of diagnostic imaging	<ul style="list-style-type: none"> • How to improve availability of data about stage of disease • Develop less invasive procedures for diagnosis 	<ul style="list-style-type: none"> • Effect of functional imaging on outcomes in T1 or T2 rectal cancer • Health economic analyses of diagnostic technologies based on level of risk • Trials that address diagnostic tools and treatment together to see if benefit is due to selection for better risk or treatment effect 	
Surgery	<ul style="list-style-type: none"> • Identify better bowel preparation procedures • Benefits of dietary and nutrition information after surgery 	<ul style="list-style-type: none"> • Patient selection for local excision of rectal cancer • The effect of time to commencing adjuvant therapy after closure of an ileostomy on outcomes 	<ul style="list-style-type: none"> • Extent to which high quality surgical care is delivered • Assess new biological agents before surgery
Adjuvant therapy for rectal and colorectal cancer	<ul style="list-style-type: none"> • How to better predict response to adjuvant therapy 	<ul style="list-style-type: none"> • A trial like the Intergroup trial (E5202) for stage III CRC 	

Category	Consumers	Health care professionals	Researchers
Advanced disease	<ul style="list-style-type: none"> • Risks and benefits of earlier diagnosis and treatment of advanced disease • Surgical options for liver metastases • Managing patient expectations in advanced disease 		<ul style="list-style-type: none"> • Use of targeted therapies to personalise treatment • Understanding mechanisms of resistance to existing treatments • Identification and testing of new targets (eg stem cells)
Quality of life and survivorship	<ul style="list-style-type: none"> • Role of complementary therapies 		
Palliative care	<ul style="list-style-type: none"> • Extent of use of best practice palliative care guidelines • Better ways of managing end of life issues • Is home death preferable or a burden to relatives • Identify models to improve access to palliative care nurses 		<ul style="list-style-type: none"> • Better symptom management for people with advanced disease